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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition under Section 919 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"), to request that the Secretary assess user fees in a manner that no manufacturer or importer of tobacco products is required to pay such fees in an amount greater than its actual market share-based percentage.

I. ACTION REQUESTED

Pursuant to 21 C.F.R. §§ 10.25, 10.30, R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Company, LLC ("ASC"), and Santa Fe Natural Tobacco Company, Inc. ("SFNTC") (collectively, the "Petitioners") request that the Secretary promulgate a regulation to calculate and assess user fees in such a way that no manufacturer or importer of tobacco products is required to pay such fees in an amount greater than its actual market share-based percentage of a particular class of tobacco products. To ensure that no manufacturer or importer pays user fees in excess of its market share, FDA must develop a process to (a) identify every manufacturer and importer of tobacco products sold in the United States, (b) determine each manufacturer's and importer's respective sales volume, and (c) properly calculate their respective and actual market share for each particular class of tobacco products currently subject to the United States Food and Drug Administration's ("FDA") jurisdiction. If any manufacturer or importer of a particular class of tobacco product is omitted from the market share calculations, the user fees assessed are incorrect, flawed, and overstated.

II. STATEMENT OF GROUNDS

A. Statutory Background

On June 22, 2009, President Obama signed the Tobacco Control Act into law (Public Law No. 111-31). The Tobacco Control Act amended the FDCA to give FDA the authority to

regulate tobacco products. Section 919 requires FDA to "assess user fees on, and collect such fees from, ***each manufacturer and importer of tobacco products***" subject to the Tobacco Control Act.[1] These fees are collected by FDA for paying the costs of the Agency's activities "related to the regulation of tobacco products."[2]

In order to collect such fees, the fees must first be calculated. There are three steps in calculating a user fee under Section 919. First, the total amount of user fees to be paid by the entire tobacco industry is fixed by statute.[3] Second, those user fees are apportioned among classes[4] of tobacco products subject to the Tobacco Control Act (such as cigarettes and smokeless tobacco) based on each class's percentage share of the overall tobacco market.[5] Third, each company is assessed a share of the user fees based on that company's percentage share of the market for that class.[6]

Through fiscal year 2014, the market share figures that determine the amount of user fees assessed against each manufacturer are not FDA's responsibility. Instead, the Tobacco Control Act directs FDA to rely on figures determined by the Department of Agriculture under Section 625 of Public Law 108-357 (the Fair and Equitable Tobacco Reform Act of 2004, or "FETRA," codified at 7 U.S.C. § 518d).[7] FETRA imposes quarterly assessments on tobacco manufacturers and importers to provide funds for annual transitional payments to eligible tobacco quota holders and producers. The FETRA assessments are calculated using a methodology similar to that of the Tobacco Control Act. That is, the total annual assessment is allocated pro rata among manufacturers and importers based on each manufacturer's or importer's share of gross domestic volume for each class of tobacco product.[8]

Beginning in fiscal year 2015, FDA assumes complete responsibility for the assessment of tobacco user fees. FDA is required "[b]eginning not later than fiscal year 2015, and for each subsequent fiscal year, [to] ensure that the [FDA] is able to determine" the applicable percentages for a fiscal year for each of the classes of tobacco products and the percentage share

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[1] FDCA § 919 (emphasis added).
[2] *Id.* at § 919(c)(2).
[3] Id. at § 919(b)(1).
[4] Class refers to a category of tobacco products. Section 919(b)(1) identifies cigarettes, snuff, chewing tobacco, and roll-your-own tobacco as examples of categories or classes of tobacco products. FDCA § 919(b)(2)(B).
[5] *Id.* at § 919(b)(2).
[6] *Id.* § 919(b)(3).
[7] *Id.* at § 919(b)(2), (4), (7).
[8] 7 U.S.C. § 518d(e). To facilitate the necessary market share calculations under FETRA, each manufacturer and importer of tobacco products is required to submit to the Department of Agriculture copies of certain tax and customs forms, filed with the Treasury Department and the Department of Homeland Security, that relate to "(A) the removal of tobacco products into domestic commerce … and (B) the payment of taxes imposed under charter 52 of the Internal Revenue Code of 1986." 7 U.S.C. § 518d(h); 7 C.F.R. § 1463.7(b); *see also Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 681 (D.C. Cir. 2010). The Department of Agriculture is required to provide each manufacturer or importer with a written notice setting forth the amount to be assessed against the manufacturer or importer for each quarterly payment. 7 U.S.C. § 518d(d)(1). Among other things, the assessment notification must contain certain information regarding the assessment, including the manufacturer's or importer's market share of each applicable class of tobacco products and the market share of each other manufacturer and importer for each applicable class of tobacco products. *Id.* § 518d(d)(2)(F), (G).

