SMARTT
COALITION

August 14, 2013

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

Re: Docket No. FDA-2012-N-0920: Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products (RIN: 0910-AG81)

Dear Sir or Madam:

The Small Manufacturers Association for the Reasonable Treatment of Tobacco ("SMARTT") submits the following comments on the proposed rule titled "Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products" (the "Proposed Rule"). SMARTT is a coalition comprised of Subsequent Participating Manufacturers to the multi-state Master Settlement Agreement who share issues of common concern with respect to the ongoing implementation of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"). We appreciate this opportunity to comment on the Proposed Rule as part of our effort to assist the U.S. Food and Drug Administration's ("FDA's") Center for Tobacco Products ("CTP" or the "Agency") in the effective and efficient implementation of the Act.

A. The Proposed Rule Fails to Leverage Existing Sources of Product Removal Information and Requires Burdensome and Duplicative Submissions

Section 1150.5 of the Proposed Rule requires manufacturers and importers (collectively, "Manufacturers") to submit certain identifying[1] and product removal information to the Agency on a monthly basis. In particular, Manufacturers are required to submit "the units of product, by class, removed and not exempt for the prior month and the Federal excise tax it paid, by class, for such removal." This information must be submitted pursuant to each tobacco permit issued by the U.S. Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau

[1] This identifying information includes certain contact information for the Manufacturer, its TTB permit number, and other basic information.

("TTB"), and a monthly report must be submitted to FDA even if the Manufacturer did not remove any amount of tobacco product into domestic commerce in the reporting period.

SMARTT believes that the monthly submissions contemplated by Section 1150.5 are unnecessary and unduly burdensome to industry, and in lieu thereof we urge CTP to utilize the existing authoritative sources of removal information for tobacco products. All of the information that CTP proposes to require is currently collected by TTB.[2] Rather than requiring the industry to make redundant submissions of the same information to CTP on a monthly basis—thereby unnecessarily expanding the number of regulatory submissions that both the Agency and industry will have to manage—SMARTT recommends that CTP acquire each company's product removal information directly from the TTB.[3]

This, then, leaves only those Manufacturers of regulated (or soon to be regulated) tobacco products which do not fit TTB's current tax excise structure[4] that should be required to affirmatively submit product removal data directly to CTP, corroborated with additional information such as duty or customs figures and supplemented by third-party information available commercially for CTP to use to verify and accurately assess market share.[5] Once CTP has obtained removal information regarding the entire industry, the Agency may then compute user fees as appropriate under Section 919 of the Act.

B. The Proposed Rule Creates Compliance Issues By Requiring Submission of Certified Copies of Returns and Forms

Section 1150.5(b)(3) of the Proposed Rule requires Manufacturers to submit, on a monthly basis, "certified copies of the returns and forms that relate to: (i) the removal of tobacco products into domestic commerce . . . and (ii) the payment of the Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986." According to FDA, these certified materials will enable the Agency to "determine allocations and verify the monthly summary information on which the allocations are based" so that user fees may be accurately assessed and collected.[6] However, SMARTT is concerned that the Agency's approach raises key compliance issues and creates an opportunity for inaccurate reporting to FDA.

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2 SMARTT and other reputable tobacco companies have a long history of compliance with TTB as part of our good stewardship in the industry. For that reason, we believe that TTB is an invaluable resource for CTP to efficiently gather verified information on a range of regulatory issues, from the calculation of market share data needed to compute user fees to the combat of illicit trade.

3 SMARTT directs CTP's attention to TTB Form 5210.5, whereby removal information is submitted to TTB by Manufacturers under penalty of perjury.

4 For example, e-cigarettes and certain innovative tobacco products do not fit TTB's current tax excise structure.

5 Another possible source includes Management Science Associates, Inc. (MSAi), located in Pittsburgh, PA, which acts, for a fee, as a data-warehouse for the tobacco industry. SMARTT understands that the National Association of Attorneys General utilizes MSAi data for purposes of establishing market share and activity within states.

6 Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products, 78 Fed. Reg. 32,581, 32,585 (proposed May 31, 2013) (to be codified at 21 C.F.R. pt. 1150).

As we noted above, TTB collects the removal and excise tax payment information sought under the Proposed Rule. TTB also has (and exercises its) authority to audit Manufacturers' underlying financial records with respect to the reported information. For this reason, TTB is the most credible source for obtaining the accurate information which the Agency seeks. There is no legitimate need for FDA to establish itself as a separate clearinghouse of the same industry submissions already collected by TTB, and requiring monthly submissions to FDA of these same data is unnecessarily burdensome to both the industry and the Agency and redundant to the requirements already in place under other federal regulations.[7] Further, FDA currently lacks the expertise and resources to duplicate TTB's audit and enforcement efforts, and it is not a good use of CTP's user fees to build a redundant and parallel audit structure.

