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VIA WWW.REGULATIONS.GOV & FED EX

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0920

Dear Sir or Madam:

The Cigar Association of America, Inc. (CAA) submits the following comments in response to the United States Food and Drug Administration's ("FDA's") May 31, 2013 proposed rule requiring domestic tobacco product manufacturers and importers to submit information FDA needs to calculate user fees under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), *see* 78 Fed. Reg. 32581.

CAA is a trade organization that represents cigar manufacturers, importers, distributors and major industry suppliers. Its manufacturing members range from producers of high-end premium cigars to manufacturers of popular priced, machine-made cigars. As a result, CAA believes it is uniquely positioned to provide feedback to FDA regarding the cigar industry's concerns and interests regarding user fee calculations.

Calculation of User Fees Among the Tobacco Product Classes

In the proposed rule, FDA explains that its proposed user fee regulation applies the framework established by the Tobacco Transition Payment Program ("TTPP") under the Fair and Equitable Tobacco Reform Act ("FETRA"), and that "the proposed rule uses the same approach as [the United States Department of Agriculture ("USDA")] for collecting data and making allocations among firms." 78 Fed. Reg. at 32583. FDA explains that "FETRA specified the initial allocation among the six classes of tobacco products" and that USDA determined Congress used publicly available volume numbers for calendar year 2003 for each class, and "and multiplied those numbers by the maximum 2003 Federal excise tax rates for each class of tobacco products." *Id.* at 32582. The resulting tax dollar amounts were added together and "[t]he allocation for each class of tobacco products was its percentage contribution to the six-class total." *Id.* FDA further states that USDA adjusts these allocations annually to reflect changes in volume, and "it does so using the same methodology that Congress used to make the initial allocation." *Id.* Specifically, FDA explains, "USDA determines the gross domestic volume of each tobacco product class by multiplying the maximum 2003 Federal excise tax rate for each class by the volume information from [the Tobacco Tax and Trade Bureau] for the most recent full calendar year." *Id.*

Calculation of User Fees Under FETRA

CAA agrees that FDA should use the FETRA methodology while FETRA is still in effect, and supports the agency's current use of that methodology to calculate user fee assessments through FY 2014. This calculation, however, unreasonably and unfairly increases the large cigar share by making an incorrect assumption about large cigars without justification. Notwithstanding the unfairness of the increased burden imposed by the methodology, CAA believes the FETRA approach should continue to be used until FETRA expires.[1]

Calculation of User Fees After FETRA Expires

When FETRA expires in September 2014, however, FDA is free to alter this methodology to more accurately reflect each tobacco class' share of the tobacco market. CAA believes that instead of relying on a calculation that incorrectly assumes all large cigars pay the maximum excise tax, the fairest, simplest, and most transparent approach would be to allocate each class's share of the user fees based on the actual Federal excise taxes paid by each class during the relevant fiscal year. Specifically, the calculation under FETRA assumes that all large cigars pay excise taxes at the pre-SCHIP cap of $48.75/1,000. In fact, however, while small cigars (weighing no more three pounds per thousand) are subject to a single tax rate, the excise taxes for large cigars are ad valorem, or a percentage of the sales

[1] Submission of these comments does not represent industry support for deeming cigars as tobacco products regulated under the Tobacco Control Act. These comments only reflect CAA's response to the agency's proposed approach to user fees for tobacco products.

price (the pre-SCHIP excise tax for large cigars is 20.719% of the sales price) with a tax cap (the tax is not to exceed $48.75 per 1,000). *See* Tobacco Tax and Trade Bureau, Federal Excise Tax Increase and Related Provisions, *available at* http://www.ttb.gov/main_pages/schip-summary.shtml. For all other tobacco products, the excise tax rate is uniform, i.e., it is not tied to the sales price and does not incorporate a cap rate. *Id.* FDA's reliance on the erroneous assumption that all large cigars are taxed at the cap is unfair to the large cigar segment of the industry because it would result in user fees that are disproportionate to its share of the tobacco product market, thereby overstating the industry's share. After FETRA expires in September 2014, FDA will have no need to perpetuate the FETRA assumption that disadvantages large cigars to the benefit of all other tobacco products subject to excise taxes.

