May 12, 2017

Via Hand Delivery

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned organizations (hereinafter "Petitioners") submit this Citizen Petition pursuant to 21 C.F.R. § 10.30.

A. Action Requested

Petitioners respectfully request that U.S. Food and Drug Administration (FDA) take the following actions:

1. Issue a revised guidance document extending the compliance periods for the filing of premarket submissions for newly deemed "new tobacco products" that were on the U.S. market as of August 8, 2016, to no earlier than 24 months from FDA's publication of final guidance or regulation describing the recommended or required contents of premarket submissions for the applicable category of tobacco products; and

2. Issue a revised guidance document that provides for the continued marketing of a product that is the subject of a timely filed premarket submission under the revised compliance policy throughout the entire period of the Agency's review (not limited to 12 months).

B. Background

The so-called "Deeming Rule" extended FDA's tobacco product authorities in Chapter IX of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA), to include all tobacco products (except accessories of newly deemed tobacco products).[1] In the preamble to the Deeming Rule, as well as in the companion guidance, entitled "FDA Deems Certain Tobacco Products Subject to FDA

[1] 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, 81 Fed. Reg. 28973 (May 10, 2016).

Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements" (Deemed Products Guidance) (Revised Dec. 2016), FDA established certain compliance periods regarding the premarket review requirements for deemed "new tobacco products" that were on the U.S. market as of the effective date of the Deeming Rule.

In FDA's Deemed Products Guidance, the Agency articulated its enforcement policies with respect to the premarket review requirements as applied to deemed products as follows:

> The compliance periods for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways are as follows:
>
> - SE Exemption Requests – 12 months from the effective date of the Deeming Rule
> - SE Reports – 18 months from the effective date of the Deeming Rule
> - PMTAs – 24 months from the effective date of the Deeming Rule
>
> New products for which no application has been submitted by 24 months from the effective date of the Deeming Rule will no longer be subject to this compliance policy, and will be subject to enforcement. Unless FDA has issued an order denying or refusing to accept the submission, newly deemed tobacco products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described above.

FDA recently issued a guidance document extending these compliance periods by three months.[2]

At the same time it published the Deeming Rule, FDA issued a Draft Guidance on Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (Draft ENDS PMTA Guidance) (May 2016). Although the Draft ENDS PMTA Guidance describes FDA's initial expectations for ENDS PTMAs, in many respects it is vague and subject to various interpretations, leaving industry without sufficient information to prepare complete applications in an efficient and effective manner. For example, there is substantial ambiguity in the Draft Guidance as to when clinical studies will be required and when they will not be, whether clinical studies, where required, need to be conducted according to Good Clinical Practice standards (which substantially adds to cost), and whether, to the extent a clinical study is required, there will be a need for an investigational new drug (IND) application. Indeed, the Draft Guidance itself notes "that, when finalized, this guidance's focus on ENDS products may result in more specific recommendations for an ENDS PMTA than recommendations in FDA's draft premarket review guidance."

[2] Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (May 10, 2017).

C. Statement of Grounds

Now almost one year after issuance of the Draft ENDS PMTA Guidance, as the end of the compliance deadlines near, FDA has not issued any more specific recommendations for ENDS PMTAs. Likewise, the Agency has issued little meaningful guidance on the substance of substantial equivalence (SE) reports and instead appears to be regulating company by company and report by report in an inconsistent and seemingly arbitrary fashion.[3] The fact that FDA attempted to issue a proposed regulation relating to SE reports (which was subsequently withdrawn pursuant to the dictates of a memo from the White House) emphasizes the need for significantly more information regarding the content of such reports.

In order to prepare and file complete submissions, industry requires a full and complete understanding of the approval requirements and sufficient time to prepare regulatory filings based on that guidance. Many companies market dozens of individual products, with each flavor, strength, packaging configuration, and other variation qualifying as an individual product for purposes of the marketing authorization requirements. Providing sufficient time for industry to prepare and submit PMTAs and SE reports with the benefit of clear final guidance or regulations will result in higher quality and more complete applications, reducing both industry and FDA workload and shortening review times.

In addition, revising the guidance to permit companies to continue marketing their products during FDA's reviews without the 12-month limitation will minimize the burden on industry and avoid premature product withdrawals. This approach will also permit the Agency to conduct careful, science-based reviews of these submissions and allow applicants the ability to respond to FDA requests without the unnecessary pressure of having to ensure completion of the reviews by the 12-month deadline. Based on FDA's performance since 2011 in the context of SE reviews,[4] 12 months is plainly inadequate for review of the huge volume of premarket submissions that will be filed by the close of the compliance period. This is particularly the case where FDA's information requests will require outside laboratory testing and analysis and advice from scientific consultants (all of which have limited capacity).

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[3] The Agency has publicly posted documents from reviews of successful SE reports, documents from reviews of unsuccessful provisional SE reports, and summary information about its bases for issuing not substantially equivalent (NSE) orders in response to regular (i.e., non-provisional) SE reports for products not yet on the market. However, most of the specific information in the review documents that would provide relevant and useful direction to industry (e.g., product specifications or other comparative data, the modifications that were the subject of the report, testing that was requested or submitted, etc.) has been broadly redacted, offering little, if any, meaningful practical information that would increase industry's understanding of the SE process. Likewise, industry has filed numerous Freedom of Information Act (FOIA) requests for FDA's SE reviewer guide documents in response to which only a fraction of those documents, also redacted, have been released.

[4] Based on publicly available statistics, only 22% of the 3589 provisional reports filed by March 22, 2011, have been resolved by FDA, a significant number of which by the applicant's own withdrawal. Of all 6090 SE reports filed with FDA thus far (provisional and regular), only 16% have resulted in orders issued by the Agency; the remaining 84% of the reports are either still pending or were withdrawn by the applicant.

