COMMONWEALTH OF PENNSYLVANIA BY JOSH SHAPIRO, in his official capacity as Attorney General of the Commonwealth of Pennsylvania Plaintiff, v. JUUL LABS, INC., Defendant.	:	IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY _____ TERM, 2020 No. _____ **JURY TRIAL DEMANDED**

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

You should take this paper to your lawyer at once. If you do not have a lawyer or cannot afford one, go to or telephone the office set forth below to find out where you can get legal help.

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Lawyer Referral
and Information Service
1101 Market St., 11th Floor
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(215) 238-6333

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AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decider a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

Lleve esta demanda a un abogado immediatamente. Si no tiene abogado o si no tiene el dinero suficiente de pagar tal servicio. Vaya en persona o llame por telefono a la oficina cuya direccion se encuentra escrita abajo para averiguar donde se puede conseguir asistencia legal.

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CIVIL ACTION COMPLAINT

AND NOW, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, brings this action to obtain injunctive and other equitable relief, compensatory damages, restitution, punitive damages, civil penalties, and other damages as more fully set forth below, and in support thereof avers as follows:

PURPOSE OF ACTION

1. Pennsylvania's youth face a significant public health crisis with the epidemic in nicotine addiction caused by electronic cigarettes, driven in large part by a single product which only entered the marketplace four and a half years ago and was developed and marketed to appeal to youth – the JUUL e-cigarette.

2. The following graph illustrates how Defendant has contributed to the nationwide youth vaping epidemic. While the rest of the e-cigarette industry stayed relatively stable from 2017 through 2018, Defendant experienced meteoric growth. Through that same timeframe, youth vaping rates nearly doubled from 11.7% in 2017 to 20.8% in 2018. Through October 5, 2019 (the last date for which data was available), as Defendant continued to grow, youth vaping rates continued to increase to 27.5%.

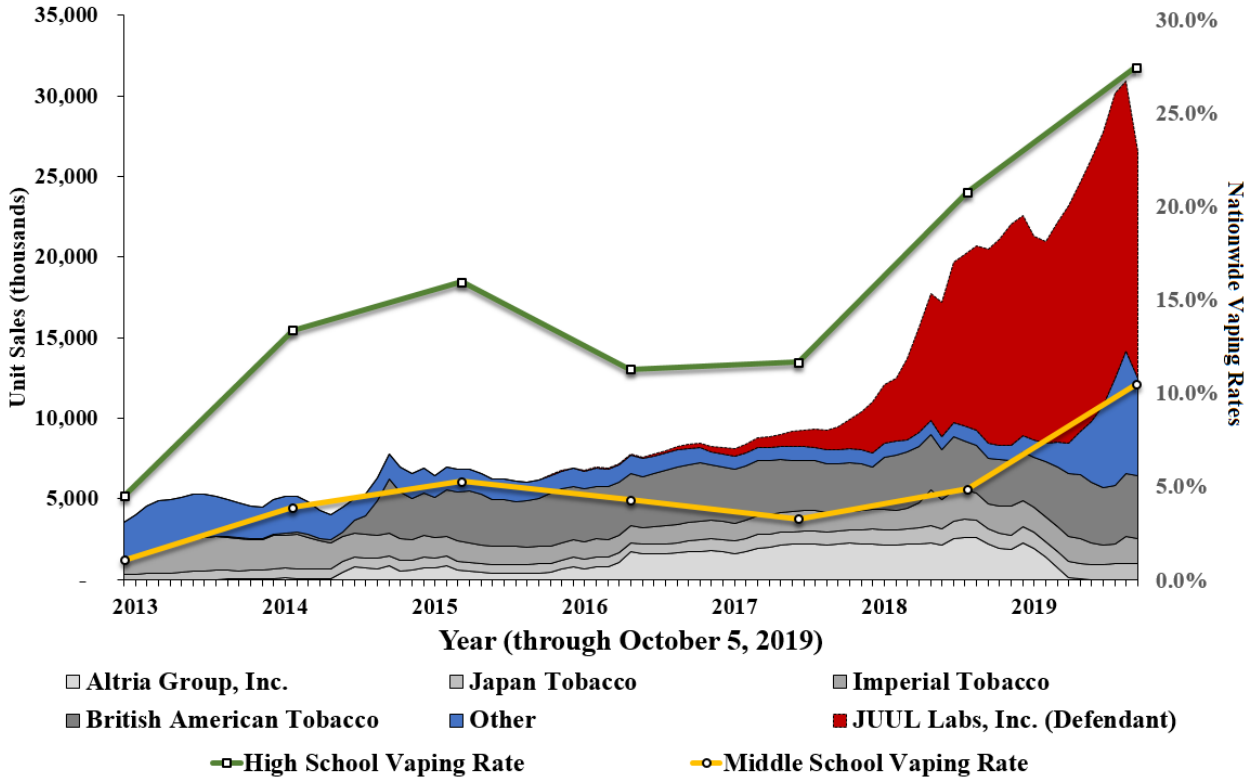

FIGURE 1: The area graph depicts e-cigarette unit sale volumes by manufacturer and month from 2013 through October 5, 2019; the line graph depicts national high school and middle school e-cigarette past-30-day usage rates as percentages from 2013 through 2019, with each data point representing a year. Sources: Nielsen all channel unit sales data; National Youth Tobacco Survey.

3. The creators of JUUL utilized the playbook of Big Tobacco from the last century by cynically lying to, deceiving, and manipulating the American public. Defendant leveraged tobacco industry marketing and design research to market JUUL to youth despite knowing about

the unique vulnerability of youth to nicotine addiction. These tactics included promoting JUUL as a hip lifestyle product, heightening JUUL's addictive potential, using sweet, fruity, chocolatey, and minty flavors that appeal to youth, and minimizing awareness and concern over its safety. JUUL's creators found it acceptable for an entirely new generation of youth to fall prey to the lifelong addiction and health risks associated with tobacco products.

4. We are now presented with the need for immediate action. With nearly one quarter of Pennsylvania high school students reporting current use of e-cigarettes and more than one-in-ten students starting to use e-cigarettes in middle school, the Commonwealth seeks prompt action to stop Defendant from taking entirely new generations of youth down the path of addiction and debilitating health outcomes that American cigarette users have traveled for the last century.

JURISDICTION AND VENUE

5. This Honorable Court has jurisdiction over this action pursuant to 42 Pa.C.S.A. §931(a).

6. The Commonwealth brings this action exclusively under the common law and statutes of the Commonwealth of Pennsylvania. No federal claims are being asserted. To the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such claim is expressly disavowed and disclaimed by the Commonwealth.

7. Venue is proper with the Court of Common Pleas of Philadelphia County pursuant to Pa.R.C.P. 2103(a) and Pa.R.C.P. 2179(a).

THE PARTIES

8. Plaintiff, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, brings this action in its capacity as sovereign under its authority pursuant to Section 201-4 of the Unfair Trade Practices

and Consumer Protection Law ("UTPCPL"), 73 P.S. §201-4, and as *parens patriae* on behalf of all of its residents, including its youth (for purposes of this complaint, defined as anyone under the age of 25 years old), to protect their health and welfare, and to recover damages which the Commonwealth and its residents have sustained and will sustain as a result of the unlawful conduct of the Defendant.

9. Defendant, JUUL Labs, Inc. (formerly known at different times as "PAX Labs, Inc." and "PLOOM, Inc."), is a Delaware corporation authorized to do business in Pennsylvania and which actually does business in Pennsylvania, and has its principal place of business at 560 20th Street, San Francisco, California 94107.

10. Defendant is a tobacco product manufacturer that manufactures, distributes, advertises, and sells electronic cigarettes ("e-cigarettes") under the brand name "JUUL" (pronounced "jewel").

11. Defendant was founded on March 12, 2007 by Adam Bowen and James Monsees.

12. Defendant was formerly known and conducted business as "PLOOM, Inc." from March 12, 2007 through February 10, 2015, and as "PAX Labs, Inc." from February 11, 2015 through June 12, 2017. Defendant has been known as "JUUL Labs, Inc." since June 13, 2017.

13. In June 2015, Defendant launched the JUUL e-cigarette in the United States and has since continued to sell JUUL throughout the United States, including within the Commonwealth.

14. On June 13, 2017, Defendant spun-off the PAX brand into its own company called PAX Labs, Inc., and renamed itself JUUL Labs, Inc. PAX Labs, Inc. now focuses primarily on vaporizers of loose cannabis leaf, whereas Defendant focuses on e-cigarettes.

FACTUAL ALLEGATIONS

I. THE JUUL E-CIGARETTE IS SIMILAR TO CIGARETTES BY DESIGN

a. JUUL e-cigarettes are nicotine delivery devices that also deliver other harmful chemicals to users' bloodstreams.

15. The JUUL e-cigarette consists of two components, the JUUL device and various flavored JUUL pods.

16. The JUUL device contains a rechargeable battery, electrical contacts, a light-emitting diode, and other electrical components.

17. JUUL pods are plastic, replaceable containers or cartridges filled with nicotine liquid which also contain a metal heating element. Each pod is intended to be disposed of upon completion of use.

18. The active ingredient contained in JUUL pods is known as "nicotine salt," which is a combination of nicotine liquid with organic acid, forming salt in solution. The specific organic acid used in JUUL products is benzoic acid, and the resulting nicotine salt is known as sodium benzoate.

19. The JUUL e-cigarette is used by inserting the pod into the device and inhaling from the pod end of the device, which serves as the mouthpiece.

20. A pressure sensor within the JUUL device senses the user inhaling and activates the heating element, heating the nicotine liquid and creating an aerosol that is inhaled by the user.

21. JUUL suspends nicotine in the resulting aerosol and delivers it to the user's lungs where it is then absorbed into the user's bloodstream.

22. This aerosol also contains other substances which can vary depending on which flavor JUUL pod is being used. Some of these substances are or may be harmful, including formaldehyde and carbonyl compounds.

23. Although nicotine salt is the active ingredient in JUUL, it is suspended in a solution mostly composed of propylene glycol and glycerine, substances that according to Defendant's website are "commonly used by the medical, beauty and food industries."

24. While it is true that propylene glycol and glycerine are generally recognized as safe to ingest as food additives, there is limited evidence as to their safety when inhaled, especially over the long-term.

b. Cigarettes are nicotine delivery devices that also deliver other harmful chemicals to smokers' bloodstreams.

25. Cigarettes, like JUUL e-cigarettes, are nicotine delivery devices.

26. Cigarettes consist of one primary component: highly-processed tobacco leaf rolled in paper and often attached to a plastic filter. Cigarettes also contain various additives meant to reduce the harshness of cigarette smoke, increase addictiveness, and alter the flavor of cigarette smoke to make it more palatable.

27. Cigarettes are used by burning the cigarette and inhaling the resulting smoke.

28. During combustion, nicotine contained in the tobacco leaf is heated and becomes suspended in smoke particles along with tar and other harmful chemicals.

29. When inhaled, the nicotine suspended in these smoke particles is deposited in the lungs where it is then absorbed into the smoker's bloodstream.

c. Nicotine is a harmful and addictive chemical, especially when used by youth and young adults.

30. Nicotine is a highly addictive drug derived primarily from the tobacco plant.

31. Both cigarettes and e-cigarettes deliver nicotine in highly-efficient ways to the user's airway, bloodstream, and brain.

32. Nicotine use can result in the rapid onset of both physiological and psychological dependence and various physical and behavioral side effects, including but not limited to increased heart rate and blood pressure, peripheral vasoconstriction, headache, dizziness, nausea, irritability, and sleep disturbance.

33. Heavy use of nicotine can lead to nausea, vomiting, seizures, and bradyarrhythmia.

34. Use of nicotine while pregnant is associated with severe health risks to children after they are born, including but not limited to hypertension, infertility, respiratory dysfunction, and type 2 diabetes.

35. Youth are especially vulnerable to the addictive properties of nicotine because it alters their brain chemistry during growth and development.

36. Research suggests that youths who use e-cigarettes are also more likely to subsequently begin smoking.

II. DEFENDANT DESIGNED JUUL IN WAYS THAT OPTIMIZED NICOTINE DELIVERY AND ABSORPTION, INCREASING JUUL'S PROPENSITY TO CAUSE NICOTINE DEPENDENCE, ESPECIALLY AMONG YOUTH, LEADING TO THE CURRENT NATIONWIDE EPIDEMIC ANNOUNCED BY THE FDA AND THE SURGEON GENERAL

37. Defendant has engaged in and continues to engage in unlawful acts and practices in the design, manufacturing, marketing, distribution, and sale of e-cigarettes within the Commonwealth to the detriment of hundreds of thousands of Commonwealth residents, especially youth. These acts and practices include:

i. Deceiving the public and consumers, especially youth, regarding critical and material factual information about JUUL, specifically relating to nicotine content, nicotine absorption rates, the risk of developing nicotine dependence, other known or potentially adverse health effects of nicotine and other components of its product as well as vaping generally;

ii. Misrepresenting whether JUUL, or e-cigarettes generally, could be used effectively as a smoking cessation device or as a less-dangerous tobacco product;

iii. Capitalizing on its knowledge of successful tobacco marketing strategies to manipulate consumers, especially youth, into purchasing and using JUUL by marketing JUUL as a hip, fun, sexy, safe lifestyle product, offering a variety of sweet, fruity, and minty flavors that appeal to youth, focusing its marketing efforts on social media and other youth-oriented platforms, and working to undermine adverse findings in public health research;

iv. Placing JUUL into the tobacco marketplace despite the well-known and widely-established risks for creating youth nicotine dependence and other adverse health effects among its users, including the risk that JUUL's flavors and design and Defendant's marketing strategies would appeal to youth, and that Defendant's aggressive expansion into convenience stores would lead to greater exposure and access to youth;

v. After having established its product in the marketplace through deceptive marketing strategies such as those used to promote cigarettes, failing then to mount a prompt, timely and effective response to direct evidence of widespread JUUL use among youth and widespread concerns and criticism expressed by government agencies and public health advocacy organizations regarding the epidemic of e-cigarette use among youth.

38. Defendant's deception, manipulation, and disregard for the risks created by JUUL's design and marketing resulted in a historic increase and FDA-declared epidemic in e-cigarette use among youth. Such actions potentially caused the nicotine dependence of hundreds of thousands of Pennsylvania residents, especially youth, who are highly susceptible to the addictive properties of nicotine and Defendant's marketing tactics.

39. Defendant modeled its product design and marketing in many ways after tactics that the tobacco industry has used. These tactics included:

i. Increasing the addictive properties of JUUL e-cigarettes, similar to cigarette manufacturers' efforts to increase the addictive properties of cigarettes;

ii. Designing and marketing JUUL e-cigarettes to be appealing to youth, similar to marketing used by cigarette manufacturers;

iii. Creating and preserving youth access to JUUL e-cigarettes through its focus on expanding JUUL availability in convenience stores and its misguided industry-sponsored youth education efforts, similar to cigarette manufacturers' fake and counter-productive youth prevention programs meant to appease regulators;

iv. Deceiving consumers about the health effects and addictive potential of JUUL e-cigarettes through its marketing, public relations, and lobbying efforts, similar to approaches used by cigarette manufacturers to influence public opinion; and

v. Manipulating consumers by altering the narrative around public health research and the health effects of e-cigarettes through marketing, public relations and sponsorship of its own research to defend its standing with regulators, similar to tactics used by cigarette manufacturers.

40. Defendant's acts and practices resulted in and largely contributed to what U.S. Food and Drug Administration Commissioner Scott Gottlieb, M.D., and U.S. Surgeon General Vice Admiral Jerome M. Adams, M.D., M.P.H., declared to be an "epidemic" of e-cigarette use among youth.

41. On October 4, 2018, Pennsylvania Secretary of Health, Dr. Rachel Levine, said in a statement warning against youth e-cigarette use that "most e-cigarettes contain nicotine, which

is a highly addictive drug that can harm brain development, which continues until about age 25," and that "young people who use e-cigarettes may be more likely to go on to use regular cigarettes."

42. Defendant's sales and marketing of its product to Pennsylvania residents without appropriate warnings regarding the harmful effects of its product and without adequate consideration of the susceptibility of youth to the harmful effects of its product were a substantial factor in causing harm to the health, comfort and welfare of Pennsylvania's residents, especially its youth.

43. As a result, today it is estimated that approximately 24.4% of Pennsylvania high school students, or approximately 134,200 youth, are current users of e-cigarettes. It is also estimated that 10.5% of Pennsylvania middle school students, or approximately 43,680 students, are current e-cigarette users.

a. Defendant specifically designed JUUL to emulate the characteristics of cigarettes that make cigarettes so addictive, namely nicotine content, rate of nicotine delivery to the user's bloodstream, and tolerability.

44. Cigarettes and JUUL share a number of key characteristics. Specifically, they both contain nicotine, allow users to inhale nicotine easily and efficiently, and contain other features that mask the otherwise unpleasant or off-putting characteristics of their products.

45. The tobacco industry designed cigarettes to maximize their addictive potential and their users' tolerability, recognizing that cigarettes are not pleasant to use and are harmful to the user's health. Therefore, cigarettes need to provide an addictive response for people to continue to want to smoke them, or else smoking rates would be much lower and, consequently, the tobacco industry would be much less profitable.

46. Cigarette manufacturers made cigarettes more tolerable by adding sugar and menthol flavoring to cigarette tobacco and adding filtered tips to cigarettes. Added sugar also increases the addictive effects of smoking cigarettes.

47. Defendant designed JUUL to emulate the nicotine delivery and experience of smoking cigarettes and, by extension, the addictive effects of smoking.

48. From the outset, Defendant touted the similarities between the nicotine absorption accomplished by JUUL and that accomplished by cigarettes as a benefit to using JUUL. Rather than explicitly referring to addiction, Defendant described JUUL to consumers, retailers, and investors as "satisfying," referring to the fact that JUUL would satisfy one's involuntary craving for nicotine by delivering more and more nicotine in as pleasing and efficient of a way as possible, perhaps prolonging their addiction rather than treating it. Examples of such descriptions made by Defendant in Facebook posts and through a promotional article are attached hereto as "Exhibit A" and incorporated herein by reference.

49. Plain unflavored nicotine liquid can be bitter and hard to inhale, especially at higher concentrations, so Defendant designed JUUL to come in various sweet, fruity, chocolatey, and minty flavors that would help mask the bitter taste of JUUL aerosol.

50. Defendant also improved JUUL's tolerability by incorporating nicotine salts, which, in addition to increasing nicotine absorption, also cut the bitter taste and harshness of high concentrations of nicotine.

b. Defendant deceptively understated the "nicotine strength" of JUUL and failed to advise consumers of the higher nicotine absorption caused by the nicotine salts used in JUUL.

51. Chemically speaking, nicotine is a weak base, and a "salt" is a compound formed from the reaction between an acid and a base.

52. While reviewing tobacco industry research that was made public as a result of the Tobacco Master Settlement Agreement ("MSA"), Defendant's founders claimed that they discovered that benzoic acid could be used to create nicotine salts in e-cigarette liquid for the purpose of increasing nicotine absorption rates when using those liquids. Statements to this effect made by Defendant's founders during an interview are attached hereto as "Exhibit B" and incorporated herein by reference.

53. As illustrated in Defendant's patent for JUUL's nicotine salts, this addition of benzoic acid caused the test subject's blood nicotine content to track very similarly to someone smoking a cigarette. A copy of Defendant's patent for JUUL's nicotine salt formulation (U.S. Patent No. 9,215,895) is attached hereto as "Exhibit C" and is incorporated herein by reference.

54. Because nicotine is a weak base, when organic acids are added to nicotine in suspension, the reaction of those two substances creates what are known as "nicotine salts." For example, when benzoic acid is added to nicotine, it forms the nicotine salt known as sodium benzoate.

55. Defendant's examination of tobacco industry research together with product testing derived from that research led Defendant to discover that nicotine salts increase nicotine absorption when inhaled in aerosol expelled by e-cigarettes.

56. Further testing revealed that, due to certain chemical similarities between benzoic acid and nicotine compared to other organic acids, sodium benzoate was most efficient at delivering nicotine quickly to the bloodstream and at a similar speed and rate as a cigarette.

57. Blood plasma test results described in Defendant's patent filed in October 2014, as reflected in Table 1 below, showed that inhalation of nicotine liquids containing sodium benzoate caused nicotine absorption at nearly the same or higher rates compared to the control cigarettes.

TABLE 1

Time	Pall Mall	2% Freebase	2% Benzoate	4% Benzoate
−2	0.46	0.03	0.09	0.05
0	−0.46	−0.03	−0.09	−0.05
1.5	1.54	0.08	5.67	6.02
3	9.98	1.19	8.60	11.47
5	11.65	1.70	11.44	15.06
7.5	11.34	3.09	6.43	12.12
10	9.24	3.42	5.03	11.08
12.5	8.85	3.35	4.68	10.10
15	8.40	2.81	4.47	8.57
30	5.51	1.74	2.72	5.56
60	3.39	0.79	1.19	3.60
T_{max} (min)	5.17	10.00	6.67	5.83
C_{max} (ng/mL)	11.65	3.42	11.44	15.06
AUC (ng * min/mL)	367.5	106.2	207.8	400.2

FIGURE 2: *Table 1 on Page 26 of Defendant's Patent for the nicotine salt solution used in JUUL e-cigarettes, Patent No. 9,215,895 B2 (emphasis added by high-lighting line 40).*

58. The "2%" and "4%" designations on line 35 of FIGURE 2 above denote the nicotine strength of each solution being tested. "2% Freebase" indicates a 2% nicotine concentration without the addition of organic acids, "2% Benzoate" indicates a 2% nicotine concentration with the addition of benzoic acid, and "4% Benzoate" indicates a 4% nicotine concentration with the addition of benzoic acid.

59. Despite the fact that Defendant found 2% nicotine strength solution containing sodium benzoate produced nicotine absorption rates very similar to those of cigarettes, Defendant designed JUUL to contain more than twice as much nicotine, offering JUUL pods at 5% nicotine strength.

60. Also, despite the 2014 patent claims showing nicotine absorption equal to or higher than the control cigarette, Defendant then used graphs in its promotional materials, which were distributed to online magazines and product reviewers in 2015 and after, which depict JUUL's nicotine absorption as ***lower*** than that of cigarettes ("promotional graph").

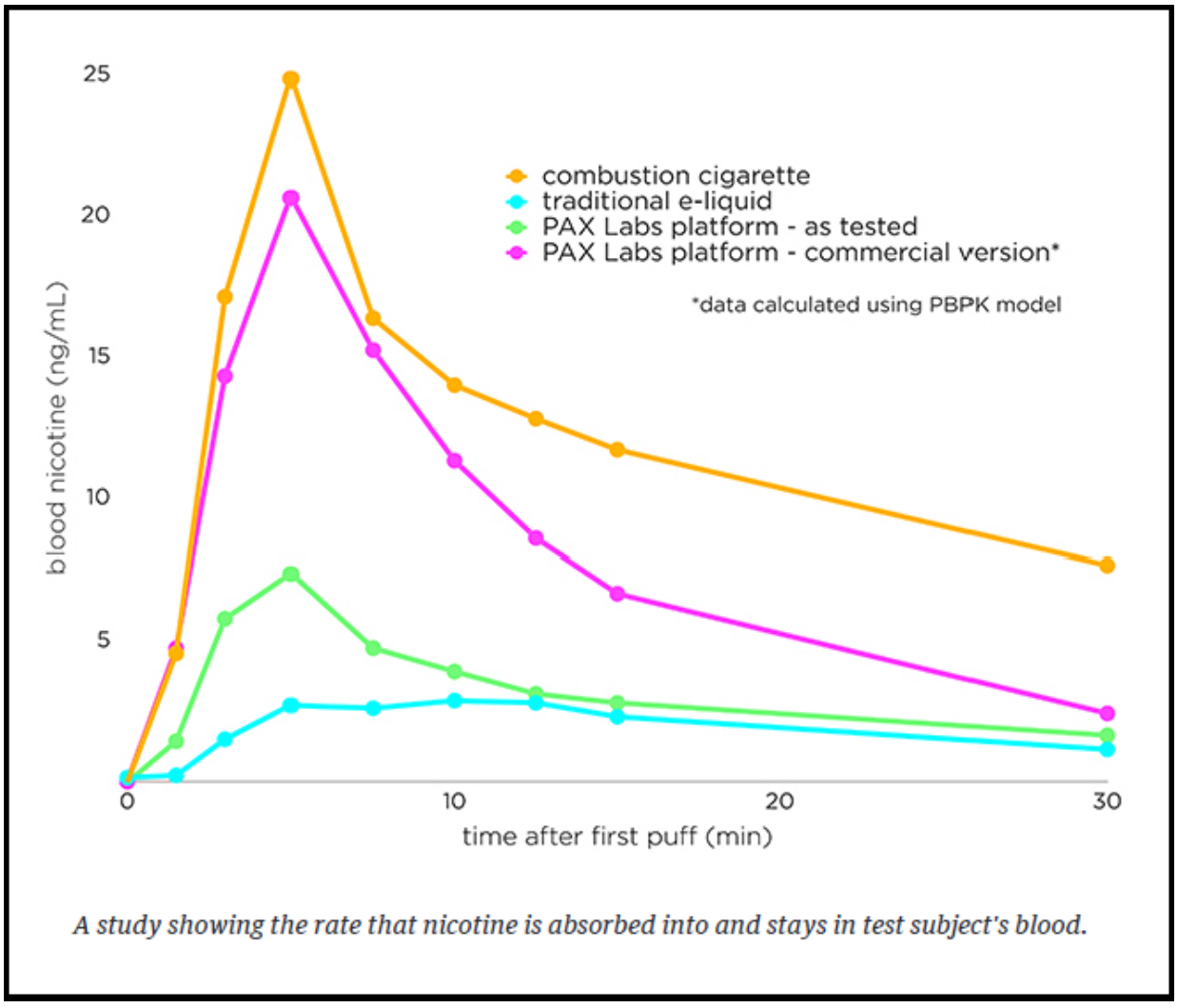

FIGURE 3: *The graph referred to in paragraph 61 above. Image Credit: Engadget.com review of the JUUL e-cigarette. https://www.engadget.com/2015/06/03/pax-labs-juul-e-cigarette.*

61. A key part of this promotional sleight of hand is that, while the promotional graph shows the unnamed reference cigarettes producing blood nicotine concentration of about 25

nanograms per milliliter after five minutes, the Pall Mall cigarettes used in Defendant's patent produced blood nicotine concentration of about 11.65 nanograms per milliliter after five minutes.

62. This allowed Defendant to raise the nicotine content of JUUL even higher than as tested for its patent while still leading consumers to believe JUUL did not deliver any more nicotine than traditional cigarettes.

63. In reality, JUUL now delivers nearly twice as much nicotine as the cigarettes used during the tests illustrated in Defendant's patent. The promotional graph shows JUUL delivering over 20 ng/mL of nicotine after five minutes, whereas the cigarettes referenced in Defendant's patent delivered only 11.65 ng/mL of nicotine after five minutes.

64. Defendant's promotional graph was deceptive to consumers due to Defendant's manipulation of the data, in that it effectively underrepresented the nicotine absorption rates experienced with JUUL.

65. Defendant's characterization of JUUL pods as equivalent to a pack of cigarettes was deceptive to consumers.

66. The data above illustrate another reason why comparing JUUL's nicotine content and absorption to that of a cigarette is deceptive to consumers: cigarettes can vary widely in their nicotine content between brands.

67. As shown by Defendant's own research, Pall Mall brand cigarettes produced blood nicotine concentration of about 11.65 ng/mL after 5 minutes, whereas Defendant's unnamed cigarettes from their promotional graph delivered over twice as much nicotine (25 ng/mL).

68. By comparing JUUL to a high-nicotine content unidentified cigarette in its marketing materials, Defendant led consumers to believe that JUUL had a lower nicotine content or delivered nicotine at lower rates than the average cigarette.

69. Even for consumers who were familiar with e-cigarettes, Defendant's statement in packaging, marketing, and advertising materials of JUUL's "nicotine strength" is deceptively low.

70. Prior to JUUL's launch, e-cigarette manufacturers typically expressed the nicotine content in their products as milligrams of nicotine per milliliter of liquid (mg/mL). In some cases, e-cigarette manufacturers would express these concentrations as "percent by volume." For example, nicotine liquid containing 10 mg/mL of nicotine would be expressed as "1% nicotine by volume."

71. JUUL contains 59 mg/mL nicotine, so if Defendant would express JUUL's nicotine strength in terms of nicotine by volume, it would say 5.9%.

72. Rather than use the industry standard characterization, Defendant characterized JUUL's nicotine content as "5% nicotine by weight." Images of JUUL packaging used by Defendant are attached hereto as "Exhibit D" and are incorporated herein by reference.

73. Due to the difference in the density of liquid nicotine and other constituents in JUUL's nicotine liquid, Defendant was able to say "5%" rather than "5.9%." However, this was not clearly communicated to consumers, so even the most informed e-cigarette user would be led to believe that JUUL contained only 50 mg/mL nicotine, over 15% less than it actually does.

74. Because Defendant's misleading marketing and advertising underrepresented the nicotine content of JUUL pods relative to cigarettes, Defendant likely enhanced and furthered the nicotine addiction of its users who smoke rather than merely satisfying their cravings for nicotine.

75. For non-smokers, especially youth and young adults, Defendant's misleading marketing and advertising set them on the potentially lifelong path of nicotine dependence by rapidly delivering high doses of nicotine to their bloodstream, laced with sweet, fruity, and minty flavoring compounds to help the bitter aerosol go down more easily.

c. Defendant marketed JUUL without warning consumers of the health risks associated with JUUL, including its highly addictive nature, the effects of nicotine and nicotine dependence, or the effects of other harmful byproducts produced by JUUL.

76. Despite the significant risks associated with nicotine and nicotine dependence, all of which were well-known to Defendant, Defendant marketed JUUL as if it had no risks since it was launched in June 2015 until mid-2018 just before FDA required all e-cigarettes to have a warning regarding the presence of nicotine and the fact that nicotine is addictive.

77. Defendant did not include the word "nicotine" on the front of JUUL packaging prior to mid-2018, and only disclosed the fact that nicotine was an ingredient in ***fine print*** on the back of the package. See "Exhibit D."

78. In fact, Defendant did not even use the word "nicotine" to describe JUUL's "nicotine strength," rather characterizing it as simply "5% strength" on the front of the package with no reference to nicotine or JUUL's potential to cause nicotine dependence. See "Exhibit D."

79. On the back of the package, Defendant wrote in fine print "5% nicotine by weight // approximately equivalent to about 1 pack of cigarettes." See "Exhibit D."

80. Defendant did not provide consumers any other warnings of well-established health risks associated with nicotine either in their labeling or in its marketing and advertising.

81. Defendant's failure to warn consumers of the dangers inherent to JUUL likely led many consumers, including youth, to use and continue to use JUUL under the mistaken impression that it would not be harmful to their health, when in fact they were causing or reinforcing nicotine dependence and inhaling harmful or potentially harmful compounds of which they were not aware.

82. During an interview for The Verge in April 2015, the Research and Development Engineer credited with formulation of JUUL's flavors, Ari Atkins, said "we don't think a lot about

addiction here because we're not trying to design a cessation product at all," adding "anything about health is not on our mind." See "Exhibit A."

83. Defendant disregarded the risk that JUUL posed to users of causing, reinforcing, or prolonging nicotine dependence or potentially causing other health issues.

III. DEFENDANT DESIGNED AND MARKETED JUUL IN WAYS THAT WOULD APPEAL TO YOUTH

a. JUUL's aesthetic qualities appealed to youth by evoking fun, coolness, tech, and simplicity

84. Defendant's stated mission today, now prominently displayed on its website, is to "improve the lives of the world's one billion adult smokers by eliminating cigarettes," and Defendant has proudly claimed in promotional materials that "We are not big tobacco." Examples of Defendant's disavowing the label of "big tobacco" through email and social media are attached hereto as "Exhibit E" and are incorporated herein by reference.

85. But, the original mission of Defendant's founders was to improve the ritual of smoking, not to eliminate it. In a January 2015 article in Social Underground, co-founder James Monsees indicated that he and co-founder Adam Bowen loved the ritual of smoking cigarettes and that they wanted to design a better experience. Mr. Monsees also characterized cigarettes as "an amazing product," and "probably the most successful consumer product of all time." See "Exhibit B."

86. As a matter of fact, rather than a "success," cigarettes have been responsible for debilitating illness and the premature deaths of millions of Americans.

87. Defendant drew inspiration from historical cigarette marketing and media representations that characterized cigarettes as fun, hip, cool, sexy, intriguing, easy to use, and an integral part of many social interactions for those who smoke.

88. Defendant incorporated these same themes and characterizations into its design of JUUL, creating a product that was simple, sleek, interesting, and looked really cool.

89. JUUL's modern design, small size, and simplicity make it similar to other modern electronic devices such as smartphones, tablets, smart watches, MP3 players, and the like. In fact, Defendant explicitly compared JUUL to devices like the iPhone during and after the design process, calling it the "iPhone of E-Cigarettes" in promotional materials. An example of Defendant's use of the term "iPhone of E-Cigarettes" through online product reviews is attached hereto as "Exhibit F" and is incorporated herein by reference.

90. In addition to its traditional definition related to the Christian feast of Easter, Merriam-Webster Dictionary defines "Easter egg" as "a hidden feature in a commercially released product (such as software or a DVD)." Likewise, the Cambridge Dictionary defines it as "a hidden surprise or extra feature that is included in something such as a computer game, a piece of software, or a film, for the person using or watching it to find and enjoy."