The most effective way to calculate user fee assessments that accurately reflects each tobacco class' share of the tobacco market would be to use actual excise taxes paid for each sector of the tobacco industry and the excise taxes paid by each company within each sector to determine user fees. Changing the allocation method to rely on actual excise taxes paid to the government represents the most exact means of describing the volume of tobacco products through the common unit of money, and thus, each category's real share of the market. Because the government possesses complete excise tax information this approach is a simple, straightforward, and a more transparent method for calculating user fees than the FETRA methodology. In effect, FDA would determine the amount of excise taxes paid for all tobacco products by totaling the amount paid by each tobacco class in the preceding year. From this amount, FDA could derive the user fee burden for each class and then each class member's individual user fee. Actual excise taxes paid better represents the removal of the volume of tobacco products because dollars represent common units of volume for tobacco products that are measured in the first instance with different volume units.[2] As a result, using actual excise taxes paid in the user fee calculation would lead to a user fee assessment that reflects each product's "real" share of the market.

The FD&C Act Recognizes Excise Taxes Paid as an Alternative Method for Calculating User Fees

Importantly, the FD&C Act incorporates the notion of using "excise taxes paid" for cigars. Specifically, and as discussed below, for purposes of allocating user fees within each class of tobacco product, the Act states that "if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year." FD&C Act § 919(b)(5). CAA requests that upon FETRA's expiration in FY 2014, the agency apply "excise taxes paid" to the calculation of user fee assessments for tobacco product classes using the approach identified above.

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[2] The term "removal" or "remove" refers to "the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from the internal revenue bond . . . or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States." 26 U.S.C. § 5702(j).

The Proposed Calculation of User Fees for Individual Manufacturers or Importers Inside the Cigar Category is Appropriate And Consistent With the FD&C Act

In the proposed rule, FDA states that "for each class of tobacco products except cigars, [the agency] would calculate the domestic manufacturer's or importer's percentage share". . . "by dividing the Federal excise taxes that the domestic manufacturer or importer paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers in that class paid for the class for that same quarter." 78 Fed. Reg. at 32586. For cigars, the agency explains, the percentage share would be based on the excise taxes paid by the manufacturer or importer during the prior fiscal year. As a result, FDA states that "if a user fee assessment were to be applied to cigars [the agency] would calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior fiscal year by the total excise taxes that all domestic manufacturers and importers in the cigar class paid for the prior fiscal year." *Id.* FDA seeks comments on this proposed calculation for cigars. *Id.*

CAA believes that the proposed calculation is appropriate and consistent with the language and intent of the FD&C Act that states that "the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year." FD&C Act § 919(b)(5). As a result, CAA supports the agency's proposed approach.

User Fees Must Be Assessed for E-Cigarettes and Other Products FDA Regulates Under the FD&C Act

In the proposed rule, FDA explains that the agency will only allocate user fees among the six classes of tobacco products that are specified in section 919(b)(2)(B)(i) of the FD&C Act, *i.e.*, cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.[3] *See* 78 Fed. Reg. at 32586. FDA states that "[t]hese are the same classes of tobacco products that have been subject to TTTP assessments under FETRA" and, as a result, a method exists for determining the applicable percentages for purposes of the user fee allocation. *Id.* The agency explains that the FETRA percentage is based on gross domestic volume, defined as the volume of tobacco products removed within the meaning of the Internal Revenue Code ("IRS Code")[4], and that the six product classes "are the only ones defined as 'tobacco products' that are removed and that are subject to the excise tax requirements (26 U.S.C. 5701 and 5702(c) and (i))." *Id.* FDA states that under the proposed rule, if a tobacco product that is not included in the six classes is deemed by regulation subject to the FD&C Act, "fees would not be allocated to such product." *Id.* Nonetheless, the agency invites comments on how user fee calculations would be made if

[3] Cigars and pipe tobacco are not currently subject to regulation and therefore do not pay user fees.

[4] *See* fn. 1, *supra.*

additional classes, particularly those not subject to federal excise taxes, were to be added to the classes upon which user fees are assessed. *Id.*

The FD&C Act Requires that User Fees be Imposed on any Regulated Products

FDA's user fee allocation must consider and include e-cigarettes and other tobacco products if and when these products are deemed subject to the FD&C Act. As discussed below, FDA is required to collect user fees for any tobacco product that is subject to its authority under the FD&C Act, and has no discretion to the contrary. *See* FD&C Act § 919(a). The agency has authority over e-cigarettes and other products made or derived from tobacco through its ability to "deem" such products subject to the Act's Tobacco Control Act provisions. *See* § 901(b), (stating that the law applies "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to *any other tobacco products that the Secretary by regulation deems to be subject to this chapter*.") (emphasis added); *see also* FD&C Act § 201(rr)(1) (stating, "[t]he term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product. . . "); *see also Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010) (holding that e-cigarettes and other products made or derived from tobacco are regulated as "tobacco products" under the Tobacco Control Act and are not drugs or devices under FDA's drug and device authorities, unless they are marketed for therapeutic purposes). [5] As a result, there is no question that if FDA should deem e-cigarettes and other products made or derived from tobacco, such as dissolvables, subject to the FD&C Act, it then must assess user fees for such tobacco products.

