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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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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
Regulatory Information Number (RIN) 0910-AG81

Lorillard, Inc., on behalf of its subsidiaries Lorillard Tobacco Company and LOEC, Inc., d/b/a blu eCigs (hereinafter "Lorillard"), is pleased to provide comments on the Food and Drug Administration's Proposed Rule on tobacco product user fees.

Lorillard supports FDA's efforts to assure continuity and predictability in the calculation and collection of quarterly user fees pursuant to the Family Smoking Prevention and Tobacco Control Act Pub.L. 111-31 (the "Act"). As more fully described below, FDA has noted in its proposed rule that the Act references the Fair and Equitable Tobacco Reform Act, Pub.L. 108-357 ("FETRA") and requires FDA to follow FETRA with respect to the methodology to be used for both allocations of assessments by class of tobacco product (section 919(b)(2)(B)(ii) of the Act) and for allocations within each class of tobacco product (section 919(b)(4) of the Act). We strongly agree.

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Submission of Required Information

As correctly noted in the Proposed Rule, the Department of Agriculture will continue to collect information from tobacco product manufacturers through September 2014 to enable FDA to assess its user fee. Beginning October 2014, FDA will be responsible for collecting the information directly from all manufacturers and importers in order to calculate and assess user fees. FDA proposes that manufacturers and importers submit to FDA essentially the same information as they are submitting to USDA currently, which includes information on the volume of domestic removals (as currently reported on Form CCC-974), and certified copies of certain tax returns and forms, including TTB Form 5000.24 (relating to excise taxes) and TTB Form 5210.5 (relating to production reports). Lorillard supports this aspect of the Proposed Rule. The Proposed Rule would not appear to add any additional burdens on those who currently submit such information to USDA. Manufacturers and importers are familiar with the reporting of this information, and the submissions will continue to be made to a single federal agency.

Treatment of Additional Classes

For tobacco products not included in one of the existing six classes[1] specified in section 919(b)(2)(B)(i) of the Act, FDA is seeking comment on "what the additional classes would be," and "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."

Our comments in this regard are directed at the possible future regulation and classification of electronic cigarettes, or "e-cigarettes." In the release of its Spring 2013 Unified Regulatory Agenda, FDA indicated its intention to issue a proposed rule in October, 2013 that would "deem products meeting the statutory definition of 'tobacco product' to be subject to the FD&C Act and would specify additional restrictions." RIN: 0910-AG38.

[1] The six classes include 1) cigarettes, 2) cigars, 3) snuff, 4) chewing tobacco, 5) pipe tobacco, and 6) roll-your-own tobacco. These are the same classes used by FETRA for calculating its assessment and the only classes of tobacco products defined in the Internal Revenue Code, section 5702.

E-Cigarettes as an Additional Class

There are many important unanswered questions regarding any proposal by FDA to regulate the category of e-cigarettes. In Sottera, Inc. v. Food and Drug Administration, 627 F.3d 891 (D.C. Cir. 2010), the Court of Appeals for the D.C. Circuit found that "the FDA has authority to regulate customarily marketed tobacco products – including e-cigarettes – under the Tobacco Act." This finding was based on the definition of "tobacco product" in the Act, which includes "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C. 321(rr) (emphasis added). In the Sottera case, the e-cigarette products at issue did not contain tobacco, but contained liquid nicotine that "is derived from natural tobacco plants."

However, not all e-cigarette products fit neatly into this category. For example, nicotine can be produced synthetically for e-cigarette products and some e-cigarette products do not contain any nicotine. Such products would fall outside of the definition of "tobacco product" in the Act, and therefore would not be subject to FDA jurisdiction.

Lack of Authority to Impose Assessments on E-Cigarettes

For those e-cigarettes that may meet the definition of "tobacco product" under the Act, it is clear that FDA would need to create a new class of tobacco products in order to regulate them. Although, Section 919(a) of the Act authorizes FDA to collect user fees from each manufacturer of tobacco products subject to FDA jurisdiction, the Act is clear that such fees must be collected "in accordance with this section" (emphasis added). Section 919 of the Act references and relies on the FETRA methodology, providing FDA with no authority to assess user fees outside of the six classes of tobacco products. Thus, FDA lacks authority under the Act to impose any user fee assessments on e-cigarette manufacturers, both at the class and the individual manufacturer level.

FDA has already complied with the precise requirements of section 919, imposing assessments only on those entities subject to the requirements of section 919 and FETRA. For example, section 905(b) of the Act requires that "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" register with FDA the name, places of business, and all establishments engaged in

these activities owned or operated by that person. Violations are subject to regulatory and enforcement action, including seizure and injunction. Yet all of these entities currently subject to FDA regulation under Section 905(b) do not pay assessments. Only those entities subject to assessments collected "in accordance with" section 919 are assessed such fees.

