Tobacco Product User Fees: Responses to Frequently Asked Questions

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Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to https://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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Contains Nonbinding Recommendations

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Guidance for Industry[1]

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I. INTRODUCTION

This guidance provides information in response to frequently asked questions related to tobacco product user fees assessed and collected under section 919 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). In particular, this guidance provides information regarding:

- the submission of information needed to assess user fees owed by each domestic manufacturer or importer of tobacco products; and
- how FDA determines whether a company owes user fees in each quarterly assessment.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Public Law 111-31), amending the FD&C Act and providing

[1] This guidance was prepared by the Office of Management and the Office of Regulations in the Center for Tobacco Products at FDA.

FDA with the authority to regulate tobacco products. Included in the Tobacco Control Act is the requirement that FDA assess and collect user fees.

Section 919(a) of the FD&C Act requires FDA, in accordance with that section, to "assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products" subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). Under the calculations required by section 919 of the FD&C Act, the tobacco products that are subject to user fee assessments are cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco. The total amount of user fees for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and, under section 919(a), we are to assess and collect one-fourth of that total each quarter of the fiscal year. The FD&C Act provides for the total quarterly assessment to be allocated among specified classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco products removed[2] into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its market share for that tobacco product class.

In the *Federal Register* of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking to add 21 Code of Federal Regulations (CFR) part 1150 to require domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees to assess each domestic manufacturer and importer under the FD&C Act. In the *Federal Register* of July 10, 2014 (79 FR 39302), FDA finalized portions of the User Fee proposed rule related to cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, which is codified at 21 CFR part 1150. In the *Federal Register* of May 10, 2016 (81 FR 28707), FDA finalized a rule which, among other things, amended part 1150 to include user fee requirements for domestic manufacturers and importers of cigars and pipe tobacco.

III. QUESTIONS AND ANSWERS

A. How does FDA determine which companies are included in the quarterly tobacco user fee assessments?

Companies are included in quarterly user fee assessments when they meet the definition of a domestic manufacturer or importer of tobacco products during the fiscal quarter being assessed ("assessment quarter"). Under 21 CFR 1150.3, a domestic manufacturer is a person who is required to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau (TTB) with respect to the production of tobacco products under title 27 of the CFR. Under 21 CFR 1150.3, an importer is a person who is required to obtain a permit from TTB with respect to the importation of tobacco products under title 27 of the CFR.

[2] *Removal* is defined at 26 U.S.C. 5702 as "the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from internal revenue bond under section 5704, as the Secretary [of Treasury] shall by regulation prescribe, or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States."

FDA considers a company maintaining a TTB permit for the production or importation of tobacco products at any point during the assessment quarter as evidence that the company meets the definition of a domestic manufacturer or importer during such quarter. FDA receives information as to a company's permit status directly from TTB every fiscal quarter and as requested. For each assessment quarter, each company meeting the definition of a domestic manufacturer or importer during such quarter will receive a user fee assessment, with such amount determined under the calculations set forth in 21 CFR 1150.9.

If a company never meets the definition of a domestic manufacturer or importer during a fiscal quarter, then FDA generally does not intend to include it in the user fee assessments for such fiscal quarter. In this case, this can mean that even though the company had taxable removals in a prior fiscal quarter (for tobacco products except cigars) or fiscal year (for cigars), it will not receive a user fee assessment for the fiscal quarter being assessed. Regardless of whether a company meets the definition of a domestic manufacturer or importer during a given quarter, a company may still receive, and be liable for, a user fee assessment adjustment for a past fiscal quarter in which it did meet either definition (see section III.G. [setting out the circumstances and process by which FDA makes user fee assessment adjustments]).

B. How does FDA determine that a company is no longer a domestic manufacturer or importer subject to user fee assessments?

FDA considers a company no longer maintaining a TTB permit for the production or importation of tobacco products as evidence that the company no longer meets the definition of a domestic manufacturer or importer. Generally, FDA considers this to occur beginning on the date that the company's TTB permit is closed or expires. FDA refers to TTB permit status dates (date issued and date closed, if applicable), which FDA receives directly from TTB (as stated in section III.A.), as the primary source for determining status as a domestic manufacturer or importer; however, FDA may determine that a company stopped meeting the definition of a domestic manufacturer or importer on a different date (e.g., a date that differs from the date(s) shown in the TTB data), where established by sufficient documentation provided by the company. Examples of sufficient documentation may include, but are not necessarily limited to:

- Bond expiration or termination letters;
- State documents showing the closure or dissolution of the business that held the TTB permit; and
- Proof that the company surrendered the permit to TTB and requested permit closure or termination.

