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October 6, 2022

Submitted Electronically via Docket No. FDA 2013-S-0610

Robert Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring MD 20993

Re: Citizen Petition

Dear Commissioner:

The undersigned submits this petition under Sections 801, 902, and 903 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§371, 381, 387, 387b, 387c, 387e, 387f, 387i, 387t, and 21 C.F.R. §10.30. This Citizen's Petition requests that the Commissioner of the Food and Drug Administration (FDA) (1) amends the regulation pertaining to the export of tobacco products, namely, 21 C.F.R. §1.101(b), (2) issue a Guidance document for industry for Tobacco Product Inspections at manufacturing facilities that are engaged, in whole or in part, in the manufacture of tobacco products for export, and (3) issue an update to FDA's Investigations Operations Manual (IOM) regarding inspections of manufacturers that export a tobacco product.

Unless FDA moves in Notice and Comment Rulemaking to modify its regulation, issues a Guidance document for industry providing for Tobacco Product Inspections at manufacturing facilities where entities are engaged, in whole or in part, in the manufacture of tobacco products for export, and amends its IOM to provide additional parameters when evaluating such class of manufacturer, the tobacco industry will continue to operate amid a vacuum of necessary guidance and regulation, and will remain at risk of subjective decision making by FDA inspectors rendering products unadulterated or misbranded due to an inability to discern products lawfully made for export.

A. Action Requested

Petitioner, Vapor Vapes, Inc., respectfully requests that the Commissioner of the FDA amend 21 C.F.R. §1.101(b) to further provide for parameters in relation to the export of tobacco products, including electronic nicotine delivery systems ("ENDS"). Alternatively, or in addition to, the amendment, a request is made to issue a Guidance document which establishes the actions a manufacturer of exported tobacco products could take to comport with such standards that FDA would recognize as being in compliance with the FD&C Act. Further, Petitioner requests that an update to the IOM be drafted that would enable an inspector to affirmatively discern, based on objective criteria, that the tobacco products are being manufactured and sold for export only.

21 C.F.R. §1.101(b)

As explained further below, the current statutes and regulations governing exports relates to four (4) narrow points per 21 C.F.R. §1.101(b). They are with respect to:

1. The foreign purchaser's specifications
2. The laws of the foreign destination
3. The labeling of the shipping package, and
4. The requirement that it is not sold in the U.S.

It is with this fourth requirement that a need for clarification arises, which is an issue for both the FDA and that of a tobacco product's manufacturer. Regarding FDA, it is in relation to its inspectors having an objective criteria against which to determine, during an inspection, such elements that when found at a manufacturer's facility enables a confirmation of goods being manufactured for export. Without specific criteria, such as the layout of the manufacturer's facility, certain signage, and even specific records (discussed further below) to demonstrate compliance with the FD&C Act during an inspection, inspectors are left to subjectively determine whether or not such products are being manufactured for export.

Upon information and belief, in Petitioner's experience, FDA has made no distinction between its products destined for export and has instead considered all of Petitioner's manufactured goods to be adulterated and misbranded under the subjective belief that all tobacco products are being sold unlawfully in the US. Despite Petitioner's repeated requests to FDA personnel in response to a Warning Letter for the agency to provide recommendations that Petitioner could implement which would demonstrate compliance with the FD&C Act in relation to its exports FDA's only response orally was that no such recommendation could be given.[1] Further, no written response has been provided to address this. Therefore, this regulation is in need of amendment to provide guidance to FDA on the requirements for a manufacturer to demonstrate its products are intended for export.

In relation to tobacco product manufacturers, no standards exist against which a manufacturer could align its operations in order to make a lawful showing that some, or all, of its goods are for export, which would enable it to overcome an allegation of selling such products unlawfully. The result is that now all of its products are unfairly and erroneously considered by FDA to be adulterated and misbranded.

Therefore, this regulation is in need of amendment to also provide guidance to the tobacco industry in relation to operational mechanisms it can implement to demonstrate how some or all of its products are manufactured for export only, and thereby avoid an allegation of non-compliance with the FD&C Act.

