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March 23, 2018

Via Electronic Mail

Brendan Woodward
Flavorah
P.O. Box 2624
Woodlinville, 98072 WA

Re: Status of Flavorah Flavor Compounds Under Tobacco Control Act and FDA's Deeming Rule

Dear Mr. Woodward:

The purpose of this letter is to respond to your request for our opinion on whether Flavorah's flavor compounds are subject to the U.S. Food and Drug Administration's (FDA's) "Deeming Rule," which deems previously unregulated "tobacco products" subject to the requirements of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Actfs).[1] For the reasons set forth herein, in our opinion, Flavorah's flavor compounds are not tobacco products and, therefore, are not subject to the Tobacco Control Act and Deeming Rule requirements for deemed tobacco products. Moreover, even if a commercial or consumer manufacturer ultimately incorporates the flavor compounds into a nicotine containing e-liquid or other tobacco product on its own, Flavorah's products would still not be considered "covered" or "finished" tobacco products. Accordingly, even in that scenario, Flavorah would not be subject to the requirements of the Tobacco Control Act including, but not limited to, the nicotine addiction warning, age restriction, premarket authorization, registration and product listing, ingredient listing, health document submission and harmful constituent testing.

I. The Tobacco Control Act and the Deeming Rule

a. Background

By way of background, the Tobacco Control Act was enacted in 2009 and amended the Food, Drug and Cosmetic (FDCA) to give FDA authority over the manufacture, distribution and marketing of tobacco products. Although a tobacco product is defined broadly in the FDCA as anything made or derived from tobacco intended for human consumption, including its

[1] 81 Fed. Reg. 28,973 (May 10, 2016).

components, parts and accessories[2], the Act only gave FDA the immediate authority over four specific categories of tobacco products; namely, cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. The law also gave FDA the ability to use its rulemaking procedures to promulgate a regulation that would "deem" other, previously unregulated tobacco products (*e.g.*, cigars, e-cigarettes, hookah, pipe tobacco, etc.), under its tobacco authority. The final Deeming Rule was published on May 10, 2016 and became effective 90 days thereafter on August 8, 2016, capturing all current and future products that fall within the definition of "tobacco product".

b. Categories of Deemed Tobacco Products

Because of how broadly Congress defined tobacco product above, even non-tobacco components and parts of deemed vapor products are themselves considered tobacco products subject to the TCA. But, FDA applies the Tobacco Control Act requirements differently to different categories of deemed products; namely, components and parts, covered tobacco products, and finished tobacco products.

i. Components and Parts (and Accessories)

As noted above, the tobacco product definition includes "components, parts and accessories" of such products. We note that when the Deeming Rule expanded FDA's authority beyond the original regulated product categories (cigarettes, smokeless and roll-your-own) to include products like vapor products, the rule included components and parts, but specifically exempted accessories of deemed products from the regulation.[3] With respect to vapor products,

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[2] A tobacco product is defined in the Tobacco Control Act (TCA) 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)" that is not a drug, device, or combination product. See 21 U.S.C. § 321(rr).

[3] An "accessory" is defined in the Deeming Rule as "any product that is intended or reasonably expected to be used with or for the human consumption of tobacco; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product." Examples of accessories provided by FDA include screwdrivers, lanyards, and decorative cases. 81 Fed. Reg. 28974, 29102 (May 10, 2016) (codified at 21 C.F.R. 1140.3).

which FDA refers to as Electronic Nicotine Delivery Systems (ENDS)[4], the Deeming Rule and relevant guidance documents define components, parts and accessories as "any software or assembly of materials intended to or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product." 81 Fed. Reg. 28974, 29103 (May 10, 2016) (codified at 21 C.F.R. 1140.3).

In the preamble of the final Deeming Rule, as well as FDA's Draft Guidance on *Premarket Tobacco Applications for Electronic Nicotine Delivery Systems*, FDA has further described the distinctions between components, parts and accessories of vapor products. Specifically, FDA has indicated that components and parts of vapor products include the following non-exclusive list of items[5]:

- e-liquids;
- atomizers;
- batteries (with or without variable voltage);
- cartomizers (atomizer plus replaceable fluid-filled cartridge);
- digital display/lights to adjust settings;
- clearomisers;
- tank systems;
- flavors;
- bottles that contain e-liquids; and
- programmable software.

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[4] In the Deeming Rule, FDA makes clear that all ENDS, which include "e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes," are subject to the Tobacco Control Act because they contain or are used with nicotine derived from tobacco, provided they are intended for recreational (*i.e.*, non-therapeutic) human consumption. *See* 81 Fed. Reg at 28976; *see also Sottera Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010) (holding that e-cigarettes that contain tobacco-derived nicotine are tobacco products and not drug delivery devices so long as they are customarily marketed for recreational use and without any therapeutic intent).