The law is clear: FDA is required to collect user fees for all tobacco products it regulates under the FD&C Act, including tobacco products that are deemed subject to the Act through regulations. The FD&C Act unambiguously states that FDA "shall in accordance with this section assess user fees on, and collect such fees from, *each manufacturer and importer of tobacco products subject to this chapter*." FD&C Act § 919(a) (emphasis added). For products that are not specifically identified in the FD&C Act, the requirement to collect user fees is effective as soon as those products are deemed subject to the FD&C Act through a regulation. § 919(b)(2)(B)(iii) (stating that "no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is

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[5] In *Sottera*, the court stated that "the Tobacco Act gives the FDA broad regulatory authority over tobacco products, including, for instance, authority to impose restrictions on their sale, and on the advertising and promotion of such products, see 21 U.S.C. § 387f(d), to regulate the mode of manufacture of tobacco products, see *id.* § 387f(e), and to establish standards for tobacco products, see *id.* § 387g." Sottera, *supra*, at 898. This regulatory authority also includes the collection of user fees.

FDA fully acknowledged the Sottera court's conclusions, and in a 2011 Letter to Stakeholders, the agency stated that "[t]he government has decided not to seek further review of [the Sottera] decision, and FDA will comply with the jurisdictional lines established by Sottera." Letter from Lawrence R. Deyton, M.S.P.H., M.D., then-Director, Center for Tobacco Products and Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Regulation of E-Cigarettes and Other Tobacco Products (April 25, 2011).

deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter."). Legislative history confirms that once a product is deemed subject to the Act, it is automatically subject to user fees. *See* H. REP. NO. 111-58 (Part 1), at 47 (2009) (stating that the Tobacco Control Act "limits the imposition of user fees to cigarettes, smokeless tobacco products, and roll-your-own tobacco until the Secretary exercises jurisdiction over other tobacco products.")

Simply put, there is no question that under the FD&C Act user fees must be assessed on, and collected for, all tobacco products that are subject to the FD&C Act, including those identified in the statute and those deemed subject to the FD&C Act through a regulation. For user fee purposes, Congress did not distinguish between listed tobacco products and those deemed subject to the FD&C Act. User fees are required from both.

Failure to Impose User Fees on all Regulated Products Raises Significant Legal Issues

Indeed, limiting the collection of user fees to those products that are subject to excise taxes runs afoul of at least two settled legal principles. First, such a position ignores specific congressional intent regarding the purposes of the Tobacco Control Act, which include the imposition of "appropriate regulatory controls on the tobacco industry," and promoting "cessation to reduce disease risk and the social costs associated with tobacco-related diseases." Tobacco Control Act § 3. Because these goals relate to all tobacco products that have an impact on the public health, Congress clearly intended that all parts of the regulated tobacco industry be subject to user fees.

Moreover, collecting user fees from only those who "remove" tobacco products that are identified in the FD&C Act would undermine the user fee notion. A user fee, unlike a tax, is predicated upon a voluntary act such as "a request that a public agency permit an applicant to practice law or medicine or construct a house or run a broadcast station." *Nat'l Cable Television Ass'n v. United States*, 415 U.S. 336, 340-41 (1974). Therefore, "[t]he public agency performing those services normally may exact a fee for a grant which, presumably, bestows a benefit on the applicant, not shared by other members of society." *Id.* In other words, user fees are connected to a benefit that, for the regulated tobacco industry, is being able to sell their products in the United States. Bestowing a benefit upon the new products without collecting user fees would allow these products to be free riders, contrary to the notion that only those who pay the fee receive the benefit. In effect, the amount of fee paid by manufacturers of listed tobacco products over and above the amount prescribed by the FD&C Act would be used to regulate these other products not identified in FETRA. This amounts to a tax because there is no benefit to the manufacturers making the payments other than having the government regulate a competitor. This use is inconsistent with the purpose of a user fee, which is to pay for a direct benefit.