In order to avoid any potential compliance issues, we propose that FDA require Manufacturers to execute a release/waiver permitting TTB to report directly to FDA the removal and excise tax payment information that the Agency requires. In the event that a Manufacturer fails to provide FDA with the release/waiver, CTP could construe such an action as an admission of adulteration under FDCA Section 902(4)—similar to such considerations as currently exist when a foreign manufacturer of any product regulated by FDA fails to facilitate an inspection of a foreign facility. As it did with the U.S. Department of Agriculture ("USDA"), FDA could develop a memorandum of understanding with TTB to help facilitate the free flow of information between the two agencies.

Our recommended approach is the most direct and efficient means for obtaining, and confirming the accuracy of, the information FDA seeks. It avoids the need for burdensome and duplicative submissions from industry and mitigates the risk that Manufacturers will be able to manipulate their user fee assessments without detection. Further, SMARTT believes that its solution also allows CTP to concentrate on its core mission of regulating the US tobacco industry without being distracted by the compliance and enforcement issues it may otherwise confront under the proposed rules. Finally, we note that this approach is consistent with the one taken by state attorneys general ("State AGs") in connection with the Master Settlement Agreement. In that instance, we and other participating manufacturers executed the necessary federal releases/waivers to permit State AGs and PricewaterhouseCoopers to inspect our TTB tax returns directly.

C. The Proposed Rule Fails to Account for the Growing Diversity of Product Classes Within the Tobacco Industry and the Impact of the Forthcoming Deeming Regulation

Only four classes of tobacco products—namely, cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own-tobacco—are currently subject to the Act. However, FDA intends to issue regulations in October 2013 deeming other tobacco products meeting the

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[7] Consult 40 CFR Section 202 for regulatory requirements regarding the domestic manufacture of tobacco products and 41 CFR Sections 206 and 208 for requirements for the importation of tobacco products.

statutory definition of "tobacco product" to be subject to the Act (the "Deeming Regulation").[8] As FDA prepares to undertake this regulatory action, SMARTT underscores the importance of ensuring that the Agency's approach to the computation of user fees under FDCA Section 919 accounts for the impact of the Deeming Regulation and the ever-increasing diversity of product classes and tobacco product manufacturers within the tobacco industry.

In the Proposed Rule, FDA requires that user fees be allocated among only the six classes of tobacco products specified in Section 919(b)(2)(B)(i) of the Act—namely, cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco.[9] Thus it appears any new class of tobacco product made subject to the Act by the Deeming Regulation, but which falls outside of the six specified classes, will not automatically become subject to user fees. It also appears that even some currently regulated products—for example, dissolvable tobacco products and other unspecified smokeless tobacco products—are not automatically subject to user fees either. SMARTT disagrees with this approach, and we urge FDA in considering these issues to be fair and equitable in its regulation of the entire industry, which under the Proposed Rule would be financed only by a certain segment of the industry. User fees, by their very nature, are imposed based on the notion that the Agency will be required to expend resources in the course of regulation in order to properly assure regulatory compliance by each industry segment and participant. Certainly, the explosive growth of e-cigarettes, for example, will require the dedication and allocation of significant resources by the Agency in order to develop and enforce appropriate regulations. E-cigarettes now account for 1 percent of U.S. cigarette sales, and industry analysts project that sales could top $10 billion by 2017.[10] The same logic applies to other types of tobacco products which may be encompassed in any new regulatory scheme. To fail to assess user fees on entire classes of tobacco products—or on certain types of product within a class—is inequitable to those other industry segments which will be forced to cover these costs through their respective allocations. For this reason, we urge the FDA to consider appropriate user fees on all classes and types of regulated tobacco products based on an appropriate assessment mechanism.

Furthermore, the fair and equitable assessment of user fees across product classes and Manufacturers will also require that CTP's regulatory approach build in the flexibility to periodically revise Section 919 percentage allocations under the Act. As CTP well knows, some currently-marketed tobacco products (e.g., dissolvable tobacco products) were not even conceivable a few years ago, and new product developments are continually advanced in presently unregulated parts of the industry. It is imperative therefore that FDA's user fee regulations take a holistic approach to the entire industry and neither overcharge nor undercharge any tobacco product class or manufacturer. Thus, SMARTT strongly recommends that CTP

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8 *See* HHS Semiannual Regulatory Agenda, 78 Fed. Reg. 44252 (Jul. 23, 2013) (announcing RIN: 0910–AG38, "Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act).