of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products.[9]

The Tobacco Control Act and FETRA both expressly prohibit the government from charging a manufacturer or importer more than its pro rata share within any class of tobacco products in which the manufacturer participates.[10]

On December 12, 2012, FDA submitted to the Office of Information and Regulatory Affairs ("OIRA") a proposed rule regarding the requirements for the submission of data needed to calculate user fees for manufacturers and importers of tobacco products for review under Executive Order 12866 (and its predecessor, Executive Order 12291). FDA is proposing to require tobacco product manufacturers and importers to submit certain market share data to FDA because the Department of Agriculture's program to collect such data sunsets at the end of September 2014. FDA is proposing this rule to enable it to continue calculating market share percentages needed to compute user fees.

B. Certain Cigarette Manufacturers Have Been Omitted From The Market Share Calculations

Based on information that we have obtained in New York and through information obtained from FDA in response to Freedom of Information Act requests, we believe that at least twenty (20) cigarette manufacturers in New York are not being included in the cigarette market share calculation because FDA has neither assessed user fees on nor collected user fees from these manufacturers during the fiscal year starting October 1, 2011.[11] In failing to receive an assessment or pay a fee, each of these manufacturers was, therefore, improperly omitted from the market share calculation used to allocate the total user fees required those categories currently under FDA's jurisdiction by understating the total cigarette market share and overstating the market share for the roll-your-own and smokeless tobacco segments. In turn, these omissions have resulted in the assessment of user fees on RJRT and other tobacco product manufacturers

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[9] FDCA § 919(b)(7)(B).

[10] *See id.* at § 919(b)(3)(B) ("No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer."); 7 U.S.C. § 518d(e) ("No manufacturer or importer shall be required to pay an assessment that is based on a share that is in excess of the manufacturer's or importer's share of gross domestic volume.").

[11] *See* FDA's December 7, 2012 response to a Freedom of Information Act Request for manufacturers and importers assessed user fees during the fiscal year starting October 1, 2011 (Attachment 1). The manufacturers that we have determined were manufacturing cigarettes during the fiscal year 2011 and were not assessed a user fee are: Harry Wallace; Onondaga Nation's; Little Braves Manufacturing; T&D Enterprises; Bonnie Square; Gabe Oakes; Action Race Sports; King Enterprises LLC; Flint/MPH Manufacturing; Phillip Gray/Joe Burns Tobacco MFG; Katmandew's; Morris Oakes; Swamp's Performance Shop; Faith and Anthony Thomas; Dave and Curtis Thompson; Billy Sears; Gail's Tobacco (and Gail's Tobacco #2); Randy Chrysler; Sacajawea; Grand River Enterprises (GRE). Not surprisingly, these manufacturers are also not registered with FDA under Section 905 of the Act. *See* FDA's January 31, 2012 response to a Freedom of Information Act Request for December 2011 establishment registrations (Attachment 2).

and importers in an amount that was greater than the amount that should have been imposed based on the actual market share percentage.[12]

The failure to account for these manufacturers stems in large part from the Department of Agriculture's reliance on federal excise tax payment data to determine the size of the market and each company's individual portion. To the extent that manufacturers or importers evade taxes and/or otherwise do not comply with FDA requirements, such as establishment and product registration, the Department of Agriculture, and subsequently the FDA, if it were to adopt this process, will underestimate the size of the total market, leaving those companies that do pay taxes and otherwise comply with FDA requirements paying more than Section 919 requires, thereby subsidizing those companies who continue to violate the law.

While this initial information focuses on New York, we believe that other cigarette manufacturers elsewhere in the United States are likewise not being allocated their percentage share of the total user fee to be paid by all cigarette manufacturers or importers.

C. FDA Should Promulgate A Regulation That Requires Each And Every Manufacturer To Submit Market Sales Volume Data

Because Section 919 prohibits FDA from assessing a manufacturer or importer more than its pro rata share, each and every manufacturer and importer of tobacco products sold in the United States should be identified, and their respective sales volume included in the market share calculations. If any manufacturer or importer of a particular class of tobacco product is not included in the market share calculation, the user fees assessments previously made are incorrect and flawed.