Second, from the plain language of the FD&C Act that requires that FDA collect user fees for all regulated products, CAA believes that once e-cigarettes and other tobacco products are deemed subject to the FD&C Act there is no conceivable and rational factual circumstance that could provide a basis for

treating these products differently from the other regulated tobacco products, and not assessing user fees on these products would violate the equal protection guarantee inherent in the Fifth Amendment's Due Process Clause. *See, e.g., Weinberger v. Wiesenfeld*, 420 U.S. 636, 637 (1975) (stating that the Court's "approach to *Fifth Amendment* equal protection claims has always been precisely the same as to equal protection claims under the *Fourteenth Amendment*."); *see also FCC v. Beach Communications*, 508 U.S. 307, 313 (1993) ("In areas of social and economic policy, a statutory classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge *if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.*") (emphasis added); *see also Steward Machine Co. v. Davis*, 301 U.S. 548, 584-85 (1937) (finding that certain exemptions did not violate the Fifth Amendment where they would "be upheld if they had been adopted by a state and the provisions of the *Fourteenth Amendment* were invoked to annul them" and stating that "discrimination, if gross enough, is equivalent to confiscation and subject under the *Fifth Amendment* to challenge and annulment.") Here, tobacco products listed in the FD&C Act and those deemed subject to the Act's provisions are the same from a legal and commercial perspective and therefore all must be subject to the same fee obligations, unless there is a conceivable and rational basis to differentiate between them on a fee basis. Because we believe that no such basis exists, CAA submits that FDA cannot pick and choose among tobacco products or companies when no differences exist under the Tobacco Control Act that would justify differences in user fee obligations. *As a result, FDA must assess user fees on all tobacco products subject to the FD&C Act, or none of them.*

Not assessing user fees on e-cigarettes and other tobacco products not subject to excise taxes would unfairly and impermissibly shift the user fee burden to those tobacco products that are subject to excise taxes. It would do so irrespective of the fact that tobacco products that are not taxed nonetheless represent a growing part of the tobacco product market in the U.S., and would be regulated by FDA based on contributions of other parties. Regulating e-cigarettes based on contributions of other parties would be particularly unfair because the e-cigarette industry represents a growing part of the tobacco product market with annual sales expected to top $1 billion this year. *See* Bloomberg Business Week, E-Cigarettes Want Your Attention Now (Before the FDA Steps In) (June 10, 2013); *see also* ABC News, E-Cigarette Sales to Hit $1 Billion (July 31, 2013).

In sum, CAA believes there is no question FDA is required to collect user fees for e-cigarettes and other products made or derived from tobacco once these products are deemed subject to the FD&C Act. We believe that providing manufacturers of new products the benefit to sell their products in the U.S. without collecting user fees is contrary the language of the FD&C Act and the user fee notion that only those who pay the fee receive the benefit. In other words, all manufacturers of tobacco products who receive a benefit must pay a user fee, irrespective of whether they are subject to excise taxes.

Refunds on Erroneous Payments Should Include Interest

FDA requires user fee payments by a date certain, notwithstanding disputes about the amount owed. In the proposed rule, FDA states that if, after receipt of payment, the agency "determines there was an error in the amount of the assessment, [it] would refund the amount that was incorrectly assessed." 78 Fed. Reg. at 32587. CAA believes that if there is an error with regard to the assessed user fees, any refund should not only include the amount that was incorrectly assessed, but also interest on that amount.

There is precedent for the payment of interest on overpayment. For example, the Internal Revenue Code provides that "[i]nterest shall be allowed and paid upon any overpayment in respect of any internal revenue tax at the overpayment rate established under section 6621." 26 U.S.C. § 6611(a).[6] The Internal Revenue Manual states that "[a]n overpayment includes any amount that is: (A) Erroneously assessed and collected…" IRS Manual, Part 20, Chapter 2, Section 4: Overpayment Interest.

CAA requests that FDA employ the same or a similar approach to the refund of user payments that were erroneously assessed. In other words, the amount assessed in error should be refunded with interest that is paid in accordance with an established overpayment rate. The need for interest compensation is particularly acute here where the agency requires payment by a date certain, notwithstanding a legitimate dispute regarding the amount owed to the agency.

Conclusion

CAA hopes that the agency finds these comments useful and constructive, and will take them into consideration in determining the scope of the FD&C Act's user fee obligation and how to calculate user fees under the FD&C Act for tobacco products subject to excise taxes and those that are deemed subject to the FD&C Act and are not. Additionally, CAA requests the opportunity to meet with FDA to further discuss the issue of user fees under the Tobacco Control Act.

Sincerely,

Craig P. Williamson

Craig Williamson
President
Cigar Association of America, Inc.

[6] Section 6621 establishes the rate on the interest to be paid on overpayments.