91. To make JUUL even more fun and engaging for its users, Defendant included an "Easter egg" called "Party Mode" in the device's only interactive element, a small light-emitting-diode (LED) on the front near the mouthpiece which normally indicates battery strength, charging status, and whether the device is functioning.

92. Party Mode would be activated when the user would shake the device rapidly while the light is on, causing the LED to flash multiple colors rapidly like a multi-colored strobe light one might find at a party (hence, "party mode").

93. This subtle but fun design element was highly engaging to youth and would cause youth users of JUUL to turn on "party mode" at parties or in videos posted to social media to demonstrate the function to their friends.

b. JUUL was made available in fruity, sweet, and minty flavors that would appeal to youth

94. Flavors in e-cigarettes, including JUUL, help mask the bitter and harsh taste of pure nicotine and the other byproducts expelled by e-cigarettes.

95. Defendant designed and sold JUUL in flavors that would appeal to youth by offering fruity, sweet, chocolatey, and minty flavors, specifically Peanut Jam, Spicy Watermelon, Cinnamon Snap, Lemon Poppyseed, Apple Cran, Apple Crumble, Mixed Berry, Crisp Pear, Cool Mint, Coco Mint, Fruit Medley, Crème Brulee, Cool Cucumber, Mango, and Classic Menthol. Initially, these flavors were advertised using funky spellings like Miint, Fruut, and Bruule, playing on the spelling of "JUUL."

96. The United States Congress and the FDA recognize that sweet, fruity, chocolatey, and minty flavors appeal to youth and lead youth to using tobacco products, as evidenced by the prohibition of such flavors (except menthol) in cigarettes back in 2009 and FDA's ongoing efforts to regulate flavored tobacco products (including menthol-flavored tobacco products).

97. Defendant's own "education program" that was meant to educate parents about e-cigarettes, tells parents that fruit-based flavors in e-cigarettes are youth-friendly and that youth perceive that the risks of using such e-cigarettes are low.

98. By offering JUUL in sweet, fruity, chocolatey, and minty flavors despite their appeal to youth, Defendant manipulated youth into trying and continuing to use JUUL.

99. In a sense, Defendant has been successful in its original mission to create a better cigarette, because cigarettes were designed and marketed to cause and reinforce nicotine dependence and to manipulate consumers, especially youth, into using nicotine, which Defendant has accomplished faster than cigarette manufacturers were able to in the past.

100. As a result of Defendant's success with JUUL, according to the FDA, 27.5% of high school students and 10.5% of middle school students nationwide now use e-cigarettes, with most youth reporting JUUL as their usual brand of e-cigarette.

101. Unfortunately, these statistics are consistent with e-cigarette use among Pennsylvania's youth. According to the latest data from Pennsylvania's 2019 Youth Risk Behavior Survey, 24.4% of Pennsylvania high school students currently use e-cigarettes, with 7.4% of Pennsylvania high school students indicating that they use e-cigarettes every day. This means there are almost 200,000 current high school and middle school students currently using e-cigarettes in the Commonwealth. This does not include those who became addicted as students in high school and are now using e-cigarettes as young adults. The data also indicate that Pennsylvania high school students are desperately trying to quit tobacco products, with 46.7% reporting having tried to quit in the past year.

c. JUUL was launched with a patently youth-oriented marketing campaign called the "Vaporized Campaign"

102. Like they were selling any other must-have electronic consumer product meant to appeal to as broad of an audience as possible, in June 2015, Defendant officially rolled out the launch campaign for JUUL, referred to as the "Vaporized Campaign." Defendant also conducted significant marketing activity, planning, and implementation prior to this date.

103. Defendant marketed JUUL before and throughout the Vaporized Campaign through many direct and indirect channels, including, without limitation, social media, youth-oriented online magazines and media outlets, experiential pop-up stores and sampling events, influencer marketing, PR-directed introductory articles and reviews in tech and lifestyle magazines and blogs, retail marketing and brand ambassadorship, in-person sampling events in convenience stores, billboards, and direct email marketing.

104. The Vaporized Campaign and the marketing activities leading up to it were patently youth-oriented in both style and medium.

105. Defendant's focus on social media is especially telling due to its ubiquity in the lives of people belonging to "Generation Z," which includes youth who were under 18 years old when JUUL was launched.

FIGURE 4: *Examples of images used by Defendant on social media to promote JUUL. Image Credit: Dr. Robert K. Jackler, Stanford Research into the Impact of Tobacco Advertising (SRITA), "JUUL Advertising Over its First Three Years on the Market" (January 31, 2019).*

106. As explained by Robert K. Jackler, M.D. in his study of Defendant's social media marketing activity, "Gen Z youth have never experienced the world without the internet and live immersed in social media, most often viewed on mobile phones." Jackler, Robert K. et al., "JUUL Advertising Over its First Three Years on the Market," Stanford Research into the Impact of Tobacco Advertising ("SRITA"), P. 33, January 31, 2019.

107. In 2015, according to Pew Research, more than 85% of teenagers in the United States reported using social media on at least a daily basis, mostly on Facebook and Instagram. About one third of teenagers at this time also used Twitter.

108. The social media platforms chosen by Defendant for the Vaporized Campaign were Facebook, Instagram, and Twitter.

109. Defendant's social media content included bright colors, bold lettering, and young models posing and acting in ways more evocative of youth than of a mature adult, creating an image that teens would be attracted to and want to emulate.

110. Defendant used branded and unbranded tags or hashtags on its social media posts on Facebook, Instagram, and Twitter to cause organic user-generated content related to JUUL to be linked to JUUL's own direct social media posts and pushing that content on users interested in those tags. This turned social media users, including youth, into unwitting spokespeople, leading their friends and followers to advertisements for JUUL.

111. Defendant made social media a core component of its Vaporized Campaign in order to market JUUL to youth.

112. Even if Defendant claims that it did not intend to market JUUL to youth through social media, it should have known that marketing JUUL to youth would have been the result of

the Vaporized Campaign considering the ubiquity of social media in the lives of youth, especially teenagers.

113. Defendant also arranged for advertisements and articles in youth-oriented online magazines, such as "VICE," which touts itself as the "fastest growing, #1 youth media company in the world," with "26% of the VICE audience [being] under 24 years old." Defendant knew or should have known that such content would be delivered to and viewed by young people, including teenagers, demonstrating that Defendant intended to target such content to youth.

114. Another important aspect of the Vaporized Campaign that teed-up JUUL's future growth and "success" was Defendant's use of sampling events at retailers and convenience stores, including many stores throughout the Commonwealth.

115. Defendant's retail and convenience store approach was two-fold:

i. First, Defendant would meet with and train store employees to turn them into brand ambassadors for Defendant, hopefully causing them to tout JUUL to the thousands of customers that go through their store;

ii. Second, Defendant would conduct sampling events where customers in convenience stores would be intercepted by Defendant's own representatives who would then engage the customer regarding the JUUL product and offer free samples.

116. After the sampling was complete, the representative would offer the customer the rest of the sampled JUUL pod for free and encourage them to buy a JUUL device in order to use the rest of the pod.

117. During these sampling events, Defendant's representatives would wear brightly-colored shirts and were often young attractive people, mirroring the bright and youthful images Defendant propagated through social media and other marketing outlets.

118. Defendant targeted Pennsylvania in particular for its retail sampling tour, seeking opportunities specifically with Wawa, Sheetz, and Rutter's, all Pennsylvania-based companies with hundreds of stores throughout the Commonwealth.

119. Between August 3, 2015 and November 27, 2015, Defendant conducted more than 400 such sampling events at retailers and convenience stores throughout the Commonwealth, covering at least 19 counties. During these events, about 2,500 free sample JUUL pods were distributed to consumers in Pennsylvania and more than 16,000 consumers were intercepted by Defendant's representatives for face-to-face direct marketing.

120. The convenience stores targeted by Defendant during the Vaporized Campaign, especially those based in Pennsylvania, offer a wide selection of candies, snacks, gums, desserts, ice cream treats, milkshakes, sweet coffee drinks, sweet sodas, and other items likely to attract younger customers to shop at those stores.

121. Defendant knew or should have known that holding these sampling events in convenience stores and similar retailers would likely expose youth to its product and its advertising, causing JUUL to appeal to youth and manipulating youth into buying and using JUUL.

d. Defendant sent direct marketing emails and discount offers to hundreds of thousands of email addresses that had not been age-verified

122. On July 31, 2018, Robert K. Jackler, M.D of SRITA (Stanford University Research Into the Impact of Tobacco Advertising) alerted Defendant to the fact that he was aware of a minor who had been rejected by Defendant's age verification system but nonetheless continued to receive direct marketing emails encouraging the minor to buy JUUL and offering discounts.

123. After an internal review, Defendant discovered that over 500,000 email addresses that were receiving regular direct marketing emails from Defendant were not age-verified. This constituted the majority of Defendant's email marketing list at the time.

124. These emails included messages encouraging users to buy JUUL, encouraging them to use Defendant's "store locator," offering discounts, and sending flavor-specific advertisements. Examples of such emails are attached hereto as "Exhibit G" and are incorporated herein by reference.

125. The fact that Defendant was so unconcerned with youth prevention and avoiding youth targeting that it went unaware of such a problem for over three years demonstrates Defendant's blatant disregard for youth prevention and for the risk of harm their acts, practices, and products pose to youth.

IV. DEFENDANT'S "SWITCH CAMPAIGN" DECEPTIVELY MARKETED JUUL AS SAFE WHEN THE FDA SPECIFICALLY PROHIBITED THESE TYPES OF CLAIMS

126. In early 2016, Defendant gradually transitioned its marketing efforts into a new campaign that focused more on themes of relaxation, romance, satisfaction, and switching from smoking to using JUUL, known as the "Switch Campaign."

127. As it had during the Vaporized Campaign, Defendant marketed JUUL throughout the Switch Campaign in many of the same channels, including social media (Facebook, Instagram, Twitter, Reddit, YouTube, and its own social media platform known as "JUUL Talk"), content created and shared by social media influencers, direct email marketing, retail advertisements, and billboards. Defendant also began advertising in print media, radio, and via third-party affiliate sellers.

128. Where the Vaporized Campaign blatantly targeted youth, the Switch Campaign was more muted and reserved, but it still focused on advertising channels that would frequently expose youth to Defendant's marketing, disregarding the risk that such advertisements would manipulate youth into using JUUL.

129. Defendant also began making more brazen claims about the supposed health benefits of using JUUL and the appropriateness of using JUUL as a smoking cessation device. Defendant's advertising encouraged smokers to "switch" to JUUL in order to improve their lives, implying that JUUL was safer to use than cigarettes. It is believed, and therefore averred, that Defendant has not conducted the scientific research necessary to determine whether such a safety claim is true and does not know to what extent e-cigarettes may be safer than smoking cigarettes.

130. FDA regulations prohibit tobacco product manufacturers, including Defendant, from making claims regarding relative risk of particular tobacco products without FDA first issuing a marketing order ("MRTP Order") approving the use of such claims after extensive scientific analysis is conducted and submitted to FDA.

131. Defendant has never received an MRTP Order from FDA.

132. There is limited evidence that some e-cigarettes may be effective as smoking cessation devices, but most of those studies involve devices containing much lower nicotine levels than JUUL and did not address other potential health problems that may be associated with e-cigarette use.

133. Defendant has also made specific representations on its website and in other advertising media about JUUL's temperature control systems, claiming JUUL presents less risk of harm to users than smoking cigarettes by producing harmful compounds in lesser amounts.

134. On September 9, 2019, the FDA issued a warning letter to Defendant asserting that its statements regarding the risk of harm presented by JUUL constitute unauthorized modified risk claims under federal law and regulation, directing Defendant to cease making or publishing such statements and to take immediate corrective action. These statements included those made to students during Defendant's youth outreach and education program indicating that JUUL was

about to be approved by FDA and that it was at least 99% safer than cigarettes, as well as Defendant's former CEO, Kevin Burns, making statements regarding the supposedly reduced levels of harmful compounds produced by JUUL's temperature control system. An FDA Warning Letter detailing the illegal representations made by Defendant is attached hereto as "Exhibit H" and is incorporated herein by reference.

135. Defendant has also made unfair, deceptive, and misleading statements and representations regarding levels of harmful and potentially harmful compounds that are found in the aerosol expelled by JUUL, including formaldehyde. Specifically, Defendant has previously indicated that formaldehyde was not present in JUUL aerosol, despite formaldehyde being detected in Defendant's own internal test results.

136. Defendant used these statements and characterizations of the health risks and benefits of using JUUL to deceive consumers into believing that JUUL was either completely safe or much safer than smoking cigarettes, when in reality Defendant does not know how much safer using JUUL is than smoking cigarettes.

137. Admittedly, there is evidence that JUUL aerosol delivers lower levels of some harmful and potentially harmful compounds than cigarette smoke, but Defendant's characterizations and implications ignore the unknown long-term effects of e-cigarette use, the propensity for JUUL to cause and reinforce nicotine dependence, the risk that nicotine dependence can make users more susceptible to addiction to other drugs, and the propensity for JUUL to be used by youth leading to nicotine dependence and subsequent combustible tobacco use.

138. By promoting its product as a safe, or safer, lifestyle choice and omitting information about other potentially harmful effects of using JUUL, Defendant deceived consumers and manipulated them into purchasing and using their product, exposing those consumers to

possible nicotine dependence, harmful and potentially harmful compounds delivered by JUUL, and, among youth especially, the risk of subsequent combustible tobacco use.

139. These overt and implicit safety and health claims made by Defendant were deceptive and they caused a likelihood of confusion or misunderstanding among consumers, especially youth, leading such consumers to believe that JUUL is safe for them to use when that is not the case.

140. Defendant also worked with public relations professionals and tobacco industry organizations to undermine and discredit public health research that tended to establish or reveal facts regarding the appeal of flavors to youth, the effects of e-cigarette advertising on youth, and other adverse effects e-cigarettes may have on youth and on public health overall.

141. This concerted effort had a likelihood to mislead the public and to cause confusion by sowing doubt in the minds of consumers about public health research into the effects of e-cigarettes, all for Defendant's own benefit and for the benefit of the e-cigarette industry.

V. DEFENDANT DISTRIBUTED AND SOLD JUUL IN WAYS THAT PROVIDED YOUTH ACCESS TO JUUL

a. Defendant focused specifically on growth into convenience stores, disregarding the increased risk of sales to minors occurring and the increased exposure of youth to JUUL advertising in those stores

142. In the United States, most of Defendant's products are sold in convenience stores. In fact, Defendant's position as the leading e-cigarette manufacturer in the U.S. is due in large part to its focus on aggressively partnering with brick-and-mortar retailers, especially convenience stores like Wawa, Sheetz, and Rutter's.

143. By doing this, Defendant sought to emulate and shadow other tobacco products, especially cigarettes, which are omnipresent in U.S. convenience stores.

144. Convenience stores also offer many youth-oriented or youth-friendly products, such as candies, snacks, gums, desserts, ice cream treats, milkshakes, sweet coffee drinks, sweet sodas, and other snacks that are often flavored and characterized as tasting sweet, fruity, or minty. By design, convenience stores are meant to draw in and sell to youth.

145. In addition to Defendant's sampling events described above, Defendant advertised extensively in convenience stores and used video displays and product displays that featured bright colors and young adults acting youthfully while using and displaying the JUUL device.

146. Many convenience stores were initially wary of carrying another e-cigarette brand because of poor experiences with other brands. To assuage these concerns, Defendant touted the nicotine levels and addictive qualities of JUUL by referring to the comparable satisfaction it provides to cigarettes. This convinced enough convenience store chains to sell JUUL that JUUL has been the most popular e-cigarette sold in convenience stores since late-2017 according to Nielsen data.

147. JUUL's widespread availability and advertising in convenience stores exposed countless youth to pervasive JUUL advertising in an enclosed area where youth were commonly present. Convenience stores in Pennsylvania such as Wawa, Sheetz, and Rutter's were particularly targeted by Defendant from the commencement of Defendant's retail push in 2015.

148. JUUL's availability for purchase in brick-and-mortar retail locations, especially convenience stores, provided thousands of new points of access from which youth could obtain JUUL and third-party resellers could buy bulk JUUL product for second-hand distribution to youth.

149. Defendant did not take appropriate steps to ensure retailers would use appropriate age-verification practices or prevent such bulk-sales to resellers.

150. Defendant could have negotiated terms in its distribution agreements with retailers to prohibit bulk sales, to reduce youth access to JUUL advertising in stores, to ensure proper age verification measures are taken, and to monitor the retailer's age verification process.

151. Defendant's primary concern was entry into convenience stores as quickly as possible to drive growth, at the expense of youth prevention and increasing youth access to JUUL.

152. According to the Truth Initiative, most youth who currently use JUUL obtained JUUL from physical retail locations.

153. Defendant has failed to adequately abate the problem of youth access through physical retail locations despite being aware of the problem and continuing to distribute millions of pods and devices to such entities, putting profit above youth prevention.

154. Defendant's rapid and aggressive entry into and advertising within convenience stores, especially in Pennsylvania, and its failure to adequately address the problem of youth access to its products, demonstrates Defendant's intent to market to youth and its disregard for the risk of providing thousands of new potential points of access for youth to obtain JUUL.

b. Defendant disregarded shortcomings and loopholes within its online sales system that allowed youth to purchase JUUL online through Defendant's own website.

155. Defendant's website allows visitors to purchase JUUL products and have them delivered to their homes.

156. From the outset, Defendant's online sales system has been marred by defects and loopholes that have allowed underage users to purchase JUUL online despite not being of age to purchase tobacco products.

157. Defendant's age verification vendor, Veratad, implemented mechanisms into Defendant's age verification system that were not robust enough to ensure purchasers were of age.

For example, at one point Veratad's system did not require a full match between a user's information and the information found in official data sources. Rather, any one of several combinations of partial information would suffice and lead to age verification approval, increasing the risk that youth could bypass age verification measures and purchase JUUL directly from Defendant online.

158. Defendant originally required all online buyers to have an adult sign at the point of delivery, an important youth prevention measure that Defendant paid for rather than passing the cost on to its customers. However, in mid-2016, in response to complaints from some customers and in order to make more profit on every online order, Defendant decided to stop requiring an adult signature at point of delivery but rather to offer it as an optional service at an additional cost to the consumer.

159. Defendant was aware at the time that no longer requiring adult signatures would increase the risk of approving and completing sales to minors through Defendant's own website, and that Defendant's age verification processes would require substantial changes as a result.

160. Defendant's warranty processing system also allowed youth to access JUUL products and circumvent age verification. Many individuals were identified by Defendant as submitting dozens of warranty claims every month using slightly different email addresses. Defendant was aware as early as late-2017 that some of these individuals were likely either youth or people selling JUUL to youth.

161. Defendant's failure to detect these significant loopholes for so long demonstrates Defendant's disregard for youth prevention and the fact that profits were far more important to Defendant than preventing youth from accessing its tobacco products.

VI. DEFENDANT'S PRIOR AND CONTINUING ACTS AND PRACTICES HAVE HARMED AND WILL CONTINUE TO HARM PENNSYLVANIANS, ESPECIALLY OUR YOUTH, IF ALLOWED TO CONTINUE

162. Defendant's acts and practices described above have caused harm to the Commonwealth and its residents, especially its youth.

163. Defendant's actions have risked causing hundreds of thousands of Pennsylvania youth and non-smokers to become nicotine dependent, which is harmful to their health in and of itself but may also lead to other negative health effects like initiation of combustible tobacco smoking or increased susceptibility to other substance abuse disorders.

164. Defendant's actions have reinforced and prolonged nicotine dependence among smoking adults trying desperately to save their own lives by quitting smoking.

165. Defendant has deceived and manipulated consumers in Pennsylvania by its various acts, practices, and omissions.

166. Defendant's tobacco products may cause adverse health effects the nature and scope of which are yet unknown. Unlike combustible cigarettes, e-cigarettes have not existed for long enough for us to fully understand the effects of long-term use, and JUUL has only been commercially available for less than 5 years at this point.

167. Defendant has squandered an opportunity to lead the e-cigarette industry and develop a product that would actually help eliminate combustible tobacco smoking while protecting vulnerable youth, instead prioritizing profits and growth with an ultimate goal of selling out to Big Tobacco by maximizing addictiveness and appealing to youth in its marketing and design of JUUL, all at the expense of Pennsylvania residents, especially its youth.

168. Defendant's product poses an environmental and poisoning hazard for small children and wildlife who may ingest discarded or misplaced JUUL pods, risking substantial

physical damage or death to both very young Pennsylvanians and to the wildlife that the Commonwealth is obligated to protect by the Pennsylvania Constitution.

169. Defendant's acts, practices, and omissions will cause damages to the Commonwealth as a result of the increased rates of and reinforcement of nicotine dependence among Pennsylvania residents, especially among youth who are now more likely to begin smoking and are now more susceptible to other substance abuse disorders.

170. In the past, the design and marketing of cigarettes by the tobacco industry has required the Commonwealth to spend billions of dollars paying for and attempting to mitigate the damages smoking has caused to its residents, including by spending state Medicaid funds and incurring other state healthcare expenses, and the Commonwealth will pay more if Defendant's actions lead people, especially youth, to begin or continue smoking or to develop health problems unique to e-cigarette or JUUL use, including health effects of which we are currently unaware.

171. Many of Defendant's acts, practices, and omissions described herein and the harms caused thereby to the Commonwealth and its residents are continuing in nature and such harm will continue if Defendant is allowed to continue to engage in such acts.

COUNT 1 – VIOLATIONS OF THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW ("UTPCPL")

172. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

173. Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") is intended to protect the people of the Commonwealth from being harmed by deceptive and misleading business practices carried out within the Commonwealth. This function is especially vital when the health and safety of Commonwealth residents, and especially its vulnerable youth, are at risk.

174. Section 2(4) of the UTPCPL defines "unfair methods of competition" and "unfair or deceptive acts or practices" as "causing likelihood of confusion or of misunderstanding as to the… approval or certification of goods," "causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another," "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have," or "engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. §201-2(4)(ii), (iii), (v), (xxi).

175. Section 3 of the UTPCPL declares that "unfair methods of competition or deceptive acts or practices in the conduct of any trade or commerce," as defined in Section 2(4), are unlawful. 73 P.S. §201-3.

176. Defendant is engaged in the conduct of trade and commerce within the Commonwealth and has been so engaged since at least June 2015.

177. As described above, Defendant misrepresented JUUL's nicotine content, nicotine absorption rates, and addictive power, and made unsubstantiated claims about JUUL's safety and effectiveness as a smoking cessation product. Such claims and misrepresentations were unfair, deceptive, and misleading because they indicated to consumers that JUUL had characteristics, uses, benefits, or quantities of ingredients that JUUL did not have and created a likelihood of confusion or of misunderstanding.

178. As described above, Defendant targeted its marketing and promotion of JUUL to youth. Those actions were unfair, deceptive, and misleading because such actions represented to consumers that JUUL was appropriate for use by youth when, in fact, it is not, causing a likelihood of confusion or misunderstanding as to whether JUUL was appropriate for use by youth.

179. As described above, Defendant characterized JUUL as a luxurious lifestyle product "to go along with your iProducts." This characterization was unfair, deceptive, and misleading because it indicated to consumers, especially youth, that the risks associated with JUUL were comparable to the risks posed by products like the iPhone, not to the serious health risks associated with tobacco products, leading to a likelihood of confusion or misunderstanding among consumers as to what kinds of risks JUUL poses to consumers.

180. As described above, Defendant characterized JUUL as a safe product that could improve the lives and health of its users without obtaining approval of such characterizations from the FDA. Such characterizations were unfair, deceptive, and misleading because they created a likelihood of confusion or of misunderstanding as to whether: (i) Defendant was authorized or approved to make such characterizations by the FDA or another regulatory entity, or (ii) as to whether JUUL was approved or certified for use as a smoking cessation device by the FDA or another regulatory entity.

181. Whether a product presents a risk of addiction or other health concerns constitutes material information to a consumer, because such information may affect the consumer's decision whether to purchase and use such product.

182. Consumers have a reasonable expectation that any company marketing a product containing addictive compounds such as nicotine would provide appropriate warnings concerning its addictiveness.

183. Consumers have a reasonable expectation that any company marketing a product that has both short-term and long-term health consequences would provide appropriate warnings regarding those health consequences.

184. Young consumers have a reasonable expectation that any product that is marketed toward them will be designed and marketed with consideration for their particular vulnerabilities, including the effects of the product on their physical, neurological, and behavioral development and their particular susceptibility to nicotine addiction. Given these facts, it was unfair, deceptive, and misleading for Defendant to establish a marketing campaign for JUUL that was targeted to or appealing to youth. It was unfair, deceptive, and misleading to target young consumers in its marketing without providing warnings of the susceptibility of youth to heightened harm and risk of addiction.

185. Consumers have a reasonable expectation that products that differentiate themselves through an increase in their harmful and addictive effect will advise consumers of that increased effect. It was unfair, deceptive, and misleading for Defendant to market a product that Defendant knew had such heightened harmful and addictive effects as compared to other e-cigarettes without providing appropriate warnings regarding the addictiveness of the product, especially when they were marketing the product to especially vulnerable youth.

186. Consumers have a reasonable expectation that products that create harmful effects will not be marketed based upon the attributes of those harmful effects that appeal to consumers without also making clear the harmful effects created by those attributes. By advertising and promoting its product as "satisfying" without making clear that the satisfaction was associated with its addictive effects, Defendant acted unfairly, deceptively, and misleadingly toward consumers.

187. Consumers have a reasonable expectation that when a product is marketed to them that has associated health risks that such risks will be disclosed and represented accurately relative to alternative products. Defendant's claims in public media and through its Switch campaign that

JUUL "improved lives" and, therefore, impliedly was safe or safer than cigarettes was not substantiated by sound scientific evidence and did not indicate to consumers how much safer JUUL actually was than smoking, nor did those claims disclose the negative health effects associated with JUUL that would tend to make JUUL unsafe or less safe. Therefore, such claims made by Defendant were unfair, deceptive, and misleading.

188. It was unfair, deceptive, and misleading for Defendant to market JUUL without appropriate warnings regarding its addictiveness or other health consequences.

189. Defendant disregarded the risk of targeting youth by focusing on social media marketing, a platform frequented by youth almost compulsively. Defendant's efforts in this regard were highly successful, generating viral popularity among youth nationwide via social media.

190. Defendant's acts and practices had the capacity and tendency to deceive consumers regarding material information about JUUL, including its nicotine concentrations, rate of nicotine delivery, harmful and potentially harmful compounds produced by JUUL, the relative safety of JUUL as a tobacco product, whether JUUL was appropriate for use by youth or non-smokers, and JUUL's supposed utility as a smoking cessation device.

191. Defendant's unfair, deceptive, and misleading conduct in all of these respects was comparable to many of the acts and practices utilized by the cigarette industry over many years to promote its product and have led to the epidemic of youth e-cigarette use and nicotine addiction that has arisen since JUUL's introduction.

192. Defendant's conduct described above constitutes unlawful unfair or deceptive acts or practices as defined by the UTPCPL.

193. Defendant represented and continues to represent, as described above, that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

194. Defendant has willfully engaged in and continues to engage in deceptive conduct which, as described above, creates a likelihood of confusion or misunderstanding.

195. Defendant is willfully engaging in methods, acts, and practices declared unlawful by the UTPCPL, and Defendant has so willfully engaged in such methods, acts, and practices since at least June 2015, if not earlier.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. A preliminary and permanent injunction be entered enjoining Defendant from continuing to sell the JUUL e-cigarette into the Commonwealth of Pennsylvania, or, in the alternative, enjoining Defendant from engaging in the deceptive acts and unfair trade practices complained of herein, including the following conduct:

a. Marketing, distributing, or selling any e-cigarettes within the Commonwealth:

(1) Containing more than 20 milligrams of nicotine per 1 milliliter of nicotine liquid;

(2) Containing more than 1 milliliter of nicotine per pod or cartridge;

(3) Containing any flavoring substances, compounds, or ingredients that taste like, are characterized as, or could reasonably be characterized as anything but tobacco-flavored;

(4) That have not received either Pre-Market Tobacco Application approval or official approval as a smoking cessation drug or device from the United States Food and Drug Administration;

b. Using any marketing or sales practices that target, appeal to, or encourage youth or adolescents to begin or continue to use tobacco products, including JUUL, or facilitate their opportunity to do so;

c. Using any outdoor, transit advertising, or event sponsorship except where the patrons are exclusively 21 years old or older;

d. Using any person younger than 30 in its advertising;

e. Using social media in any form as a marketing tool, either directly or indirectly through social media influencers or other third parties;

f. Using samples and giveaways or discounting any product more than 50% from the regular retail price;

g. Making or implying any material misrepresentation regarding the health consequences of using the JUUL e-cigarette;

h. Making any claims, suggestions, or characterizations in any marketing or advertising that JUUL is a lifestyle product rather than a tobacco product;

i. Marketing or advertising JUUL in any way that suggests that there are positive social attributes, such as hipness or coolness, associated with the use of JUUL;

j. Making claims or implying in any way that JUUL e-cigarettes are safe or healthy, whether compared to other products or otherwise, except as permitted by an MRTP Marketing Order issued by the FDA;

k. Making claims or implying in any way that JUUL's nicotine content and potency are less than they actually are, including by comparing JUUL's potency in any way to that of cigarettes;

l. Making any claims regarding JUUL's nicotine content in terms of weight rather than the industry standard expression in terms of volume, specifically expressed as milligrams of nicotine per milliliter of nicotine liquid or expressed as a percent nicotine by volume;

m. Making any claims regarding JUUL's characteristics, uses, benefits, or quantities of ingredients that do not fully and completely describe the known and potential risks associated with JUUL, except as specifically authorized by the FDA pursuant to a Modified Risk Tobacco Product Marketing Order or any other FDA order that otherwise approves JUUL as a smoking cessation device;

n. Making any claim or suggestion that JUUL has been approved for any use by any regulatory authority without an order supporting such claim;

o. Making any effort to suppress research regarding e-cigarettes and failing to publish any research conducted by Defendant or of which it is aware that is adverse to the e-cigarette industry;

p. Using any marketing or sales practices that directly or indirectly target ethnic or racial communities, LGBTQ communities, or veterans or active duty service members;

q. Selling the JUUL e-cigarette at any convenience store in the Commonwealth;

r. Failing to require sound age-verification procedures for all sales of the JUUL e-cigarette;

s. Failing to accept returns and provide refunds to any distributor or retailer that elects to no longer sell the JUUL e-cigarette in the Commonwealth of Pennsylvania

t. Distributing JUUL e-cigarettes without providing clear information to Pennsylvania consumers, schools, and government officials regarding proper disposal of JUUL e-cigarettes.

ii. Judgement be entered ordering Defendant to disclose all research, studies, and accompanying data in its possession, including such research and studies previously conducted directly or indirectly by Defendant, its agents, affiliates, servants, officers, directors, employees, owners, and all persons acting in concert with them, as well as any related correspondence or other documents, that relate to the issue of tobacco products and health or addiction;

iii. Judgement be entered declaring that Defendant has willfully engaged and continues to willfully engage in the unlawful, unfair, and deceptive conduct described above in violation of Section 201-3 of the Unfair Trade Practices and Consumer Protection Law;

iv. Judgement be entered against Defendant for compensatory damages in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

v. Civil penalties be assessed against Defendant in the amount of $1,000.00 for each violation of the Unfair Trade Practices and Consumer Protection Law, and $3,000.00 for each violation involving a victim 60 years old or older, together with such other damages as provided for under that statute;

vi. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the unfair and deceptive acts and practices complained of herein.

The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

vii. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate; and

viii. The Court grant such other and further relief as it deems just and proper.

COUNT 2 – PUBLIC NUISANCE

196. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

197. By introducing JUUL to the e-cigarette market, Defendant enticed youth and non-smokers with sweet flavors and a nicotine buzz that Defendant led consumers to believe was safe, despite not really knowing the long-term effects of e-cigarette use, and despite knowing the negative effects of youth and young-adult nicotine dependence on neural and behavioral development.

198. While some consumers may be able to use JUUL to help them stop smoking cigarettes, some of them have reinforced their own nicotine dependence and many other consumers who never smoked before using JUUL (including youth) are now more likely to begin smoking as a result of their nicotine dependence.

199. Defendant's conduct drove competitors to emulate JUUL's design, creating an e-cigarette market that is more appealing to youth, more accessible to youth, and includes many more products that are more highly addictive than before the launch of JUUL in June 2015.

200. Defendant's conduct has led to increased e-cigarette use and nicotine dependence among youth and young adults at epidemic proportions, which is detrimental to public health and public safety.

201. To the extent that JUUL e-cigarettes have addicted new tobacco product users, regardless of age, or have extended the addiction of existing tobacco product users, Defendant's actions have been detrimental to public health and safety.

202. Defendant's conduct constitutes a significant interference with the public health and public safety.

203. Defendant's conduct unreasonably interferes with a public right embodied by federal laws and regulations prohibiting the sale or marketing of tobacco products to minors and prohibiting unsubstantiated and unauthorized claims regarding the safety of such products or such product's appropriateness as a smoking cessation device.

204. Defendant's conduct, coupled with its failure to provide complete and accurate public disclosure of information regarding the addictive potential and health effects of Defendant's products, deceived and confused the public regarding the addictive nature and health effects of JUUL and interfered with the public's right to be free from the widespread distribution of products that cause addiction and may cause disease and to be knowledgeable about the dangers of such products.

205. Defendant's conduct described above unreasonably interferes with the public's right to be free from addictive substances hazardous to health, and has caused harm to the public health, public safety, and the general well-being of the residents of the Commonwealth.