As FDA begins to develop programs and processes to assume responsibility for the calculation of the amount of user fees assessed, FDA must take the necessary steps to ensure that each and every manufacturer and importer that sells tobacco products within the United States[13] (1) is identified; and (2) all volume sold per class of product is accounted for so as to perform the necessary calculations. Although it may pose a challenge to identify every tobacco product manufacturer and importer in the United States, it is essential that FDA promulgate a regulation that contains such a mechanism and that also requires all tobacco product manufacturers and importers to submit certain sales volume data to FDA. Because Section 919 of the Tobacco Control Act covers all tobacco products and does not exclude tobacco products sold through illicit trade[14], the user fee calculation must include those tobacco products that are being sold in the United States but for which (1) the manufacturer or importer fails to pay federal excise tax, (2) the manufacturer or importer underreports the volume of tobacco products sold in the United

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[12] Because the total user fees authorized to be assessed and collected by FDA are apportioned among classes of tobacco products subject to the Tobacco Control Act based on each class's percentage share of the overall tobacco market, by extension, it is likely that each manufacturer and importer of smokeless tobacco products and other tobacco products were also required to pay a user fee in excess of their percentage share.

[13] *See* 21 U.S.C. § 321(a).

[14] The Tobacco Control Act defines illicit trade to mean "any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity. FDCA § 900(8).

States, and/or (3) the manufacturer or importer fails to register with FDA. The regulation must provide a mechanism for FDA to collect this data from every manufacturer and/or importer of tobacco products of which FDA is aware (or made aware) that does not submit the requested information. In the absence of such a mechanism (and/or FDA enforcement action against such manufacturers or importers to remove the product from the market), there is no incentive for such manufacturers and/or importers to register with FDA and report the requested information that will subject them to user fees under the Tobacco Control Act and allow FDA to correctly calculate such fees.

In addition, the regulation must also provide a mechanism for manufacturers and importers to challenge a user fee assessment if there is a reasonable basis to conclude that tobacco product manufacturers and/or importers have been omitted from the market share calculation or there has been underreporting of the volume of tobacco product sold in the United States. In challenging an assessment, the manufacturer or importer must be able to use all information that is available, including third party data on industry or individual company sales volumes. While FDA is determining the validity of the challenge, a manufacture or importer should provide for the immediate payment to FDA only that portion of the assessment that is not in dispute, while placing the disputed portion in escrow. Finally, if the information provided in challenging an assessment is sufficient to establish that the original assessment was incorrect, the regulation must also provide a mechanism for FDA to properly correct assessments to ensure that each manufacturer and importer is responsible for no more than its correct share as determined by the statute.

A regulation that requires market sales volume data from each and every manufacturer and importer of tobacco products is especially important as FDA contemplates promulgating regulations to extend its jurisdiction to "other tobacco products" under Section 901(b) of the Tobacco Control Act. Unless FDA promulgates a regulation requiring every tobacco product manufacturer and importer to provide certain market sales volume data to FDA, manufacturers and importers of "other tobacco products" about which FDA is less knowledgeable than cigarettes and/or smokeless tobacco products will likely also not be included in market share calculations. Thus, before FDA issues a deeming regulation, FDA must consider and adopt reliable mechanisms to identify the manufacturers and importers of "other tobacco products," and properly calculate their market share. The regulation must determine how the user fees are apportioned among both classes of tobacco products currently subject to the Tobacco Control Act (such as cigarettes and smokeless tobacco) and "other tobacco products" that may be deemed by regulation subject to the Tobacco Control Act. The regulation must also ensure that each manufacturer or importer of an "other tobacco product" is assessed a share of the user fees for each class of tobacco products based on that company's percentage share of the market for that class.

III. ENVIRONMENTAL IMPACT

Pursuant to 21 C.F.R. § 25.30(h), the actions requested in this petition are categorically excluded from the required submission of an environmental assessment.

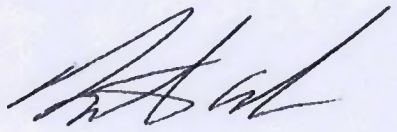
IV. ECONOMIC IMPACT

An economic impact assessment will be provided upon request.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and believe of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner which is unfavorable to the petition.

Sincerely yours,



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