IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC
7916 Evolutions Way, Suite 200
Trinity, FL 34655

Plaintiff,

vs.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

ROBERT CALIFF, M.D.,
Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

and

SYLVIA MATHEWS BURWELL,
Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiff Nicopure Labs, Inc. ("Nicopure") brings this Complaint to set aside Defendants' unlawful final rule, "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule").

INTRODUCTION

1. This suit concerns FDA's regulation of vaping devices and e-liquids.

2. Vaping devices are innovative new products that do not contain tobacco and do not generate smoke. Instead, they use a heat source to convert e-liquid into a vapor, which the user inhales through a mouthpiece.

3. E-liquid is a liquid product consumed using a vaping device. E-liquid generally consists of propylene glycol, glycerol, and flavors. Some forms of e-liquid contain nicotine derived from tobacco; others include nicotine derived from non-tobacco sources. In addition, some forms of e-liquid contain no nicotine and no tobacco extracts at all.

4. Vaping devices are principally classified into two categories: open and closed systems. In closed systems, the amount of liquid, flavor, and nicotine content (if any) is set by the manufacturer and cannot be altered by the consumer. Closed system products are available in both disposable form for single use and "rechargeable" form for multiple use—for instance through the use of proprietary replacement cartridges containing e-liquid. In contrast, open systems, sometimes known as "tank systems," can be refilled by the consumer without restriction by the manufacturer. Consumers can fill the "tank" in an open-system vaping device with virtually any e-liquid produced by third parties, including retail outlets known as "vaping shops." E-liquids featuring a wide variety of flavors and nicotine levels (including e-liquids with zero nicotine and zero tobacco content) are currently on the market.

5. Peer-reviewed studies have concluded that vaping is much safer than using cigarettes, cigars, and other traditional forms of smoking, because the vaping devices do not generate the toxins associated with combustion of tobacco. In April 2016, a group of U.S. tobacco-control experts (including a professor in the Department of Oncology at the Georgetown Lombardi Comprehensive Cancer Center) explained that vaping devices offer important public-health benefits, such as an alternative to cigarette smoking. Earlier in 2016, the Royal College of Physicians likewise concluded that vaping devices are likely to be beneficial to public health in Great Britain.

6. Nicopure produces open-system vaping devices, closed-system vaping devices, and e-liquids.

7. Some of the e-liquids sold by Nicopure contain nicotine made or derived from tobacco, while other e-liquids sold by Nicopure do not contain nicotine or tobacco.

8. None of the products sold by Nicopure contains tobacco.

PARTIES

9. Nicopure is a limited liability company with a principal place of business at 7916 Evolutions Way, Trinity, FL 34655. Nicopure distributes battery-powered vaping devices under the Triton, Reactor, Tracer, and G6 brand names. (The Triton, Reactor, and Tracer devices are open-system devices. The G6 devices are closed-system devices.) Nicopure also manufactures and distributes nicotine-

and non-nicotine-containing "e-liquid" under the Halo and eVo brand names. Nicopure is a small entity under the Regulatory Flexibility Act ("RFA").

10. Defendant FDA is an agency of the United States Government within the Department of Health and Human Services, with an office at 10903 New Hampshire Ave., Silver Spring, MD 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Act, 21 U.S.C. §§ 387a, 387a–1.

11. Defendant Robert Califf, M.D., is Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Califf maintains an office at 10903 New Hampshire Ave., Silver Spring, MD 20993.

12. Defendant Sylvia Mathews Burwell is Secretary of Health and Human Services and the official charged by law with administering the Act. She is sued in her official capacity. Secretary Burwell maintains an office at 200 Independence Avenue SW, Washington, DC 20201.

13. All defendants are collectively referred to hereinafter as "FDA" or "Defendants."

REGULATORY AND STATUTORY BACKGROUND

14. The Deeming Rule was adopted and publicly released by FDA on May 5, 2016, and was published in the Federal Register on May 10, 2016.