206. Defendant's conduct is of a continuing nature and has knowingly produced a permanent or long-lasting effect on public health and public safety.

207. Defendant's conduct complained of in this Complaint is outrageous and demonstrates Defendant's willful, wanton, and reckless indifference to the rights of others.

208. Unless Defendant is enjoined from continuing such conduct and ordered to take affirmative steps to undo and abate the harm and confusion caused thereby, the unreasonable interference with public health and public safety as described above will continue, for which the Commonwealth has no adequate remedy at law.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. Judgement be entered granting the equitable relief described in Count 1 above;

ii. Judgement be entered against Defendant for compensatory damages in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

iii. Judgement be entered against Defendant for punitive damages in an amount which is just and proper under the circumstances, and which will sufficiently punish Defendant, taking into account its financial position and that of its affiliates, partners, investors, and owners, and will discourage repetition of its outrageous, reckless, willful, and wanton conduct;

iv. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the public nuisance complained of herein. The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

v. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

vi. The Commonwealth recover its disbursements of this suit, costs, and reasonable attorney's fees; and

vii. The Court grant such other and further relief as it deems just and proper.

COUNT 3 – STRICT PRODUCTS LIABILITY

209. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

210. Defendant designed, manufactured, and sold JUUL in a defective condition unreasonably dangerous to its users within the Commonwealth from June 2015 onward by:

i. Increasing the nicotine content of JUUL to maximize its addictive power;

ii. Adding benzoic acid to JUUL to maximize its addictive power;

iii. Manipulating the nicotine delivery capabilities of JUUL to exceed those of many cigarette brands, maximizing its addictive power;

iv. Adding flavoring compounds to JUUL that appealed to youth;

v. Failing to warn consumers of the inherent risk of developing or reinforcing nicotine dependence or other negative health effects associated with JUUL.

211. The defective condition of JUUL is a substantial factor causing the injuries and damages suffered by the Commonwealth and by users of JUUL within the Commonwealth.

212. A product such as JUUL that causes or reinforces nicotine dependence is not safe for its intended purpose.

213. The risks of nicotine dependence and other negative health outcomes inherent in the JUUL product outweigh its utility as an e-cigarette or smoking cessation device (if any).

214. It is believed and therefore averred that, due to Defendant's deception, misrepresentations, omissions, and other unfair and misleading acts and practices, consumers were not aware of or expecting the unreasonably dangerous condition of JUUL before purchasing and using the product.

215. The dangers inherent to JUUL were not open and obvious, and Defendant had a duty to label its product to identify the dangers associated with the product. Defendant failed to label its product appropriately during such period.

216. In addition, Defendant had a duty, in the context of marketing and advertising its product, to provide warnings to consumers about the inherent risks of using JUUL, because such consumers would otherwise be unaware of such risks. Defendant's failure to provide such warnings and its continuing failure to provide appropriate warnings rendered and continues to render JUUL defective due to its latent dangerous characteristics.

217. It was reasonably foreseeable to Defendant that JUUL would be used by youth within the Commonwealth and Defendant had actual knowledge of use of JUUL by youth soon after its launch in June 2015.

218. The manner in which Defendant marketed and advertised JUUL demonstrates that youth and non-smokers were intended users of JUUL.

219. Defendant did not design JUUL in a way that would have prevented or limited its use by or appeal to youth.

220. Youth are generally less able than older adults to fully appreciate the risks of using e-cigarettes, including the ease with which one can become addicted to nicotine, the risks posed

by addiction on the developing brain, the harmful effects of lifelong nicotine use on their health, the health risks presented by inhaling other harmful and potentially harmful compounds produced by e-cigarettes, the possibility that they will switch to other tobacco products like cigarettes, and the additional harmful effects of cigarette smoking.

221. Defendant designed JUUL to be at least as addictive as cigarettes, if not more so, delivering more nicotine to users' bloodstreams than necessary to emulate cigarette smoking.

222. The defective condition of JUUL is the proximate cause of injuries and damages that have been and will be sustained by the Commonwealth and by users of JUUL within the Commonwealth.

223. These injuries and damages suffered by individual Pennsylvanians have and will cause damages to the Commonwealth by damaging the public health and public safety within the Commonwealth, causing Commonwealth residents to incur medical expenses as a result of their nicotine dependence and subsequent smoking or other substance abuse disorders, requiring public health and law enforcement action to abate the negative effects of e-cigarette use and associated health problems among residents of the Commonwealth, and causing any negative health effects that will be associated with e-cigarette use but are yet unknown.

224. Defendant's conduct complained of in this Complaint is outrageous and demonstrates Defendant's willful, wanton, and reckless indifference to the rights of others.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. Judgement be entered granting the equitable relief described in Count 1 above;

ii. Judgement be entered against Defendant for compensatory damages in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or

any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

iii. Judgement be entered against Defendant for punitive damages in an amount which is just and proper under the circumstances, and which will sufficiently punish Defendant, taking into account its financial position and that of its affiliates, partners, investors, and owners, and will discourage repetition of its outrageous, reckless, willful, and wanton conduct;

iv. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the conduct complained of herein. The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

v. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

vi. The Commonwealth recover its disbursements of this suit, costs, and reasonable attorney's fees; and

vii. The Court grant such other and further relief as it deems just and proper.

COUNT 4 - NEGLIGENCE

225. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

226. Nicotine dependence is physically and neurologically harmful to humans, especially youth and young adults, causing symptoms of withdrawal that are difficult to cope with, a greater susceptibility to addiction later in life, and changes in brain chemistry that negatively affect mood and behavior.

227. E-cigarettes, including JUUL, deliver harmful and potentially harmful chemicals via aerosol into the lungs.

228. The long-term health effects of e-cigarette use, including JUUL, are unknown at this time, presenting a risk that depositing such substances into one's lungs and delivering such substances to one's bloodstream and brain over the long-term may lead to disease or other negative health effects in addition to those associated with nicotine use and dependence.

229. Defendant learned of JUUL's popularity among and access to youth soon after launch in June 2015 and knew or should have known of its appeal to youth prior to launch.

230. Defendant was aware of JUUL's highly addictive nature prior to launch in June 2015 as evidenced by Defendant's own patent for JUUL and Defendant's own representations to retail customers comparing JUUL's nicotine absorption to that of cigarettes.

231. Defendant's conduct described above created an unreasonable risk of causing physical harm to consumers who use JUUL.

232. Defendant was aware or should have been aware of the unreasonable risk of causing physical harm to consumers who use JUUL.

233. Defendant was and is under a duty to exercise reasonable care to prevent the unreasonable risk of physical harm from taking effect.

234. Defendant has breached and continues to breach such a duty by failing to take corrective action to make its products less addictive, less appealing to youth, and less accessible

to youth. Despite warnings from state and federal authorities to the seriousness of these risks, Defendant took as few steps as possible to prevent the unreasonable risk of physical harm from taking effect and ensured that the youth e-cigarette epidemic continued long enough to allow Defendant to have millions of nicotine-dependent youth and young adults available to buy Defendant's products for years to come.

235. Defendant's breach of its duty to prevent the unreasonable risk of physical harm from taking effect has caused and continues to cause known and unknown harms to consumers within the Commonwealth, especially youth users of JUUL.

236. Defendant's conduct complained of in this Complaint is outrageous and demonstrates Defendant's willful, wanton, and reckless indifference to the rights of others.

237. The Commonwealth and its residents have suffered damages as a result of Defendant's breach of its duty to prevent the unreasonable risk of physical harm from taking effect.

238. These injuries and damages suffered by individual Pennsylvanians have and will cause damages to the Commonwealth by damaging the public health and public safety within the Commonwealth, causing Commonwealth residents to incur medical expenses as a result of their nicotine dependence and subsequent smoking or other substance abuse disorders, requiring public health and law enforcement action to abate the negative effects of e-cigarette use and associated health problems among residents of the Commonwealth, and causing any negative health effects that will be associated with e-cigarette use but are yet unknown.

239. The full extent of the damages caused by Defendant's breach will not be known until the long-term health effects of e-cigarette use are better understood.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. Judgement be entered granting the equitable relief described in Count 1 above;

ii. Judgement be entered against Defendant for compensatory damages in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

iii. Judgement be entered against Defendant for punitive damages in an amount which is just and proper under the circumstances, and which will sufficiently punish Defendant, taking into account its financial position and that of its affiliates, partners, investors, and owners, and will discourage repetition of its outrageous, reckless, willful, and wanton conduct;

iv. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the conduct complained of herein. The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

v. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

vi. The Commonwealth recover its disbursements of this suit, costs, and reasonable attorney's fees; and

vii. The Court grant such other and further relief as it deems just and proper.

COUNT 5 – WILLFUL BREACH OF A SPECIAL DUTY

240. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

241. Defendant's website advertises its mission is to "improve the lives of the world's one billion adult smokers by eliminating cigarettes." It states further: "We envision a world where fewer adults use cigarettes, and where adults who smoke cigarettes have the tools to reduce or eliminate their consumption entirely, should they so desire."

242. Under the heading "OUR COMMITMENT" on Defendant's website, it states that "We welcome dialogue, debate and data, and will register and publish results from vapor-related research we conduct."

243. Since as early as its founding in March 2007, Defendant undertook a special duty, as prescribed by the Restatement (Second) of Torts §324A, to the Commonwealth and to its residents. This special duty was to accept an interest in the public's health as a basic and paramount responsibility, to conduct and publish research into the health effects of e-cigarette use and the efficacy of e-cigarette as a smoking cessation device, and to cooperate with state and federal public health and law enforcement agencies to prevent youth access to e-cigarette products.

244. Defendant publicly undertook to discharge such special duty, recognizing that it was necessary for the public health, including the health of Pennsylvania residents, especially youth.

245. Despite Defendant's commitments to public health, Defendant has breached this special duty by selling and marketing JUUL without fully understanding its long-term health effects or its efficacy for smoking cessation, seeking to undermine or discredit public health and medical research that tended to cast e-cigarettes or JUUL in a negative light, and conducting and

publishing internal studies with the primary goal of buoying Defendant's reputation and legitimizing the use of youth-oriented flavors in e-cigarettes rather than actually determining JUUL's health effects or its effect on public health.

246. In reliance on Defendant's undertaking of this special duty to keep public health as one of its core responsibilities, consumers within the Commonwealth began or continued to use Defendant's e-cigarettes. Defendant's breach of this special duty has caused and continues to cause many Commonwealth residents (especially youth) to develop nicotine dependence and, as a direct result of this breach, many such residents will suffer serious health problems, including nicotine dependence, nicotine withdrawal symptoms, altered mood and behavioral development, increased propensity for addiction, increased likelihood of subsequent combustible tobacco use and all the serious and often fatal health problems associated therewith, and any health problems that have not yet been linked as a long-term effect of e-cigarette use.

247. Defendant failed to exercise reasonable care in carrying out this special duty, increasing the risk of and resulting in physical harm to individuals and to the public health and public safety as described herein.

248. The harms to individuals, the public health, and the public safety complained of herein were caused by the public's reliance on Defendant undertaking of this special duty.

249. Defendant's conduct complained of in this Complaint is outrageous and demonstrates Defendant's willful, wanton, and reckless indifference to the rights of others.

250. As a direct and foreseeable result of Defendant's breach of its special duty, the Commonwealth and its residents have suffered and continue to suffer damages.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. Judgement be entered granting the equitable relief described in Count 1 above;

ii. Judgement be entered against Defendant for compensatory damages in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

iii. Judgement be entered against Defendant for punitive damages in an amount which is just and proper under the circumstances, and which will sufficiently punish Defendant, taking into account its financial position and that of its affiliates, partners, investors, and owners, and will discourage repetition of its outrageous, reckless, willful, and wanton conduct;

iv. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the conduct complained of herein. The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

v. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

vi. The Commonwealth recover its disbursements of this suit, costs, and reasonable attorney's fees; and

vii. The Court grant such other and further relief as it deems just and proper.

COUNT 6 – UNJUST ENRICHMENT

251. The Commonwealth incorporates the preceding paragraphs by reference as though they were fully set forth herein.

252. The Commonwealth, through the Department of Health, Department of Education, the Office of Attorney General, and other state and local agencies and political subdivisions, have expended and will continue to expend substantial amounts of money and resources to address nicotine dependence among its residents due to e-cigarette use, as well as subsequent combustible tobacco use resulting therefrom.

253. The Commonwealth has conferred a benefit on the Defendant by satisfying and continuing to satisfy part of Defendant's legal duties and saving Defendant from initially bearing the cost for harm proximately caused by Defendant's wrongful conduct, thereby enabling Defendant to reap substantial and unconscionable profits from the sale of its tobacco products in the Commonwealth.

254. Pennsylvania residents have directly conferred a benefit upon the Defendant as a result of its wrongful conduct by purchasing its products when they might not otherwise have done so if they were fully informed, thereby generating profits for the Defendant.

255. As a result of Defendant's wrongful conduct described above, Defendant has profited enormously from sales of its highly addictive products to Pennsylvania consumers, including youth and non-smoking adults, many of whom are now or will become nicotine dependent, profits which Defendant otherwise would not have received and which it would be inequitable to allow Defendant to retain.

256. The Commonwealth and its residents are therefore entitled to disgorgement of such profits for benefits conferred upon the Defendant by the Commonwealth and its residents and to

the extent required by equity to prevent Defendant's unjust enrichment as a result of its wrongful and unlawful conduct.

WHEREFORE, the Commonwealth of Pennsylvania, by Josh Shapiro, in his official capacity as Attorney General of the Commonwealth of Pennsylvania, respectfully requests that:

i. Judgement be entered against Defendant for restitution in an amount in excess of $50,000.00, including interest and delay damages, reserving the Commonwealth's or any other person or entity's right to seek additional compensatory damages in the event that additional long-term negative health effects or other damages associated with e-cigarette use are discovered in the future;

ii. Defendant be ordered to fund an independent corrective public education campaign to inform Pennsylvanians about the true health risks and consequences of use of Defendant's tobacco products and to remedy the conduct complained of herein and to make whole those who have been injured by Defendant's conduct. The education program so established is to be administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

iii. Defendant be ordered to fund tobacco product cessation programs for Pennsylvanians addicted to nicotine, including the provision of nicotine replacement therapy and addiction counseling for dependent tobacco users, administered and controlled by the Commonwealth or such other independent third party as the Court may deem appropriate;

iv. The Commonwealth recover its disbursements of this suit, costs, and reasonable attorney's fees; and

v. The Court grant such other and further relief as it deems just and proper.

Respectfully submitted,

JOSH SHAPIRO
Attorney General

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Attorneys for Plaintiff,
Commonwealth of Pennsylvania

Date: February 10, 2020

COMMONWEALTH OF PENNSYLVANIA BY JOSH SHAPIRO, in his official capacity as Attorney General of the Commonwealth of Pennsylvania	:	IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
	:	_____ TERM, 2020
Plaintiff,	:	
v.	:	No. _____
JUUL LABS, INC.,	:	
Defendant.	:	

VERIFICATION

I, Kathleen K. DeLone, hereby state that I am a Supervisory Civil Investigator with the Pennsylvania Office of Attorney General, Tobacco Enforcement Section, and am authorized to make this verification on behalf of the Plaintiff in this action. I hereby verify that the facts set forth in the foregoing Complaint are true to the best of my knowledge or information and belief.

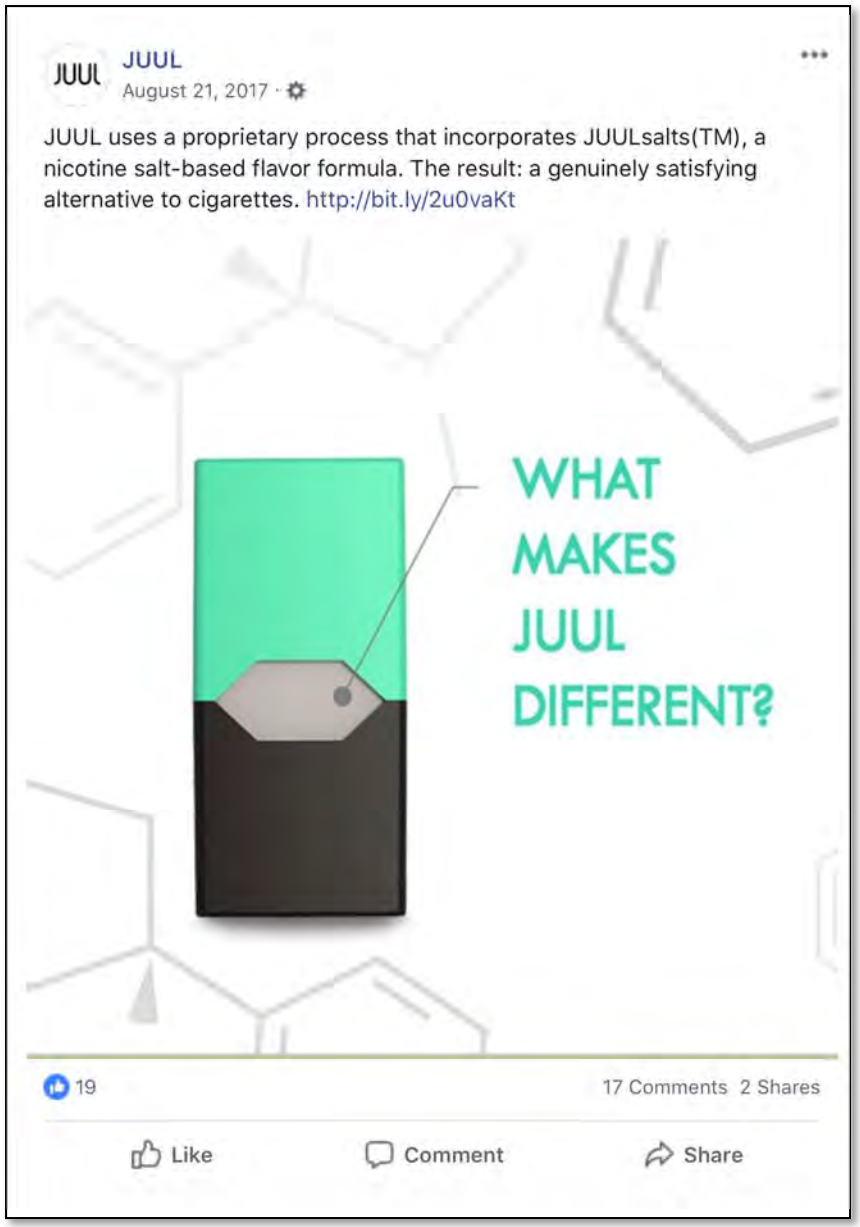
I understand that the statements contained herein are subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

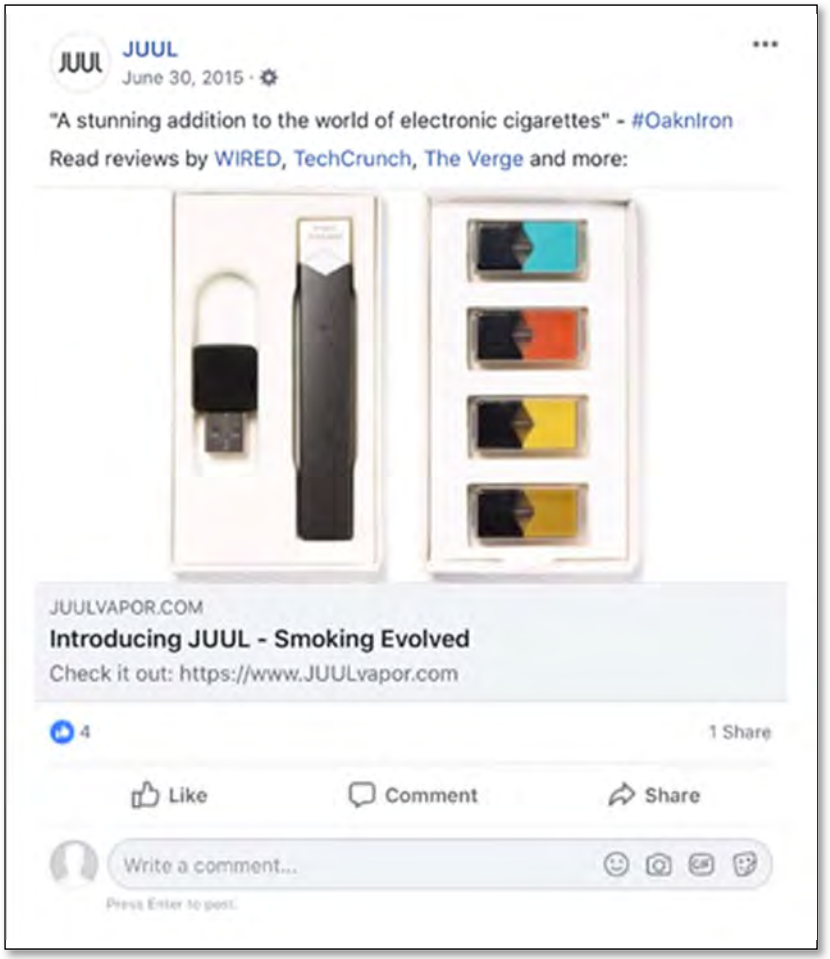
Date: 1/17/20

Kathleen K. DeLone

Kathleen K. DeLone
Supervisory Civil Investigator
Tobacco Enforcement Section

Exhibit A





LEFT: Facebook post touting the satisfaction created by using nicotine salts, like those found in JUUL; ABOVE: Facebook post promoting JUUL and linking to product reviews on various sites like Wired, TechCrunch, and The Verge.

Image Credit: SRITA

THE VERGE

SCIENCE TECH

Startup behind the Lambo of vaporizers just launched an intelligent e-cigarette

31

Surprise, it's a rectangle

By Nitasha Tiku | Apr 21, 2015, 8:00am EDT

The office for Pax Labs, the San Francisco company behind the stylish and popular Pax loose-leaf vaporizer, is located in the same building as the headquarters for Burning Man. Sometimes the two tenants have joint happy hours and the Burners help out with costumes. It's "a good cultural match for us," Sarah Richardson, Pax's director of communications said during a recent visit to the company. "They make us look conservative."

Richardson was sitting at a conference table puffing on Pax's newest product: a slim, rectangular e-cigarette called Juul. Seated around the table were the mechanical and electrical engineers behind Juul, including Pax's research scientist Chenyue Xing, who has a PhD in chemical engineering and experience with inhalation products.

THE KEY TO SMOKER SATISFACTION IS HITTING PEAK NICOTINE FIVE MINUTES IN

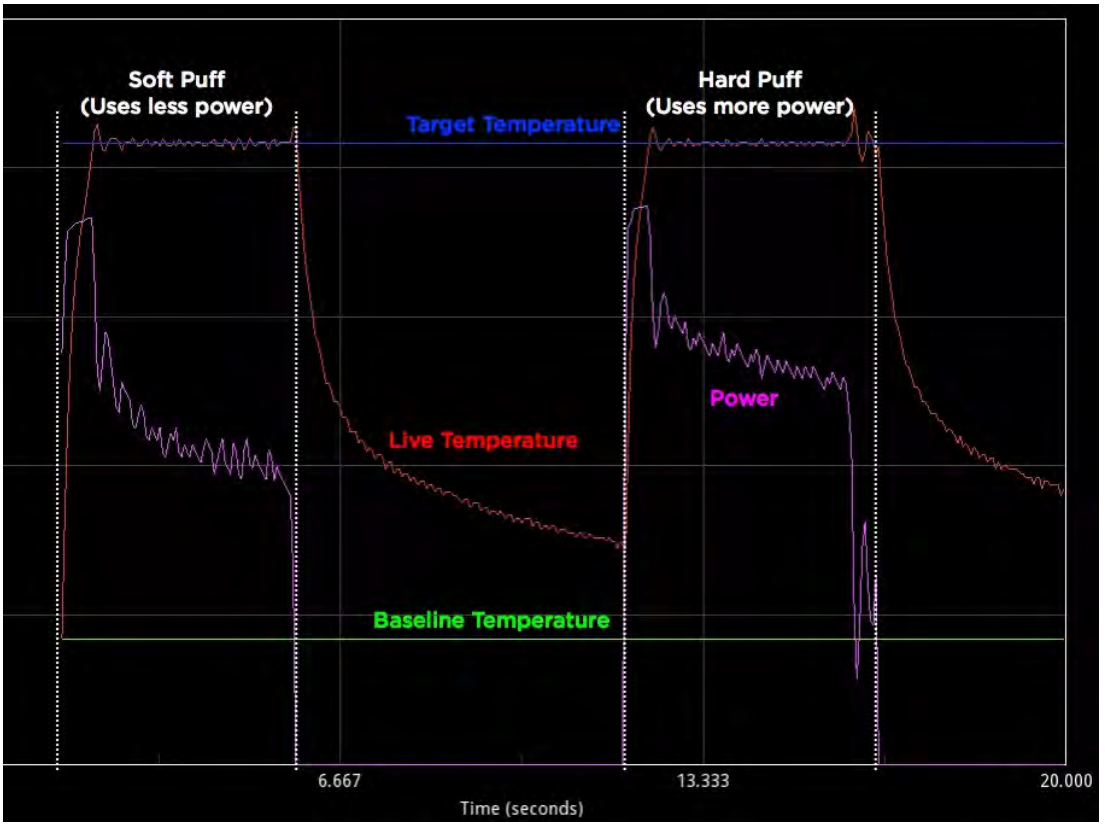
The small team has helped create what Pax Labs (formerly known as Ploom) is calling "an intelligently engineered and intensely satisfying new vapor experience." What makes it intelligent? "That's up for personal interpretation isn't it? Just kidding," CEO James Monsees told me later, by phone.

In Monsees' interpretation, Juul is smarter than the competition because of its ability to mimic the satisfaction of smoking a regular "combustion" cigarette. The key to that buzz is a sharp peak of nicotine in the consumer's blood profile about five minutes after she takes her first puff. To recreate that spike, the team started with the chemistry of its liquid-nicotine cartridges, or "Juulpods," which use nicotine salts, rather than "free-base nicotine." Using salts allowed Pax to increase the nicotine concentration from two percent to five percent without being unpalatable. Adding organic acids were also a key part to make inhaling smoother. It's not delivering more nicotine overall, it's delivering it in a more satisfying way, the team told me.

"JUULPODS" JUST ROLLS OFF THE TONGUE

The other differentiator that makes Juul smarter is temperature control, using what they called a precision resistance measurement circuit to figure out the ideal temperature for vaporization. "When you're able to control the temperature really well," said Monsees, the flavor doesn't change and you don't create degradation compounds that you don't want to inhale. Although tank-based e-cigarettes allow users to adjust the temperature, it's less controlled because the liquids and device are from different companies and changes depending on whether the user puffs faster or slower.

To demonstrate Juul's precision in this area Ari Atkins, an R&D engineer, connected Juul to his Macbook, started inhaling, and the graph below appeared on the conference room screen.



Juul is definitely not for the *keep vaping weird* crowd, who care about customization, but I found Juul's design simple and intuitive. The disposable cartridges easily popped into the device. Each puff did seem standardized. Sure, I felt a little like an alien whipping it out at a bar, but a really minimalist alien. The device comes with a one-year warranty and uses a magnetic USB deck to recharge. It takes one hour to charge and that will last you for about one pod or 200 "puffs per charge," the company says. To figure out whether it needs to be charged, you gently tap the device twice and a little light on the front glows red, yellow, or green.

Consumers can purchase Juul starting June, 2015. Pax is selling the starter kit (the device, a multi-pack of Juulpods in four flavors, and a USB charger) for $49.99 and the 4-packs of the pods for $15.99.

A REALLY MINIMALIST ALIEN

For novices or fans of clean design, it's less clunky than skeuomorphic devices like Njoys, which are built to look like a cigarette, and involves fewer parts than Blu's rechargeable model. Plus, there's no glowing light or specter of Jenny McCarthy.

Pax Labs recently released a new model of its vaporizer (happy belated 4/20, buddies). But it's a dicey time to get into the e-cig business. The Food and Drug Administration (FDA) formally proposed regulations for e-cigarettes last April. According to *The Hill*, the FDA is unlikely to act before June, but academics and researchers aren't waiting around. In February, a study was published showing that exposing mice to e-cigarette vapor for just two weeks had damaged their immune system. For the study, they tested Njoy, one of the biggest brands in the market. The most alarming report came from a survey published by the Centers for Disease Control and Prevention last week, which found that e-cigarette usage was now more popular than cigarettes in middle and high schools. However as *The New York Times* pointed out, the shift could also suggest "that some teenage smokers may be using e-cigarettes to quit."

E-CIGARETTES ARE MORE POPULAR THAN CIGARETTES IN HIGH SCHOOL

While the data is being debated, officials like the California Department of Public Health, which put out the video below, are already campaigning over advertising e-cigarettes to kids.

Pax Labs is very careful not to make any claims about health or smoking cessation. Monsees is the first to acknowledge that his company has "a vested interest" in calling itself a healthier cigarette, and therefore should not be the one to analyze its own risks. E-cigs have been popular for the past five years, but the industry still doesn't have the kind of "conclusive studies" the agency requires for over-the-counter medications, food, or cosmetics, he said. "All I can do is encourage regulators."

When I pressed Monsees about how Pax thinks of the issue, he called combustion cigarettes "the most popular consumer product of all time that has known issues." Pax's goal is to make "compellingly better products."

"THE MOST POPULAR CONSUMER PRODUCT OF ALL TIME THAT HAS KNOWN ISSUES"

Atkins, the R&D engineer, was a less diplomatic. "We don't think a lot about addiction here because we're not trying to design a cessation product at all," he said, later noting "anything about health is not on our mind," before his colleagues collectively winced. Atkins, who used to smoke close to half a pack of Marlborough Reds a day, may make a good poster boy for Juul regardless. While developing the product, "I just realized one day that I hadn't smoked cigarettes in a month," he said. Atkins didn't think of it as quitting smoking, "I just like it better."

Addiction and obligation are issues that Silicon Valley would rather avoid. Filings with the Security and Exchange Commission from earlier this month show that Pax has been trying to raise $25 million in funding, but has only sold investors on $6.5 million so far. Companies sometimes file Form D's before the round has closed and Monsees would not disclose anything about ongoing funding efforts, but he did acknowledge that Sand Hill Road hasn't welcomed him with open wallets. "Venture firms are generally set up to invest in innovation, but the kind of innovation that comes out of the Valley, and we're not exactly that." Although he declined to share revenue, Monsees said Pax was in a "growth phase" and now "well beyond" the milestone of selling half a million Pax devices, which the company announced in February.

Juul's name is supposed to be a play on the word *jewel* because Pax wanted to create something more lasting and precious than throwaway cigarettes. "We didn't want to spell it the same because we like being different," said Monsees. The four flavors of the liquid — miint, fruut, bruulé , and tabaac — also exhibit the same devil may care attitude towards spelling. This contrarian impulse may serve Juul better when it comes to its thin, rectangular design. As Atkins put it: "I like to wear skinny jeans."

Verge Video archive: *This is what vape-hacking looks like (2014)*

TOP ARTICLES 1/5

Quibi tries to explain what Quibi is in a new Super Bowl commercial

READ MORE »

Exhibit B

PAX LABS: ORIGINS WITH JAMES MONSEES

In Everything / By Gabriel Montoya

Some people think of Silicon Valley as a foreign land of luxury prototypes and endless apps that may or may not change the world for the better. But it can also be a place where the most innovative of dreams can be realized. Few inventions made anywhere ever actually live up to that kind of promise on any level. The PAX vaporizer by PaxVapor is one of those exceptions. Sleek enough to fit in a three-piece suit, discreet enough to be pulled out on the dance floor, and cool enough to start a conversation, the portable PAX has helped revolutionize the smoking experience. Today, "vaping" is quickly becoming the method of choice for smokers of all kinds.

The device and related products were first envisioned in the early 2000's by two Stanford product design grad students, James Monsees and Adam Bowen. Standing out back of the design lab, smoking cigarettes, Monsees and Bowen had a thought.

Adam Bowen – Co Founder

"[We said to each other] 'We're relatively smart people and we're standing out here burning sticks," laughed Monsees as he recanted the origin story to me at Ploom HQ in San Francisco's Mission District. "We kind of love this ritual and these products in certain ways. But we had a lot of problems with it. What would happen if we try to design a better experience for ourselves?"

Where that shared vision led them would culminate in their 2005 Master's Thesis and ultimately into a successfully growing company that has just scratched the surface of it's potential.

"We realized really quickly this is probably the largest innovation to market size ratio of anything, right? There's almost no innovation [to the cigarette]. At least at that time [2005]. The e-cigarettes had not been out at all yet," said Monsees. "Cigarettes are not the only smoking experience but they are the majority. Cigarettes are 90% plus of everything that smoked tends to be cigarettes. The cigarette is probably the most successful consumer product of all time. It's hardly changed in its life cycle. It's been highly optimized. There are cigarette manufacturing machines. One machine can spit out 20,000+ cigarettes a minute. It's insane. Get in your car and what's red line on a car? 5000, 6000 RPMs? So your car, every minute is cranking its motor 5000 RPMs. That's like its limit, right? You go to a cigarette manufacturing plant and its spitting out 20,000 cigarettes a minute. It's doing four times as much work and weighing each of these things down to the microgram. It's unbelievable the level of refinement that's gone into that industry. It's an amazing product. But it's got some problems, right? Some long-standing problems that just aren't going away."

Webster's defines the word "PAX" as "a tablet decorated with a sacred figure (as of Christ) and sometimes ceremonially kissed by participants at mass." It's otherwise known as "the kiss of peace in mass;" a fitting name for a device that will bring peace to smokers everywhere who've always had to take their chosen luxury with a touch of dread about their future health.

