PIPE TOBACCO COUNCIL

August 13, 2013

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 Pipe Tobacco Council ("PTC") submits the following comments in response to the United States Food and Drug Administration's ("FDA's") 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 (May 31, 2013).

Submission of these comments should not be understood as an acquiescence to any rule deeming pipe tobacco subject to regulation under the FD&C Act.

The PTC is the national trade association for manufacturers and importers of pipe tobacco. As a representative of the pipe industry, PTC is submitting these comments to provide feedback to FDA regarding the pipe tobacco industry's concerns and interests regarding user fee calculations.

User Fees Must Be Assessed for E-Cigarettes and Other "Deemed" Tobacco Products

In the proposed rule, FDA states that it is allocating user fees only among those classes of tobacco products that are identified in the FD&C Act, i.e., cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. 78 Fed. Reg. at 32586 (May 31, 2013). The reason appears to be based on simplicity and administrative convenience: FDA's user fee calculation uses the framework established by the Tobacco Transition Payment Program ("TTPP") under the Fair and Equitable Tobacco Reform Act ("FETRA"), and only the specified tobacco product classes are subject to TTTP assessments under FETRA. *Id.* at 32583, 32586. As a result, limiting the user fee assessment to the products specified in the FD&C Act allows FDA to continue to use the FETRA method for determining the applicable percentages for purposes of the user fee allocation. *See id.* at 32586.

The FETRA methodology's percentage calculation is based on gross domestic volume, which is defined as the volume of tobacco products removed within the meaning of the Internal Revenue Code ("IRS

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Code")[1]. *Id.* FDA explains that the six product classes specified in the FD&C Act "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.* In other words, the FETRA methodology relies on volume and excise tax information that is only available for those six product classes. As a result, FDA states that if an additional tobacco product is deemed by regulation subject to the FD&C Act, "fees would not be allocated to such product." *Id.* Nonetheless, FDA "invites comments on what the additional classes would be; how user fee calculations would be made if additional classes were to be added, particularly if added classes were not subject to Federal excise taxes; and support for [the] view." *Id.*

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. *See* FD&C Act § 919(a). This means that FDA's user fee allocation must cover additional tobacco products such as e-cigarettes if and when these products are deemed subject to the FD&C Act. FDA has accepted the court's ruling that e-cigarettes are tobacco products within the meaning of the FD&C Act. *See Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010) (the court held 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/devices under FDA's drug and device authorities unless they are marketed for therapeutic purposes).[2] Accordingly, FDA has authority over e-cigarettes and other tobacco-derived products. *See* 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* FD&C Act § 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.").

The FD&C Act is clear: user fees must be assessed on all regulated tobacco products, including those that are deemed subject to the FD&C Act through a regulation. Specifically, the FD&C Act 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 deemed by the Secretary in a regulation under

[1] 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).

[2] In a 2011 Letter to Stakeholders, FDA states that "[t]he government has decided not to seek further review of this 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).

section 901(b) to be subject to this chapter."). Legislative history also reinforces that once a product is deemed subject to the FD&C Act and thereby under FDA's jurisdiction, it is 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.") In sum, there is no question that the law requires that user fees be shared by all tobacco product classes that are subject to the FD&C Act, including products deemed subject to the FD&C Act through a regulation.

We understand that FDA's difficulty with assessing user fees on additional products that are not specified in the FD&C Act is the lack of excise tax rates for purposes of the user fee calculation. *See* 78 Fed. Reg. at 32586. However, PTC believes that the lack of an excise tax rate is not an impediment to the user fee assessment. Importantly, excise tax rates are entirely separate from user fee assessments, and the position that only parts of the regulated tobacco industry be subject to user fees is inconsistent with the purposes of the Tobacco Control Act that 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. While excise taxes represent the amount of money that the Treasury Department will receive from the sale of a specific good, excise taxes have no monetary significance in the context of calculating user fees beyond reflecting a tobacco class's volume share of the industry, and each individual company's user fee obligation.

Moreover, we believe that collecting user fees for only those 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.* Here, the payment of user fees bestows the benefit of being able to sell tobacco products in the United States. Granting this benefit 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 and would amount 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. As stated above, FDA must collect user fees for e-cigarettes and other tobacco products once these products are deemed subject to the FD&C Act. Not assessing user fees on e-cigarettes and other tobacco products that are not subject to excise taxes would unfairly shift the user fee burden on only those tobacco products that are taxed, irrespective of the fact that the non-taxed tobacco products represent a significant part of the tobacco product market in the U.S. Indeed, the e-cigarette industry represents a growing and emerging part of the tobacco product market with annual sales expected to top $1 billion in

the next few years. *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).

Apart from the plain language of the FD&C Act that requires that FDA collect user fees for all regulated products, PTC 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 rational 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, we submit that FDA cannot pick and choose between tobacco products or companies, and must assess user fees on all tobacco products subject to the FD&C Act, or none of them. Either FDA must require user fees for each tobacco product subject to the FD&C Act, or none.

In sum, FDA is required under the law to collect user fees for all tobacco products, whether listed in the FD&C Act or deemed subject to the Act through a regulation. In other words, all tobacco products who receive the benefit of FDA regulation that permits marketing in the U.S. must pay a user fee, irrespective of whether they are subject to excise taxes.

Refunds on Erroneous Payments Should Include Interest

FDA requires the payment of user fees even if there is a dispute about the amount owed. In the proposed rule, FDA states that if there was an error related to the assessment and the assessment was too high, FDA would refund the amount that was incorrectly assessed. 78 Fed. Reg. at 32587, 32594. PTC believes that if there was an error with regard to the assessed user fees, any refund should include interest on the amount that was incorrectly assessed, in addition to the overpayment refund.

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).[3] 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.

PTC requests that FDA use 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.

Conclusion

PTC hopes that the agency finds these comments useful, informative and constructive, and will take them into consideration in determining how to calculate user fees under the FD&C Act. PTC requests the opportunity for a meeting with FDA to further discuss the issue of user fees for the tobacco industry.

Sincerely,

Craig P. Williamson

Craig Williamson
President
Pipe Tobacco Council, Inc.

[3] Section 6621 establishes the rate on the interest to be paid on overpayments. The section states that "[t]he overpayment rate established under this section shall be the sum of - (A) the Federal short-term rate determined under subsection (b), plus (B) 3 percentage points (2 percentage points in the case of a corporation)." 26 U.S.C. § 6621(a)(1). It further states that "[t]o the extent that an overpayment of tax by a corporation for any taxable period . . . exceeds $10,000, subparagraph (B) shall be applied by substituting '0.5 percentage point' for '2 percentage points.'" *Id.* The underpayment rate is "the sum of - (A) the Federal short-term rate determined under subsection (b), plus (B) 3 percentage points." *Id.* § 6621(a)(2). The Federal short-term rate for any month is "the Federal short-term rate determined during such month by the Secretary in accordance with section 1274(d)", *see* § 6621(b)(3), and Section 1274(d) states that "[t]he Federal short-term rate shall be the rate determined by the Secretary based on the average market yield (during any 1-month period selected by the Secretary and ending in the calendar month in which the determination is made) on outstanding marketable obligations of the United States with remaining periods to maturity of 3 years or less." 26 U.S.C. § 1274(d)(1)(C)(i).