August 14, 2013

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
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Rockville, MD 20852

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

The Council of Independent Tobacco Manufacturers of America (CITMA) respectfully submits these comments to the above-referenced docket with respect to the Food and Drug Administration's (FDA's) proposal to require domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). CITMA is a trade coalition group that represents small tobacco product manufacturers (STPMs), defined in the FD&C Act as domestic tobacco manufacturers and importers that employ fewer than 350 people. Section 901(16) of the FD&C Act.

I. FDA Must Determine an Appropriate and Reliable Mechanism to Calculate User Fees for All Deemed Products

In the preamble, FDA states that, "under the proposed rule, if a tobacco product that is not included in one of the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act is deemed by regulation to be subject to chapter IX of the FD&C Act, fees would not be allocated to such product." 78 Fed. Reg. 32,581, 32,586 (May 31, 2013). FDA appears to propose this approach because the Agency has not devised a method to calculate user fees for classes of products outside of those six that are not subject to federal excise taxes.

If the Agency issues so-called "deeming regulations" subjecting additional tobacco or tobacco derived products to its jurisdiction, FDA would incur substantial additional costs to fund its regulation of these "deemed" products. However, because the statute fixes the amount of user fees FDA may collect each year to fund its regulation of all tobacco products—see section 919(b)(1) and (c)(2)(B) of the FD&C Act—FDA's tobacco regulation resources are finite. Under the Agency's proposed approach, the Center for Tobacco Products (CTP) would therefore need to divert resources currently used to regulate products for which FDA collects user fees in order to fund regulation of "deemed" products for which FDA would not collect user fees. This

would be fundamentally unfair to some manufacturers and inconsistent with the clear language of the FD&C Act.

Section 919(a) explicitly requires that user fees be assessed on and collected from "each manufacturer and importer of tobacco products subject to" Chapter IX of the FD&C Act (emphasis added), which would include manufacturers and importers of all products covered by deeming regulations issued under Section 901(b) of the FD&C Act. Expanding FDA's jurisdiction to include additional tobacco products for which user fees would not be assessed would require only a portion of the tobacco industry to shoulder all of the costs of FDA's regulation of tobacco products. In other words, manufacturers and importers of fee-assessed products would foot the user fee bill for manufacturers and importers of deemed products that do not fall within the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act (i.e., products containing tobacco for which the federal government assesses excise taxes).

As the statute limits CTP's ability to set total annual user fee assessments, companies actually paying tobacco user fees would presumably receive less regulatory service for their user fee dollars than they otherwise would, while companies manufacturing or importing untaxed deemed products would receive regulatory services for free. The amount companies would pay solely to fund FDA's regulation of untaxed, deemed products would effectively be a tax because there would be no "benefit" to the companies making the payments other than having the government regulate potential competitors. This approach is inconsistent with the purpose of a user fee, which is to pay for a direct benefit. As stated above, FDA must collect user fees for all deemed tobacco products.

CITMA submits that, to avoid this inequitable situation and comply with the statute's directive to assess fees on all regulated tobacco products, FDA must determine an appropriate and reliable mechanism to calculate the user fees for deemed products that do not fall within the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act before any deeming regulations covering these product may take effect. FDA should not begin providing regulatory services to manufacturers and importers of new classes of tobacco products without first establishing how the manufacturers and distributors of all such products will pay their required share of the costs of tobacco product regulation. Should FDA force only some manufacturers and importers of regulated products to pay user fees, this disparate treatment of industry members would be inconsistent with applicable Fifth Amendment and basic Administrative Procedure Act standards. *See, e.g.*, Bracco Diagnostics Inc. v. Shalala, 963 F. Supp. 20, 27-28 (D.D.C. 1997) (discussing the "repeatedly held" requirement that an agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so).

II. FDA Should Not Adopt the USDA Buy-out Program's Retrospective Calculation Methods for Determining Market Share

In determining Buy-out Program assessments, USDA calculates the tobacco class market share percentages based on annual data. However, when determining how to divide up each class's share among industry members, USDA bills each manufacturer or importer based on market share data that is much more recent. This approach could have significant consequences in the event of a dramatic market shift due to, for example, the impacts of the deeming regulations.

For instance, the Buy-out Program currently calculates tobacco class market shares based on the gross excise tax removals from calendar year 2011. For that year, 13.7 billion cigars were deemed removed to the market. USDA thus calculates its quarterly payment assessments using market share data that is at least one year removed from the market share data used to calculate each class's market share percentage. During the first quarter of fiscal year 2013, only 2.4 billion cigars were removed for excise tax purposes. Annualizing this number results in 9.6 billion removals or approximately 30% fewer removals than were used to calculate the class's share. This means that the class's share must be covered by assessments on significantly fewer removals than were used to calculate the share, resulting in a higher per-removal assessment.

While some of this change may be seasonal fluctuation, it is a large difference that must be absorbed by manufacturers and importers. In many cases, the amount of the increase on a per unit basis may be greater than the profit the manufacturer or importer expected to make on the product. CITMA's main concern with applying the retrospective Buy-out Program's approach to user fee calculations is that regulatory changes could dramatically alter market shares from year to year. Such changes could have devastating financial consequences, particularly for small businesses like CITMA members.

