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**Submitted via www.regulations.gov**
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: FDA Docket No. FDA–2012–N–0920, Request for Comments – Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

To Whom It May Concern:

On behalf of the Electronic Cigarette Industry Group ("ECIG"), I am writing to submit the following comments regarding FDA Docket No. FDA-2012-N-0920 pertaining to user fees imposed upon domestic manufacturers and importers of tobacco products by the Food and Drug Administration ("FDA"), and specifically the requirements for the submission of data needed to calculate those fees.

## Background

ECIG is a non-profit association of consumers, manufacturers, importers and distributors of electronic cigarettes. ECIG believes that reasonable regulation of this emerging industry is critical to its future. Accordingly, ECIG's interest in the proposed rule relates to potential FDA regulation of electronic cigarettes under the Family Smoking Prevention and Tobacco Control Act ("TCA").

FDA does not currently regulate electronic cigarettes under the TCA. The TCA immediately subjects cigarettes, roll-your-own tobacco and smokeless tobacco to FDA's jurisdiction and allows FDA, by regulation, to assert jurisdiction over other tobacco products. FDA has advised the public that it intends to assert jurisdiction over electronic cigarettes under the TCA, and recently indicated that it intends to issue proposed regulations by October 2013.

## The Proposed Rule and Electronic Cigarettes

Section 919(a) of the TCA provides that FDA shall "assess user fees on, and collect such fees from, each domestic manufacturer and importer of tobacco products subject to" the TCA's tobacco product provisions. 21 U.S.C. § 387s(a). The TCA provides that the total user fee assessment shall be divided among the six classes of tobacco products set forth in the statute: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco and roll-your-own tobacco. The proposed rule makes clear that domestic manufacturers and importers of the two classes that are not currently subject to FDA regulation (cigars and pipe tobacco) are not required to pay user fees unless they are deemed subject to FDA's jurisdiction.

Under the proposed rule, FDA plans to use the United States Department of Agriculture's ("USDA") methodology to determine the amount of assessments levied upon tobacco product manufacturers and importers under the Fair and Equitable Tobacco Reform Act ("FETRA"). Under FETRA, Congress adopted a two-step process for the USDA to determine assessments owed by tobacco product manufacturers and importers. Step A of the process allocates assessments among the six classes of tobacco products.[1] Step B then allocates the assessments on a pro-rata basis among the manufacturers and importers within each of the six classes. FDA's proposed rule is modeled on this two-step process.

As discussed above, electronic cigarettes are not currently subject to FDA regulation, although FDA has stated its intent to regulate electronic cigarettes. Thus, under the proposed rule, tobacco products such as electronic cigarettes, which are not currently subject to FDA regulation, are not subject to user fees unless and until FDA issues the so-called "deeming regulations." Perhaps more importantly, electronic cigarettes also would not be subject to user fees under the proposed rule because only those tobacco products that are subject to assessments under FETRA are subject to FDA user fees. Electronic cigarettes are not subject to assessments under FETRA.

## Discussion

### I. Consistent with Congress' Methodology for Allocating FDA User Fees, Electronic Cigarettes Should Be Exempt from Those Fees.

ECIG concurs with the proposed rule's methodology for allocating user fees among the six classes of tobacco products identified in the TCA, and that are subject to assessments under FETRA and federal excise taxes under the Internal Revenue Code. As noted above, under 21 U.S.C. § 387s(b)(2)(B)(i), only cigarettes, cigars, snuff, chewing tobacco, pipe tobacco and roll-your-own tobacco are potentially subject to FDA user fees. And the applicable percentage of the total amount of user fees for each class of tobacco products is defined by reference to FETRA, 7 U.S.C. § 518d(c). See 21 U.S.C. § 387s(b)(2)(B)(ii). FETRA lists only those six classes of tobacco products as subject to assessments. 7 U.S.C. 518d(c). Electronic cigarettes are not listed among the classes of tobacco products subject to user fees or to FETRA assessments.