9 In the absence of a deeming regulation, the latter two product categories (namely, cigars and pipe tobacco) are not yet subject to the Act and, hence, will have their fee assessments reallocated to the other classes of currently regulated tobacco products.

10 Chris Burritt, *E-Cigarette Pioneers Holding Breath as Big Firms Invade*, Bloomberg (June 21, 2013, 10:16 AM), http://www.bloomberg.com/news/2013-06-20/e-cigarette-pioneers-holding-breath-as-big-firms-invade-retail.html.

develop a schedule for periodically reevaluating and adjusting user fee percentage allocations amongst tobacco products classes and Manufacturers to ensure that allocations are fair and equitable.

D. The Proposed Rule Produces Inaccurate Computations of User Fee Allocation Percentages at both the Class and Individual Manufacturer Levels

The Proposed Rule's approach to the allocation of user fees borrows heavily from the USDA's approach to the Tobacco Transition Payment Program (TTPP) assessments under the Fair and Equitable Tobacco Reform Act of 2004 ("FETRA"). Historically, the applicable FETRA percentages for class and individual Manufacturers have been based on "gross domestic volume, which is defined as the volume of tobacco products removed within the meaning of the Internal Revenue Code (section 625(a)(2) of FETRA)."[11] Yet this historic approach has no mechanism for taking into account any tobacco products which were ultimately returned to the Manufacturer as unsalable even though taxes had already been paid therefor under FETRA. In certain instances, manufacturers are able to reclaim such unsalable product and, under supervision of the TTB, destroy the unsalable products and receive a refund on the paid excise tax. However, FETRA's reliance on *gross* domestic volume overestimates the actual amount of product ultimately removed into domestic commerce, thereby producing inaccurate user fee assessments at both the class and individual Manufacturer levels. To avoid replicating these inequities, CTP should calculate the applicable percentages for class and individual Manufacturers on the basis of *net* domestic volume only; this information is available from TTB which regularly adjusts its figures for tobacco products removed into US commerce to reflect such occurrences.[12] Moreover, SMARTT recommends that CTP utilize the trailing quarter's net domestic volume to ensure that the most accurate picture of tobacco products in actual interstate commerce is being utilized to calculate user fees. Such an approach would ensure that user fees are assessed in a fair, equitable, and accurate manner, and that no product class or Manufacturer pays a user fee in excess of the most feasible calculation of the individual Manufacturer's actual percentage share. This approach would impose no burden upon CTP and rely simply upon CTP accessing the most accurate information already collected by TTB.

E. The Proposed Rule May Unfairly and Inequitably Burden Small Manufacturers

As CTP well knows, the Regulatory Flexibility Act requires the Agency to consider the impact of any proposed rule on small entities and to analyze regulatory options that would minimize any significant impact of a rule on small entities.[13] In this case, FDA has acknowledged that the Proposed Rule's "potential impact on small entities is uncertain" and that the Agency "is unable to rule out the possibility that this proposed rule may have a significant

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[11] Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products, 78 Fed. Reg. at 32,586.

[12] Note that this approach is also consistent with that taken under the Master Settlement Agreement (MSA), which makes assessments on the basis of the *net* federal excise taxes ("FET") paid —not the *gross* FET paid—to most accurately compute a Manufacturer's sales volume.

[13] Regulatory Flexibility Act, 5 U.S.C. §§ 601-612 (2012).

economic impact on a substantial number of small entities."[14] Thus, by the Agency's own admission, the Proposed Rule may subject small manufacturers to significant economic consequences that FDA has not been able to adequately calculate or determine, and user fees could possibly amount to "a substantial portion of profits" for certain low-volume manufacturers.[15] SMARTT is concerned about the disproportionate impact that the Proposed Rule may have on the industry's smallest players, especially given the fairness and equity concerns previously raised above. We encourage the Agency to give more careful consideration to the unreasonable financial burden that the Proposed Rule may place on small manufacturers, and to take steps to ensure that the regulation more appropriately recognizes "differences in the scale and resources of regulated entities."[16]

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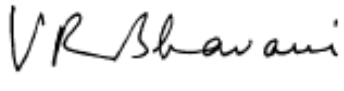
We thank you in advance for your attention to these considerations, and appreciate this opportunity to share our perspectives once again on an issue of critical business concern to our members. We look forward to working cooperatively and collaboratively towards the effective and efficient implementation of Section 919 and various other provisions of the Act.

Respectfully,



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14 Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products, 78 Fed. Reg. at 32,588.

15 *Id.* at 32,590.

16 Regulatory Flexibility Act § 601.