The issues raised in the pending litigation challenging the Deeming Rule also strongly weigh in favor of the compliance date extensions requested in this petition. The litigation challenges the legality of the Deeming Rule and FDA's authority to require the industry submissions that are the subjects of the compliance dates, and seeks a bar on FDA's enforcement of the Deeming Rule during the pendency of the litigation. Raised in numerous lawsuits, these issues may not be fully resolved until after industry has been required to expend considerable resources to meet the current unrealistic compliance dates for these submissions.[5] FDA has already acknowledged the need to extend its unduly aggressive compliance deadlines, first with respect to domestic establishment registration, product listing and ingredient listing,[6] and more recently in issuing guidance extending all compliances dates beginning on May 10, 2017, by three months.[7] The Agency should similarly revise its Deemed Products Guidance with respect to the compliance periods for premarket submissions to further a more fair and reasonable approach to implementing the new, uncertain, and potentially onerous regulatory requirements associated with these submissions.

Based on the foregoing, Petitioners request that the Commissioner issue revised guidance (1) extending the compliance periods for filing premarket submissions to a date no earlier than 24 months from FDA's publication of final guidance or regulations describing the recommended or required contents of premarket submissions for the particular applicable category of tobacco products and (2) providing for the continued marketing of a subject product throughout the Agency's period of review.

D. Environmental Impact

The actions requested by the Petitioners are subject to categorical exclusion pursuant to 21 C.F.R. § 25.30.

E. Economic Impact

An economic impact statement will be submitted if requested by the Commissioner, pursuant to 21 C.F.R. § 10.30(b).

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[5] See, e.g., Nicopure Labs, LLC et al., v. Food and Drug Administration, No. 1:16-cv-0878-ABJ (D.D.C.), Cigar Association of America, et al., v. U.S. Food and Drug Administration, et al., No. 1:16-cv-1460 (D.D.C.); Cylcops Vapor 2, LLC v. Food and Drug Administration, No. 2:16-cv-00556 (M.D.Ala. (2016); Lost Art Liquids, LLC v. U.S. Food and Drug Administration, No. 2:16-cv-3468 (C.D. Cal. 2016).

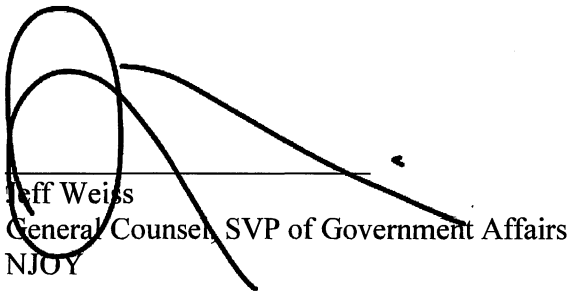
[6] Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised) (Dec. 9, 2016); Listing of Ingredients in Tobacco Products (Revised) (Dec. 29, 2016).

[7] Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (May 10, 2017).

F. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the petition relies, and that it includes representative data known to the Petitioners which are unfavorable to the petition.

Respectfully submitted,



Jeff Weiss
General Counsel, SVP of Government Affairs
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Additional signatories on the following pages:

Vapor Technology Association
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CITMA
Turning Point Brands, Inc.
Mistic Electronic Cigarettes
Johnson Creek Vapor Company
Nicopure Labs LLC
Five Pawns Inc.
Gaiatrend USA
Glas, LLC
Shift Ventures, Inc.
E-Alternative Solutions, Inc.
Saffire Vapor

Respectfully submitted,

Tony Abboud
Executive Director
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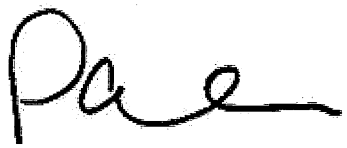

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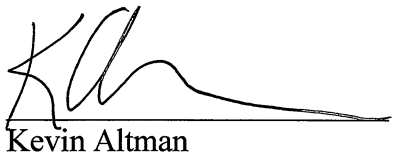

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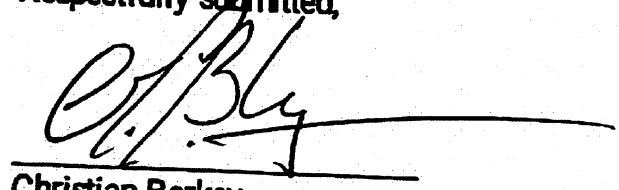

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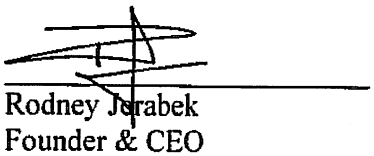

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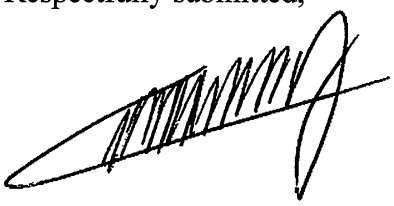

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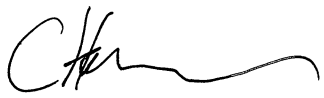

D. Christopher Howard
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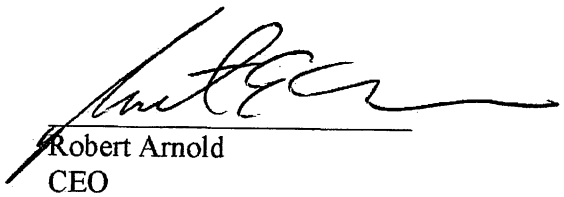

Robert Arnold
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