Following their epiphany, Monsees and Bowen began to educate themselves on tobacco and its consumption. Along the research path, they came across a treasure trove of information on the tobacco industry.

"We started looking at patent literature. We are pretty fluent in 'Patentese.' And we were able to deduce what had happened historically in the tobacco industry. In particular, after the "Master Settlement Agreement,' the big settlement where everyone was suing the tobacco companies and there was one master lawsuit that was kind of rolled together. One of the results was that a lot of

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tobacco industry documentation was mandated to become public," explained Monsees. "You can still go to a website called tobaccodocuments.org and you can read board minutes and other things. [Writer's note: that site is now down but offers info on where to go get those documents: UCSF Legacy Tobacco Documents Library]. "It became a very intriguing space for us to investigate because we had so much information that you wouldn't normally be able to get in most industries. And we were able to catch up, right, to a huge, huge industry in no time. And then we started building prototypes."

The testing phase featured many prototypes of varying quality tested on both themselves and campus smokers.

"We'd sort of hand something to [test subjects] and help them use it because it was usually a really shitty prototype," laughed Monsees. "And we'd see how it kind of worked for them. And as the prototypes got more refined, we'd give one to someone for a week for them to use and check in with them every once a while and see how it was going. None of these were market-ready. But it gave us a lot of insights we kind of knew to some degree because we had done all this research on the tobacco industry. We kind of knew that these weren't the kind of insights that these guys were looking for. And they were ultimately really valuable."

By 2006, Monsees and Bowen were living and working in San Francisco, chasing down the finished version of their dream.

"We had a friend with a fuel cell startup that was co-founded by the head of Mechanical Engineering at Stanford. They give us space in their office in exchange for us brainstorming stuff with them once in a while. Figure that was a good way to start a company. Low-cost," he laughed. "And Adam and I sat across from each other at a tiny coffee table desk like this [indicating the smallish low glass table in front of us] for about a year working on prototypes and trying to create something that was potentially commercializable, building a business plan, meeting with potential investors, understanding the landscape, that sort of thing."

By 2007, the partners had enough money to get started and incorporate the business. PaxVapor was born.

"We started working in the pods business. Sort of "espresso for tobacco." The start of what is known as the PaxVapor's products. The pods products," explained Monsees.

James Monsees – Co Founder

What's a pod? I'll let the creators tell you. From the Ploom website: "Ploom pods are single-serving tobacco capsules used in the Ploom modelTwo. They are filled with the highest quality ingredients including whole leaf tobacco, botanicals and all-natural flavors. Ploom pods are made from anodized, food-grade aluminum. Pods can also be recycled." https://www.ploom.com/pods

“It’s very forward thinking. Although a little ahead of it’s time, right?” Monsees asked rhetorically. “The e-cigarette industry by that time had really started to show some life. And one of the reasons was that it was more understandable. ‘Hey, If you want to smoke, people are making these things that look like cigarettes and they’re trying to mimic cigarettes.’ While those products didn’t quite deliver on that promise, it was really understandable to consumers.

“Whereas the product that we were building, we were like ‘This is like the dystopian future of tobacco,” Monsees reflected with a wry smile. “[Pods are] a totally different ritual and it’s pretty cool but there’s a ton of consumer re-education involved.”

With knowledge and trial comes understanding and the path towards a creative breakthrough. Everything learned has value.

“So what we ended up doing is understanding, ‘Hey, we’ve built a lot of know-how in vaporization in general and we wanted to leverage that into new categories,” Said Monsees. “We realized that vaporization is a really valuable core science that is really simple and deployable across a lot of different industries and consumer groups. And there’s a lot of needs besides directly people that are just smoking cigarettes. People that are smokers or want something in the more broad smoking experience. Anything under that umbrella, which is actually pretty big , there are different verticals that we can address. And that’s where PAX kind of was born.”

I’ve heard variations on how the PAX heats up. Some call it a convection device. Others conduction. Monsees explained that a variety of things that make the PAX go.

“Convection, conduction and radiation, right, those are the three general modes of thermal transfer,” explained Monsees. “A lot of the products that are sort of in the PAX space are pigeonholed into one of those three things. It makes sense. One of these three methods is going to be the primary way that you heat whatever it is [you are vaping]. They don’t work alone. PAX is primarily conduction-based. There is also a radiation and convection components to the product. So you’re always kind of optimizing all these different thermal transfers. Some people would label it as a conduction-based vaporizer but when you really dig into it, there is a lot more going on to make [the PAX] work really well.”

I’ve tried a variety of vaporizers. Only one, in my opinion, compares to the PAX. [Writer’s note: See the other vaporizer articles I’ve written for socialunderground.com. It’s kind of rude to advertise another brand in this article]. But of those two in my home, only one makes the cut when I want to go out dancing or for an herbally-enhanced run: the PAX. Lightweight and small enough to fit in the palm of your hand, The PAX is as sleek as vaporizers come and easier to use than most. On the bottom is a magnetically sealed heating chamber to put your material in. The device is activated by pushing down on the top, which reveals the mouthpiece. The device takes a moment to heat up

but once it does, the logo on the side glows green and let's you know the time is now. And with a strong battery life, that time lasts quite a good long while.

"Our methodology was we just don't want this thing to look overtly gadgety," said Monsees of the design. "These are luxury experiences for lack of a better way to put it. Smoking anything, the whole smoking experience, is not like eating, right? You don't have to do it but you want to do it. It's something that you decide to do and because it's sort of a chosen thing that you want in your life, you want that to be an awesome experience, right? Just a sort of elegant, refined experience. Because food doesn't have to be that. It *can* be at times. You go out to a nice restaurant or whatever, you want it to be a refined experience. You're elevating something that you just have to do every day into something that is something more of a social moment. But generally, you have to eat, right?

"Smoking is in a different category," he continued. "It has the capability of always being luxurious, always being sort of a wonderful experience. The products that were on the market before then were sort of wooden boxes. weird stuff. That's fun in a sort of novelty way, right? That's fun from time to time. We want to build products that have kind of a magical consumer experience that you can have all the time and keep with you and it's sort of precious. A sort of obvious and intuitive consumer interface. And something that is really elegant and, contrary to concealment, you're sort of proud to be with it. That's what we were going after."

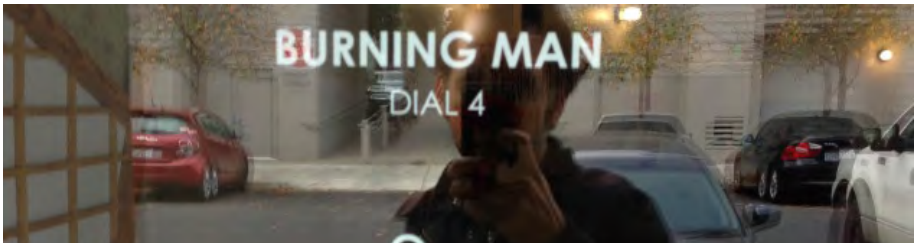
The vaping space is a wide open one. Walk into any smoke shop today and what used to be your dad's tobacco store is now overrun by vaporizers of varying kinds. Mod shops where vapeologists piece together devices of their own are also all the rage now. It's tough to stand out in a rapidly changing world. But Ploom has done exactly that by taking all the knowledge gleaned through their pioneering trial and error and applying it to a simple, elegant and user-friendly design: The PAX.

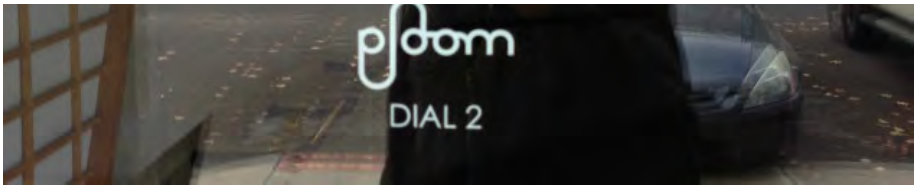
"We saw people with looseleaf vaporizers and a lot of companies doing that. We knew that we could do that a lot better and there would be a lot less consumer education because we make something that's radically better and differentiated. But it's good to be comparable, right, to these other products. So we did that. And PAX did really well," said Monsees. "And with [Director of Marketing Sarah Richardson's] help and other people we were able to get that product out there and get people to understand the virality of that product because it was such a superior experience and there was a lot of interest in that category. It just grew really rapidly."

Today, Ploom is a growing company looking to the future in a variety of directions. Ploom shares a building with Burning Man. The company not the festival.

"They're the only people who could make us look like squares," joked Richardson.

Ploom HQ is equal parts engineering lab, office space and creative think tank. As I stepped off the elevator and into the Ploom offices, the first thing I saw was a full size pool table where the team blows off steam between ground-breaking ideas. I only spent about an hour there but the vibe was pleasant, relaxed, and low pressure.





"At this phase, we've been able to build a much bigger team with a lot of core competencies in the science behind vaporization, file a ton of intellectual property on new things and over the next couple of years, we will be doing some really, really cool stuff in those categories as well as others," said Monsees.

With the past paving the way for a vibrant present, the immediate future of Ploom is top secret. For now.

"We are a company that are never satisfied with what were doing," said Monsees. "We're happy about it. We're real proud of PAX and our other products but we're always looking at what's next, what could be better. Because if we don't look with an overly critical eye at our products, someone else will."

Will there be a next-gen PAX? Or an expansion of the pod product line? Or something none of us has dared to dream? What is next for Ploom and its products?

"A lot of great stuff," Monsees smiled conspiratorially. "We can't really say at this moment right now. It probably won't be long. The business has some exciting new announcements. Things that we'll be really excited to talk about. But at this moment all I can say is that we will have more than one really awesome new product out this year."

Needless to say, the vaping world can't wait.

You can purchase PAX Vaporizers at the SocialUnderground Store

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"A person with knowledge of the situation."
Co-host/co-producer: Leave it in the ring radio

TAGS: JAMES MOONSES | PAX | PLOOM | TOBACCO | VAPEOLOGY | VAPING | VAPORIZER

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Exhibit C

US009215895B2

(12) **United States Patent**
Bowen et al.

(10) **Patent No.: US 9,215,895 B2**
(45) **Date of Patent: Dec. 22, 2015**

(54) **NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF**

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(73) Assignee: **PAX Labs, Inc.**, San Francisco, CA (US)

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(51) **Int. Cl.**

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A24B 15/16	(2006.01)
A61K 31/465	(2006.01)
A61K 9/12	(2006.01)

(52) **U.S. Cl.**

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(58) **Field of Classification Search**

CPC A24F 47/008

See application file for complete search history.

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(57) **ABSTRACT**

A nicotine salt liquid formulation for generating an inhalable aerosol in an electronic cigarette comprising nicotine salt that forms about 0.5% to about 20% nicotine is provided.

26 Claims, 8 Drawing Sheets

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FIG. 1

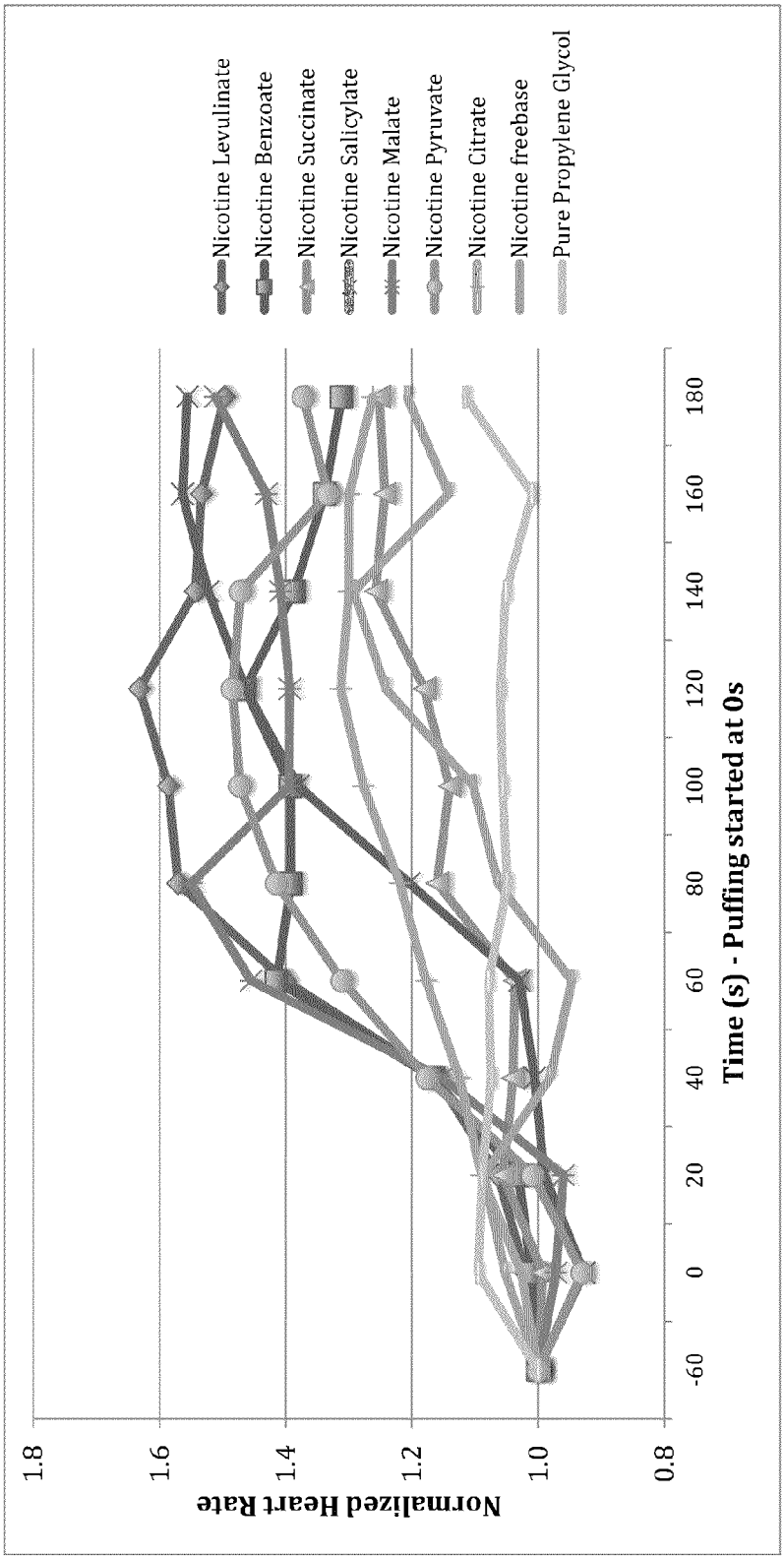

Nicotine Levulinate
Nicotine Benzoate
Nicotine Succinate
Nicotine Salicylate
Nicotine Malate
Nicotine Pyruvate
Nicotine Citrate
Nicotine freebase
Pure Propylene Glycol
Normalized Heart Rate
1.8
1.6
1.4
1.2
1.0
0.8
-60
0
20
40
60
80
100
120
140
160
180
Time (s) - Puffing started at 0s

FIG. 2

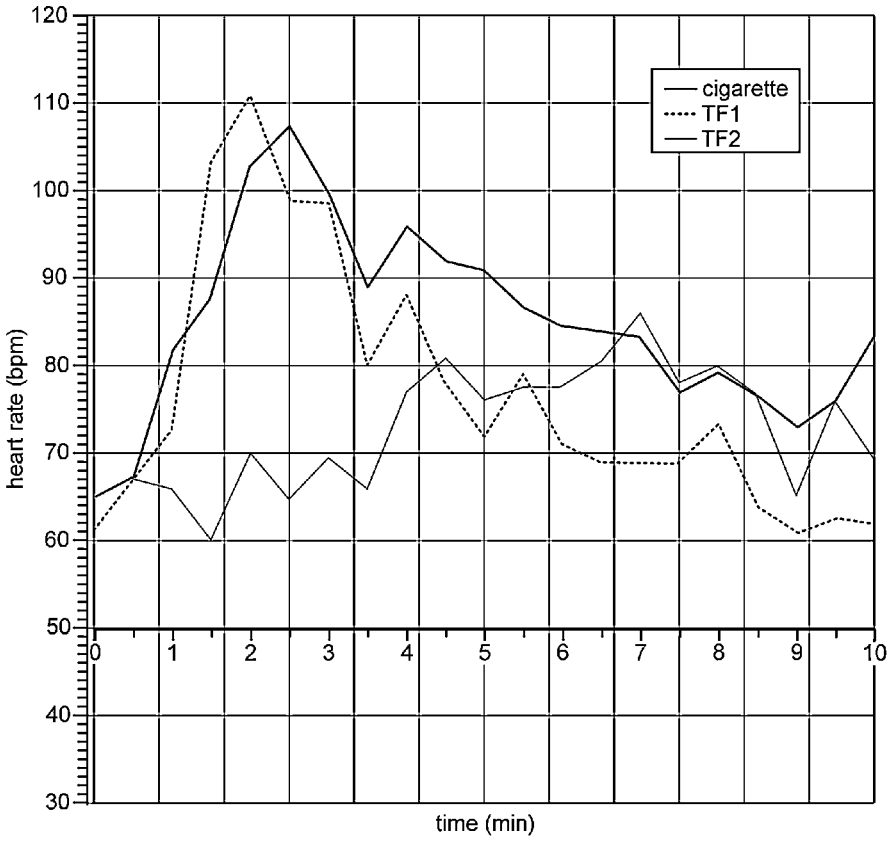

120
110
100
90
80
70
60
50
40
30
heart rate (bpm)
0
1
2
3
4
5
6
7
8
9
10
time (min)
cigarette
TF1
TF2

FIG. 3

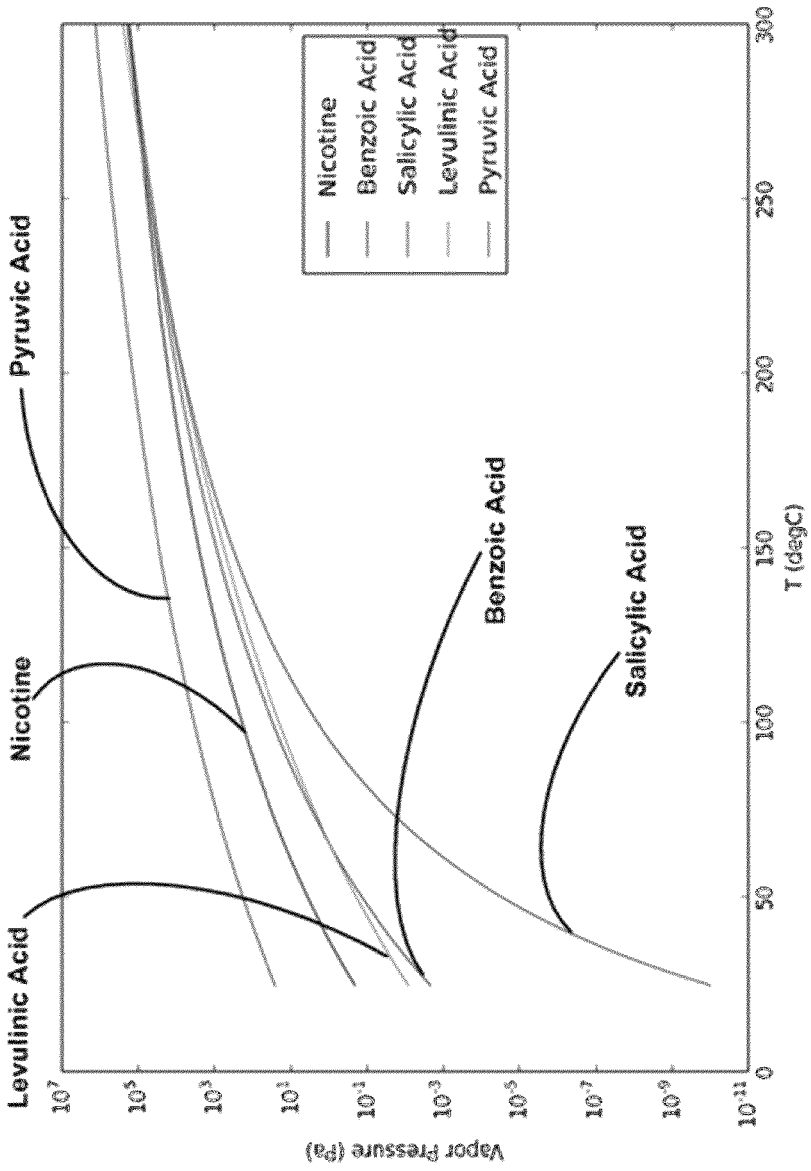
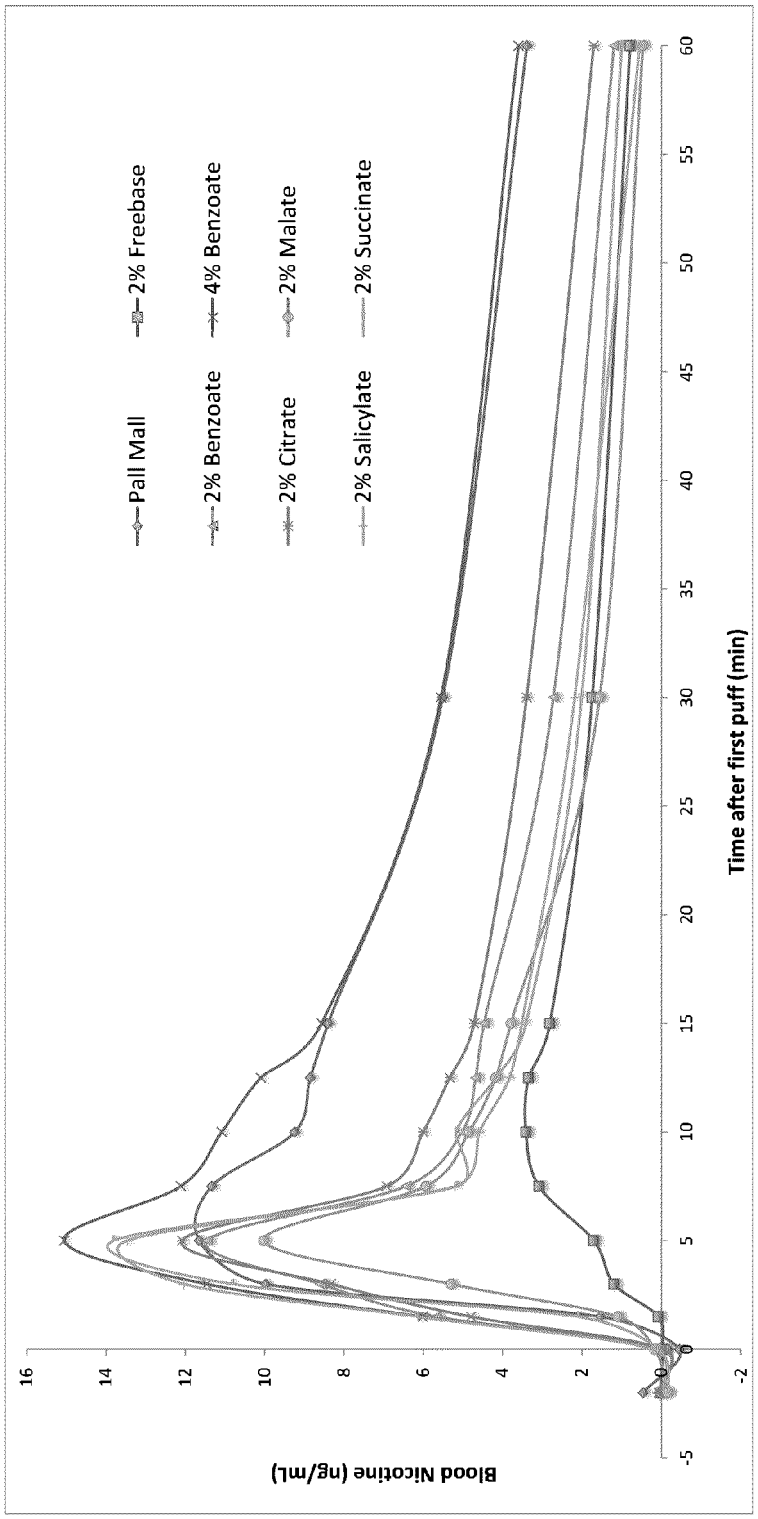

Nicotine
Benzoic Acid
Salicylic Acid
Levulinic Acid
Pyruvic Acid
Vapor Pressure (Pa)
T (degC)
0
50
100
150
200
250
300
10^{7}
10^{5}
10^{3}
10^{1}
10^{-1}
10^{-3}
10^{-5}
10^{-7}
10^{-9}
10^{-11}

FIG. 4


Pall Mall
2% Freebase
2% Benzoate
4% Benzoate
2% Citrate
2% Malate
2% Salicylate
2% Succinate
Blood Nicotine (ng/mL)
Time after first puff (min)
16
14
12
10
8
6
4
2
0
-2
-5
0
5
10
15
20
25
30
35
40
45
50
55
60

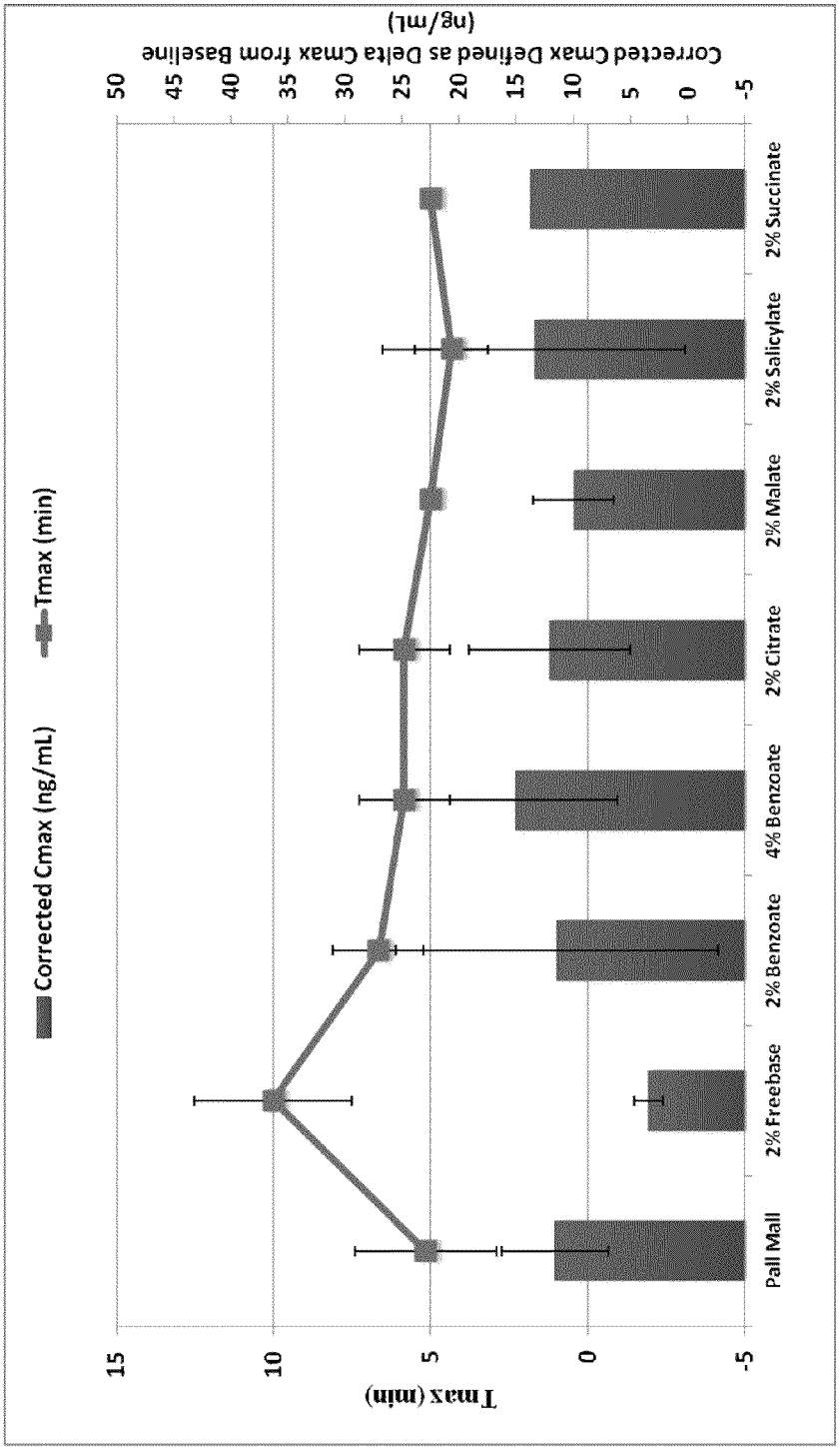

Corrected Cmax (ng/mL)
Tmax (min)
Corrected Cmax Defined as Delta Cmax from Baseline (ng/mL)
Tmax (min)
50
45
40
35
30
25
20
15
10
5
0
-5
15
10
5
0
-5
Pall Mall
2% Freebase
2% Benzoate
4% Benzoate
2% Citrate
2% Malate
2% Salicylate
2% Succinate

FIG. 5

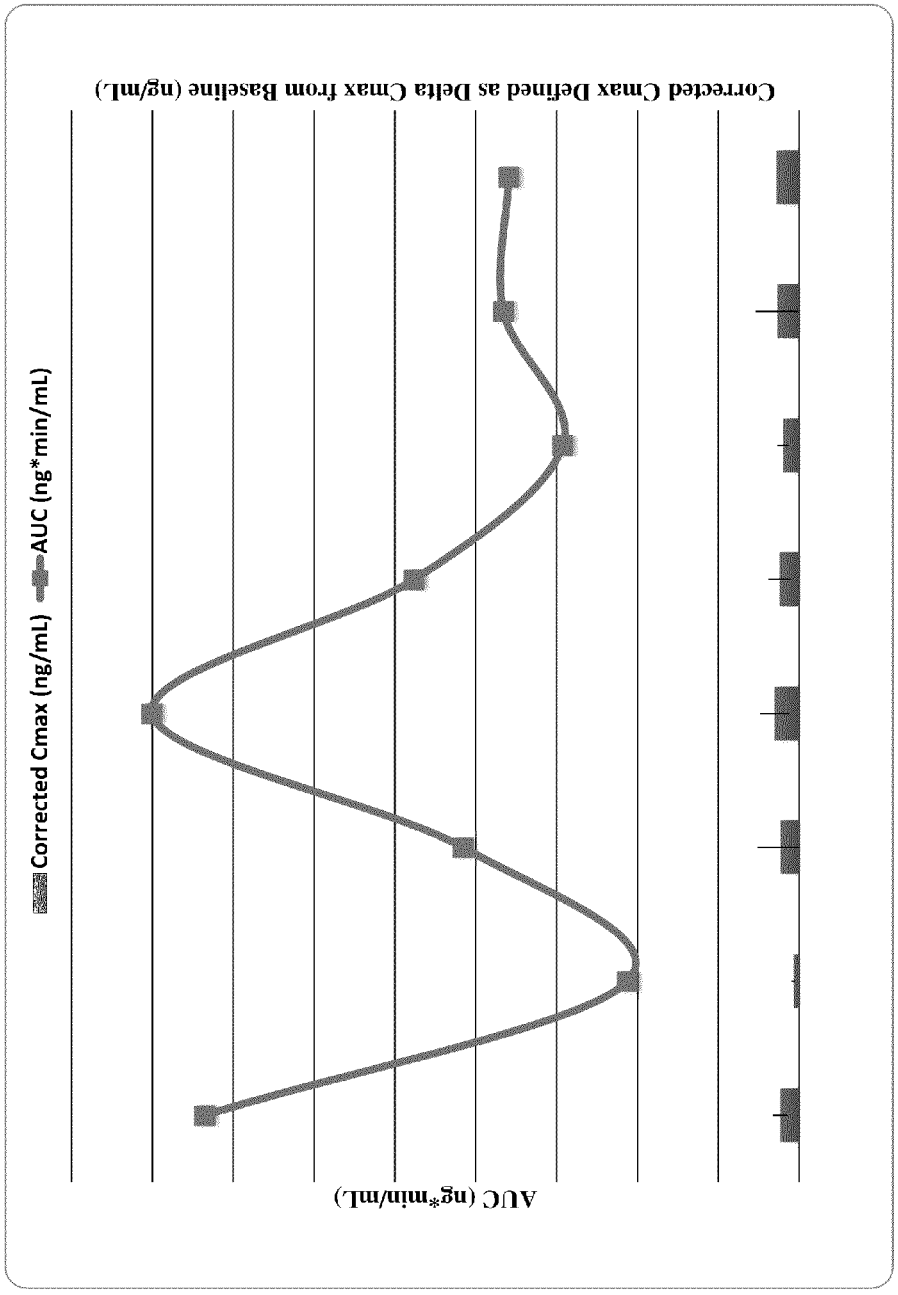
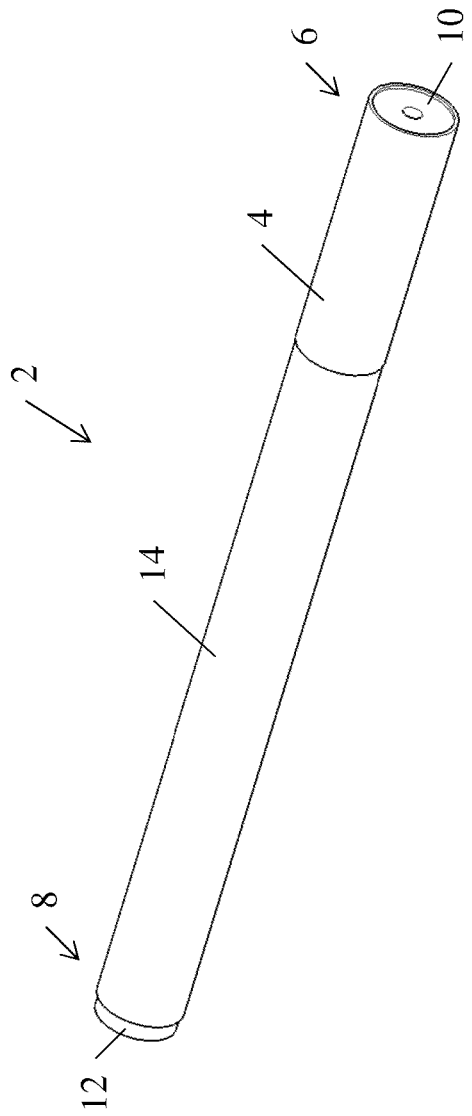

Corrected Cmax Defined as Delta Cmax from Baseline (ng/mL)
AUC (ng*min/mL)
Corrected Cmax (ng/mL)
AUC (ng*min/mL)

FIG. 6

FIG. 7



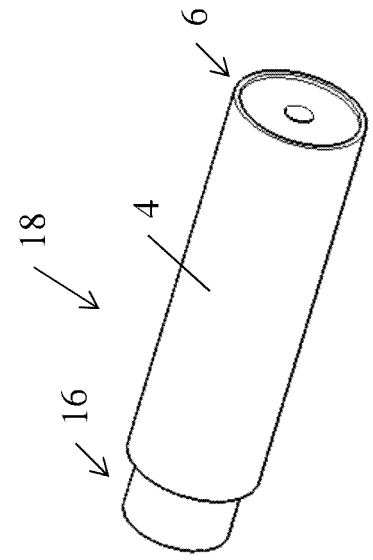


FIG. 8

NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF

CROSS REFERENCE

This application is a continuation of U.S. patent application Ser. No. 14/271,071, filed May 6, 2014, which claims the benefit of U.S. Provisional Patent Application Ser. No. 61/820,128, filed May 6, 2013, and U.S. Provisional Patent Application Ser. No. 61/912,507, filed Dec. 5, 2013, all of which are incorporated herein by reference in their entirety.

