Nicopure Labc LLC Comments to FDA's Proposed Regulations: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"

Docket No. FDA-2015-N-2002-0008 (as reopened, originally FDA-2015-N-2002-0001) (RIN 0910-AH19)

Nicopure Labs LLC is a Florida-based entity and the leading e-liquid and vaping device manufacturer of American-made Halo and eVo e-liquids and Reactor, Tracer, Triton and G6 vaping devices. The following comments are submitted on behalf of Nicopure Labs LLC.

The Food and Drug Administration (FDA) is proposing regulations to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (the "Proposed Rule" or the "Rule")). In FDA's opinion, "this action is intended to provide direction to regulated industry and to help avoid consumer confusion."

Nicopure Labs LLC support and applauds FDA's expressed intention to be more transparent and to provide guidance and insights into its decision-making process.

However, in connection with the above captioned docket, we respectfully submit that the Proposed Rule exceeds FDA's authority and that, even if it were within FDA's authority, there is no compelling need to issue the Rule. Furthermore, if finalized as drafted, the Rule would not achieve its stated goals.

FDA Authority

Section 101(a) of the 2009 Family Smoking Prevention and Tobacco Control Act ("TCA") amends section 201 of the FD&C Act by adding paragraph (rr), which defines the term "tobacco product." In general, a "tobacco product" is defined 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). Section 201(rr)(2) of the FD&C Act excludes from the definition of a tobacco product any article that is defined as a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C 353(g)). Section 201(rr)(3) of the FD&C Act explains that any article that is a drug, device, or combination product will be regulated under chapter V of the FD&C Act (the authorities for drugs and devices) rather than chapter IX (the authorities for tobacco products).

When it comes to products made or derived from tobacco, FDA now feels the need for a rule "clarifying" the very definitions of drug, device and combination products it has lived with for many years now, and which were obviously clear to Congress when it enacted the TCA.

We believe FDA is exceeding its authority in issuing such rule because the effect of the Rule would be, among other, to expand and modify impermissibly a statutory definition to include under the definition of a drug, subjectively, products supported with consumer-oriented marketing statements, such as "for people who wish to quit smoking", even absent a more definitive product labeling statement to the effect that the product actually accomplishes a therapeutic goal. Furthermore, in this Rule FDA attempts to codify FDA's own reading of two court rulings, *Brown and Williamson* and *Sottera*. In the Rule preamble FDA itself agrees that "the *Brown & Williamson* and *Sottera* decisions do not reach the issue of intended uses that fall outside the disease prong of the drug/device definition *and* that are outside the area of "customarily marketed" tobacco product claims", but then proceeds to interpret what these decisions should mean for today's tobacco products, whereas at least *Brown and Williamson* was clearly issued before the Tobacco Control Act, only addressed conventional tobacco products existing at the time, and did not even remotely contemplate novel, complex products such as electronic cigarettes and other products about to be deemed tobacco products by the FDA under the TCA definition.

We acknowledge that FDA is, at present, well within its authority to commence enforcement against unapproved drug claims that a product (such as, for instance, an e-cigarette) is intended for use in the diagnosis, cure, mitigation, treatment or prevention of a disease (such as for instance, COPD or diabetes). We also acknowledge that a nicotine

containing product (such as, for instance, a gum) could hypothetically not have to be regulated as a drug should its manufacturer choose to forgo making any drug claim.

Given its already broad powers, FDA should therefore exercise its current authority constructively to ensure its public health goals are achieved. One of FDA's stated public health goals, and the premise of the TCA, is to reduce the death and disease burden cause by smoking. FDA's public health goals will be hindered by further limiting consumer access to products that do not contain combustible tobacco by tweaking and expanding the definition of a drug to reach *more* non-combustible smoking alternatives (whether nicotine containing or not) and therefore eventually taking such non-combustible products off the market. Consequently, FDA should seek to act consistent with its statutory authority and refrain from rulemaking that undermines its stated public health priorities.

Need for rulemaking

The preamble to the proposed rule states that there is "ambiguity" surrounding "the circumstances under which a product that is made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product".