15. The Deeming Rule dramatically expands FDA's exercise of its regulatory authority under the Tobacco Control Act ("Act"), a statute enacted in 2009 that is designed to address the "cancer, heart disease, and other serious adverse health

effects" associated with use of "tobacco products." Pub. L. No. 111-31, 123 Stat. 1777, § 2(1) (2009); *see also id.* § 3 (reciting ten statutory purposes, each focused on "tobacco" or "tobacco products").

16. The Act appears in chapter IX of the Food, Drug, and Cosmetic Act ("FDCA") and grants FDA authority to regulate the manufacture, sale, and marketing of "tobacco products."

17. The Act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr).

18. Among other things, the Act: (i) imposes a rigorous premarket approval procedure, similar to the procedure for new drug applications under the FDCA, for many new tobacco products; (ii) makes it unlawful to market misbranded or adulterated tobacco products; (iii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iv) requires manufacturers to register manufacturing facilities with FDA and open such facilities for biannual FDA inspections; (v) authorizes FDA to impose restrictions on the sale and distribution of tobacco products, and to require warning labels for tobacco products; (vi) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vii) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (viii) directs tobacco product

manufacturers to keep certain records; (ix) requires manufacturers to obtain advance FDA approval before making a variety of advertising and labeling claims; and (x) grants FDA authority to promulgate testing requirements for tobacco products. 21 U.S.C. §§ 387a–387k, 387o, 387t.

19. These mandates "apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary [of HHS] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b).

20. In the Deeming Rule, FDA purports to exercise the deeming authority provided in section 387a by subjecting "all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products," to regulation under the Act. The Deeming Rule concludes that vaping devices (or the constituent parts or components of vaping devices) are "tobacco products" subject to the Act's provisions, even though vaping devices (or their parts) are not made or derived from tobacco or intended for human consumption.

21. The breadth of the Deeming Rule's purported reach is staggering. Indeed, the Rule classifies as "tobacco products"—and thus asserts regulatory authority over—*inter alia*, "programmable software," "batteries," "digital display/lights," and "glass or plastic vial[s]."

JURISDICTION AND VENUE

22. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq*.; the FDCA, 21 U.S.C. § 301 *et seq*.; and the Act, 21 U.S.C. § 387 *et seq*. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 2201–02.

23. Judicial review is authorized by the APA, 5 U.S.C. § 701 *et seq.*, which provides for judicial review of final agency actions.

24. FDA's promulgation of the Deeming Rule constitutes final agency action within the meaning of 5 U.S.C. § 704.

25. Venue is proper under 28 U.S.C. § 1391(e).

THE DEEMING RULE'S EFFECTS ON NICOPURE

26. Once the Deeming Rule goes into effect on August 8, 2016, the overwhelming majority of Nicopure's products—including hundreds of products that are neither made nor derived from tobacco nor intended for human consumption—will be subject to the premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements imposed by the Act.

27. Such regulation will severely burden Nicopure and its operations—costing millions of dollars.

28. The Deeming Rule's premarket approval requirements will force Nicopure to discontinue existing product lines and will also prevent Nicopure from introducing new product lines after the Rule's effective date.

29. Nicopure will be forced to redirect resources from day to day business operations and research and development to compliance with the Deeming Rule's premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, and other requirements.

30. Even if the Court ultimately sets aside the Deeming Rule, Nicopure will suffer irreparable harm from its promulgation due to the immediate and irrep-

arable consequences of being subject to unlawful regulation, including the unlawful deprivation of Nicopure's constitutional rights.

31. For these reasons and the others given in this Complaint, there exists an actual and justiciable controversy between Nicopure and Defendants requiring resolution by this Court.

FIRST CLAIM FOR RELIEF
Violation of APA—Unlawful Statutory Interpretations

32. The above paragraphs are incorporated herein by reference.

33. The APA, 5 U.S.C. § 706(2)(A), (C), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."

34. The Deeming Rule violates those provisions because, *inter alia*, its definition of "tobacco product" and attendant proposed reach of its provisions is unambiguously foreclosed by, and is an unreasonable construction of, the text of the Act.