SUMMARY OF THE INVENTION

Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C., and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C., and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

Provided herein is a method of delivering nicotine to a user comprising operating an electronic cigarette wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

Provided herein is a method of delivering nicotine to a user comprising providing an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

Provided herein is a method of delivering nicotine to the blood of a user, said method comprising providing an aerosol that is inhaled by the user from an electronic cigarette that comprises a nicotine salt formulation wherein providing the aerosol comprises the electronic cigarette heating the formulation thereby generating the aerosol, wherein the aerosol is effective in delivering a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid

carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C., and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C., and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

Provided herein is a use of a nicotine salt formulation for delivery of nicotine to the blood of a user from an electronic cigarette, wherein the nicotine salt formulation in the electronic cigarette is heated to form an aerosol which delivers a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

Provided herein is a use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

Provided herein is a cartomizer for an electronic cigarette comprising:

- a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;
- an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and
- a fluid storage compartment that stores the nicotine salt liquid formulation.

Provided herein is a cartomizer for an electronic cigarette comprising:

- a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;
- an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and
- a fluid storage compartment that stores the nicotine salt liquid formulation.

Provided herein is a cartomizer for an electronic cigarette comprising:

- a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;
- an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and
- a fluid storage compartment that stores the nicotine salt liquid formulation.

Provided herein is a cartomizer for an electronic cigarette comprising:

- a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;
- an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and
- a fluid storage compartment that stores the nicotine salt liquid formulation.

Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

- a fluid storage compartment;
- a heater; and
- a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;
- a battery; and
- a mouthpiece.

Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

- a fluid storage compartment;
- a heater; and
- a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;
- a battery; and
- a mouthpiece.

Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

Provided herein is an electronic cigarette for generating an inhalable aerosol comprising:

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

Provided herein is a kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

Provided herein is a kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

Provided herein is a kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

Provided herein is a kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

INCORPORATION BY REFERENCE

All publications, patents and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication,

patent or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are used, and the accompanying drawings of which:

FIG. **1** illustrates results of heart rate data measured for six minutes from start of puffing. Y-axis is heart rate (bpm) and X-axis represent duration of the test (−60 to 180 seconds);

FIG. **2** illustrates results of heart rate data measured for ten minutes from start of puffing. Y-axis is heart rate (bpm) and X-axis represents duration of the test (0 to 10 minutes);

FIG. **3** illustrates the calculated vapor pressures of various acids relative to nicotine;

FIG. **4** illustrates the pharmacokinetic profiles for eight test articles in a blood plasma study;

FIG. **5** illustrates the comparison of C_{max} and T_{max} for eight test articles in a blood plasma study;

FIG. **6** illustrates the comparison of C_{max} and AUC for eight test articles in a blood plasma study;

FIG. **7** depicts an example embodiment of an electronic cigarette having a fluid storage compartment comprising an embodiment nicotine salt formulation described herein; and

FIG. **8** depicts an example embodiment of an electronic cigarette cartomizer having a fluid storage compartment, a heater, and comprising an embodiment nicotine salt formulation described herein.

DETAILED DESCRIPTION OF THE INVENTION

Nicotine is a chemical stimulant and increases heart rate and blood pressure when provided to an individual or animal. Nicotine transfer to an individual is associated with a feeling of physical and/or emotional satisfaction. Conflicting reports have been published regarding the transfer efficiency of free base nicotine in comparison to mono- or di-protonated nicotine salts. Studies on the transfer efficiency of free base nicotine and nicotine salts are complex and have yielded unpredictable results. Further, such transfer efficiency studies have been performed under extremely high temperature conditions, comparable to smoking; therefore, they offer scant guidance on the transfer efficiency of free base nicotine and nicotine salts under low-temperature vaporization conditions. Some reports have posited that nicotine free base should give rise to a greater satisfaction in a user than any corresponding nicotine salt.

It has been unexpectedly discovered herein that certain nicotine salt formulations provide satisfaction in an individual superior to that of free base nicotine, and more comparable to the satisfaction in an individual smoking a traditional cigarette. The satisfaction effect is consistent with an efficient transfer of nicotine to the lungs of an individual and a rapid rise of nicotine absorption in the plasma as shown, for non-limiting example, in Example 8, at least. It has also been unexpectedly discovered herein that certain nicotine salt formulations provide greater satisfaction than other nicotine salt formulations, and such effect has been shown in blood plasma levels of example nicotine salt formulations herein, for non-limiting example, in Example 8, at least. These results show a difference in rate of nicotine uptake in the blood that is higher for some nicotine salt formulations aerosolized by an electronic cigarette than for other nicotine salt formulations, and likewise higher than nicotine freebase formulations, while the peak concentration of the nicotine in the blood and total amount of nicotine delivered appears comparable to a traditional cigarette, and do not appear to vary significantly between the various nicotine formulations. Therefore, described herein are nicotine salt formulations for use in an electronic cigarette, or the like, that provide a general satisfaction effect consistent with an efficient transfer of nicotine to the lungs of an individual and a rapid rise of nicotine absorption in the plasma. Provided herein, therefore, are devices, formulation of nicotine salts, systems, cartomizers, kits and methods that are used to inhale an aerosol generated from a nicotine salt liquid formulation through the mouth or nose as described herein or as would be obvious to one of skill in the art upon reading the disclosure herein.

Consistent with these satisfaction effects, it has unexpectedly been found herein that there is a difference between the C_{max} (maximum concentration) and T_{max} (time at which the maximum concentration is measured) when measuring blood plasma nicotine levels of freebase nicotine formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of a traditional cigarette. Also consistent with these satisfaction effects, it has unexpectedly been found herein that there is a difference between the C_{max} (maximum concentration) and T_{max} (time at which the maximum concentration is measured) when measuring blood plasma nicotine levels of freebase nicotine formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of nicotine salt formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette. Additionally, it has unexpectedly been found that there is a difference between the rate of nicotine uptake in the plasma of users inhaling freebase nicotine formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling smoke of a traditional cigarette. Furthermore, it has unexpectedly been found that there is a difference between the rate of nicotine uptake in the plasma of users inhaling freebase nicotine formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette.

Thus, looking at freebase nicotine as a source of nicotine in compositions used in e-cigarettes, freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels (C_{max} and T_{max}) to a traditional cigarette's nicotine delivery to blood when inhaled. Freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels (C_{max} and T_{max}) to nicotine salt formulations' nicotine delivery to blood when inhaled. Freebase nicotine compositions' delivery of nicotine to blood when inhaled using is not necessarily comparable in blood plasma levels when measuring the rate of nicotine uptake in the blood within the first 0-5 minutes to a traditional cigarette's nicotine delivery to blood when inhaled. Freebase nicotine compositions' delivery of nicotine to blood when inhaled using necessarily is not comparable in blood plasma levels when measuring the rate of nicotine uptake in the blood within the first 0-5 minutes to nicotine salt formulations' nicotine delivery to blood when inhaled.

Also consistent with these satisfaction effects, it has unexpectedly been found herein that while there appears to be comparable C_{max} and T_{max} values (measuring blood plasma

nicotine levels) of nicotine salt formulations inhaled using a low temperature vaporization device, i.e. electronic cigarette, as compared to the C_{max} and T_{max} (similarly measuring blood plasma nicotine levels) of a traditional cigarette, there is a demonstrable difference between the rate of nicotine uptake in the plasma of users inhaling certain nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette, as compared to the rate of nicotine uptake in the plasma of users inhaling other nicotine salt formulations using a low temperature vaporization device, i.e. electronic cigarette. It is also unexpected that while the C_{max} and T_{max} values are comparable to those of a traditional cigarette, (or are approaching that of a traditional cigarette), the rate of nicotine uptake in the plasma of blood of users is higher in certain nicotine salt formulations than that of the traditional cigarette. The nicotine salt formulations which demonstrate the quickest rate of nicotine uptake in the plasma were more preferred in satisfaction evaluations, and were rated more equivalent to cigarette satisfaction than the nicotine salt formulations showing the slowest rates of rise of nicotine in the subjects' blood plasma. In addition, doubling the concentration of the nicotine salt in the formulation may not necessarily impact the rate of absorption of nicotine in the blood (see, for non-limiting Example 8, nicotine benzoate tested in 4% and 2% concentrations).

Thus, looking at nicotine salt formulations used in e-cigarettes, nicotine salt formulations delivered using an e-cigarette appear comparable in C_{max} and T_{max} values (measuring blood plasma nicotine levels), however, not all nicotine salts perform similarly to each other or to a traditional cigarette with respect to the rate of nicotine uptake in the blood at early time periods (0-1.5 minutes). These results are unexpected. Nicotine salt formulations made using acids having a Vapor Pressure between 20-300 mmHg @ 200° C., or Vapor Pressure >20 mmHg @ 200° C., or a Vapor Pressure from 20 to 300 mmHg @ 200° C., or a Vapor Pressure from 20 to 200 mmHg @ 200° C., a Vapor Pressure between 20 and 300 mmHg @ 200° C. appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). For non-limiting example, acids that meet one or more criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, lauric acid, and levulinic acid. Nicotine salt formulations made using acids that have a difference between boiling point and melting point of at least 50° C., and a boiling point greater than 160° C., and a melting point less than 160° C. appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). For non-limiting example, acids that meet the criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid. Nicotine salt formulations made using acids that have a difference between boiling point and melting point of at least 50° C., and a boiling point at most 40° C. less than operating temperature, and a melting point at least 40° C. lower than operating temperature appear to have a higher rate of nicotine uptake in the blood at early time periods (0-1.5 minutes, 0-3 minutes, 0-2 minutes, 0-4 minutes for non-limiting example) than other nicotine salt formulations, however, they also provide satisfaction comparable to a traditional cigarette or closer to a traditional cigarette (as compared to other nicotine salt formulations or as compared to nicotine freebase formulations). Operating temperature can be 100° C. to 300° C., or about 200° C., about 150° C. to about 250° C., 180 C to 220° C., about 180° C. to about 220° C., 185° C. to 215° C., about 185° C. to about 215° C., about 190° C. to about 210° C., 190° C. to 210° C., 195° C. to 205° C., or about 195° C. to about 205° C. For non-limiting example, acids that meet the criteria of the prior sentence include salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid. Combinations of these criteria for preference of certain nicotine salt formulations are contemplated herein.

Other reasons for excluding certain acids from formulations may be unrelated to the rate of nicotine uptake, however. For example, an acid may be inappropriate for use with the device materials (corrosive or otherwise incompatible). Sulfuric acid is an example of this, which may be inappropriate for the e-cigarette device. An acid may be inappropriate for use in inhalation or for toxicity reasons—thus not be compatible for human consumption, ingestion, or inhalation. Sulfuric acid again is an example of this, which may be inappropriate for a user of an e-cigarette device, depending on the embodiment of the composition. An acid that is bitter or otherwise bad-tasting may also provide a reason for exclusion, such as acetic acid in some embodiments. Acids that oxidize at room temperature or at operating temperature may be inappropriate for certain embodiments, for example, sorbic acid, as this indicates a decomposition or reaction or instability that may be undesirable in the formulation. Decomposition of acids at room or operating temperatures may also indicate that the acid is inappropriate for use in the embodiment formulations. For example, citric acid decomposes at 175° C., and malic acid decomposes at 140° C., thus for a device operating at 200° C., these acids may not be appropriate. Acids that have poor solubility in the composition constituents may be inappropriate for use in certain embodiments of the compositions herein. For example, nicotine bitartrate with a composition of nicotine and tartaric acid as 1:2 molar ratio will not produce a solution at a concentration of 0.5%(w/w) nicotine or higher and 0.9%(w/w) tartaric acid or higher in propylene glycol (PG) or vegetable glycerin (VG) or any mixture of PG and VG at ambient conditions. As used herein, weight percentage (w/w) refers to the weight of the individual component over the weight of the total formulation.

As used in this specification and the claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

The term "organic acid" as used herein, refers to an organic compound with acidic properties (e.g., by Brønsted-Lowry definition, or Lewis definition). A common organic acid is the carboxylic acids, whose acidity is associated with their carboxyl group —COOH. A dicarboxylic acid possesses two carboxylic acid groups. The relative acidity of an organic is measured by its pK_a value and one of skill in the art knows how to determine the acidity of an organic acid based on its given pKa value. The term "keto acid" as used herein, refers to organic compounds that contain a carboxylic acid group and a ketone group. Common types of keto acids include alpha-keto acids, or 2-oxoacids, such as pyruvic acid or oxaloacetic acid, having the keto group adjacent to the carboxylic acid; beta-keto acids, or 3-oxoacids, such as acetoacetic acid, having the ketone group at the second carbon from the carboxylic acid; gamma-keto acids, or 4-oxoac-

ids, such as levulinic acid, having the ketone group at the third carbon from the carboxylic acid.

The term "electronic cigarette" or "e-cigarette" or "low temperature vaporization device" as used herein, refers to an electronic inhaler that vaporizes a liquid solution into an aerosol mist, simulating the act of tobacco smoking. The liquid solution comprises a formulation comprising nicotine. There are many electronic cigarettes which do not resemble conventional cigarettes at all. The amount of nicotine contained can be chosen by the user via the inhalation. In general, an electronic cigarette contains three essential components: a plastic cartridge that serves as a mouthpiece and a reservoir for liquid, an "atomizer" that vaporizes the liquid, and a battery. Other embodiment electronic cigarettes include a combined atomizer and reservoir, called a "cartomizer" that may or may not be disposable, a mouthpiece that may be integrated with the cartomizer or not, and a battery.

As used in this specification and the claims, unless otherwise stated, the term "about" refers to variations of 1%, 2%, 3%, 4%, 5%, 10%, 15%, or 25%, depending on the embodiment.

Suitable carriers (e.g., a liquid solvent) for the nicotine salts described herein include a medium in which a nicotine salt is soluble at ambient conditions, such that the nicotine salt does not form a solid precipitate. Examples include, but are not limited to, glycerol, propylene glycol, trimethylene glycol, water, ethanol and the like, as well as combinations thereof. In some embodiments, the liquid carrier comprises 0% to 100% of propylene glycol and 100% to 0% of vegetable glycerin. In some embodiments, the liquid carrier comprises 10% to 70% of propylene glycol and 90% to 30% of vegetable glycerin. In some embodiments, the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin. In some embodiments, the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

The formulations described herein vary in concentration. In some formulations, a dilute concentration of the nicotine salt in the carrier is utilized. In some formulations, a less dilute concentration of the nicotine salt in the carrier is utilized. In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 25% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 20% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 18% (w/w). In some embodiments the concentration of nicotine in the nicotine salt formulation is about 1% (w/w) to about 15% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 4% (w/w) to about 12% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is about 4% (w/w). In some embodiments the concentration of nicotine in the nicotine salt formulation is about 2% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 25% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 20% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 18% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 1% (w/w) to 15% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 4% (w/w) to 12% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 4% (w/w). In some formulations the concentration of nicotine in the nicotine salt formulation is 2% (w/w). In some formulations, a less dilute concentration of one nicotine salt is used in conjunction with a more dilute concentration of a second nicotine salt. In some formulations, the concentration of nicotine in the first nicotine salt formulation is about 1% to about 20%, and is combined with a second nicotine salt formulation having a concentration of nicotine therein from about 1% to about 20% or any range or concentration therein. In some formulations, the concentration of nicotine in the first nicotine salt formulation is 1% to 20%, and is combined with a second nicotine salt formulation having a concentration of nicotine therein from 1% to 20% or any range or concentration therein. As used with respect to concentrations of nicotine in the nicotine salt formulations, the term "about" refers to ranges of 0.05% (i.e. if the concentration is about 2%, the range is 1.95%-2.05%), 0.1 (i.e. if the concentration is about 2%, the range is 1.9%-2.1%), 0.25 (i.e. if the concentration is about 2%, the range is 1.75%-2.25%), 0.5 (i.e. if the concentration is about 2%, the range is 1.5%-2.5%), or 1 (i.e. if the concentration is about 4%, the range is 3%-5%), depending on the embodiment.

Nicotine salts are formed by the addition of a suitable acid, including organic or inorganic acids. In some formulations provided herein, suitable organic acids are carboxylic acids. Examples of organic carboxylic acids disclosed herein are monocarboxylic acids, dicarboxylic acids (organic acid containing two carboxylic acid groups), carboxylic acids containing an aromatic group such as benzoic acids, hydroxycarboxylic acids, heterocyclic carboxylic acids, terpenoid acids, sugar acids; such as the pectic acids, amino acids, cycloaliphatic acids, aliphatic carboxylic acids, keto carboxylic acids, and the like. In some formulations provided herein, the organic acids used herein are monocarboxylic acids. Nicotine salts are formed from the addition of a suitable acid to nicotine. In some formulations provided herein, the stoichiometric ratios of the nicotine to acid (nicotine:acid) are 1:1, 1:2, 1:3, 1:4, 2:3, 2:5, 2:7, 3:4, 3:5, 3:7, 3:8, 3:10, 3:11, 4:5, 4:7, 4:9, 4:10, 4:11, 4:13, 4:14, 4:15, 5:6, 5:7, 5:8, 5:9, 5:11, 5:12, 5:13, 5:14, 5:16, 5:17, 5:18, or 5:19. In some formulations provided herein, the stoichiometric ratios of the nicotine to acid are 1:1, 1:2, 1:3, or 1:4 (nicotine:acid).

Nicotine is an alkaloid molecule that comprises two basic nitrogens. It may occur in different states of protonation. For example, if no protonation exists, nicotine is referred to as the "free base." If one nitrogen is protonated, then the nicotine would be "mono-protonated."

Nicotine salt formulations may be formed by adding a suitable acid to nicotine, stirring the neat mixture at ambient temperature or at elevated temperature, and then diluting the neat mixture with a carrier mixture, such as a mixture of propylene glycol and glycerin. In some embodiments, the suitable acid is completely dissolved by the nicotine prior to dilution. The suitable acid may not completely dissolved by the nicotine prior to dilution. The addition of the suitable acid to the nicotine to form a neat mixture may cause an exothermic reaction. The addition of the suitable acid to the nicotine to form a neat mixture may be conducted at 55° C. The addition of the suitable acid to the nicotine to form a neat mixture may be conducted at 90° C. The neat mixture may be cooled to ambient temperature prior to dilution. The dilution may be carried out at elevated temperature.

Nicotine salt formulations may be prepared by combining nicotine and a suitable acid in a carrier mixture, such as a mixture of propylene glycol and glycerin. The mixture of nicotine and a first carrier mixture is combined with a mixture of a suitable acid in a second carrier mixture. In some embodiments, the first and second carrier mixtures are identical in composition. In some embodiments, the first and second carrier mixtures are not identical in composition. In some

embodiments, heating of nicotine/acid/carrier mixture is required to facilitate complete dissolution.

In some embodiments, nicotine salt formulations may be prepared and added to a solution of 3:7 ratio by weight of propylene glycol (PG)/vegetable glycerin (VG), and mixed thoroughly. While described herein as producing 10 g of each of the formulations, all procedures noted infra are scalable. Other manners of formulation may also be employed form the formulations noted infra, without departing from the disclosure herein, and as would be known to one of skill in the art upon reading the disclosure herein.

The optimal nicotine salt formulation may be determined by the vapor pressure of the constituent acid. In some embodiments, the nicotine salt formulations comprise an acid with a vapor pressure that is similar to the vapor pressure of free base nicotine. In some embodiments, the nicotine salt formulations are formed from an acid with a vapor pressure that is similar to the vapor pressure of free base nicotine at the heating temperature of the device. FIG. **3** illustrates this trend. Nicotine salts formed from nicotine and benzoic acid; nicotine and salicylic acid; or nicotine and levulinic acid are salts that produce a satisfaction in an individual user consistent with efficient transfer of nicotine and a rapid rise in nicotine plasma levels. This pattern may be due to the mechanism of action during heating of the nicotine salt formulation. The nicotine salt may disassociate at, or just below, the heating temperature of the device, resulting in a mixture of free base nicotine and the individual acid. At that point, if both the nicotine and acid have similar vapor pressures, they may aerosolize at the same time, giving rise to a transfer of both free base nicotine and the constituent acid to the user.

The nicotine salt liquid formulation for generating an inhalable aerosol upon heating in an electronic cigarette may comprise a nicotine salt in a biologically acceptable liquid carrier; wherein the acid used to form said nicotine salt is characterized by a vapor pressure between 20-4000 mmHg at 200° C. In some embodiments, the acid used to form the nicotine salt is characterized by vapor pressure between 20-2000 mmHg at 200° C. In some embodiments, the acid used to form the nicotine salt is characterized by vapor pressure between 100-300 mmHg at 200° C.

Unexpectedly, different nicotine salt formulations produced varying degrees of satisfaction in an individual. In some embodiments, the extent of protonation of the nicotine salt affected satisfaction, such that more protonation was less satisfying as compared to less protonation. The nicotine salt formed may be monoprotonated. The nicotine salt formed may be diprotonated. The nicotine salt may exist in more than one protonation state, e.g., an equilibrium of mono-protonated and di-protonated nicotine salts. The extent of protonation of the nicotine molecule may be dependent upon the stoichiometric ratio of nicotine:acid used in the salt formation reaction. The extent of protonation of the nicotine molecule may be dependent upon the solvent. The extent of protonation of the nicotine molecule may be unknown. In some embodiments, monoprotonated nicotine salts produced a high degree of satisfaction in the user. For example, nicotine benzoate and nicotine salicylate are mono-protonated nicotine salts and all produce a high degree of satisfaction in the user. The reason for this trend may be explained by a mechanism of action wherein the nicotine is first deprotonated prior to transfer to the vapor with the constituent acid and then retained and stabilized after re-protonated by the acid going down stream to the lungs of the user. It may be easier to remove one proton versus two protons, thus resulting in better transfer efficiency. In addition, the lack of satisfaction of free base nicotine indicates that a second factor may be important. A nicotine salt may be best performing when it is at its optimal extent of protonation, depending on the salt. For example, nicotine pyruvate is a nicotine salt with 1:2 nicotine:acid ratio. The formulation containing nicotine pyruvate (1:2) may deliver more satisfaction to the user than the one containing same amount of nicotine but only half amount of pyruvic acid, i.e. nicotine pyruvate (1:1). This may be explained as 1 mole of nicotine produces a salt with 2 moles of pyruvic acid. When there is not enough pyruvic acid to associate with all nicotine molecules, the free base nicotine left unprotonated in the formulation may reduce the satisfaction the formulation provides.

The flavor of the constituent acid used in the salt formation may be a consideration in choosing the acid. A suitable acid may have minimal or no toxicity to humans in the concentrations used. A suitable acid may be compatible with the electronic cigarette components it contacts or could contact at the concentrations used. That is, such acid does not degrade or otherwise react with the electronic cigarette components it contacts or could contact. The odor of the constituent acid used in the salt formation may be a consideration in choosing a suitable acid. The concentration of the nicotine salt in the carrier may affect the satisfaction in the individual user. In some embodiments, the flavor of the formulation is adjusted by changing the acid. In some embodiments, the flavor of the formulation is adjusted by adding exogenous flavorants. In some embodiments, an unpleasant tasting or smelling acid is used in minimal quantities to mitigate such characteristics. In some embodiments, exogenous pleasant smelling or tasting acid is added to the formulation. Examples of salts which can provide flavor and aroma to the mainstream aerosol at certain levels include nicotine acetate, nicotine oxalate, nicotine malate, nicotine isovalerate, nicotine lactate, nicotine citrate, nicotine phenylacetate and nicotine myristate.

Nicotine salt formulations may generate an inhalable aerosol upon heating in an electronic cigarette. The amount of nicotine or nicotine salt aerosol inhaled may be user-determined. The user may, for example, modify the amount of nicotine or nicotine salt inhaled by adjusting his inhalation strength.

Formulations are described herein comprising two or more nicotine salts. In some embodiments, wherein a formulation comprises two or more nicotine salts, each individual nicotine salt is formed as described herein.

Nicotine salt formulations, as used herein, refer to a single or mixture of nicotine salts with other suitable chemical components used for e-cigarette, such as carriers, stabilizers, diluents, dispersing agents, suspending agents, thickening agents, and/or excipients. In certain embodiments, the nicotine salt formulation is stirred at ambient conditions for 20 minutes. In certain embodiments, the nicotine salt formulation is heated and stirred at 55 C for 20 minutes. In certain embodiments, the nicotine salt formulation is heated and stirred at 90 C for 60 minutes. In certain embodiments, the formulation facilitates administration of nicotine to an organism (e.g., lung).

The nicotine of nicotine salt formulations provided herein is either naturally occurring nicotine (e.g., from extract of nicotineous species such as tobacco), or synthetic nicotine. In some embodiments, the nicotine is (−)-nicotine, (+)-nicotine, or a mixture thereof. In some embodiments, the nicotine is employed in relatively pure form (e.g., greater than about 80% pure, 85% pure, 90% pure, 95% pure, or 99% pure). In some embodiments, the nicotine for nicotine salt formulation provided herein is "water clear" in appearance in order to avoid or minimize the formation of tarry residues during the subsequent salt formation steps.

Nicotine salt formulations used for e-cigarettes described herein, in some embodiments, have a nicotine concentration of about 0.5% (w/w) to about 20% (w/w), wherein the concentration is of nicotine weight to total solution weight, i.e. (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 20% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 18% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 15% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 4% (w/w) to about 12% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 18% (w/w), about 3% (w/w) to about 15% (w/w), or about 4% (w/w) to about 12% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 4% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 3% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 2% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 0.5% (w/w) to about 1% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 4% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 3% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 1% (w/w) to about 2% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 10% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 5% (w/w). In certain embodiments, nicotine salt formulations provided herein have a nicotine concentration of about 2% (w/w) to about 4% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, 1.0%, 1.1%, 1.2%, 1.3%, 1.4%, 1.5%, 1.6%, 1.7%, 1.8%, 1.9%, 2.0%, 2.1%, 2.2%, 2.3%, 2.4%, 2.5%, 2.6%, 2.7%, 2.8%, 2.9%, 3.0%, 3.1%, 3.2%, 3.3%, 3.4%, 3.5%, 3.6%, 3.7%, 3.8%, 3.9%, 4.0%, 4.5%, 5.0%, 5.5%, 6.0%, 6.5%, 7.0%, 7.5%, 8.0%, 8.5%, 9.0%, 9.5%, 10%, 11%, 12%, 13%, 14%, 15%, 16%, 17%, 18%, 19%, or 20% (w/w), or more, including any increments therein. Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 5% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 4% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 3% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 2% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 1% (w/w). Certain embodiments provide a nicotine salt formulation having a nicotine concentration of about 0.5% (w/w).

The formulation further may comprise one or more flavorants.

The suitable acid for the nicotine salt formulation may have a vapor pressure >20 mmHg at 200° C. and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, formic acid, sorbic acid, acetic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

The suitable acid for the nicotine salt formulation may have a vapor pressure of about 20 to 200 mmHg at 200° C. and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, benzoic acid, lauric acid, and levulinic acid.

The suitable acid for the nicotine salt formulation may have a melting point <160° C., a boiling point >160° C., at least a 50-degree difference between the melting point and the boiling point, and is non-corrosive to the electronic cigarette or is non-toxic to humans. In some embodiments, the suitable acid for nicotine salt formation has a melting point at least 40 degrees lower than the operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, at least a 50-degree difference between the melting point and the boiling point, and is non-corrosive to the electronic cigarette or is non-toxic to humans; wherein the operating temperature is 200° C. In some embodiments, the suitable acid for nicotine salt formation is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

The suitable acid for the nicotine salt formulation does not decompose at the operating temperature of the electronic cigarette. In some embodiments, the suitable acid for nicotine salt formation does not oxidize at the operating temperature of the electronic cigarette. In some embodiments, the suitable acid for nicotine salt formation does not oxidize at room temperature. In some embodiments, the suitable acid for nicotine salt formation does not provide an unpleasant taste. In some embodiments, the suitable acid for nicotine salt formation has good solubility in a liquid formulation for use in an electronic cigarette.

Provided herein is an electronic cigarette **2** having a fluid storage compartment **4** comprising an embodiment nicotine salt formulation of any embodiment described herein within the fluid storage compartment described herein. An embodiment is shown in FIG. **7**. The electronic cigarette **2** of FIG. **7** includes a mouth end **6**, and a charging end **8**. The mouth-end **6** includes a mouthpiece **10**. The charging end **8** may connect to a battery or a charger or both, wherein the battery is within a body of the electronic cigarette, and the charger is separate from the battery and couples to the body or the battery to charge the battery. In some embodiments the electronic cigarette comprises a rechargeable battery within a body **14** of the electronic cigarette and the charge end **8** comprises a connection **12** for charging the rechargeable battery. In some embodiments, the electronic cigarette comprises a cartomizer that comprises the fluid storage compartment and an atomizer. In some embodiments, the atomizer comprises a heater. In some embodiments the fluid storage compartment **4** is separable from an atomizer. In some embodiments the fluid storage compartment **4** is replaceable as part of a replaceable

cartridge. In some embodiments the fluid storage compartment **4** is refillable. In some embodiments, the mouthpiece **10** is replaceable.

Provided herein is a cartomizer **18** for an electronic cigarette **2** having a fluid storage compartment **4** comprising an embodiment nicotine salt formulation of any embodiment described herein within the fluid storage compartment described herein. The cartomizer **18** embodiment of FIG. **8** includes a mouth end **6**, and a connection end **16**. The connection end **16** in the embodiment of FIG. **8** couples the cartomizer **14** to a body of an electronic cigarette, or to a battery of the electronic cigarette, or both. The mouth end **6** includes a mouthpiece **10**. In some embodiments, the cartomizer does not include a mouthpiece, and in such embodiments, the cartomizer can be coupled to a mouthpiece of an electronic cigarette, or the cartomizer can be coupled to a battery or body of an electronic cigarette, while the mouthpiece is also coupled to the battery or the body of the electronic cigarette. In some embodiments, the mouthpiece is integral with the body of the electronic cigarette. In some embodiments, including the embodiment of FIG. **8**, the cartomizer **18** comprises the fluid storage compartment **4** and an atomizer (not shown). In some embodiments, the atomizer comprises a heater (not shown)

EXAMPLES

Example 1

Preparation of Nicotine Salt Formulations

Various nicotine formulations were prepared and added to a solution of 3:7 ratio by weight of propylene glycol (PG)/vegetable glycerin (VG), and mixed thoroughly. The examples shown below were used to make 10 g of each of the formulations. All procedures are scalable.

For example, in order to make nicotine formulations with a final nicotine free base equivalent concentration of 2% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.15 g benzoic acid was added to a beaker followed by adding 0.2 g nicotine to the same beaker. The mixture was stirred at 55° C. for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.65 g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the mixture was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.15 g benzoic acid to a beaker followed by adding 0.2 g nicotine and 9.65 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55° C. for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine citrate salt formulation was made by adding 0.47 g citric acid to a beaker followed by adding 0.2 g nicotine and 9.33 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine malate salt formulation was made by adding 0.33 g L-malic acid to a beaker followed by adding 0.2 g nicotine and 9.47 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine succinate salt formulation was made by adding 0.29 g succinic acid to a beaker followed by adding 0.2 g nicotine and 9.51 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation was made by adding 0.17 g salicylic acid to a beaker followed by adding 0.2 g nicotine and 9.63 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine salicylate salt formulation can also be made by adding 0.17 g salicylic acid to a beaker followed by adding 0.2 g nicotine to the same beaker. The mixture was stirred at 90° C. for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90° C. when 9.63 g PG/VG (3:7) solution was added. The mixture was then stirred at 90° C. until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine free base formulation was made by adding 0.2 g nicotine to a beaker followed by adding 9.8 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 3% (w/w), the following procedures were applied to each individual formulation.