[5] *See* FDA Draft Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems at page 5, May 2016, *available at* http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499351.htm.

The regulatory requirements for components and parts of vapor products depends on whether the component and part is also considered a "covered" tobacco product and/or a "finished" tobacco product.

ii. Covered Tobacco Products

A covered tobacco product is any deemed tobacco product, but *excludes* any component or part that is *not* made or derived from tobacco. See 21 C.F.R. § 1140.3. In other words, components or parts of deemed tobacco products that are *not* made or derived from tobacco or do not contain such substances are tobacco products (because of the broad tobacco product definition), but *not* "covered tobacco products". Examples of components and parts of vapor products that are not covered tobacco products include any device hardware (e.g., tanks, wicks, atomizers, wires, etc.), zero-nicotine e-liquids that do not contain any other tobacco-derived ingredients. The following requirements only apply to covered tobacco products:

1) Minimum purchase age restrictions (18 years old);
2) Nicotine addiction warnings on packaging and advertising pursuant to 21 CFR § 1143.3: "WARNING: This product contains nicotine. Nicotine is an addictive chemical"; and
3) Vending machine sales only permitted in adult-only facilities.

Note that e-liquids that do not contain nicotine but do contain *other* tobacco-derived ingredients (e.g., tobacco extracts or flavors derived from tobacco) are covered tobacco products, but exempt from the nicotine addiction warning. Manufacturers are required to self-certify that that these products do not contain nicotine and must include a separate disclaimer on their packaging and advertisements: "This product is made from tobacco." 21 CFR 1143.3(c).

If a component or part of a deemed tobacco product is not a covered tobacco product does not mean it is not subject to the Tobacco Control Act. Whether the various requirements in the Act beyond the three listed above (e.g., registration, ingredient listing, harmful chemical testing, premarket review, etc.) apply to a deemed tobacco product depends on whether the product is a "finished" tobacco product.

ii. Finished Tobacco Products

A finished tobacco product is defined in the Deeming Regulation and FDA guidance as "a tobacco product, including all components and parts, sealed in final packaging intended for consumer use." This would include components and parts of vapor products (e.g., bottle e-liquid, open-system devices and parts that are sold directly to consumers), but *not* e-liquids, flavors or device components and parts that are sold to manufacturers who incorporate those products into another product (e.g., a pre-filled cigalike), which is ultimately sold to consumers. FDA states in the draft PMTA guidance that, at this time, it does not intend to enforce the premarket authorization requirements against e-liquids or other components and parts of newly deemed products that are not finished tobacco products. The agency has similarly indicated in various guidance documents that, at this time, it only intends to enforce the facility

registration, product listing, ingredient reporting, harmful constituent testing, and health document submission requirements against finished tobacco products.

II. Flavorah Flavor Compounds

You indicated that Flavorah flavor compounds are all "food grade" and made from materials determined by FDA to be Generally Recognized as Safe (GRAS) for ingestion, do not contain nicotine or any tobacco-derived substances, are not marketed for use with such materials, are not bundled or sold with any nicotine or tobacco derived products, cannot directly be used in an ENDS or vapor device (they must be processed with PG/VG by the commercial or consumer manufacturer to create a finished "vapable" e-liquid), and have a number of non-tobacco applications, including use in foods.[6]

Based on this, the Flavorah flavor compounds do not fall within meaning of "tobacco product," as they are not made or derived from tobacco and are not intended or reasonably expected to be used with a tobacco product. Moreover, even if a commercial or consumer manufacturer ultimately incorporates the flavor compounds into a nicotine containing e-liquid or other tobacco product on its own, Flavorah's products would still not be considered covered or finished tobacco products. Accordingly, even in that scenario, Flavorah would not be subject to the requirements of the Tobacco Control Act including, but not limited to, the nicotine addiction warning, age restriction, premarket authorization, registration and product listing, ingredient listing, health document submission and harmful constituent testing.[7]

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[6] See e-mail from Brendan Woodward to Azim Chowdhury dated March 5, 2018, and subsequent conference calls. Please not that we have not reviewed the chemical composition or formulation of the flavors.

[7] While your flavor compounds are not tobacco products subject to the Tobacco Control Act or the Deeming Rule, this does not mean that FDA could not take the position that your flavors are food or food additives, or even drugs or drug ingredients even in the absence of any drug or health claims, given the broad definition of a drug in FDCA § 321(g), which includes "articles (other than food) intended to affect the structure or function of the body of man or other animals."

We hope this letter fully addresses your request for our opinion. If you have any questions or concerns, please do not hesitate to let us know.

Sincerely,

Azim Chowdhury

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