For example, assume FDA uses USDA's approach for calculating the class market share and then for calculating individual companies' contributions to the respective class shares. Then assume that FDA's deeming regulations require a substantial number of products to come off the market by operation of the "new tobacco product" provisions of Section 910 of the FD&C Act. In particular, unless the deeming regulations provide otherwise, subjecting additional tobacco products to the requirements of Chapter IX of the FD&C Act will require manufacturers and importers to immediately remove from the market any products that were not commercially marketed "as of" February 15, 2007, or that have been modified in any respect since (i.e., products that qualify as "new tobacco products" that cannot be marketed without an FDA order). The impact on newer categories of deemed products (e.g., dissolvables, electronic cigarettes) and on the cigar category, which has recently experienced significant growth, cannot be overstated.

If class shares are calculated before the deeming regulations take effect, but class share contributions assessed against individual companies are calculated thereafter, small businesses that would no longer be able to sell affected products would still have to pay their share of the respective classes' user fees. For at least one fiscal year, small businesses could face massive user fee bills without the ability to sell products that represented a significant percentage of the removals (or other basis for determining market share for untaxed products) upon which the class share's calculation was based, thereby preventing them from having the revenue necessary to meet their user fee obligations. Similarly, the next year, companies that continue to market grandfathered deemed products could face enormous user fee bills based on their later-determined class shares of category shares that were calculated based on pre-deeming-regulations market conditions.

In fashioning a fair user fee calculation system, FDA must consider this potential problem and include safeguards against inequitable retrospective user fee assessments. Alternatively (and preferably), the deeming regulations should permit the continued marketing of deemed products that meet the definition of "new tobacco product" pending FDA review of an appropriate premarket submission filed by a specified date.

III. FDA Should Reassess the Proposed Rule's Potentially Inequitable Impact on Cigar Manufacturers and Importers

In revising its Proposed Rule, FDA needs to fully consider the significant differences that currently exist in taxation of cigar products as compared to any other taxable classes of tobacco products. All classes of tobacco, except cigars, are taxed at a set rate per stick or unit weight, depending on the class. Thus, each manufacturer or importer remitting taxes for products in the cigarette, roll-your-own tobacco, loose-leaf chewing tobacco or snuff tobacco classes pays the same amount per unit or by weight as other manufacturers and importers of these products. Because USDA Buy-out Program and user fee assessments are based on removals, within these classes, these payments are likewise consistent and proportional to the number or weight of products removed from bond.

Cigars, on the other hand, have two different federal excise tax classes. Small cigars are taxed at a *specific* rate of $50.33 per 1000 ($.05033 per stick), and large cigars are taxed at an *ad valorem* rate of 52.75% of the first wholesale price, with a maximum of $.4026 per stick. In the context of user fees, the different federal excise tax structures within the cigar class have the unintended consequence of forcing manufacturers and importers with similar products to pay radically different user fees under USDA's Buy-out Program and the proposed FDA user fee structure.

To further complicate matters, almost all manufacturers and importers of large cigars likely have different first wholesale prices for the purposes of calculating federal excise taxes.

Some of these pricing differences are due to economies of scale or other efficiency factors. Those companies that enjoy significant economies of scale will likely benefit further under the proposed FDA user fee calculation for cigars as these larger companies will likely pay lower excise tax due to their large cigar products being produced at a lower cost, thereby resulting in lower wholesale prices. This significantly disadvantages the small tobacco companies in the cigar segment, which will inevitably pay more in user fees than their larger industry counterparts.

To illustrate the magnitude of the problem for small manufacturers, attached is an example of three different companies all making cigars, but each making a cigar that is taxed at a different rate. Company A makes small filtered cigars taxed at .05033 cents per stick. Company B makes filtered large cigars and, because the excise tax varies on these products, we assume an industry average of .0125 cents per stick for purposes of illustration. Last, Company C makes a super-premium cigar taxed at the maximum rate of .4026 cents per stick. The attached example highlights significant inequities in that, when these companies remove product from bond and remit excise tax on an equal number of cigars, the resulting FDA user fee assessment ranges from a low of $19,750 to a high of $630,336.[1]

CITMA uses the attached example solely to demonstrate the likely impact on many small cigar manufacturers were FDA to finalize the user fee regulations as proposed. The attached example assumes that FDA will not apportion user fees for any products that do not fall within the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act and that cigar companies' user fees will be determined within the class by each company's percentage of total excise tax paid as compared to the total excise tax paid for the cigar class.

This example starkly highlights the fact that cigar companies that remove exactly the same number of cigars would pay vastly different amounts in user fees. This is unique among classes of taxable tobacco products that are currently subject to, or will be subject to, FDA user fees. FDA should not overlook these economic differences but rather must take them into consideration in determining the economic impact of deeming and user fee regulations on small businesses. When companies remove the same number of cigars, but the FDA user fee payments range from $19,750 to $630,366, true inequity in the fee structure exists. In the example given, the company selling premium cigars would pay $610,616 more than a company selling large filtered cigars, an amount nearly 32 times greater than the amount filtered cigar companies would pay. No matter the selling price of a specific manufacturer's products, no manufacturer should have to pay 32 times more in potential FDA user fees than another company within the same product class. FDA must carefully assess the impact that user fees will have on small cigar manufacturers before it implements a structure that economically disadvantages these companies.

[1] The calculation of the hypothetical FDA user fees in this example are based on the current fiscal year FDA user fee assessment of $505,000,000.00, the most recent USDA Buy-out Program calculations for the cigar class share (9.7932%), and total estimated federal excise tax remitted for the class ($631,752,819.00).

In sum, CITMA requests that FDA fully consider all implications of its proposed user fee regulation, particularly those impacting small manufacturers, and take a cautious approach to implementing user fee calculations.

Respectfully Submitted,

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