SECOND CLAIM FOR RELIEF
Violation of APA—Arbitrary and Capricious Agency Action

35. The above paragraphs are incorporated herein by reference.

36. The APA, 5 U.S.C. § 706(2)(A), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Under this provision, agency action is unlawful if the agency failed to articulate a rational connection between

the facts found and the choice made, failed to consider an important aspect of the problem, or offered an explanation for its decision that runs counter to the evidence. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

37. The Deeming Rule is unlawful when judged against that standard.

38. Under the Act, "tobacco products" may not be sold without prior approval from FDA. 21 U.S.C. § 387j(a)(2). The Act provides three options for obtaining FDA approval:

- The substantial equivalence ("SE") pathway, which requires the manufacturer to show that its product "is substantially equivalent to a tobacco product commercially marketed … in the United States as of February 15, 2007," 21 U.S.C. § 387j(b)(2);

- The SE exemption pathway, under which the manufacturer must show that its product is only a "minor modification" of a tobacco product that was on the market as of February 15, 2007, and that the modification only involves a change in additive levels, *id.* §§ 387(j)(3), 387j(a)(2)(A)(ii); and

- The premarket tobacco application ("PMTA") pathway, under which the manufacturer must obtain FDA approval based on a detailed application documenting the product's health risks, ingredients, manufacturing methods, and other characteristics, *id.* § 387j(b)(1).

39. The PMTA process is similar to the new drug application (NDA) process set forth in the FDCA, which courts have described as "expensive and time-consuming." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001). Indeed, the language of the provision outlining the PMTA process repeats verbatim several portions of the provision governing the NDA process. *Compare* 21 U.S.C. § 355(b)(1) *with* 21 U.S.C. § 387j(b)(1).

40. The PMTA pathway is the only avenue open to the vast majority of vaping devices and e-liquids, and the only avenue open to Nicopure's products. Vaping devices and e-liquids generally were not on the market "as of February 15, 2007," and thus do not meet FDA's stringent test for the SE pathway. Similarly, vaping devices and e-liquids do not meet the criteria for the SE exemption pathway because they are not "minor modifications" of tobacco products that were marketed as of February 15, 2007.

41. Thus, under the Deeming Rule, Nicopure will be required to file and obtain FDA approval of PMTAs for hundreds of its products, and for every new product that it brings to market in the future. Other manufacturers will likewise be required to go through the PMTA process for all of the vaping devices, e-liquids, and components and parts they sell. The Deeming Rule fails to come to grips with the extraordinary burden this approval regime will have, both on manufacturers and on FDA itself.

42. The Deeming Rule also arbitrarily discounts the safety benefits offered by vaping devices and e-liquids. As the Deeming Rule acknowledges, studies have concluded that (i) vaping devices enable "substantial reductions in the exposure to harmful constituents typically associated with smoking" when "compared to cigarettes"; (ii) "most of the chemicals causing smoking related disease from combusted tobacco use are absent" in the vapor generated by vaping devices; (iii) "the chemicals that are present" in vapor generated by vaping devices "present limited

danger"; and (iv) vaping devices "are likely to be much less, if at all, harmful to users or bystanders" in comparison to cigarettes.

43. Despite that compelling safety data, the Deeming Rule subjects vaping devices and e-liquids to the same extensive regulatory regime designed for cigarettes and smokeless tobacco—products Congress has characterized as causing "over 400,000 deaths in the United States each year." Act § 2(13).

44. The Deeming Rule is particularly arbitrary in its treatment of new vaping devices and e-liquids introduced after the Rule's August 8, 2016, effective date. Although the Rule adopts a compliance policy that will allow existing vaping devices and e-liquids to remain on the market temporarily, so long as the manufacturer timely files a corresponding PMTA, the Rule also mandates that products introduced after its effective date are "not covered by th[e] compliance policy" and therefore are "subject to [immediate] enforcement if marketed without" an approved PMTA. As a result, manufacturers will be unable to introduce new vaping devices and e-liquids for several years. The Deeming Rule does not articulate a reasoned basis for imposing such a *de facto* moratorium. Nor does the Deeming Rule come to grips with the reality that the lack of new vaping products, and removal of existing ones for non-compliance, will drive consumers back to cigarettes, thereby undercutting the Act's objectives.