Although FDA may have the authority to deem additional products subject to regulation under the TCA, such "deeming regulations" could not subject electronic cigarettes to FDA user fees. Pursuant

[1] These six classes are the only classes of "tobacco products" defined in the Internal Revenue Code and subject to federal excise taxes. 26 U.S.C. §§ 5701 and 5702(c) and (j).

to 21 U.S.C. § 387s(b)(2)(B)(iii), no user fees may be assessed on a class of tobacco products unless the class is listed in 21 U.S.C. § 387a(b) (which is limited to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco) or the class is deemed subject to FDA authority under 21 U.S.C. § 387a(b). However, in the event of a "deeming regulation," the allocation of user fees for each class of tobacco products is explicitly defined by reference to FETRA, see 21 U.S.C. § 387s(b)(2)(B)(iv), and the FETRA class allocations are limited to cigarettes, cigars, snuff, roll-your-own tobacco, chewing tobacco and pipe tobacco. Because the FETRA classes do not include electronic cigarettes, any "deeming regulation" subjecting electronic cigarettes to FDA authority could not likewise subject electronic cigarettes to FDA user fees.

II. Electronic Cigarettes' Exemption from FDA User Fees is Indicative of Congress' Intent that FDA Should Not Regulate Electronic Cigarettes.

As discussed above, ECIG concurs with FDA's conclusion, as reflected in the proposed rule, that electronic cigarettes are exempt from user fees, even though electronic cigarettes may be encompassed within the TCA's definition of "tobacco products," see 21 U.S.C. § 321(rr), and even if FDA deems electronic cigarettes subject to FDA jurisdiction. Electronic cigarettes' exemption from FDA user fees is strongly indicative of Congress' intent that electronic cigarettes not be deemed subject to FDA jurisdiction. Congress' intent is reflected in 21 U.S.C. § 387s, which provides that FDA shall assess user fees from "each manufacturer and importer of tobacco products subject to this subchapter." Yet the remainder of §387s expressly exempts electronic cigarettes from FDA user fees. Because electronic cigarettes are exempted from FDA user fees under the TCA, these products similarly should not be subject to FDA jurisdiction under the TCA.

Exempting electronic cigarettes from the TCA is consistent with the law's purpose. Congress' rationale for enacting the TCA (as reflected in the law's preamble) is generally inapplicable to electronic cigarettes. Congress enacted the TCA primarily in light of cigarettes' undisputed health effects and the major cigarette companies' decades of marketing conduct. That rationale is inapplicable to electronic cigarettes, which have no known health effects.

Moreover, FDA's regulation of tobacco products should be consistent with FDA's obligation, as set forth in Section 918 of the TCA, to "promote and encourage the development of innovative products . . . to better achieve . . . reductions in the harm associated with continued tobacco use." There is already an emerging consensus in the scientific community that electronic cigarettes hold immense promise for tobacco harm reduction. This is because electronic cigarettes deliver a nicotine vapor without the combustion byproducts primarily responsible for traditional smoking's adverse health effects. Thus, the health effects of electronic cigarettes are likely at or below those of smokeless tobacco, which has approximately 1% of the mortality risk of smoking. Phillips CV, Rabiu D, Rodu B, *Calculating the Comparative Mortality Risk from Smokeless Tobacco Versus Smoking*, American Journal of Epidemiology (2006).

In light of electronic cigarettes' undisputed benefits vis-à-vis traditional tobacco products, FDA's regulatory policy regarding electronic cigarettes should foster the laudable goals required by Section 918 of the TCA. In order to do so, FDA's regulations should promote the growth of this industry, and not stifle it.

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Thank you for allowing ECIG the opportunity to comment on FDA's proposed rule regarding the submission of data needed to calculate user fees under the TCA and on potential FDA regulation of electronic cigarettes.

Warmest regards,

R. Eric Criss
President
Electronic Cigarette Industry Group