Guidance Document

As stated in 21 U.S.C. §371(h), a Guidance document, though non-binding, will present the views of the Secretary on matters under the jurisdiction of the FDA, and shall ensure that FDA employees "do not deviate from such guidances without appropriate justification and supervisory occurrence."[2]

[1] On August 10, 2022, counsel for Petitioner met via teleconference with Mr. Earl Echon CTP Consumer Safety Officer and Mr. Max Essen CTP, Regulatory Counsel.
[2] 21 U.S.C. §371(h)(1)(A)-(B).

As described in the above section, guidance regarding governance over manufacturers of tobacco products intended for export, to support an objective determination that a manufacturer is, in fact, manufacturing products for export, whether in whole or in part, is needed.

Manufacturers likewise need guidance regarding operational standards to demonstrate compliance with the FD&C Act in relation to exported goods.

Subject to certain exceptions, ensuring that public participation occurs prior to the implementation of a guidance document is a key component where such guidance is intended to "set forth initial interpretations of a statute or regulations, changes in interpretation or policy that are of more than a minor nature, [a] complex scientific issue, or a highly controversial issue."[3] Recognizing that this may be considered a change in interpretation or policy, the notice and comment period for such a Guidance document should be immediately undertaken.

IOM

The IOM is a document that sets forth the protocols for fundamental field activities carried out by FDA employees.

Further to any newly amended regulation and Guidance document, updates to the IOM are needed to provide actual guidance to inspectors during an inspection to make the distinctions regarding lawful exports as described above.

B. Statement of Grounds

Background

The FDA is the federal agency entrusted with approving applications for new tobacco products, including ENDS and its components and parts. While those sold for U.S. commerce require pre-market authorization by FDA, those intended for export do not.

Petitioner manufactures a combination of products for which some are considered to be "tobacco products" while others are not. In relation to such merchandise that is considered a tobacco product, Petitioner manufactures a component of an ENDS, namely e-liquid.

Upon information and belief, within the category of "tobacco products," sold by Petitioner, a portion of them are sold which are intended solely for further manufacturing in the U.S., with the other portion for export only. Many of the exported tobacco products are made-to-order.

Similar to the products sold in the U.S., some exports are intended for further manufacturing only. Other products, however, namely those made-to-order, are not authorized for sale in the U.S.

As Petitioner is permitted to export tobacco products so long as it comports to the statutory and regulatory framework provided in the section below, such activity is permissible and lies beyond FDA's statutory misbranding and adulterated enforcement authority.

[3] 21 U.S.C. §371(h)(1)(C).

Due to a lack of guidance, however, with respect to:

> (1) operational recommendations for manufacturers of tobacco products to demonstrate to FDA that such operations are, in whole or in part, specifically for that of export sales, and
>
> (2) distinctions, and even parameters, for FDA inspectors conducting a tobacco product's inspection to objectively render a decision that an entity is engaged in the manufacture and lawful sale of goods for export (such that the inspector does not subjectively conclude that the entity is manufacturing for sale in the U.S. unauthorized goods, and therefore deems them unadulterated and misbranded),

Petitioner, and others of a similar class within the industry[4], are facing subjective determinations by FDA during inspections with respect to the lawfulness of their operations and are at risk of FDA enforcement, including fines, penalties, seizures and even closures, due to FDA's inability to objectively distinguish between lawful manufacturing operations for export, versus those which violate the FD&C Act.

Current FDA Regulations and Policy on Tobacco Manufacturer Facilities

FDA statutes, regulations, and the IOM do not provide clear guidance for implementing or evaluating compliance with operational measures on manufacturers of approved finished products versus those which are not approved for sale in the US, but which may nonetheless be sold for export.

Indeed, as it relates to the export of a tobacco product, 21 U.S.C. 801(e) merely sets forth four (4) guidelines in need of being followed, as provided below:

> (1) A food, drug, device, **tobacco product** or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter, and a tobacco product intended for export shall not be deemed to be in violation of section 387f(e), 387g, 387k, or 387t(a) of this title, if it -
>
> (A) accords to the specifications of the foreign purchaser,
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> (B) is not in conflict with the laws of the country to which it is intended for export,
>
> (C) is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) is not sold or offered for sale in domestic commerce"[5]
>
> [emphasis added]

Consistent with the statute, the regulation 21 C.F.R. §1.101, which describes the recordkeeping requirements for tobacco products, provides that

> "Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product…[t]he records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

[4] Namely, manufacturers of tobacco products which, whether in whole or in part, are sold for export.
[5] 21 U.S.C. 801(e).