- Nicotine benzoate salt formulation: 0.23 g benzoic acid was added to a beaker followed by adding 0.3 g nicotine to the same beaker. The mixture was stirred at 55° C. for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.47 g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.
- Nicotine benzoate salt formulation can also be made by adding 0.23 g benzoic acid to a beaker followed by adding 0.3 g nicotine and 9.47 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55° C. for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine citrate salt formulation was made by adding 0.71 g citric acid to a beaker followed by adding 0.3 g nicotine and 8.99 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine malate salt formulation was made by adding 0.5 g L-malic acid to a beaker followed by adding 0.3 g nicotine and 9.2 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.
- Nicotine levulinate salt formulation was made by adding melted 0.64 g levulinic acid to a beaker followed by adding 0.3 g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 9.06 g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred

at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.

Nicotine pyruvate salt formulation was made by adding 0.33 g pyruvic acid to a beaker followed by adding 0.3 g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 9.37 g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.

Nicotine succinate salt formulation was made by adding 0.44 g succinic acid to a beaker followed by adding 0.3 g nicotine and 9.26 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine salicylate salt formulation was made by adding 0.26 g salicylic acid to a beaker followed by adding 0.3 g nicotine and 9.44 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine salicylate salt formulation can also be made by adding 0.26 g salicylic acid to a beaker followed by adding 0.3 g nicotine to the same beaker. The mixture was stirred at 90° C. for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90° C. when 9.44 g PG/VG (3:7) solution was added. The blend was then stirred at 90 C until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine free base formulation was made by adding 0.3 g nicotine to a beaker followed by adding 9.7 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 4% (w/w), the following procedures were applied to each individual formulation.

Nicotine benzoate salt formulation: 0.3 g benzoic acid was added to a beaker followed by adding 0.4 g nicotine to the same beaker. The mixture was stirred at 55° C. for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.7 g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.

Nicotine benzoate salt formulation can also be made by adding 0.3 g benzoic acid to a beaker followed by adding 0.4 g nicotine and 9.7 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55° C. for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

For example, in order to make nicotine salt formulations with a final nicotine free base equivalent concentration of 5% (w/w), the following procedures were applied to each individual formulation.

Nicotine benzoate salt formulation: 0.38 g benzoic acid was added to a beaker followed by adding 0.5 g nicotine to the same beaker. The mixture was stirred at 55° C. for 20 minutes until benzoic acid was completely dissolved and an orange oily mixture was formed. The mixture was cooled down to ambient conditions. 9.12 g PG/VG (3:7) solution was added to the orange nicotine benzoate salt and the blend was stirred until a visually homogenous formulation solution was achieved.

Nicotine benzoate salt formulation can also be made by adding 0.38 g benzoic acid to a beaker followed by adding 0.5 g nicotine and 9.12 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 55° C. for 20 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine malate salt formulation was made by adding 0.83 g L-malic acid to a beaker followed by adding 0.5 g nicotine and 8.67 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine levulinate salt formulation was made by adding melted 1.07 g levulinic acid to a beaker followed by adding 0.5 g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 8.43 g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.

Nicotine pyruvate salt formulation was made by adding 0.54 g pyruvic acid to a beaker followed by adding 0.5 g nicotine to the same beaker. The mixture was stirred at ambient conditions for 10 minutes. Exothermic reaction took place and oily product was produced. The mixture was allowed to cool down to ambient temperature and 8.96 g PG/VG (3:7) solution was added to the same beaker. The mixture was then stirred at ambient conditions for 20 minutes until a visually homogenous formulation solution was achieved.

Nicotine succinate salt formulation was made by adding 0.73 g succinic acid to a beaker followed by adding 0.5 g nicotine and 8.77 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine salicylate salt formulation was made by adding 0.43 g salicylic acid to a beaker followed by adding 0.5 g nicotine and 9.07 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at 90° C. for 60 minutes until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine salicylate salt formulation can also be made by adding 0.43 g salicylic acid to a beaker followed by adding 0.5 g nicotine to the same beaker. The mixture was stirred at 90° C. for 60 minutes until salicylic acid was completely dissolved and an orange oily mixture was formed. The mixture was either cooled to ambient conditions or kept at 90 C when 9.07 g PG/VG (3:7) solution was added. The blend was then stirred at 90° C. until a visually homogenous formulation solution was achieved with no undissolved chemicals.

Nicotine free base formulation was made by adding 0.5 g nicotine to a beaker followed by adding 9.5 g PG/VG (3:7) solution to the same beaker. The mixture was then stirred at ambient conditions for 10 minutes until a visually homogenous formulation solution was achieved.

Various formulations comprising different nicotine salts can be prepared similarly, or different concentrations of the above-noted nicotine formulations or other nicotine salt for-

mulations can be prepared as one of skill in the art would know to do upon reading the disclosure herein.

Various formulations comprising two or more nicotine salts can be prepared similarly in a solution of 3:7 ratio of propylene glycol (PG)/vegetable glycerin (VG). For example, 0.43 g (2.5% w/w nicotine) of nicotine levulinate salt and 0.34 g (2.5% w/w nicotine) of nicotine acetate salt are added to 9.23 g of PG/VG solution, to achieve a 5% w/w nicotine formulation.

Also provided is another exemplary formulation. For example, 0.23 g (1.33% w/w nicotine) of nicotine benzoate salt (molar ratio 1:1 nicotine/benzoic acid), 0.25 g (1.33% w/w nicotine) of nicotine salicylate salt (molar ratio 1:1 nicotine/salicylic acid) and 0.28 g (1.34% w/w nicotine) of nicotine pyruvate salt (molar ratio 1:2 nicotine/pyruvic acid) are added to 9.25 g of PG/VG solution, to achieve a 5% w/w nicotine formulation.

Example 2

Heart Rate Study of Nicotine Solutions Via e-Cigarette

Exemplary formulations of nicotine levulinate, nicotine benzoate, nicotine succinate, nicotine salicylate, nicotine malate, nicotine pyruvate, nicotine citrate, nicotine freebase, and a control of propylene glycol were prepared as noted in Example 1 in 3% w/w solutions and were administered in the same fashion by an electronic cigarette to the same human subject. About 0.5 mL of each solution was loaded into an "eRoll" cartridge atomizer (joyetech.com) to be used in the study. The atomizer was then attached to an "eRoll" e-cigarette (same manufacturer). The operating temperature was from about 150° C. to about 250° C., or from about 180° C. to about 220° C.

Heart rate measurements were taken for 6 minutes; from 1 minute before start of puffing, for 3 minutes during puffing, and continuing until 2 minutes after end of puffing. The test participant took 10 puffs over 3 minutes in each case. The base heart rate was the average heart rate over the first 1 minute before start of puffing. Heart rate after puffing started was averaged over 20-second intervals. Puffing (inhalation) occurred every 20 seconds for a total of 3 minutes. Normalized heart rate was defined as the ratio between individual heart rate data point and the base heart rate. Final results were presented as normalized heart rate, shown for the first 4 minutes in FIG. **1**.

FIG. **1** summarizes results from heart rate measurements taken for a variety of nicotine salt formulations. For ease of reference in reviewing FIG. **1**, at the 180-second timepoint, from top to bottom (highest normalized heart rate to lowest normalized heart rate), the nicotine formulations are as follows: nicotine salicylate formulation, nicotine malate formulation, nicotine levulinate formulation (nearly identical to nicotine malate formulation at 180 seconds, thus, as a second reference point: the nicotine malate formulation curve is lower than the nicotine levulinate formulation curve at the 160-second time point), nicotine pyruvate formulation, nicotine benzoate formulation, nicotine citrate formulation, nicotine succinate formulation, and nicotine free base formulation. The bottom curve (lowest normalized heart rate) at the 180-second timepoint is associated with the placebo (100% propylene glycol). The test formulations comprising a nicotine salt cause a faster and more significant rise in heart rate than the placebo. The test formulations comprising a nicotine salt also cause faster and more significant rise when compared with a nicotine freebase formulation with the same amount of nicotine by weight. In addition, the nicotine salts (e.g., nicotine benzoate and nicotine pyruvate) prepared from the acids having calculated vapor pressures between 20-200 mmHg at 200° C. (benzoic acid (171.66 mmHg), with the exception of pyruvic acid (having a boiling point of 165 C), respectively) cause a faster rise in heart rate than the rest. The nicotine salts (e.g., nicotine levulinate, nicotine benzoate, and nicotine salicylate) prepared from the acids (benzoic acid, levulinic acid and salicylic acid, respectively) also cause a more significant heart rate increase. Thus, other suitable nicotine salts formed by the acids with the similar vapor pressure and/or similar boiling point may be used in accordance with the practice of the present invention. This experience of increased heart rate theoretically approaching or theoretically comparable to that of a traditional burned cigarette has not been demonstrated or identified in other electronic cigarette devices. Nor has it been demonstrated or identified in low temperature tobacco vaporization devices (electronic cigarettes) that do not burn the tobacco, even when a nicotine salt was used (a solution of 20% (w/w) or more of nicotine salt) as an additive to the tobacco. Thus the results from this experiment are surprising and unexpected.

Example 3

Satisfaction Study of Nicotine Salt Solution Via e-Cigarette

In addition to the heart rate study shown in Example 2, nicotine formulations (using 3% w/w nicotine formulations as described in Example 1) were used to conduct a satisfaction study in a single test participant. The test participant, an e-cigarette and/or traditional cigarette user, was required to have no nicotine intake for at least 12 hours before the test. The participant took 10 puffs using an e-cigarette (same as used in Example 2) over 3 minutes in each case, and then was asked to rate the level of physical and emotional satisfaction he or she felt on a scale of 0-10, with 0 being no physical or emotional satisfaction. The results indicated that the least satisfying compound was the nicotine free base. Nicotine benzoate, nicotine salicylate, and nicotine succinate all performed well, followed by nicotine pyruvate, nicotine citrate, and nicotine pyruvate.

Based on the Satisfaction Study, the nicotine salts formulations with acids having vapor pressure ranges between >20 mmHg @ 200° C., or 20-200 mmHg @ 200° C., or 100-300 mmHg @ 200° C. provide more satisfaction than the rest (except the pyruvic acid which has boiling point of 165° C.). For reference, it has been determined that salicylic acid has a vapor pressure of about 135.7 mmHg @ 200° C., benzoic acid has a vapor pressure of about 171.7 mmHg @ 200° C., lauric acid has a vapor pressure of about 38 mmHg @ 200° C., and levulinic acid has a vapor pressure of about 149 mmHg @ 200° C.

Example 4

Test Formulation 1 (TF1)

A solution of nicotine levulinate in glycerol comprising nicotine salt used: 1.26 g (12.6% w/w) of 1:3 nicotine levulinate 8.74 g (87.4% w/w) of glycerol—Total weight 10.0 g.

Neat nicotine levulinate was added to the glycerol, and mixed thoroughly. L-Nicotine has a molar mass of 162.2 g, and levulinic acid molar mass is 116.1 g. In a 1:3 molar ratio,

the percentage of nicotine in nicotine levulinate by weight is given by: 162.2 g/(162.2 g+(3×116.1 g))=31.8% (w/w).

Example 5

Test Formulation 2 (TF2)

A solution of free base nicotine in glycerol comprising 0.40 g (4.00% w/w) of L-nicotine was dissolved in 9.60 g (96.0% w/w) of glycerol and mixed thoroughly.

Example 6

Heart Rate Study of Nicotine Solutions Via e-Cigarette

Both formulations (TF1 and TF2) were administered in the same fashion by an electronic cigarette to the same human subject: about 0.6 mL of each solution was loaded into "eGo-C" cartridge atomizer (joyetech.com). The atomizer was then attached to an "eVic" e-cigarette (same manufacturer). This model of e-cigarette allows for adjustable voltage, and therefore wattage, through the atomizer. The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C.

The atomizer in both cases has resistance 2.4 ohms, and the e-cigarette was set to 4.24V, resulting in 7.49 W of power. (P=V^2/R)

Heart rate was measured in a 30-second interval for ten minutes from start of puffing. Test participants took 10 puffs over 3 minutes in each case (solid line (2^{nd} highest peak): cigarette, dark dotted line (highest peak): test formulation 1 (TF1—nicotine salt formulation), light dotted line: test formulation 2 (TF2—nicotine formulation). Comparison between cigarette, TF1, and TF2 is shown in FIG. **2**.

It is clearly shown in FIG. **2** that the test formulation with nicotine levulinate (TF1) causes a faster rise in heart rate than just nicotine (TF2). Also, TF1 more closely resembles the rate of increase for a cigarette. Other salts were tried and also found to increase heart rate relative to a pure nicotine solution. Thus, other suitable nicotine salts that cause the similar effect may be used in accordance with the practice of the present invention. For example, other keto acids (alpha-keto acids, beta-keto acids, gamma-keto acids, and the like) such as pyruvic acid, oxaloacetic acid, acetoacetic acid, and the like. This experience of increased heart rate comparable to that of a traditional burned cigarette has not been demonstrated or identified in other electronic cigarette devices, nor has it been demonstrated or identified in low temperature tobacco vaporization devices that do not burn the tobacco, even when a nicotine salt was used (a solution of 20% (W/W) or more of nicotine salt) as an additive to the tobacco. Thus the results from this experiment are surprising and unexpected.

In addition, the data appears to correlate well with the previous findings shown in FIG. **2**.

As previously noted in the Satisfaction Study, the nicotine salts formulations with acids having vapor pressures between 20-300 mmHg @ 200° C. provide more satisfaction than the rest, with the exception of the nicotine salt formulation made with pyruvic acid, which has a boiling point of 165° C., as noted in FIG. **3**. Based on the findings herein, it was anticipated that these nicotine salt formulations having either:

- a Vapor Pressure between 20-300 mmHg @ 200° C.,
- a Vapor Pressure >20 mmHg @ 200° C.,
- a difference between boiling point and melting point of at least 50° C., and a boiling point greater than 160° C., and a melting point less than 160° C.,
- a difference between boiling point and melting point of at least 50° C., and a boiling point greater than 160° C., and a melting point less than 160° C.,
- a difference between boiling point and melting point of at least 50° C., and a boiling point at most 40° C. less than operating temperature, and a melting point at least 40° C. lower than operating temperature, or
- a combination thereof produce one or more of the following effects:

T_{max}—Time to maximum blood concentration: Based on the results established herein, a user of an e-cigarette comprising the nicotine salt formulation will experience a comparable rate of physical and emotional satisfaction from using a formulation comprising a mixture of nicotine salts prepared with an appropriate acid at least 1.2× to 3× faster than using a formulation comprising a freebase nicotine. As illustrated in FIG. **1**: Nicotine from a nicotine salts formulation appears to generate a heartbeat that is nearly 1.2 times that of a normal heart rate for an individual approximately 40 seconds after the commencement of puffing; whereas the nicotine from a nicotine freebase formulation appears to generate a heartbeat that is nearly 1.2 times that of a normal heart rate for an individual approximately 110 seconds after the commencement of puffing; a 2.75× difference in time to achieve a comparable initial satisfaction level.

Again this would not be inconsistent with the data from FIG. **2**, where the data illustrated that at approximately 120 seconds (2 minutes), the heart rate of test participants reached a maximum of 105-110 bpm with either a regular cigarette or a nicotine salt formulation (TF1); whereas those same participants heart rates only reached a maximum of approximately 86 bpm at approximately 7 minutes with a nicotine freebase formulation (TF2); also a difference in effect of 1.2 times greater with nicotine salts (and regular cigarettes) versus freebase nicotine.

Further, when considering peak satisfaction levels (achieved at approximately 120 seconds from the initiation of puffing (time=0) and looking at the slope of the line for a normalized heart rate, the approximate slope of those nicotine salt formulations that exceeded the freebase nicotine formulation range between 0.0054 hr_n/sec and 0.0025 hr_n/sec. By comparison, the slope of the line for the freebase nicotine formulation is about 0.002. This would suggest that the concentration of available nicotine will be delivered to the user at a rate that is between 1.25 and 2.7 times faster than a freebase formulation.

In another measure of performance; C_{max}—Maximum blood nicotine concentration; it is anticipated that similar rates of increase will be measured in blood nicotine concentration, as those illustrated above. That is, it was anticipated based on the findings herein, and unexpected based on the art known to date, that there would be comparable C_{max} between the common cigarette and certain nicotine salt formulations, but with a lower C_{max} in a freebase nicotine solution.

Similarly, anticipated based on the findings herein, and unexpected based on the art known to date, that certain nicotine salt formulations would have higher rate of nicotine uptake levels in the blood at early time periods. Indeed, Example 8 presents data for multiple salt formulations consistent with these predictions which were made based on the findings and tests noted herein, and unexpected compared to the art available to date.

Example 7

Heart Rate Study of Nicotine Solutions Via e-Cigarette

Exemplary formulations of nicotine levulinate, nicotine benzoate, nicotine succinate, nicotine salicylate, nicotine

malate, nicotine pyruvate, nicotine citrate, nicotine sorbate, nicotine laurate, nicotine freebase, and a control of propylene glycol are prepared as noted in Example 1 and are administered in the same fashion by an electronic cigarette to the same human subject. About 0.5 mL of each solution is loaded into an "eRoll" cartridge atomizer (joyetech.com) to be used in the study. The atomizer is then attached to an "eRoll" e-cigarette (same manufacturer). The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C.

Heart rate measurements are taken for 6 minutes; from 1 minute before start of puffing, for 3 minutes during puffing, and continuing until 2 minutes after end of puffing. The test participant takes 10 puffs over 3 minutes in each case. The base heart rate is the average heart rate over the first 1 minute before start of puffing. Heart rate after puffing started is averaged over 20-second intervals. Normalized heart rate is defined as the ratio between individual heart rate data point and the base heart rate. Final results are presented as normalized heart rate.

Example 8

Blood Plasma Testing

Blood plasma testing was conducted on three subjects (n=3). Eight test articles were used in this study: one reference cigarette and seven blends used in an e-cigarette device having an operating temperature of the e-cigarette from about 150° C. to about 250° C., or from about 180° C. to about 220° C. The reference cigarette was Pall Mall (New Zealand). Seven blends were tested in the e-cigarette: 2% free base, 2% benzoate, 4% benzoate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. Except for 2% succinate (n=1), all other blends have n=3. The seven blends were liquid formulations prepared as described in Example 1.

The concentration of nicotine in each of the formulations was confirmed using UV spectrophotometer (Cary 60, manufactured by Agilent). The sample solutions for UV analysis were made by dissolving 20 mg of each of the formulations in 20 mL 0.3% HCl in water. The sample solutions were then scanned in UV spectrophotometer and the characteristic nicotine peak at 259 nm was used to quantify nicotine in the sample against a standard solution of 19.8 μg/mL nicotine in the same diluent. The standard solution was prepared by first dissolving 19.8 mg nicotine in 10 mL 0.3% HCl in water followed by a 1:100 dilution with 0.3% HCl in water. Nicotine concentrations reported for all formulations were within the range of 95%-105% of the claimed concentrations

All subjects were able to consume 30-55 mg of the liquid formulation of each tested blend using the e-cigarette.

Literature results: C. Bullen et al, Tobacco Control 2010, 19:98-103 Cigarette (5 min adlib, n=9): T_{max}=14.3 (8.8-19.9), C_{max}=13.4 (6.5-20.3) 1.4% E-cig (5 min adlib, n=8): T_{max}=19.6 (4.9-34.2), C_{max}=1.3 (0.0-2.6) Nicorette Inhalator (20 mg/20 min, n=10): T_{max}=32.0 (18.7-45.3), C_{max}=2.1 (1.0-3.1)

Estimated C_{max} of 2% nicotine blends:

C_{max}=Mass consumed*Strength*Bioavailability/(Vol of Distribution*Body Weight)=40 mg*2%*80%/(2.6 L/kg*75 kg)=3.3 ng/mL

Estimated C_{max} of 4% nicotine blends:

C_{max}=Mass consumed*Strength*Bioavailability/(Vol of Distribution*Body Weight)=40 mg*4%*80%/(2.6 L/kg*75 kg)=6.6 ng/mL

Pharmacokinetic profiles of the blood plasma testing are shown in FIG. **4**; showing blood nicotine concentrations (ng/mL) over time after the first puff (inhalation) of the aerosol from the e-cigarette or the smoke of the Pall Mall. Ten puffs were taken at 30 sec intervals starting at time=0 and continuing for 4.5 minutes. For ease of reference and review of FIG. **4**, at the 5-minute timepoint, the curves on the graph show from top to bottom (highest average blood nicotine concentration to lowest average blood nicotine concentration) are 4% benzoate, 2% succinate, 2% salicylate, 2% citrate, Pall Mall cigarette, 2% benzoate, 2% malate, and 2% free base blend. Although noted as highest to lowest at this time point, this is not to say that there is a statistically significant difference between any of the salt formulations, or between any of the salt formulations and the Pall Mall cigarette. However, it is possible there may be a statistically significant difference between the C_{max} of particular salt formulations, and it is also likely based on the data shown in FIG. **4** and in other studies herein that the freebase formulation is statistically different from salt formulations and/or the Pall Mall with respect to C_{max}, since it appears lower than others tested at several time points. One of skill in the art, upon review of the disclosure herein could properly power a test to determine actual statistically-based differences between one or more formulations and the cigarette, or between the formulations themselves in an e-cigarette. For ease of reference Tables 1 & 2 present the amount of nicotine detected (as an average of all users) for each formulation and the Pall Mall, presented in ng/mL, along with C_{max} and T_{max} and AUC. Data from these tables, along with the raw data therefore, was used to generate FIGS. **4**, **5**, and **6**.

TABLE 1

Time	Pall Mall	2% Freebase	2% Benzoate	4% Benzoate
−2	0.46	0.03	0.09	0.05
0	−0.46	−0.03	−0.09	−0.05
1.5	1.54	0.08	5.67	6.02
3	9.98	1.19	8.60	11.47
5	11.65	1.70	11.44	15.06
7.5	11.34	3.09	6.43	12.12
10	9.24	3.42	5.03	11.08
12.5	8.85	3.35	4.68	10.10
15	8.40	2.81	4.47	8.57
30	5.51	1.74	2.72	5.56
60	3.39	0.79	1.19	3.60
T_{max} (min)	5.17	10.00	6.67	5.83
C_{max} (ng/mL)	11.65	3.42	11.44	15.06
AUC (ng * min/mL)	367.5	106.2	207.8	400.2

TABLE 2

Time	2% Citrate	2% Malate	2% Salicylate	2% Succinate
−2	0.06	−0.17	−0.19	−0.06
0	−0.06	0.17	0.19	0.06
1.5	4.80	1.09	6.14	2.10
3	8.33	5.30	12.04	10.81
5	12.09	10.02	13.46	13.81
7.5	6.93	5.93	5.21	5.15
10	6.01	4.85	4.60	5.18
12.5	5.34	4.17	3.83	4.17
15	4.72	3.79	3.52	3.41
30	3.40	1.56	2.19	2.01
60	1.70	0.46	0.55	1.00
T_{max} (min)	5.83	5.00	4.33	5.00
C_{max} (ng/mL)	12.09	10.02	13.46	13.81
AUC (ng * min/mL)	238.0	146.1	182.9	179.5

Comparison of T_{max} and C_{max} of the seven blends and reference cigarette are shown in FIG. **5**. Comparison of C_{max} and AUC of the seven blends and reference cigarette are shown in FIG. **6**. Due to the time limit of the wash-period, baseline blood nicotine concentration (at t=−2 and t=0 min) was higher for samples consumed at a later time on the test day. The data in FIGS. **4-6** show corrected blood nicotine concentration values (i.e. apparent blood nicotine concentration at each time point minus baseline nicotine concentration of the same sample).

Rates of nicotine uptake in the blood of the users of each sample within the first 90 seconds are shown in Table 3.

TABLE 3

Sample	Rate of nicotine uptake (ng/mL/min)
2% Salicylate	4.09
2% Benzoate	3.78
2% Citrate	3.20
2% Succinate	1.40
Pall Mall (reference)	1.03
2% Malate	0.73
2% Freebase	0.05
4% Benzoate	4.01

Although the T_{max} and C_{max} values are comparable between the tested blends and the reference cigarette (with the exception of the 2% free base blend), the rates of nicotine absorption within the first 90 seconds differed among the test articles. In particular, four blends (2% salicylate, 2% benzoate, 4% benzoate, and 2% citrate) showed markedly higher rates of absorption within the first 90 seconds compared to the other blends and with the reference cigarette. These four blends contain salts (salicylate, benzoate, and citrate) which performed well in the Satisfaction Study of Example 3. Moreover, 2% benzoate and 4% benzoate had comparable rates of absorption, suggesting that a lower concentration of nicotinic salt may not adversely impact the rate of absorption.

Example 9

Blood Plasma Testing

Blood plasma testing is conducted on 24 subjects (n=24). Eight test articles are used in this study: one reference cigarette and seven blends delivered to a user in an e-cigarette as an aerosol. The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C. The reference cigarette is Pall Mall (New Zealand). Seven blends are tested: 2% free base, 2% benzoate, 4% benzoate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. The seven blends are liquid formulations prepared according to protocols similar to that described infra and in Example 1.

All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time=0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0) Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 10

Blood Plasma Testing

Blood plasma testing is conducted on twenty-four subjects (n=24). Eleven test articles are used in this study: one reference cigarette and ten blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C. Ten blends are tested: 2% free base, 2% benzoate, 2% sorbate, 2% pyruvate, 2% laurate, 2% levulinate, 2% citrate, 2% malate, 2% salicylate, and 2% succinate. The ten blends are liquid formulations prepared according to protocols similar to that described infra and in Example 1.

All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time=0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0). Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 11

Blood Plasma Testing

Blood plasma testing is conducted on twenty-four subjects (n=24). Twenty-one test articles are used in this study: one reference cigarette and twenty blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C. Twenty blends are tested: 2% free base, 4% free base, 2% benzoate, 4% benzoate, 2% sorbate, 4% sorbate, 2% pyruvate, 4% pyruvate, 2% laurate, 4% laurate, 2% levulinate, 4% levulinate, 2% citrate, 4% citrate, 2% malate, 4% malate, 2% salicylate, 4% salicylate, 2% succinate, and 4% succinate. The twenty blends are liquid formulations prepared according to protocols similar to that described infra and in Example 1.

All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec intervals starting at time=0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0). Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Example 12

Blood Plasma Testing

Blood plasma testing is conducted on twenty-four subjects (n=24). Twenty-one test articles are used in this study: one reference cigarette and twenty blends delivered to a user in an e-cigarette as an aerosol. The reference cigarette is Pall Mall (New Zealand). The operating temperature of the e-cigarette is from about 150° C. to about 250° C., or from about 180° C. to about 220° C. Twenty blends are tested: 2% free base, 1% free base, 2% benzoate, 1% benzoate, 2% sorbate, 1% sorbate, 2% pyruvate, 1% pyruvate, 2% laurate, 1% laurate, 2% levulinate, 1% levulinate, 2% citrate, 1% citrate, 2% malate, 1% malate, 2% salicylate, 1% salicylate, 2% succinate, and 1% succinate. The twenty blends are liquid formulations prepared according to protocols similar to that described infra and in Example 1.

All subjects are to consume 30-55 mg of the liquid formulation of each tested blend. Ten puffs are to be taken at 30 sec

intervals starting at time=0 and continuing for 4.5 minutes. Blood plasma testing is to occur for at least 60 minutes from the first puff (t=0). Pharmacokinetic data (e.g., C_{max}, T_{max}, AUC) for nicotine in the plasma of users are obtained at various time periods during those 60 minutes, along with rates of nicotine absorption within the first 90 seconds for each test article.

Further understanding may be gained through contemplation of the numbered embodiments below.

1. A method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C., and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

2. A method of delivering nicotine to a user comprising operating an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C., and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

3. A method of delivering nicotine to a user comprising operating an electronic cigarette wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

4. A method of delivering nicotine to a user comprising providing an electronic cigarette to a user wherein the electronic cigarette comprises a nicotine salt formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and inhaling an aerosol generated from the nicotine salt formulation heated by the electronic cigarette.

5. The method of any one of embodiments 1-3, wherein an operating temperature is from 150° C. to 250° C.

6. The method of any one of embodiments 1-3, wherein an operating temperature is from 180° C. to 220° C.

7. The method any one of embodiments 1-3, wherein an operating temperature is about 200° C.

8. The method of embodiment 4, wherein the operating temperature is from 150° C. to 250° C.

9. The method of embodiment 4, wherein the operating temperature is from 180° C. to 220° C.

10. The method of embodiment 4, wherein the operating temperature is about 200° C.

11. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of the nicotine salt.

12. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine.

13. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

14. The method any one of embodiments 1-10, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

15. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

16. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

17. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

18. The method any one of embodiments 1-14, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

19. The method any one of embodiments 1-18, wherein the acid is a carboxylic acid.

20. The method of any one of embodiments 1-18, wherein the acid used to form said nicotine salt is an organic acid.

21. The method of embodiment 20, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

22. The method of embodiment 20, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

23. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is salicylic acid.

24. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is benzoic acid.

25. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is pyruvic acid.

26. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is sorbic acid.

27. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is lauric acid.

28. The method of any one of embodiments 1-18, wherein the acid used to form the nicotine salt is levulinic acid.

29. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine pyruvate.

30. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine salicylate.

31. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine sorbate.

32. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine laurate.

33. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine levulinate.

34. The method of any one of embodiments 1-18, wherein said nicotine salt comprises nicotine benzoate.

35. The method of any one of embodiments 1-34, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

36. The method of any one of embodiments 1-34, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

37. The method of any one of embodiments 1-34, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

38. The method of any one of embodiments 1-34, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

39. The method of any one of embodiments 1-38, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

40. The method of any one of embodiments 1-38, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

41. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

42. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

43. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

44. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

45. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

46. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

47. The method of any one of embodiments 1-40, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

48. The method of any one of embodiments 1-47, wherein the formulation further comprises a flavorant.

49. The method of any one of embodiments 1-48, wherein the formulation is non-corrosive to an electronic cigarette.

50. The method of any one of embodiments 1-49, wherein the acid is stable at and below operating temperature or about 200° C.

51. The method of any one of embodiments 1-50, wherein the acid does not decompose at and below operating temperature or about 200° C.

52. The method of any one of embodiments 1-51, wherein the acid does not oxidize at and below operating temperature or about 200° C.

53. The method of any one of embodiments 1-52, wherein the formulation is non-corrosive to the electronic cigarette.

54. The method of any one of embodiments 1-53, wherein the formulation is non-toxic to a user of the electronic cigarette.

55. The method of any one of embodiments 1-54, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

56. The method of embodiment 55, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

57. A method of delivering nicotine to the blood of a user, said method comprising providing an aerosol that is inhaled by the user from an electronic cigarette that comprises a nicotine salt formulation wherein providing the aerosol comprises the electronic cigarette heating the formulation thereby generating the aerosol, wherein the aerosol is effective in delivering a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

58. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

59. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

60. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

61. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature from 150° C. to 250° C.

62. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature from 180° C. to 220° C.

63. The method of any one of embodiments 57-60, wherein the heating of the formulation is at a temperature of about 200° C.

64. The method of embodiment 54, wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than the operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point; and the operating temperature is 200° C.

65. The method of any one of embodiments 57-64, wherein the Cmax is over 10 ng/mL on average.

66. The method of any one of embodiments 57-64, wherein the Cmax is over 11 ng/mL on average.

67. The method of any one of embodiments 57-64, wherein the Cmax is between 10 ng/mL and 16 ng/mL on average.

68. The method of any one of embodiments 57-64, wherein the Cmax is between 11 ng/mL and 15 ng/mL on average.

69. The method of any one of embodiments 57-64, wherein the Cmax is between 11 ng/mL and 14 ng/mL on average.

70. The method of any one of embodiments 57-69, wherein the Tmax under 10 minutes on average.

71. The method of any one of embodiments 57-69, wherein the Tmax is under 9 minutes on average.

72. The method of any one of embodiments 57-69, wherein the Tmax is under 8 minutes on average.

73. The method of any one of embodiments 57-69, wherein the Tmax is under 7 minutes on average.

74. The method of any one of embodiments 54-63, wherein the Tmax is from 3 minutes to 10 minutes on average.

75. The method of any one of embodiments 57-69, wherein the Tmax is from 3 minutes to 7.5 minutes on average.

76. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of the nicotine salt.

77. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine.

78. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

79. The method of any one of embodiments 57-75, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

80. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

81. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

82. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

83. The method of any one of embodiments 57-79, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

84. The method of any one of embodiments 57-83, wherein the acid is a carboxylic acid.

85. The method of any one of embodiments 57-83, wherein the acid used to form said nicotine salt is an organic acid.

86. The method of embodiment 85, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

87. The method of embodiment 85, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

88. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is salicylic acid.

89. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is benzoic acid.

90. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is pyruvic acid.

91. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is sorbic acid.

92. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is lauric acid.

93. The method of any one of embodiments 57-83, wherein the acid used to form the nicotine salt is levulinic acid.

94. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine pyruvate.

95. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine salicylate.

96. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine sorbate.

97. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine laurate.

98. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine levulinate.