Similarly, section 901(b) of the Act states that FDA regulatory authority "shall apply 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." This language follows the classes of cigarettes that are well established under FETRA and under the federal tax code, but also includes "cigarette tobacco" as an additional class. However, section 919 confers no authority on FDA to impose a user fee from a manufacturer or importer of "cigarette tobacco" unless that entity also has domestic removals of tobacco products subject to FETRA assessments. The mention of "cigarette tobacco" in section 901(b) is insufficient to confer authority to impose assessments. Likewise, the mere mention of "other tobacco products" in section 901(b) is insufficient to create authority to impose assessments on e-cigarettes under section 919 of the Act.

As noted above, the calculation of assessments under the Act relies extensively on the methodology already established under FETRA. The same concept of selective imposition of user fees on manufacturers and importers also exists under FETRA, as section 625(b)(1) of FETRA contains a similar provision as Section 919 of the Act. Section 625(b)(1) of FETRA provides that USDA "shall impose quarterly assessments during each of fiscal years 2005 through 2014, calculated in accordance with this section, on each tobacco product manufacturer and tobacco product importer that sells tobacco products in domestic commerce in the United States during that fiscal year." (emphasis added.) Again, the statute requires calculations to be made in accordance with the requirements set forth in the law. And in its operation, the application of the FETRA requirements has not meant that each manufacturer and each importer is assessed in each quarter. For example, a small manufacturer that sells tobacco products in a covered class during a fiscal year but that does not have domestic removals in each quarter will only be assessed for those quarters in which the requirements of the statute are met. Such manufacturer may be assessed at zero for a particular quarter even if assessed in previous quarters based on domestic sales. Section 625 of FETRA requires that the statutory formula be followed.

General Limitations Imposed by FETRA

In specifying how allocations of assessments by class of tobacco products are made by FDA, Section 919(b)(2)(i) of the Act specifies six classes that may be assessed and provides in subparagraph (ii) that the "applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c)" of FETRA.

Section 625(c)(1) provides an initial allocation for each class of tobacco products based on the 2003 volume for such class multiplied by the 2005 maximum tax rate for such class. Section 625(c)(2) requires subsequent adjustment to these allocations ("the Secretary shall periodically adjust") based on "changes in the share of gross domestic volume held by that class of tobacco product." USDA has determined that the statute requires "that changes in the relative class assessments are made only on the basis of changes in volume, not changes in tax rates." 75 Fed. Reg. 76921. USDA concluded, therefore, that it would "determine tobacco class allocations using the Federal excise tax rates that applied in fiscal year 2005," and would disregard any subsequent legislative changes to tax rates.

Under these FETRA requirements, USDA has chosen to make annual adjustments to the class allocations based solely on changes in gross domestic volume. For each year, a class percentage calculation is made, and the total percentages for the six classes add up to 100 percent. For example, for fiscal year 2013, the allocations under FETRA were as follows: cigarettes, 88.4990 %; cigars, 9.7932 %; snuff, 0.9391 %; chewing tobacco, 0.0749 %; pipe tobacco, 0.6030 %; and roll-your-own, 0.0905 %. These are based on 2011 volumes but 2005 tax rates.

Federal Tax Liability is a prerequisite for FDA Assessment Authority

It is clear that FDA cannot assess a class that does not pay federal excise taxes. The class allocations are based on volume multiplied by tax rates. If the tax rates are zero, then the class allocation must also be zero. In other words, any application of FETRA section 625(c) as required by the Act will yield a product of zero for a class not included in the FETRA calculations. Even if federal excise taxes are imposed on e-cigarettes in the future, FDA lacks authority to assess a new class of e-cigarettes absent further additional changes to the Act. Since the FETRA methodology requires assessments to be periodically adjusted based on changes in volumes multiplied by 2005 excise tax rates, any imposition of future federal

excise tax requirements is not relevant absent corresponding changes to the Act. FDA is required to follow the FETRA algorithm, which is based on domestic volumes for the six specified classes and the 2005 tax rates.