> (1) Records demonstrating that the product meets the foreign purchaser's specifications: The records must contain sufficient information to match the foreign purchaser's specifications to a particular export;
>
> (2) Records demonstrating that the product does not conflict with the laws of the importing country: This may consist of either a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001;
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> (3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export: This may consist of copies of any labels or labeling statements, such as "For export only," that are placed on the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and
>
> (4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials."[6]

With respect to the IOM, under Section 5.8.2, it merely provides, in pertinent part:

> "Inspections involving tobacco product(s) at manufacturing facilities are led by ORA's Tobacco Operations Staff (TOS) within the Office of Medical Products and Tobacco Operations and are conducted pursuant to assignments issued by CTP. These assignments are issued to conduct inspections of entities engaged in the manufacture, preparation, compounding, or processing of tobacco products. Inspections may also be conducted to support the pre-market review process. Assignments may also be issued to conduct investigations and sample collections."[7]

Even in the *Deeming Rule*[8] no further guidance was provided, as it likewise focuses on recordkeeping and recites a parallel list of requirements as set forth in the statute and regulation above.[9]

We respectfully submit that the existing regulations are inadequate to provide objective guidance to both industry and importantly, to the FDA, in its objective analysis of manufacturers when determining compliance with the FD&C Act as it relates to manufacturers of products sold either solely, or in part, for export.

In the absence of an amended regulation, the issuance of a Guidance document and an update to the IOM that legally establishes parameters that (1) a manufacturer can follow and implement to ensure compliance with the FD&C Act, and (2) that an FDA inspector can follow to objectively evaluate a manufacturer. Small businesses will be discouraged from operating in this industry due to the ongoing threat of subjective FDA enforcement decisions. The effects of amended regulations would help effectuate FDA's goal of improving efficiencies in its oversight and enforcement activities as they relate to tobacco products.

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[6] 21 C.F.R. §1.101.
[7] FDA Investigations Operations Manual, Chapter 5, Section 5.8.2, page 5-85 (2002).
[8] 81 FR 28974 (May 10, 2016).
[9] 81 FR 28974, 29089 (May 10, 2016).

Conclusion

Petitioner, Vapor Vapes, Inc., has been subjected to FDA enforcement activity for its products bound for export which remain beyond FDA's statutory misbranding and adulterated enforcement authority, pursuant to 21 U.S.C. 801(e). This is precisely the result of, on the one hand, a lack of appropriate regulation and guidance for industry covering export operations, and on the other hand, a lack of regulatory guidance and IOM content to provide sufficient guidance for FDA investigators who encounter products destined for export. These deficiencies and *ultra vires* enforcement activities which have adversely affected Petitioner, can reasonably be expected to have affected, and to continue to affect, others of a similar class within the industry, operating lawfully pursuant to 21 U.S.C. 801(e).

As manufacturing for export pursuant to the provisions of 21 U.S.C. 801(e) is a lawful activity, Petitioner and others of a similar class are entitled to appropriate regulatory frameworks and guidance under which they may arrange their business affairs to avoid such subjective enforcement.

C. Environmental Impact

The action requested in this petition will have no impact on the environment.

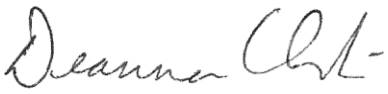
D. Economic Impact

Petitioner will submit an assessment of the economic impact of the actions it requests herein should the Commissioner determine that such assessment is necessary in evaluating this petition.

E. Certification

Petitioner certifies to the best of Petitioner's knowledge and belief: (a) this petition contains all information and views upon which the Petitioner relies; (b) this petition contains representative data and/or information known to the Petitioner which are unfavorable to the petition; and (c) Petitioner has taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed.

Respectfully,



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