99. The method of any one of embodiments 57-83, wherein said nicotine salt comprises nicotine benzoate.

100. The method of any one of embodiments 57-99, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

101. The method of any one of embodiments 57-99, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

102. The method of any one of embodiments 57-99, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

103. The method of any one of embodiments 57-99, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

104. The method of any one of embodiments 57-103, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

105. The method of any one of embodiments 57-103, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

106. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

107. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

108. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

109. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

110. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

111. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

112. The method of any one of embodiments 57-105, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

113. The method of any one of embodiments 57-112, wherein the formulation further comprises a flavorant.

114. The method of any one of embodiments 57-113, wherein the formulation is non-corrosive to an electronic cigarette.

115. The method of any one of embodiments 57-114, wherein the acid is stable at and below operating temperature or about 200° C.

116. The method of any one of embodiments 57-115, wherein the acid does not decompose at and below operating temperature or about 200° C.

117. The method of any one of embodiments 57-116, wherein the acid does not oxidize at and below operating temperature or about 200° C.

118. The method of any one of embodiments 57-117, wherein the formulation is non-corrosive to the electronic cigarette.

119. The method of any one of embodiments 57-118, wherein the formulation is non-toxic to a user of the electronic cigarette.

120. The method of any one of embodiments 57-119, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

121. The method of embodiment 120, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

122. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

123. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

124. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

125. A nicotine salt liquid formulation in an electronic cigarette for generating an inhalable aerosol upon heating in the electronic cigarette, the formulation in the cigarette comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

126. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150° C. to 250° C.

127. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180° C. to 220° C.

128. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-124, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200° C.

129. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is from 150° C. to 250° C.

130. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is from 180° C. to 220° C.

131. The nicotine salt liquid formulation in the electronic cigarette of embodiment 125, wherein the operating temperature is about 200° C.

132. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid is a carboxylic acid.

133. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form said nicotine salt is an organic acid.

134. The nicotine salt liquid formulation in the electronic cigarette of embodiment 133, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

135. The nicotine salt liquid formulation in the electronic cigarette of embodiment 133, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

136. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is salicylic acid.

137. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is benzoic acid.

138. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is pyruvic acid.

139. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is sorbic acid.

140. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is lauric acid.

141. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein the acid used to form the nicotine salt is levulinic acid.

142. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine pyruvate.

143. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine salicylate.

144. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine sorbate.

145. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine laurate.

146. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine levulinate.

147. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-131, wherein said nicotine salt comprises nicotine benzoate.

148. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

149. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

150. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

151. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-147, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

152. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-151, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

153. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-151, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

154. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

155. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

156. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

157. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

158. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

159. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

160. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-153, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

161. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-160, wherein the formulation further comprises a flavorant.

162. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-161, wherein the formulation is non-corrosive to an electronic cigarette.

163. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-162, wherein the acid is stable at and below operating temperature or about 200° C.

164. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-163, wherein the acid does not decompose at and below operating temperature or about 200° C.

165. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-164, wherein the acid does not oxidize at and below operating temperature or about 200° C.

166. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-165, wherein the formulation is non-corrosive to the electronic cigarette.

167. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-166, wherein the formulation is non-toxic to a user of the electronic cigarette.

168. The nicotine salt liquid formulation in the electronic cigarette of any one of embodiments 122-167 further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

169. The nicotine salt liquid formulation in the electronic cigarette of embodiment 168, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

170. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

171. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

172. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

173. A nicotine salt liquid formulation for generating an inhalable aerosol upon heating in the electronic cigarette, the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

174. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150° C. to 250° C.

175. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180° C. to 220° C.

176. The nicotine salt liquid formulation of any one of embodiments 170-172, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200° C.

177. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is from 150° C. to 250° C.

178. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is from 180° C. to 220° C.

179. The nicotine salt liquid formulation of embodiment 173, wherein the operating temperature is about 200° C.

180. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid is a carboxylic acid.

181. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form said nicotine salt is an organic acid.

182. The nicotine salt liquid formulation of embodiment 181, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

183. The nicotine salt liquid formulation of embodiment 181, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

184. The liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is salicylic acid.

185. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is benzoic acid.

186. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is pyruvic acid.

187. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is sorbic acid.

188. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is lauric acid.

189. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein the acid used to form the nicotine salt is levulinic acid.

190. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine pyruvate.

191. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine salicylate.

192. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine sorbate.

193. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine laurate.

194. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine levulinate.

195. The nicotine salt liquid formulation of any one of embodiments 170-179, wherein said nicotine salt comprises nicotine benzoate.

196. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

197. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

198. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

199. The nicotine salt liquid formulation of any one of embodiments 170-195, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

200. The nicotine salt liquid formulation of any one of embodiments 170-199, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

201. The nicotine salt liquid formulation of any one of embodiments 170-199, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

202. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

203. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

204. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

205. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

206. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

207. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

208. The nicotine salt liquid formulation of any one of embodiments 170-201, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

209. The nicotine salt liquid formulation of any one of embodiments 170-208, wherein the formulation further comprises a flavorant.

210. The nicotine salt liquid formulation of any one of embodiments 170-209, wherein the formulation is non-corrosive to an electronic cigarette.

211. The nicotine salt liquid formulation of any one of embodiments 170-210, wherein the acid is stable at and below operating temperature or about 200° C.

212. The nicotine salt liquid formulation of any one of embodiments 170-211, wherein the acid does not decompose at and below operating temperature or about 200° C.

213. The nicotine salt liquid formulation of any one of embodiments 170-212, wherein the acid does not oxidize at and below operating temperature or about 200° C.

214. The nicotine salt liquid formulation of any one of embodiments 170-213, wherein the formulation is non-corrosive to the electronic cigarette.

215. The nicotine salt liquid formulation of any one of embodiments 170-214, wherein the formulation is non-toxic to a user of the electronic cigarette.

216. The nicotine salt liquid formulation of any one of embodiments 170-215, further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

217. The nicotine salt liquid formulation of embodiment 216, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

218. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

219. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

220. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

221. A nicotine salt liquid formulation for use in an electronic cigarette the nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

222. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150° C. to 250° C.

223. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180° C. to 220° C.

224. The nicotine salt liquid formulation of any one of embodiments 218-220, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200° C.

225. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is from 150° C. to 250° C.

226. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is from 180° C. to 220° C.

227. The nicotine salt liquid formulation of embodiment 221, wherein the operating temperature is about 200° C.

228. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid is a carboxylic acid.

229. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form said nicotine salt is an organic acid.

230. The nicotine salt liquid formulation of embodiment 229, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

231. The nicotine salt liquid formulation of embodiment 229, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

232. The liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is salicylic acid.

233. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is benzoic acid.

234. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is pyruvic acid.

235. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is sorbic acid.

236. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is lauric acid.

237. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein the acid used to form the nicotine salt is levulinic acid.

238. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine pyruvate.

239. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine salicylate.

240. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine sorbate.

241. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine laurate.

242. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine levulinate.

243. The nicotine salt liquid formulation of any one of embodiments 218-227, wherein said nicotine salt comprises nicotine benzoate.

244. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

245. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

246. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

247. The nicotine salt liquid formulation of any one of embodiments 218-243, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

248. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

249. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

250. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

251. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

252. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

253. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

254. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

255. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

256. The nicotine salt liquid formulation of any one of embodiments 218-247, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

257. The nicotine salt liquid formulation of any one of embodiments 218-256, wherein the formulation further comprises a flavorant.

258. The nicotine salt liquid formulation of any one of embodiments 218-257, wherein the formulation is non-corrosive to an electronic cigarette.

259. The nicotine salt liquid formulation of any one of embodiments 218-258, wherein the acid is stable at and below operating temperature or about 200° C.

260. The nicotine salt liquid formulation of any one of embodiments 218-259, wherein the acid does not decompose at and below operating temperature or about 200° C.

261. The nicotine salt liquid formulation of any one of embodiments 218-260, wherein the acid does not oxidize at and below operating temperature or about 200° C.

262. The nicotine salt liquid formulation of any one of embodiments 218-261, wherein the formulation is non-corrosive to the electronic cigarette.

263. The nicotine salt liquid formulation of any one of embodiments 218-262, wherein the formulation is non-toxic to a user of the electronic cigarette.

264. The nicotine salt liquid formulation of any one of embodiments 218-263, further comprising one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

265. The nicotine salt liquid formulation of embodiment 264, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

266. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C., and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

267. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C., and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

268. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

269. Use of a nicotine salt formulation for delivery of nicotine to the blood of a user from an electronic cigarette, wherein the nicotine salt formulation in the electronic cigarette is heated to form an aerosol which delivers a level of nicotine in the blood of the user that is at least 5 ng/mL at about 1.5 minutes after a first puff of ten puffs of the aerosol, each puff taken at 30 second intervals.

270. Use of a nicotine salt formulation for delivery of nicotine to a user from an electronic cigarette wherein the nicotine salt formulation comprises a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point, and the nicotine salt formulation is heated by the electronic cigarette to generate an aerosol inhalable by the user.

271. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is from 150° C. to 250° C.

272. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is from 180° C. to 220° C.

273. The use of any one of embodiments 266-269, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature is about 200° C.

274. The use of embodiment 270, wherein the operating temperature is from 150° C. to 250° C.

275. The use of embodiment 270, wherein the operating temperature is from 180° C. to 220° C.

276. The use of embodiment 270, wherein the operating temperature is about 200° C.

277. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of the nicotine salt.

278. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine.

279. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

280. The use of any one of embodiments 266-276, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

281. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

282. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

283. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

284. The use of any one of embodiments 266-280, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

285. The use of any one of embodiments 266-284, wherein the acid is a carboxylic acid.

286. The use of any one of embodiments 266-284, wherein the acid used to form said nicotine salt is an organic acid.

287. The use of embodiment 286, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

288. The use of embodiment 286, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

289. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is salicylic acid.

290. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is benzoic acid.

291. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is pyruvic acid.

292. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is sorbic acid.

293. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is lauric acid.

294. The use of any one of embodiments 266-284, wherein the acid used to form the nicotine salt is levulinic acid.

295. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine pyruvate.

296. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine salicylate.

297. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine sorbate.

298. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine laurate.

299. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine levulinate.

300. The use of any one of embodiments 266-284, wherein said nicotine salt comprises nicotine benzoate.

301. The use of any one of embodiments 266-300, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

302. The use of any one of embodiments 266-300, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

303. The use of any one of embodiments 266-300, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

304. The use of any one of embodiments 266-300, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

305. The use of any one of embodiments 266-304, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

306. The use of any one of embodiments 266-304, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

307. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

308. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

309. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

310. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

311. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

312. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

313. The use of any one of embodiments 266-306, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

314. The use of any one of embodiments 266-313, wherein the formulation further comprises a flavorant.

315. The use of any one of embodiments 266-314, wherein the formulation is non-corrosive to an electronic cigarette.

316. The use of any one of embodiments 266-315, wherein the acid is stable at and below operating temperature or about 200° C.

317. The use of any one of embodiments 266-316, wherein the acid does not decompose at and below operating temperature or about 200° C.

318. The use of any one of embodiments 266-317, wherein the acid does not oxidize at and below operating temperature or about 200° C.

319. The use of any one of embodiments 266-318, wherein the formulation is non-corrosive to the electronic cigarette.

320. The use of any one of embodiments 266-319, wherein the formulation is non-toxic to a user of the electronic cigarette.

321. The use of any one of embodiments 266-320, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

322. The use of embodiment 321, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid

323. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

324. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

325. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

326. A cartomizer for an electronic cigarette comprising:

a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

an atomizer comprising a heating element in fluid communication with the nicotine salt liquid formulation; and

a fluid storage compartment that stores the nicotine salt liquid formulation.

327. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150° C. to 250° C.

328. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180° C. to 220° C.

329. The cartomizer of any one of embodiments 323-325, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200° C.

330. The cartomizer of embodiment 326, wherein the operating temperature is from 150° C. to 250° C.

331. The cartomizer of embodiment 326, wherein the operating temperature is from 180° C. to 220° C.

332. The cartomizer of embodiment 326, wherein the operating temperature is about 200° C.

333. The cartomizer of any one of embodiments 323-332, wherein the cartomizer further comprises a mouthpiece.

334. The cartomizer of any one of embodiments 323-333, wherein the acid is a carboxylic acid.

335. The cartomizer of any one of embodiments 323-333, wherein the acid used to form said nicotine salt is an organic acid.

336. The cartomizer of embodiment 335, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

337. The cartomizer of embodiment 335, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric

acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

338. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is salicylic acid.

339. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is benzoic acid.

340. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is pyruvic acid.

341. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is sorbic acid.

342. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is lauric acid.

343. The cartomizer of any one of embodiments 323-333, wherein the acid used to form the nicotine salt is levulinic acid.

344. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine pyruvate.

345. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine salicylate.

346. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine sorbate.

347. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine laurate.

348. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine levulinate.

349. The cartomizer of any one of embodiments 323-333, wherein said nicotine salt comprises nicotine benzoate.

350. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

351. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

352. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

353. The cartomizer of any one of embodiments 323-349, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

354. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

355. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

356. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

357. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

358. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

359. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

360. The cartomizer of any one of embodiments 323-353, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

361. The cartomizer of any one of embodiments 323-360, wherein the electronic cigarette is configured to generate an aerosol inhalable by a user.

362. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of the nicotine salt.

363. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine.

364. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine and condensate of the carrier.

365. The cartomizer of embodiment 361, wherein the aerosol comprises condensate of freebase nicotine and condensate of the acid.

366. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

367. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

368. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

369. The cartomizer of any one of embodiments 361-365, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

370. The cartomizer of any one of embodiments 361-369, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

371. The cartomizer of any one of embodiments 361-369, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

372. The cartomizer of any one of embodiments 323-371, wherein the formulation further comprises a flavorant.

373. The cartomizer of any one of embodiments 323-372, wherein the formulation is non-corrosive to an electronic cigarette.

374. The cartomizer of any one of embodiments 323-373, wherein the acid is stable at and below operating temperature or about 200° C.

375. The cartomizer of any one of embodiments 323-374, wherein the acid does not decompose at and below operating temperature or about 200° C.

376. The cartomizer of any one of embodiments 323-375, wherein the acid does not oxidize at and below operating temperature or about 200° C.

377. The cartomizer of any one of embodiments 323-376, wherein the formulation is non-corrosive to the electronic cigarette.

378. The cartomizer of any one of embodiments 323-377, wherein the formulation is non-toxic to a user of the electronic cigarette.

379. The cartomizer of any one of embodiments 323-378, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

380. The cartomizer of embodiment 379, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

381. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;

a battery; and

a mouthpiece.

382. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;

a battery; and

a mouthpiece.

383. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

384. An electronic cigarette for generating an inhalable aerosol comprising

a fluid storage compartment;

a heater; and

a nicotine salt liquid formulation in the fluid storage compartment, the liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

a battery; and

a mouthpiece.

385. The electronic cigarette of any one of embodiments 381-384, wherein the heater comprises a heater chamber, a fluid wick, and a resistive heating element in contact with the fluid wick.

386. The electronic cigarette of any one of embodiments 381-384, wherein the mouthpiece, the heater and the fluid storage compartment form a cartomizer separable from the battery.

387. The electronic cigarette of any one of embodiments 381-384, wherein the heater and the fluid storage compartment form a cartomizer separable from the battery and the mouthpiece.

388. The electronic cigarette of any one of embodiments 381-384, wherein the fluid storage compartment is separable from the heater, the battery and the mouthpiece.

389. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 150° C. to 250° C.

390. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature from 180° C. to 220° C.

391. The electronic cigarette of any one of embodiments 381-383, wherein the electronic cigarette heats the nicotine salt formulation to an operating temperature of about 200° C.

392. The electronic cigarette of embodiment 384, wherein the operating temperature is from 150° C. to 250° C.

393. The electronic cigarette of embodiment 384, wherein the operating temperature is from 180° C. to 220° C.

394. The electronic cigarette of embodiment 384, wherein the operating temperature is about 200° C.

395. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of the nicotine salt.

396. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of free-base nicotine.

397. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of free-base nicotine and condensate of the carrier.

398. The electronic cigarette of any one of embodiments 381-394, wherein the aerosol comprises condensate of free-base nicotine and condensate of the acid.

399. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 5 microns.

400. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 1 or 2 microns.

401. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.1 microns to about 0.7 microns.

402. The electronic cigarette of any one of embodiments 381-398, wherein the aerosol comprises condensate in particle sizes from about 0.3 microns to about 0.4 microns.

403. The electronic cigarette of any one of embodiments 381-402, wherein the acid is a carboxylic acid.

404. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form said nicotine salt is an organic acid.

405. The electronic cigarette of embodiment 404, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

406. The electronic cigarette of embodiment 404, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

407. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is salicylic acid.

408. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is benzoic acid.

409. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is pyruvic acid.

410. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is sorbic acid.

411. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is lauric acid.

412. The electronic cigarette of any one of embodiments 381-402, wherein the acid used to form the nicotine salt is levulinic acid.

413. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine pyruvate.

414. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine salicylate.

415. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine sorbate.

416. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine laurate.

417. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine levulinate.

418. The electronic cigarette of any one of embodiments 381-402, wherein said nicotine salt comprises nicotine benzoate.

419. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

420. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

421. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

422. The electronic cigarette of any one of embodiments 381-419, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

423. The electronic cigarette of any one of embodiments 381-422, wherein the nicotine salt is in an amount that forms about 0.5% to about 20% nicotine in the inhalable aerosol.

424. The electronic cigarette of any one of embodiments 381-422, wherein the nicotine salt is in an amount that forms about 1% to about 20% nicotine in the inhalable aerosol.

425. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

426. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

427. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

428. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

429. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

430. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

431. The electronic cigarette of any one of embodiments 381-424, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

432. The electronic cigarette of any one of embodiments 381-431, wherein the formulation further comprises a flavorant.

433. The electronic cigarette of any one of embodiments 381-432, wherein the formulation is non-corrosive to an electronic cigarette.

434. The electronic cigarette of any one of embodiments 381-433, wherein the acid is stable at and below operating temperature or about 200° C.

435. The electronic cigarette of any one of embodiments 381-434, wherein the acid does not decompose at and below operating temperature or about 200° C.

436. The electronic cigarette of any one of embodiments 381-435, wherein the acid does not oxidize at and below operating temperature or about 200° C.

437. The electronic cigarette of any one of embodiments 381-436, wherein the formulation is non-corrosive to the electronic cigarette.

438. The electronic cigarette of any one of embodiments 381-437, wherein the formulation is non-toxic to a user of the electronic cigarette.

439. The electronic cigarette of any one of embodiments 381-438, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

440. The electronic cigarette of embodiment 439, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

441. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

442. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

443. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

444. A cartridge in an electronic cigarette comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

445. The cartridge of any one of embodiments 441-444, wherein the cartridge is separable from the electronic cigarette.

446. The cartridge of any one of embodiments 441-445, wherein the acid is a carboxylic acid.

447. The cartridge of any one of embodiments 441-445, wherein the acid used to form said nicotine salt is an organic acid.

448. The cartridge of embodiment 447, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

449. The cartridge of embodiment 447, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid,

stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

450. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is salicylic acid.

451. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is benzoic acid.

452. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is pyruvic acid.

453. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is sorbic acid.

454. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is lauric acid.

455. The cartridge of any one of embodiments 441-445, wherein the acid used to form the nicotine salt is levulinic acid.

456. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine pyruvate.

457. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine salicylate.

458. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine sorbate.

459. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine laurate.

460. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine levulinate.

461. The cartridge of any one of embodiments 441-445, wherein said nicotine salt comprises nicotine benzoate.

462. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

463. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

464. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

465. The cartridge of any one of embodiments 441-461, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

466. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

467. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

468. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

469. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

470. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

471. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

472. The cartridge of any one of embodiments 441-465, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

473. The cartridge of any one of embodiments 441-472, wherein the formulation further comprises a flavorant.

474. The cartridge of any one of embodiments 441-473, wherein the formulation is non-corrosive to an electronic cigarette.

475. The cartridge of any one of embodiments 441-474, wherein the acid is stable at and below operating temperature or about 200° C.

476. The cartridge of any one of embodiments 441-475, wherein the acid does not decompose at and below operating temperature or about 200° C.

477. The cartridge of any one of embodiments 441-476, wherein the acid does not oxidize at and below operating temperature or about 200° C.

478. The cartridge of any one of embodiments 441-477, wherein the formulation is non-corrosive to the electronic cigarette.

479. The cartridge of any one of embodiments 441-478, wherein the formulation is non-toxic to a user of the electronic cigarette.

480. The cartridge of any one of embodiments 441-479, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

481. The cartridge of embodiment 480, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

482. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

483. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

484. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by

a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

485. A kit comprising:

(a) an electronic cigarette for generating an inhalable aerosol comprising

i. a device body comprising a cartridge receptacle;

ii. a cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point;

iii. a heater;

iv. a battery; and

v. a mouthpiece; and

(b) instructions for using the electronic cigarette to generate an inhalable aerosol.

486. The kit of any one of embodiments 482-485, wherein the acid is a carboxylic acid.

487. The kit of any one of embodiments 482-485, wherein the acid used to form said nicotine salt is an organic acid.

488. The kit of embodiment 487, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

489. The kit of embodiment 487, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

490. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is salicylic acid.

491. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is benzoic acid.

492. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is pyruvic acid.

493. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is sorbic acid.

494. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is lauric acid.

495. The kit of any one of embodiments 482-485, wherein the acid used to form the nicotine salt is levulinic acid.

496. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine pyruvate.

497. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine salicylate.

498. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine sorbate.

499. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine laurate.

500. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine levulinate.

501. The kit of any one of embodiments 482-485, wherein said nicotine salt comprises nicotine benzoate.

502. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

503. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

504. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

505. The kit of any one of embodiments 482-501, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

506. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

507. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

508. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

509. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

510. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

511. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

512. The kit of any one of embodiments 482-505, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

513. The kit of any one of embodiments 482-512, wherein the formulation further comprises a flavorant.

514. The kit of any one of embodiments 482-513, wherein the formulation is non-corrosive to an electronic cigarette.

515. The kit of any one of embodiments 482-514, wherein the acid is stable at and below operating temperature or about 200° C.

516. The kit of any one of embodiments 482-515, wherein the acid does not decompose at and below operating temperature or about 200° C.

517. The kit of any one of embodiments 482-516, wherein the acid does not oxidize at and below operating temperature or about 200° C.

518. The kit of any one of embodiments 482-517, wherein the formulation is non-corrosive to the electronic cigarette.

519. The kit of any one of embodiments 482-518, wherein the formulation is non-toxic to a user of the electronic cigarette.

520. The kit of any one of embodiments 482-519, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

521. The kit of embodiment 520, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

522. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure >20 mmHg at 200° C.

523. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt

liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is characterized by vapor pressure of about 20 to 200 mmHg at 200° C.

524. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point <160° C., a boiling point >160° C., and at least a 50-degree difference between the melting point and the boiling point.

525. A cartridge comprising a fluid storage compartment, wherein the fluid storage compartment stores a nicotine salt liquid formulation comprising a nicotine salt in a biologically acceptable liquid carrier wherein an acid used to form said nicotine salt is further characterized by a melting point at least 40 degrees lower than an operating temperature of the electronic cigarette, a boiling point no more than 40 degrees lower than the operating temperature of the electronic cigarette, and at least a 50-degree difference between the melting point and the boiling point.

526. The cartridge of any one of embodiments 523-526, wherein the cartridge can be connected to an electronic cigarette.

527. The cartridge of any one of embodiments 523-527, wherein the acid is a carboxylic acid.

528. The cartridge of any one of embodiments 523-527, wherein the acid used to form said nicotine salt is an organic acid.

529. The cartridge of embodiment 529, wherein the organic acid is monocarboxylic acid, aromatic acid, or keto acid.

530. The cartridge of embodiment 529, wherein the organic acid is formic acid, acetic acid, propionic acid, butyric acid, valeric acid, caproic acid, caprylic acid, capric acid, citric acid, lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, phenylacetic acid, benzoic acid, pyruvic acid, levulinic acid, tartaric acid, lactic acid, malonic acid, succinic acid, fumaric acid, finnaric acid, gluconic acid, saccharic acid, salicylic acid, sorbic acid, malonic acid, or malic acid.

531. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is salicylic acid.

532. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is benzoic acid.

533. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is pyruvic acid.

534. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is sorbic acid.

535. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is lauric acid.

536. The cartridge of any one of embodiments 523-527, wherein the acid used to form the nicotine salt is levulinic acid.

537. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine pyruvate.

538. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine salicylate.

539. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine sorbate.

540. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine laurate.

541. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine levulinate.

542. The cartridge of any one of embodiments 523-527, wherein said nicotine salt comprises nicotine benzoate.

543. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises glycerol, propylene glycol, trimethylene glycol, water, ethanol or combinations thereof.

544. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises propylene glycol and vegetable glycerin.

545. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises 20% to 50% of propylene glycol and 80% to 50% of vegetable glycerin.

546. The cartridge of any one of embodiments 523-543, wherein the liquid carrier comprises 30% propylene glycol and 70% vegetable glycerin.

547. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 25% (w/w).

548. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 20% (w/w).

549. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 18% (w/w).

550. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 1% (w/w) to about 15% (w/w).

551. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 4% (w/w) to about 12% (w/w).

552. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 4% (w/w).

553. The cartridge of any one of embodiments 523-547, wherein the liquid formulation has a nicotine concentration of about 2% (w/w).

554. The cartridge of any one of embodiments 523-553, wherein the formulation further comprises a flavorant.

555. The cartridge of any one of embodiments 523-554, wherein the formulation is non-corrosive to an electronic cigarette.

556. The cartridge of any one of embodiments 523-555, wherein the acid is stable at and below operating temperature or about 200° C.

557. The cartridge of any one of embodiments 523-556, wherein the acid does not decompose at and below operating temperature or about 200° C.

558. The cartridge of any one of embodiments 523-557, wherein the acid does not oxidize at and below operating temperature or about 200° C.

559. The cartridge of any one of embodiments 523-558, wherein the formulation is non-corrosive to the electronic cigarette.

560. The cartridge of any one of embodiments 523-559, wherein the formulation is non-toxic to a user of the electronic cigarette.

561. The cartridge of any one of embodiments 523-560, wherein the formulation further comprises one or more additional nicotine salts in a biologically acceptable liquid carrier suitable for generating the inhalable aerosol upon heating.

562. The cartridge of embodiment 561, wherein a second acid used to form the additional nicotine salt is selected from the group consisting of salicylic acid, sorbic acid, benzoic acid, pyruvic acid, lauric acid, and levulinic acid.

Although preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without

departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein can be employed in practicing the invention. It is intended that the following embodiments define the scope of the invention and that methods and structures within the scope of these embodiments and their equivalents be covered thereby.

What is claimed is:

1. A method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine, an acid, wherein the acid comprises pyruvic acid, salicylic acid, sorbic acid, lauric acid, levulinic acid, or benzoic acid, and a biologically acceptable liquid carrier, wherein:

a. the nicotine formulation has a pH between 2.1-6.7;

b. the nicotine concentration is from about 2% (w/w) to about 6% (w/w);

c. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol comprising particle sizes from about 0.1 microns to about 5 microns; and

d. inhalation of the inhalable aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min.

2. The method of claim **1**, wherein the nicotine plasma Tmax is from about 3 min to about 7 min, from about 3 min to about 6 min, from about 3 min to about 5 min, from about 3 min to about 4 min, from about 4 min to about 8 min, from about 4 min to about 7 min, from about 4 min to about 6 min, from about 4 min to about 5 min, from about 5 min to about 8 min, from about 5 min to about 7 min, from about 5 min to about 6 min, from about 6 min to about 8 min, from about 6 min to about 7 min, from about 7 min to about 8 min, less than about 8 min, less than about 7 min, less than about 6 min, less than about 5 min, less than about 4 min, about 8 min, about 7 min, about 6 min, about 5 min, about 4 min, or about 3 min.

3. The method of claim **1**, wherein the Tmax is determined based on at least three independent data sets.

4. The method of claim **1**, wherein the Tmax is a range of at least three independent data sets.

5. The method of claim **1**, wherein the Tmax is an average±a standard deviation of at least three independent data sets.

6. The method of claim **1**, wherein the nicotine formulation comprises a nicotine salt comprising nicotine and an acid.

7. The method of claim **6**, wherein nicotine formulation comprises monoprotonated nicotine.

8. The method of claim **1**, wherein the acid does not decompose at room temperature and does not decompose at the operating temperature of the electronic cigarette.

9. The method of claim **1**, wherein the acid comprises one carboxylic acid functional group.

10. The method of claim **1**, wherein the acid comprises benzoic acid.

11. The method of claim **1**, wherein the nicotine concentration is about 5% (w/w).

12. A method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation that comprises nicotine, an acid, wherein the acid comprises pyruvic acid, salicylic acid, sorbic acid, lauric acid, levulinic acid, or benzoic acid and a biologically acceptable liquid carrier, wherein:

a. the nicotine formulation has a pH between 2.1-6.7

b. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol comprising particle sizes from about 0.1 microns to about 5 microns;

c. inhalation of the inhalable aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min;

d. the nicotine concentration is from about 2% (w/w) to about 6% (w/w);

e. the nicotine formulation comprises monoprotonated nicotine; and

f. the acid does not decompose at room temperature and does not decompose at the operating temperature of the electronic cigarette.

13. The method of claim **12**, wherein the acid comprises benzoic acid.

14. The method of claim **13**, wherein the nicotine concentration is about 5% (w/w).

15. A method of delivering nicotine to a user comprising deploying an electronic cigarette comprising a nicotine formulation comprising nicotine and benzoic acid in a biologically acceptable liquid carrier, wherein:

a. the nicotine formulation has a pH between 2.1-6.7;

b. the nicotine concentration is from about 2% (w/w) to about 6% (w/w);

c. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol comprising particle sizes from about 0.1 microns to about 5 microns; and

d. inhalation of the inhalable aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 5 min to about 8 min.

16. A cartridge for use with an electronic cigarette comprising a fluid compartment configured to be in fluid communication with a heating element, the fluid compartment comprising a nicotine formulation that comprises nicotine and an acid, wherein the acid comprises pyruvic acid, salicylic acid, sorbic acid, lauric acid, levulinic acid, or benzoic acid, and a biologically acceptable liquid carrier, wherein:

a. the nicotine formulation has a pH between 2.1-6.7

b. the nicotine concentration is from about 2% (w/w) to about 6% (w/w);

c. operation of the electronic cigarette comprises heating at least a portion of the nicotine formulation to generate an inhalable aerosol comprising particle sizes from about 0.1 microns to about 5 microns; and wherein

d. inhalation of the inhalable aerosol into the user's lungs over a period of about 5 minutes at a rate of about one inhalation per 30 seconds results in a nicotine plasma Tmax from about 3 min to about 8 min.

17. The cartridge of claim **16**, wherein the nicotine plasma Tmax is from about 3 min to about 7 min, from about 3 min to about 6 min, from about 3 min to about 5 min, from about 3 min to about 4 min, from about 4 min to about 8 min, from about 4 min to about 7 min, from about 4 min to about 6 min, from about 4 min to about 5 min, from about 5 min to about 8 min, from about 5 min to about 7 min, from about 5 min to about 6 min, from about 6 min to about 8 min, from about 6 min to about 7 min, from about 7 min to about 8 min, less than about 8 min, less than about 7 min, less than about 6 min, less than about 5 min, less than about 4 min, about 8 min, about 7 min, about 6 min, about 5 min, about 4 min, or about 3 min.

18. The cartridge of claim **16**, wherein the Tmax is determined based on at least three independent data sets.

19. The cartridge of claim **16**, wherein the Tmax is a range of at least three independent data sets.

20. The cartridge of claim **16**, wherein the Tmax is an average±a standard deviation of at least three independent data sets.

21. The cartridge of claim **16**, wherein the nicotine formulation comprises a nicotine salt comprising nicotine and an acid.

22. The cartridge of claim **21**, wherein nicotine formulation comprises monoprotonated nicotine.

23. The cartridge of claim **21**, wherein the acid does not decompose at room temperature and does not decompose at the operating temperature of the electronic cigarette.