There is no more ambiguity surrounding tobacco products regulation as drug, device or combination products than there is surrounding FDA's determination that a certain dietary supplement or food meets the definition of a drug. FDA seems to have clarified such ambiguity already through a number of guidance documents, including, for instance, its September 2013 Guidance for Clinical Investigators, Sponsors, and IRBs; Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted without an IND. There, as in numerous other FDA guidance documents and warning letters issued over time to various industries, FDA seems to have a clear grasp of what is a drug, device or combination product, and where is the fine line between, for instance, drugs and other FDA regulated products. The same FDA that issued hundreds of warning letters for unauthorized marketing of drugs is now less sure what is a drug if the product in question happens to be made or derived from tobacco. As new products in all FDA-regulated industries come to market, it is subjective, unreasonable and potentially damaging to public health to expand and/or modify from time to time the definition of a

drug, device or combination product solely via examples of types of claims, and this approach is not supported by the FD&C Act.

Thus, we see no need at this particular time for a new rule in this area, since FDA has been overseeing drugs, devices and combination products for a very long time and is presumably well versed at identifying what is what.

As drafted, the rule would not achieve its stated goals

In the proposed rule preamble FDA states the following goals: (1) Provide assistance for entities intending to market products made or derived from tobacco and for entities that plan to study these products. For example, the Rule is expected to help sponsors determine which FDA Center should be consulted as they develop their products and make appropriate premarket submissions to bring new products to market. FDA expects the Rule will also assist investigators planning to use products made or derived from tobacco for an investigational use in determining the investigational use requirements that apply to their proposed studies (whether an Investigational New Drug ("IND") or investigational new tobacco product). (2) Increase clarity regarding the types of claims and other evidence that make a product made or derived from tobacco subject to regulation as a drug or device, which FDA expects will help consumers distinguish products made or derived from tobacco that are intended for medical use from products marketed for other uses. (3) Provide clarity for drug and device manufacturers generally regarding FDA's interpretation and application of its existing intended use regulations.

With respect to the Proposed Rule's purported first goal, FDA already issued several guidance documents on this topic. It is our understanding that there is no public outcry among the research community as to lack of clarity on this topic, and that, to date, FDA has not been challenged on its IND requirements for tobacco-derived products. Even if there were issues with INDs, the Rule does not even address INDs.

With respect to the proposed rule's second goal, it is hard to see how consumers would be better off if the rule were issued and how exactly the text of the rule would help consumers, for instance, read product labels in a more informed way, or help consumers make product choices. Under any circumstance it is FDA's responsibility to make sure all

regulated products are properly labeled, therefore the rule would serve, at best, only FDA and its staff by giving it more authority than the FD&C intended and potentially further limiting commercial speech in ways that could lead to legal challenges.

With respect to the Proposed Rule's third goal, the sole accomplishment of revised §201.128 and §801.4 would be to delete the last sentence of current §201.128, and of §801.4, respectively, which reads: "But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug [in §801.4: device] introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug [in §801.4: device] which accords with such other uses to which the article is to be put." If anything, the new §201.128 and §801.4 provide *less* information to manufacturers, not more clarity.

Furthermore, §1100.5 as amended can be paraphrased to complement the TCA in the following manner: "If a tobacco product is a drug, device or combination product, then it is a drug, device or combination product; and tobacco products are only those products made or derived from tobacco that are intended for human consumption and that are not drugs, devices or combination products. And we (FDA) will only allow advertising of any tobacco product if consistent/similar with advertising of conventional tobacco products in existence before March 21, 2000. If different, then the respective product is not a tobacco product, but a drug, device or combination." Once again, if clarity is the underlying goal of the Rule, it certainly cannot be accomplished by the rather circular text of the Proposed Rule as drafted.

Conclusion

We respectfully submit that FDA's public health mandate will be better served if FDA efforts and resources are allocated to rulemaking in deficient areas of public health interest (such as reasonable, science- and evidence-based product standards for novel tobacco products). With respect to the Proposed Rule, the Rule exceeds FDA's authority under the FD&C Act and will not accomplish its stated goals. FDA is already sufficiently equipped with knowledge and evidence to enforce against unauthorized drug and/or device claims, whether those claims are made by tobacco-derived products

manufacturers or by manufacturers of any other consumer product. We therefore respectfully urge FDA to refrain from spending additional resources on this rulemaking.

We remain at your disposal should you have any related questions.

Respectfully,

Patricia I. Kovacevic

General Counsel, Chief Compliance Officer

Nicopure Labs LLC