45. The net effect of the Deeming Rule is a regime that arbitrarily frustrates innovations and advances in public health while preserving the status quo that existed in 2007, i.e., a market dominated by cigarettes. The Deeming Rule does

not explain how this result serves the public interest or the Act's goals of "promot[ing] cessation" of tobacco use and "reduc[ing] … the social costs associated with tobacco-related diseases." Act § 3(9).

THIRD CLAIM FOR RELIEF
Violation of APA—Unlawful Cost-Benefit Analysis

46. The above paragraphs are incorporated herein by reference.

47. The APA, 5 U.S.C. § 706(2)(A), (C)–(D), provides that a reviewing court shall hold unlawful and set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

48. The Deeming Rule's purported cost-benefit analysis violates the APA because it overstates the Rule's benefits, fails to quantify the *Rule*'s benefits, understates the Rule's tremendous costs, and erroneously concludes that the *Rule*'s benefits outweigh its costs.

49. Among other things, the Deeming Rule grossly underestimates the number of PMTAs that manufacturers will be required to file, and that FDA will be required to review. Although the Deeming Rule estimates that 750 PMTAs will be filed annually, Nicopure alone will need to file many hundreds of PMTAs just to cover its existing product offerings. Countless other manufacturers will also have to comply.

50. A proper cost-benefit analysis, as required by law, would demonstrate that the Deeming Rule imposes severe regulatory burdens on manufacturers, in-

cluding small businesses such as Nicopure, by requiring compliance with extensive premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements. These costs vastly outweigh the benefits generated by the Deeming Rule, particularly given that vaping devices and e-liquids do not contain tobacco and/or do not pose the public-health risks associated with products that contain tobacco.

51. The Deeming Rule's flawed cost-benefit analysis infects the entirety of the Rule, and therefore requires the Rule to be vacated and set aside, because FDA could not rationally have adopted the same regulatory scheme if it had performed a reasonable cost-benefit analysis.

FOURTH CLAIM FOR RELIEF
Violation of First Amendment

52. The above paragraphs are incorporated herein by reference.

53. The APA, 5 U.S.C. § 706(2)(B), provides that a reviewing court shall hold unlawful and set aside agency action that is "contrary to constitutional right, power, privilege, or immunity."

54. The Deeming Rule violates the First Amendment by prohibiting manufacturers, including Nicopure, from making truthful and nonmisleading statements regarding vaping devices, e-liquids, and related products.

55. The Deeming Rule violates the First Amendment by prohibiting manufacturers, including Nicopure, from engaging in other forms of protected expression, including by distributing free samples of vaping devices or e-liquids.

RELIEF REQUESTED

WHEREFORE, Nicopure asks this Court issue judgment in its favor and against Defendants, and to grant the following relief:

A. Vacate and set aside the Deeming Rule;

B. Declare that:

i. the Deeming Rule is contrary to and exceeds FDA's statutory authority under the Act and the FDCA;

ii. the Deeming Rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

iii. the Deeming Rul*e*'s cost-benefit analysis is unlawful; and

iv. the Deeming Rule is contrary to the First Amendment.

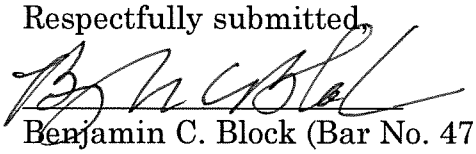
C. Issue a preliminary injunction enjoining enforcement of the Deeming Rule and prohibiting FDA from taking any action under the Deeming Rule pending resolution of this action on the merits;

D. Expedite resolution of this action on the merits;

F. Grant Nicopure reasonable attorney's fees and expenses; and

G. Award such further relief as this Court deems just and proper.

Respectfully submitted,



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May 10, 2016