E-Cigarette Manufacturers do not Meet the Definition of Domestic Manufacturer

FDA cannot deem e-cigarette manufacturers to be "manufacturers" for purposes of assessing user fees. As noted above, FDA has indicated that it is bound under the Act to follow the allocation procedures established under FETRA and used by USDA to calculate assessments for the Tobacco Transition Program. Section 625(g) of FETRA requires USDA to calculate "volume of domestic sales" based on information required to be submitted under the federal tax code, and section 625(h) of FETRA requires manufacturers to submit certified copies of these Department of Treasury forms relating to taxes paid. In reliance on this precedent, FDA has chosen in its proposed regulation to define "domestic manufacturer" as an entity "required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau of the Department of Treasury." See proposed section 1150.3, Definition of "Domestic manufacturer," 78 Fed. Reg. 32593 (May 31, 2013). Absent a change in federal law imposing federal excise taxes on e-cigarette manufacturers, there is no requirement for e-cigarette manufacturers to obtain such permits, and therefore they cannot be treated as manufacturers subject to FDA user fee assessments.

Reallocation Authority

The Act does not initially provide authority to regulate cigars and pipe tobacco. For that reason, section 919(b)(2)(v) gives FDA authority to make "reallocations." The statute allows FDA to make reallocations "to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under" section 625(c) of FETRA.

It is important to note that FDA is given authority to reallocate based solely on the percentages determined under FETRA. In other words, it can reallocate on a pro rata basis from cigars and pipe tobacco to cigarettes, snuff, chewing tobacco, and roll-your-own, based on the FETRA percentages already established for those regulated categories. FDA cannot, however, reallocate assessment obligations to categories not assessed under FETRA like a new class of tobacco products such as e-cigarettes or cigarette tobacco manufacturers or importers, even though these

product categories may also be regulated under the Act. The Act does not provide such authority to make reallocations to classes not subject to FETRA. In other words, FDA may only reallocate to one of the six listed classes.

No Fee in Excess of Percentage Share

The Act prohibits FDA from imposing an assessment on a manufacturer in excess of its market share. Section 919(b)(3)(B). As noted above, the application of the FETRA formula will result in a "zero" percentage market share for an e-cigarette manufacturer should FDA choose to assert jurisdiction. The section provides further evidence that manufacturers should only be assessed in accordance with the requirements of the Act, including adherence to the FETRA methodology. Therefore, the imposition of a user fee assessment on an individual e-cigarette manufacturer would violate section 919(b)(3)(B).

Appeals and Judicial Review

USDA has provided and administers a far more transparent process to address challenges to FETRA assessments than that proposed by FDA.

FDA has proposed giving an entity 45 days to challenge an assessment, requiring that FDA provide a dated, written response and a refund where appropriate, and allowing an entity to request a further agency review within 30 days. This process is not further defined nor detailed, will foster unexplained delays in decision making and lacks mechanisms to assure expedient action on any appeal.

In contrast, the existing USDA review process contains the following important procedural safeguards to insure an efficient and fair resolution:

- A hearing officer is assigned to each dispute to develop an administrative record
- A decision maker separate from the hearing officer is assigned to make a determination based on the administrative record
- An informal hearing is available to present oral and written evidence
- Written rules of conduct are in place for the proceeding
- The agency has a 30 day deadline to render a final administrative decision
- An aggrieved party may seek review in the U.S. District Court for the District of Columbia

We encourage FDA to duplicate the elements of the USDA dispute resolution process in its final rule.

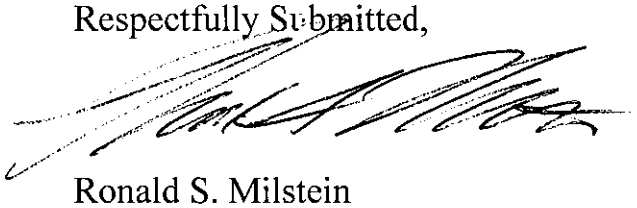
Summary

The Act is a complex statute and makes references to other complex statutes like FETRA when assessing user fees. It is clear however, when the statutes are read in their proper context and given their plain meaning, that FDA does not have authority under the Act to substitute its policy judgment for that of Congress, nor does it have the authority to assess the competitive effects of its implementation of the Act. Such policy discretion must be authorized by Congress. FDA is required to follow the language of the statutes in the absence of further legislative enhancements to its authority.

In conclusion, Lorillard's comments can be summarized as follows:

- We agree with the required information transition plan
- E-Cigarettes can only be regulated by FDA as a new class of tobacco products
- FDA must follow section 919 of the Act and it mandates adherence to FETRA in calculating assessments
- FETRA provides no authority to assess e-cigarettes
- Federal tax liability is a prerequisite for FDA assessment authority
- Section 919 provides no authority to reallocate assessments to other tobacco product categories not specified in FETRA
- Since the percentage share calculation for e-cigarettes is zero, FDA lacks authority to impose any assessment
- FDA should provide a more comprehensive dispute resolution process like the process established by USDA.

Respectfully Submitted,



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