Nicopure Labs, LLC.
7916 Evolutions Way
Suite 200
Trinity, FL 34655
888-425-6649

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NICOPURE LABS LLC (NICOPURE LABS) COMMENTS ON THE FOOD AND DRUG ADMINISTRATION'S (FDA OR THE AGENCY) ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPRM) DOCKET NO FDA-2015-N-1514-0003

The FDA issued this ANPRM to obtain information related to the regulation of "tobacco products" subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and restrictions regarding the sale and distribution of such tobacco products. Specifically, this ANPRM is seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to **nicotine exposure warnings** and **child-resistant packaging** for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as nicotine lotions, gels, and drinks.

In April 2014, FDA published a proposed rule seeking to deem products meeting the statutory definition of "tobacco product," except accessories to proposed deemed tobacco products, to be subject to the FD&C Act, as amended by the Tobacco Control Act (Proposed Deeming Rule). Specifically, the Proposed Deeming Rule seeks to extend the Agency's "tobacco product" authorities to those products that meet the statutory definition of "tobacco product," prohibiting the sale of "covered tobacco products" to individuals under the age of 18, and requiring the display of health warnings on certain tobacco product packages and in advertisements. The deeming rulemaking does not address the issues raised in this ANPRM.

Since 2009, Nicopure Labs manufactures and distributes both nicotine-containing and non-nicotine liquids (e-liquids) for use with vaping devices, as well as hardware recommended for use with its e-liquids. Nicopure Labs' leading e-liquid brands Halo and eVo are sold in the U.S. and abroad. The company also distributes proprietary Triton and G6 vaping devices, which are recommended for use with the company's e-liquids. Nicopure Labs products comply with applicable REACH regulation in the European Union (EU), as well as with all EU labeling requirements, which include nicotine warning pictograms and specific ingredient and country of origin disclosures. The e-liquids are currently manufactured in Nicopure Labs' 100,000sqf facility in Gainesville, Florida, with utmost care for the integrity of the manufacturing process and quality controls. The products are sold in 7 ml, 10 ml and 30 ml bottles equipped voluntarily with child resistant, tamper evident caps. The nicotine content ranges from 0 mg/ml to 24 mg/ml. The e-liquids are manufactured from USP grade propylene glycol, glycerin and nicotine, they are diacetyl-free and they are made with flavorings sourced from reliable suppliers who also supply flavorings to other FDA regulated industries. Careful consideration is given to product stewardship. Test results of Nicopure Labs e-liquids with respect to absence of diacetyl and acetyl propionyl are available at https://www.halocigs.com/blog/halos-eliquid-test-

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results/ Furthermore, Nicopure Labs provides Safety Data Sheets for its products to its distributors and retailers.

Nicopure Labs respectfully submits these comments to the ANPRM docket with respect to warnings and child-resistant packaging for electronic cigarettes and e-liquids only. These comments do not reference other products that have yet to be deemed tobacco products by the FDA, such as gels and hookahs, although Nicopure Labs' comments may have applicability to those other products as well.

Nicopure Labs is committed to compliance with reasonable, science-based regulation, which does not infringe constitutionally protected rights.

Timeliness of the ANPRM

FDA issued the ANPRM prematurely. Namely, the Proposed Deeming Rule issued in April 2014 has received a large number of substantive comments, which FDA must review before issuing a Final Deeming Rule. Additional research was conducted on electronic cigarettes and e-liquids since April 2014, which would not have been addressed in those comments. However, the science is far from providing a definitive answer as to the population level impact of electronic cigarettes and e-liquid use, although one thing is clear, and acknowledged by the FDA as well as by numerous anti-tobacco public health advocates and institutions: vaping presents substantially less risks to individuals than smoking conventional cigarettes. We therefore urge FDA to delay any final rule on the subject matter of the ANPRM until such time it will have successfully brought additional products under the Tobacco Control Act, and until such time FDA will have mastered a robust scientific understanding of the newly deemed products and their population effect.

Nicotine Exposure Warnings

In deciding what, if any, warnings are appropriate for each type of product FDA must be consistent with its mandate, which is to be a science-based organization. FDA has to satisfy itself that the warnings are appropriate and commensurate with the actual harm described in the warning; that they are not the Government's anti-vaping advertising designated to stigmatize e-cigarette and e-liquid users; also, FDA must gather sound science as to the effectiveness of the warnings and, last but not least, that FDA must ensure the warnings are not in violation of the First Amendment.

As raised in pervious litigation, the Supreme Court's "First Amendment precedents have established the principle that freedom of speech prohibits the Government from telling people what they must say." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 61 (2006); *see also Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion) There is a limited exception allowing the Government to require factually accurate commercial disclosures that are "reasonably related to [its] interest in preventing deception of consumers," *Zauderer*, 471 U.S. at 651, however, the Government must survive strict scrutiny if it attempts to coerce commercial speech into a campaign against the speaker or the speaker's product.

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Therefore, in support of its final rule on nicotine warnings, FDA must provide sound scientific evidence that the warnings are accurate, and that there is a compelling government interest in mandating such warnings that cannot be achieved in any other way. Further, FDA must demonstrate that the warnings will accomplish a statistically significant reduction in the harm stated in the warnings. Also, the amount of commercial information manufacturers are able to still include on the product packaging after the warnings implementation must not be adversely affected by the size, content and placement of the warnings, since the Government may mandate commercial statements that are "purely factual and uncontroversial," but not if they impose an "unjustified or unduly burdensome" restriction on the speaker. *Zauderer*, 471 U.S. at 651.

In support of its rulemaking, we respectfully direct FDA to the following resources for nicotine research and information, and for the comparative health profile of electronic cigarettes compared to conventional cigarettes:

http://nicotinepolicy.net/

http://www.oxfordjournals.org/our_journals/nictob/for_authors/general.html

https://www.dukesmoking.com/

Theory of Addiction by Robert West and Jamie Brown, Wiley-Blackwell; 2 edition (November 4, 2013).

Public Health England: E-cigarettes; an evidence update
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

In sum, FDA must conduct a careful analysis of the best available science and of the First Amendment issues surrounding nicotine warnings before engaging in final rulemaking.

Child-resistant packaging

Nicopure Labs products are sold in child resistant packaging labelled "Not for Sale to Minors". We strongly believe that underage persons should not be able to purchase the product and that packaging should be child resistant. We also believe that all tobacco products should be treated equally with respect to this requirement. However, as it is the case with any rulemaking, FDA must base its decisions on sound science.

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In conclusion, we urge FDA to engage with the scientific community and with the manufacturers and distributors of electronic cigarettes, e-liquids and vaping devices to ensure all procedural and substantive issues are addressed before the issuance of a final rule on nicotine warnings and child resistant packaging.

We are at the Agency's disposals to answer any pertinent questions and provide reasonable, non-confidential or privileged information about the manufacturing process, our products and the industry in general.

Respectfully submitted on behalf of Nicopure Labs LLC,

Patricia I. Kovacevic
General Counsel and Chief Compliance Officer
Nicopure Labs LLC
7916 Evolutions Way, Suite 200
Trinity, FL 34655 USA

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