24. The cartridge of claim **21**, wherein the acid comprises one carboxylic acid functional group.

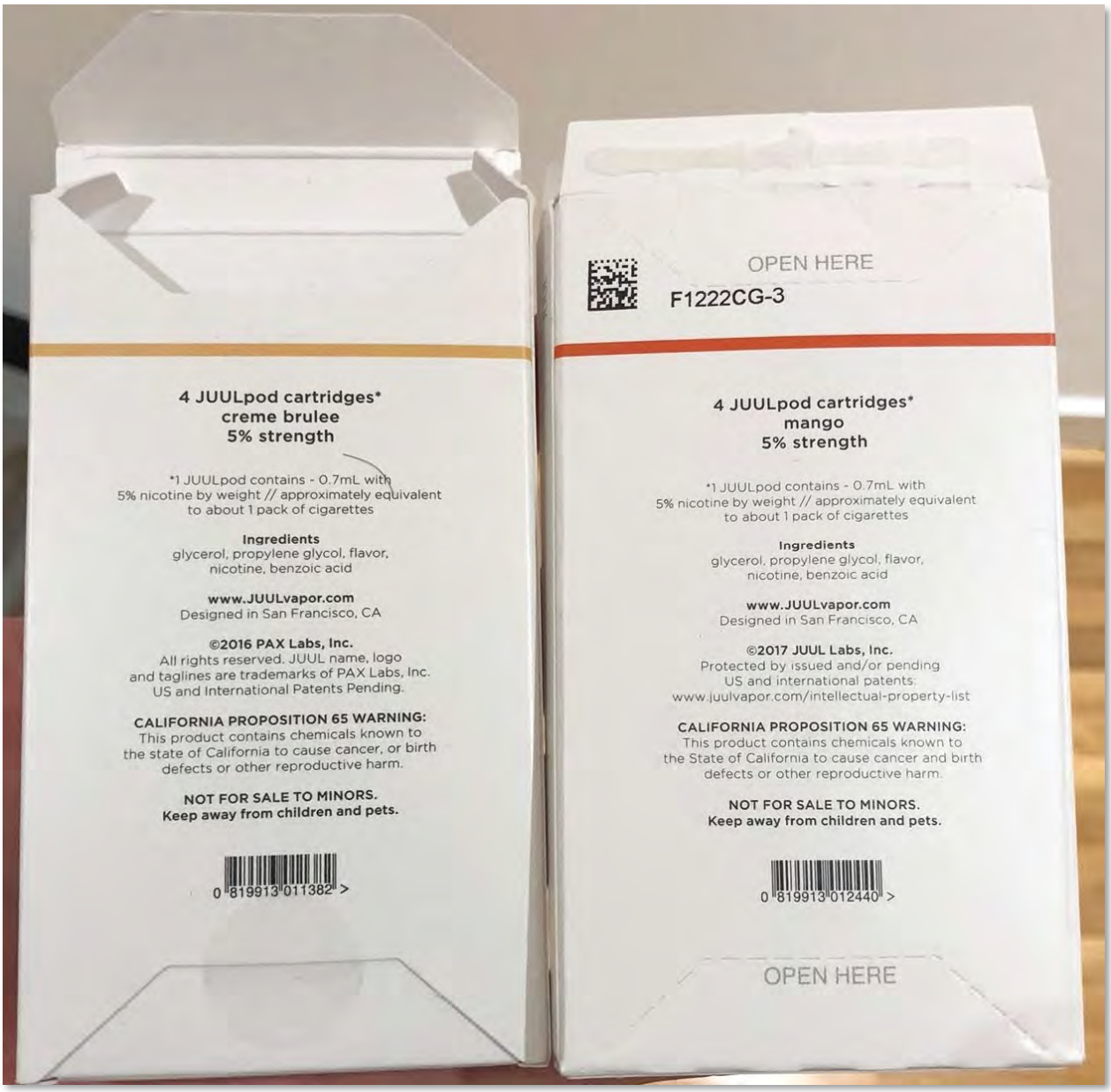
25. The cartridge of claim **16**, wherein the acid comprises benzoic acid.

26. The cartridge of claim **16**, wherein the nicotine concentration is about 5% (w/w).

* * * * *

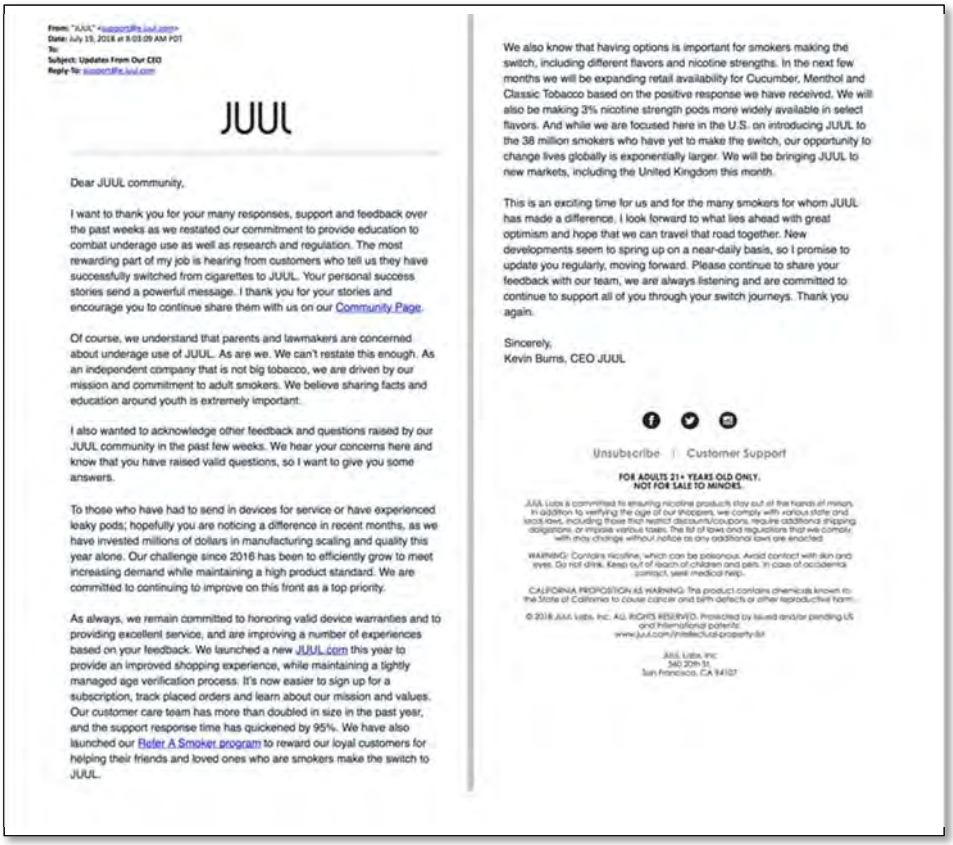
Exhibit D

ABOVE: Image of the front of JUUL packaging publicly posted to Twitter in 2018.



ABOVE: Image of the back of JUUL packaging publicly posted to Twitter in 2018.

Exhibit E



From: "JUUL" <support@e.juul.com>
Date: July 19, 2018 at 8:03:09 AM PDT
To:
Subject: Updates From Our CEO
Reply-To: support@e.juul.com

JUUL

Dear JUUL community,

I want to thank you for your many responses, support and feedback over the past weeks as we restated our commitment to provide education to combat underage use as well as research and regulation. The most rewarding part of my job is hearing from customers who tell us they have successfully switched from cigarettes to JUUL. Your personal success stories send a powerful message. I thank you for your stories and encourage you to continue share them with us on our Community Page.

Of course, we understand that parents and lawmakers are concerned about underage use of JUUL. As are we. We can't restate this enough. As an independent company that is not big tobacco, we are driven by our mission and commitment to adult smokers. We believe sharing facts and education around youth is extremely important.

I also wanted to acknowledge other feedback and questions raised by our JUUL community in the past few weeks. We hear your concerns here and know that you have raised valid questions, so I want to give you some answers.

To those who have had to send in devices for service or have experienced leaky pods; hopefully you are noticing a difference in recent months, as we have invested millions of dollars in manufacturing scaling and quality this year alone. Our challenge since 2016 has been to efficiently grow to meet increasing demand while maintaining a high product standard. We are committed to continuing to improve on this front as a top priority.

As always, we remain committed to honoring valid device warranties and to providing excellent service, and are improving a number of experiences based on your feedback. We launched a new JUUL.com this year to provide an improved shopping experience, while maintaining a tightly managed age verification process. It's now easier to sign up for a subscription, track placed orders and learn about our mission and values. Our customer care team has more than doubled in size in the past year, and the support response time has quickened by 95%. We have also launched our Refer A Smoker program to reward our loyal customers for helping their friends and loved ones who are smokers make the switch to JUUL.

We also know that having options is important for smokers making the switch, including different flavors and nicotine strengths. In the next few months we will be expanding retail availability for Cucumber, Menthol and Classic Tobacco based on the positive response we have received. We will also be making 3% nicotine strength pods more widely available in select flavors. And while we are focused here in the U.S. on introducing JUUL to the 38 million smokers who have yet to make the switch, our opportunity to change lives globally is exponentially larger. We will be bringing JUUL to new markets, including the United Kingdom this month.

This is an exciting time for us and for the many smokers for whom JUUL has made a difference. I look forward to what lies ahead with great optimism and hope that we can travel that road together. New developments seem to spring up on a near-daily basis, so I promise to update you regularly, moving forward. Please continue to share your feedback with our team, we are always listening and are committed to continue to support all of you through your switch journeys. Thank you again.

Sincerely,
Kevin Burns, CEO JUUL

Unsubscribe | Customer Support

FOR ADULTS 21+ YEARS OLD ONLY.
NOT FOR SALE TO MINORS.

JUUL Labs is committed to ensuring nicotine products stay out of the hands of minors. In addition to verifying the age of our shoppers, we comply with various state and local laws, including those that restrict discounts/coupons, require additional shipping obligations, or impose various taxes. The list of laws and regulations that we comply with may change without notice as any additional laws are enacted.

WARNING: Contains nicotine, which can be poisonous. Avoid contact with skin and eyes. Do not drink. Keep out of reach of children and pets. In case of accidental contact, seek medical help.

CALIFORNIA PROPOSITION 65 WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

JUUL Labs, Inc.
560 20th St.
San Francisco, CA 94107

ABOVE: An email from Defendant's CEO at the time, Kevin Burns, to consumers subscribed to Defendant's email marketing list making the case that Defendant is "an independent company that is not big tobacco." Image Credit: SRITA

BELOW: An image posted by Defendant on social media asserting that "JUUL Labs is not Big Tobacco." Image Credit: SRITA

Exhibit F

GEAR

Pax Juul: the IPhone of E-cigs?

by Ben Radding

It took the iPhone for most people to switch to smartphones from feature phones. It might be presumptive to say that it'll take something as well designed and subtle as Pax Labs' new Juul e-cig to make smokers switch to vaping, but that's the idea.

Released today, the Juul is a rectangular e-cigarette that promises more of the nicotine kick of a regular, combustible cigarette. I asked at least a dozen people to guess what the Juul was, and all of them guessed it was a USB stick. There's a small light on the top of the battery part—green means good to go, white means it's in use or is being charged, and red means it needs to be charged. Double-tap on the light, and it shows a light for the battery's status.

Cartridges (called them "Juulpods") come in several color-coded flavors, including tobacco and menthol. These cartridges are as unique as the USB-looking battery. They're transparent, and show the e-liquid working inside.

I've tested several e-cigs, and the Pax Juul takes a little getting used to at first. Perhaps because of the perfected chemistry, I found that initially inhaling can be harsh. Don't suck it in too fast. It's a form of temperature control; a softer inhale is a cooler vape, and a hard inhale will be very hot and harsh.

All that said, it's difficult to determine at this point the healthfulness of e-cigs. Many cities have banned them in public places like restaurants, and FDA regulation is looming. While they're certainly better for you than cigarettes, studies are showing that they're not all they're cracked up to be: a PLOS One study, for example, showed that e-cigs could possibly damage your immune system. The long-term health risks haven't been exposed yet.

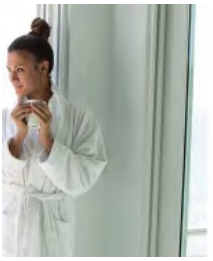
But if you're in the market for an e-cig, you'd be hardpressed to find a better (and better designed) one than the Juul. Once you get used to how to use it, it's all foggy bliss. The device retails at $50, and the Juulpods at $16, available at juulvapor.com.

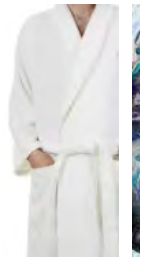
For access to exclusive gear videos, celebrity interviews, and more, subscribe on YouTube!

Topics: health technology

More from Gear

Sport Rx Debuts Prescription Ski Goggle Inserts





His & Hers Organic Cotton Robes Make The Absolute Perfect Valentine's Day Gift

Want more?

Sign up for our newsletter to get the latest adventures, workouts, destinations, and more.

Enter your email address Sign Up

How we use your email address

Exhibit G

INTRODUCING: coco miint >
1 message

JUUL <hello@juulvapor.com>
Reply-To: JUUL <hello@juulvapor.com>
To:

Mon, Nov 23, 2015 at 4:45 PM

JUUL

NEW FLAVOR

COCO MIINT IS HERE

Crisp mint meets chocolate
to create a perfectly balanced Holiday flavor.

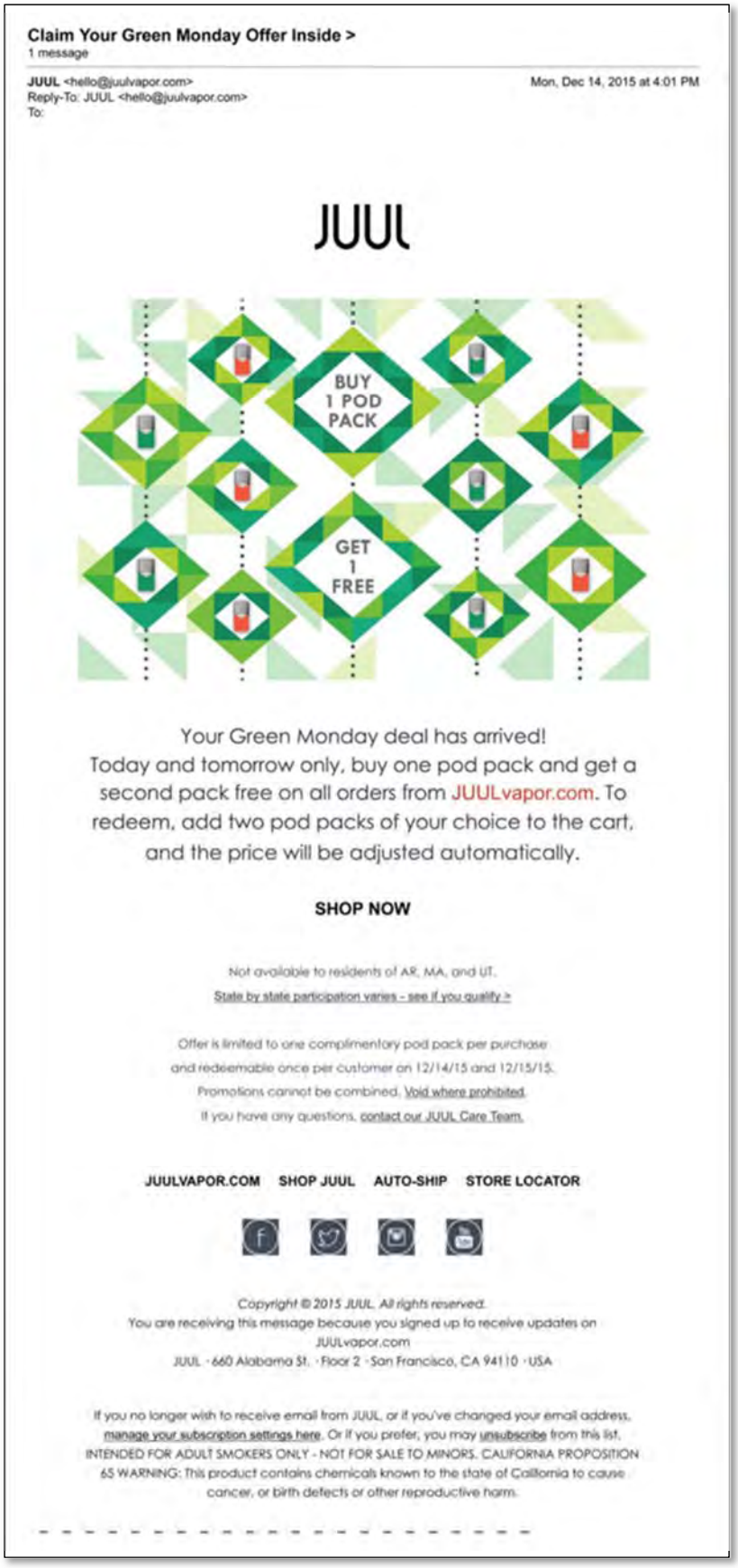
Try our newest flavor and stay satisfied.

Shop Now

JUULVAPOR.COM **SHOP JUUL** **AUTO-SHIP** **STORE LOCATOR**

LEFT: Promotional email advertising the JUUL pod flavor "Coco Miint," along with links to social media and the store locator.

Image Credit: SRITA



Claim Your Green Monday Offer Inside >
1 message

JUUL <hello@juulvapor.com> Mon, Dec 14, 2015 at 4:01 PM
Reply-To: JUUL <hello@juulvapor.com>
To:

JUUL

BUY 1 POD PACK

GET 1 FREE

Your Green Monday deal has arrived!
Today and tomorrow only, buy one pod pack and get a second pack free on all orders from JUULvapor.com. To redeem, add two pod packs of your choice to the cart, and the price will be adjusted automatically.

SHOP NOW

Not available to residents of AR, MA, and UT.
State by state participation varies - see if you qualify >

Offer is limited to one complimentary pod pack per purchase and redeemable once per customer on 12/14/15 and 12/15/15. Promotions cannot be combined. Void where prohibited.
If you have any questions, contact our JUUL Care Team.

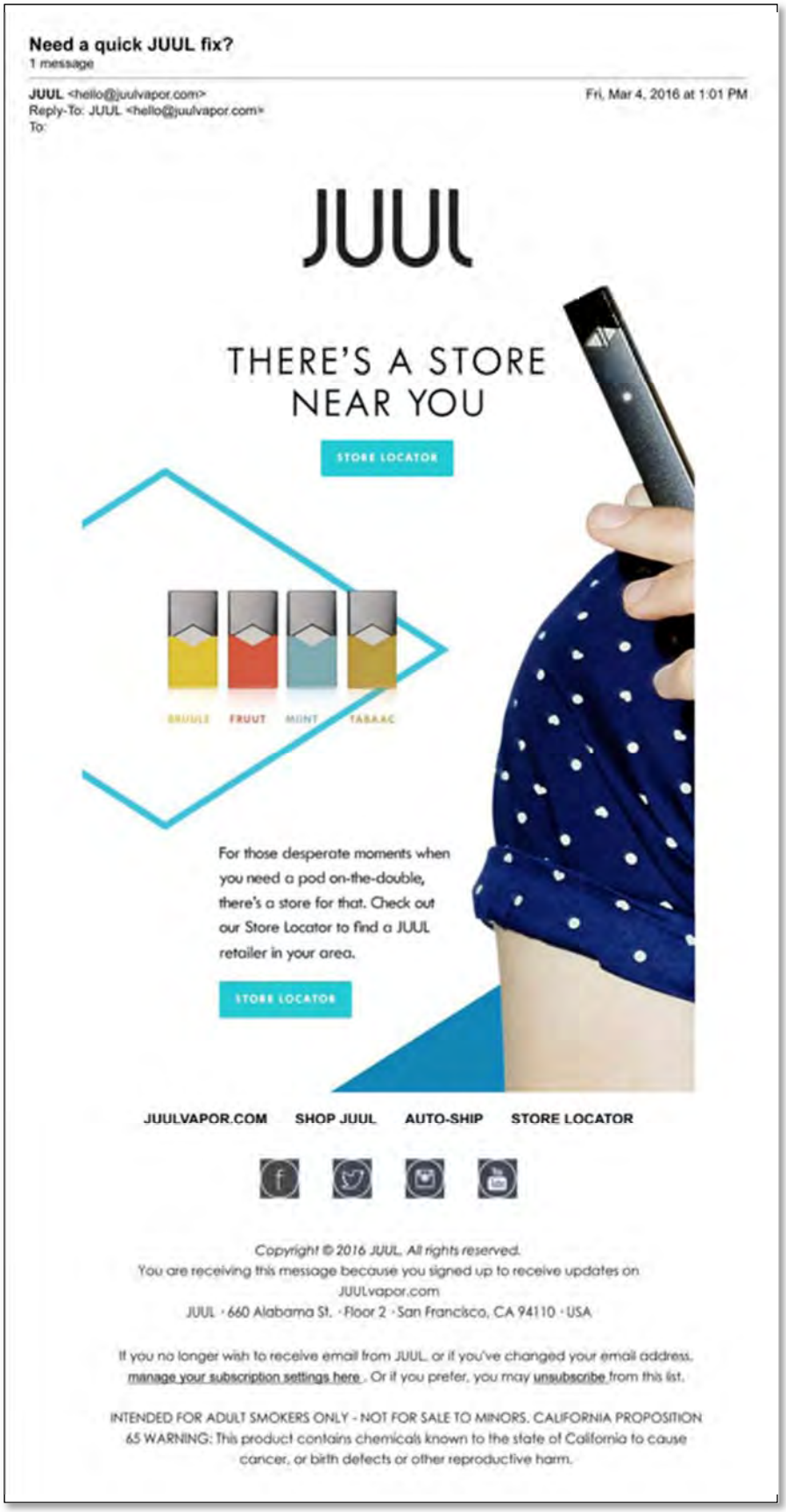
JUULVAPOR.COM SHOP JUUL AUTO-SHIP STORE LOCATOR

Copyright © 2015 JUUL. All rights reserved.
You are receiving this message because you signed up to receive updates on JUULvapor.com
JUUL · 660 Alabama St. · Floor 2 · San Francisco, CA 94110 · USA

If you no longer wish to receive email from JUUL, or if you've changed your email address, manage your subscription settings here. Or if you prefer, you may unsubscribe from this list.
INTENDED FOR ADULT SMOKERS ONLY - NOT FOR SALE TO MINORS. CALIFORNIA PROPOSITION 65 WARNING: This product contains chemicals known to the state of California to cause cancer, or birth defects or other reproductive harm.

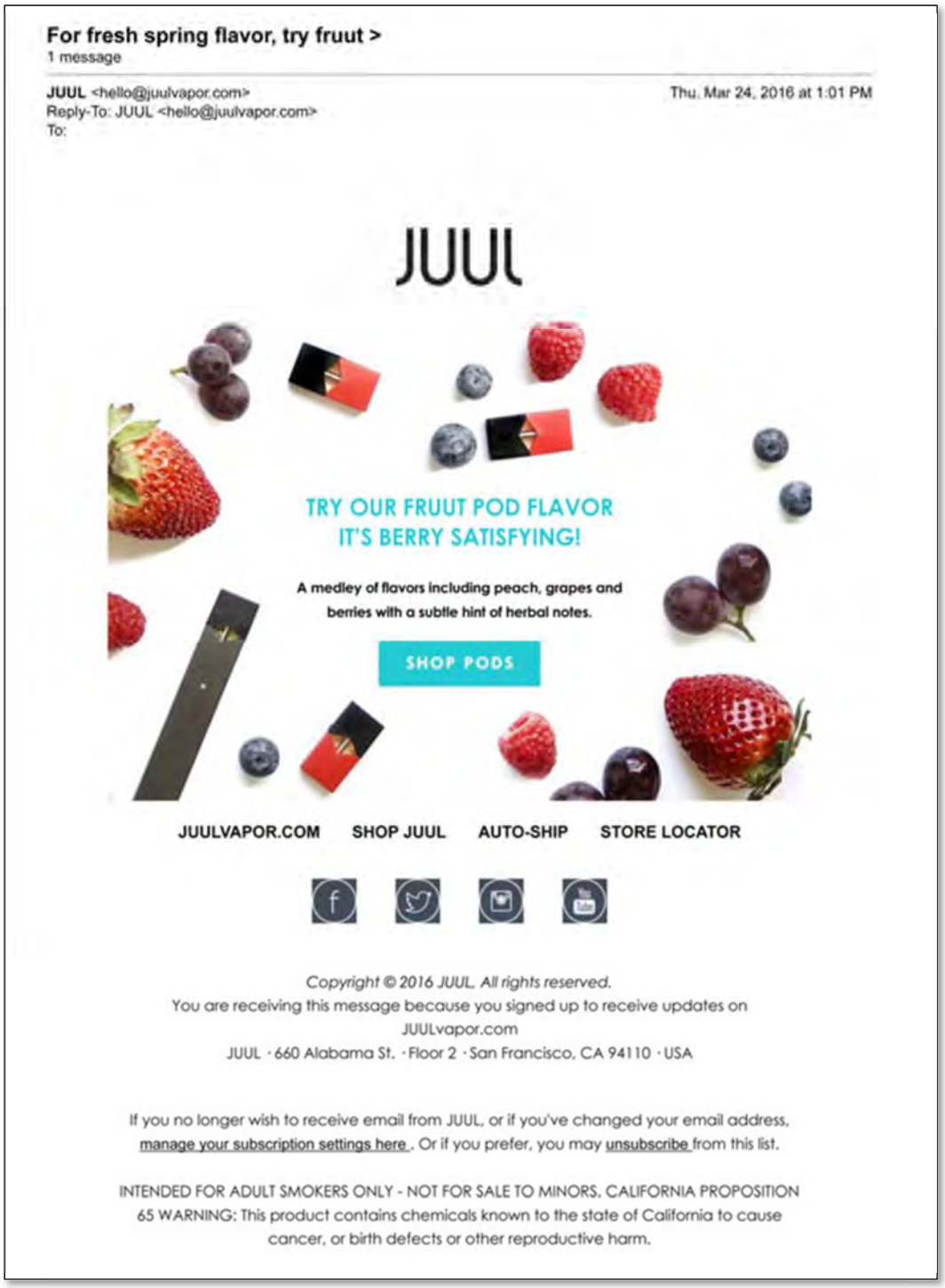
LEFT: Promotional email offering a buy-one-get-one discount on JUUL pod packs, along with links to social media and the store locator.

Image Credit: SRITA



LEFT: Promotional email advertising Defendant's store locator, along with images of various JUUL pod flavors and links to social media.

Image Credit: SRITA



ABOVE: Promotional email advertising Defendant's Fruut flavored JUUL pods (subsequently known as "Fruit Medley" and "Fruit"), along with links to social media and the store locator.

Image Credit: SRITA

Exhibit H

WARNING LETTER

JUUL Labs, Inc.

MARCS-CMS 590950 — SEPTEMBER 09, 2019

Delivery Method:

VIA UPS and Electronic Mail

Product:

Tobacco

Recipient:

Mr. Kevin Burns

CEO

JUUL Labs, Inc.

560 20th Street
San Francisco, CA 94107-4344
United States

Issuing Office:

Center for Tobacco Products

10903 New Hampshire Avenue
Silver Spring, MD 20993
United States

WARNING LETTER

Dear Mr. Burns:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) reviewed testimony from the July 24-25, 2019 hearing on "Examining JUUL's Role in the Youth Nicotine Epidemic," of the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the United States House of Representatives ("House Subcommittee"), documents from FDA's September 24-28, 2018 inspection of JUUL Labs, Inc.'s (JUUL) headquarters in San Francisco, California, JUUL's submissions to the Agency, and JUUL's website, https://www.juullabs.com (https://www.juullabs.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and determined that JUUL products, which are electronic nicotine delivery system (ENDS) products, are manufactured, marketed, advertised, labeled, and offered for sale or distribution to customers in the United States. Under section 201(rr) of the Federal Food,

Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act, these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including ENDS products (*e.g.,* e-cigarettes and e-liquids), are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)).

Based on our review of the information described above, FDA has determined that JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an FDA order in effect that permits such sale or distribution.

Modified Risk Tobacco Products Without an Appropriate FDA Order in Effect are Adulterated

Our review of testimony from the July 24-25, 2019 House Subcommittee hearing, documents from FDA's inspection of JUUL's headquarters, JUUL's submissions to the Agency, and JUUL's website, https://www.juullabs.com (https://www.juullabs.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), revealed that your firm has engaged in labeling, advertising, and/or other activities directed to consumers, in which JUUL explicitly and/or implicitly has represented that JUUL products are free of a substance, have a reduced level of or exposure to a substance, and/or that JUUL products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products.

The July 24-25, 2019 House Subcommittee hearing included the following evidence:

1. A JUUL representative speaking with students at his presentation stated that JUUL "was much safer than cigarettes" and that "FDA would approve it any day."[1]
2. The JUUL representative speaking with students at his presentation called JUUL "totally safe."[2]
3. The JUUL representative speaking with students at his presentation stated that a student "…should mention JUUL to his [nicotine-addicted] friend…because that's a safer alternative than smoking cigarettes, and it would be better for the kid to use."[3]
4. The JUUL representative speaking with students at his presentation stated, "FDA was about to come out and say it [JUUL] was 99% safer than cigarettes…and that…would happen very soon…."[4]

Referring to your ENDS products as "99% safer" than cigarettes, "much safer" than cigarettes, "totally safe," and "a safer alternative than smoking cigarettes" is particularly concerning because these statements were made directly to children in school. Our concern is amplified by the epidemic rate of increase in youth use of ENDS products, including JUUL's products, and evidence that ENDS products contribute to youth use of, and addiction to, nicotine, to which youth are especially vulnerable.[5]

In addition, your "Letter from the CEO" states: "[JUUL's] simple and convenient system incorporates temperature regulation to heat nicotine liquid and deliver smokers the satisfaction that they want without the combustion and the harm associated with it." On April 25, 2018, your letter appeared in an email that JUUL sent to a parent in response to her complaint that the firm sold JUUL products to her child. On May 8, 2018, your letter appeared on JUUL's website, https://www.juullabs.com (https://www.juullabs.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).[6] This letter provides further confirmation of the evidence from the hearing testimony that JUUL has marketed JUUL products as modified risk tobacco products.

A tobacco product is considered a "modified risk tobacco product," *inter alia*, if its label, labeling, or advertising explicitly or implicitly represents that: (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or (3) the product or its smoke does not contain or is free of a substance (section 911(b)(2)(A)(i) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(i))); or where the manufacturer has taken any action directed to consumers through media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances (section 911(b)(2)(A)(iii) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(iii))).

Under section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)), no person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A modified risk tobacco product application under section 911(d) of the FD&C Act (21 U.S.C. § 387k(d)) is required to provide scientific evidence and other information to support issuance of an order under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A product that is in violation of section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)) is adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)).

JUUL has marketed its ENDS products as modified risk tobacco products because JUUL's labeling, advertising, and/or other actions directed to consumers (examples of which are referenced above), represent, or would be reasonably expected to result in consumers believing, that the products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products; contain a reduced level of a substance or present a reduced exposure to a substance; and/or do not contain or are free of a substance or substances. JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an appropriate FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)) that permits such sale or distribution.

Conclusion

The violations discussed in this letter do not necessarily constitute an exhaustive list. To the extent you have not already done so, you should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the FD&C Act. It is your responsibility to ensure that your tobacco products, all related labeling and advertising, and all other activities by JUUL directed to consumers, such as in any media in which you advertise and any retail establishments, comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to ensure compliance with the FD&C Act may result in FDA initiating further action, including, but not limited to, civil money penalties, seizure, and/or injunction. Please note that any adulterated and misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative promotion, labeling, advertising, sale, and/or distribution of these tobacco products. In your written response, please also describe your plan for maintaining compliance with the FD&C Act, including your plan to prevent violations that are the same as or similar to those stated above, such as through, for example, new internal controls and training. You can find the FD&C Act through links on FDA's homepage at http://www.fda.gov (http://www.fda.gov). If you do not believe that your products are in violation of

section 911 of the FD&C Act (21 U.S.C. § 387k), please provide us with your reasoning and provide any and all scientific evidence and data, if any, that support that your statements and representations do not explicitly or implicitly convey that JUUL products pose less risk, are less harmful, present reduced exposure, or are safer than other tobacco products.

Please note your reference number, RW1901168, in your response and direct your response to the following address:

Anthony Villa, Senior Regulatory Counsel
Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Anthony Villa at (301) 796-7385 or via email at Anthony.Villa@fda.hhs.gov (mailto:Anthony.Villa@fda.hhs.gov).

Sincerely,
/s/
Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products

VIA Electronic Mail

cc:

Jerry Masoudi
Chief Legal Officer, JUUL Labs, Inc.
(b)(6)

[1] Hearing, July 24, 2019, Testimony of Ms. Meredith Berkman (PAVe co-founder), at minutes 52:27 – 53:31 (https://youtu.be/m3iEMrAd83o (https://youtu.be/m3iEMrAd83o) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[2] Hearing, July 24, 2019, Testimony of Mr. Caleb Mintz (son of Ms. Meredith Berkman, PAVe co-founder), at minutes 1:18:50 – 1:19:11 (https://youtu.be/m3iEMrAd83o (https://youtu.be/m3iEMrAd83o) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[3] Hearing, July 24, 2019, Testimony of Mr. Phillip Fuhrman (son of Ms. Dorian Fuhrman, PAVe co-founder), at minutes 1:20:20 – 1:21:14 (https://youtu.be/m3iEMrAd83o (https://youtu.be/m3iEMrAd83o) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[4] Hearing, July 24, 2019, Testimony of Mr. Phillip Fuhrman, at minutes 1:21:45 – 1:22:02 (https://youtu.be/m3iEMrAd83o (https://youtu.be/m3iEMrAd83o) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

[5] As discussed in the March 2019 Draft Guidance: Modifications to Compliance Policy for Certain Deemed Tobacco Products, "[R]ecent data show a significant increase in minors' use of ENDS products…For example, data from the NYTS [National Youth Tobacco Survey] show that, between 2017 and 2018, current e-cigarette use among high school students increased 78 percent (11.7 percent to 20.8 percent, $p<0.05$)…These data represent an increase of an estimated 1.32 million high school students reporting past 30-day e-cigarette use in one year. Current e-cigarette use among middle school students also increased by 48 percent over the same time period (3.3 percent to 4.9 percent, $p<0.05$), an increase of an estimated 180,000 middle school students reporting past 30-day e-cigarette use in one year…[.]" (https://www.fda.gov/media/121384/download (https://www.fda.gov/media/121384/download), at p. 8)

[6] See, *e.g.*, "Letter from the CEO" from Mr. Kevin Burns, CEO, JUUL Labs, Inc. (https://www.juullabs.com (https://www.juullabs.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) (May 8, 2018).

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