FDA recommends that a company submit information establishing the date on which its TTB permit expired, closed, or was otherwise terminated, or on which the business was closed or dissolved (especially where such information establishes a date prior to the one reflected in TTB data) with its final monthly user fee report or as soon as the company is able to provide it. Block 7 of the Form FDA 3852 provides a box for companies to check indicating the report is their final Form FDA 3852 submission—companies that have returned their permit to TTB (or otherwise had their TTB permit closed), had their TTB permit expire, or closed or dissolved their business, should check this box and attach relevant documentation with date of closure/expiration/dissolution. If a company stops meeting the definition of a domestic

manufacturer or importer before the beginning of a fiscal quarter (and does not meet either definition at any point in time during the quarter), but then nonetheless receives a user fee assessment for such quarter, it may dispute the assessment in accordance with 21 CFR 1150.15.

C. Is hookah or water pipe tobacco subject to user fee requirements?

FDA's regulations at 21 CFR part 1150, apply to domestic manufacturers and importers of six classes of tobacco products as they are defined in 26 U.S.C. 5702: cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco.[3] Hookah or water pipe tobacco is subject to user fees when it is subject to federal excise taxes—typically, as pipe tobacco—and removed into interstate commerce.

D. How should a company submit its monthly report to FDA?

Domestic manufacturers and importers must use Form FDA 3852 and attach copies of the appropriate supporting TTB and U.S. Customs and Border Protection (CBP) forms (currently TTB Forms 5210.5, 5000.24, and 5220.6 and CBP Form 7501).[4] This form is available online and in paper form. The required information may be submitted to FDA via e-mail (preferred method), fax, or mail; only one method is needed. Submit Form FDA 3852 and supporting documents to FDA

electronically: TOBACCOUSERFEES@fda.hhs.gov

by fax: 301-595-1429 or 301-595-1430, or

by mail: Food and Drug Administration,
Center for Tobacco Products
Document Control Center
ATTN: OM, Division of Financial Management, User Fee Team
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002.

E. Are tobacco product user fee assessments based on federal excise taxes owed (i.e., federal excise tax liability) or federal excise taxes paid?

Tobacco product user fee assessments are based, in part, on the gross domestic volume of tobacco products (i.e., gross removals not exempt from tax).[5] Accordingly, FDA uses the associated federal excise tax amounts owed for gross removals to calculate assessments.[6]

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[3] *See* 21 C.F.R. § 1150.3 (defining "[c]lass of tobacco products" as referring to each of these six classes as defined at 26 U.S.C. § 5702).
[4] *See* 21 C.F.R. § 1150.5.
[5] *See* 79 FR 39302, 39306 (July 10, 2014).
[6] Section 919 of the FD&C Act instructs FDA to determine class allocations and individual company assessments using the percentages determined under the Fair and Equitable Tobacco Reform Act of 2004 (FETRA, Pub. L. 108-357 (7 U.S.C. § 518 et seq.)). *See* FD&C Act §§ 919(b)(2)(B)(ii) & (b)(4). FETRA, in turn, determines percentages

F. How should adjustments to gross removals be reported by companies?

Companies should report their gross removals and associated federal excise taxes on Form FDA 3852. Any adjustments affecting gross removals should be included in a company's monthly submission (i.e., increase or decrease the volume and tax amounts reported on the Form FDA 3852 accordingly); these adjustments should be reported on the TTB Form 5000.24, *Excise Tax Return*, submitted as part of the monthly report to FDA, in the sections designated for Schedule A and B adjustments. Please note, the Schedule B adjustments identified on TTB Form 5000.24 for claims associated with withdrawn/destroyed product should not be included in the Form FDA 3852 volume or tax totals as these claims do not affect a company's gross domestic volume.[7]

FDA recommends companies include further documentation identifying what type of adjustment to gross removals is reflected on the TTB 5000.24 form (to include period of activity – month and year – and tobacco product class associated with the adjustment) if the description of the adjustment is not clearly listed on the TTB 5000.24 form.

In order to ensure that user fee market share calculations are correct for any particular fiscal quarter, when a company makes an adjustment to gross removals previously reported in a monthly report to FDA, it should submit an amended monthly report (for the month in which the adjustment occurred) that includes such adjustment, as soon as possible.

G. What process does FDA use to make user fee assessment adjustments?

Under 21 CFR 1150.9(b), FDA will make "any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (for example, to include domestic manufacturers or importers that were not included in a relevant assessment calculation)." Assessment adjustments help ensure that no domestic manufacturer or importer pays a user fee in excess of its percentage share, as required under section 919(b)(3)(B) of the FD&C Act.

Typically, FDA determines assessment adjustments through a year-end reconciliation process following the end of a fiscal year (end-of year reconciliation) and three years after a given fiscal year ends (three-year reconciliation). As part of this process, FDA accounts for unreported and corrected information provided through late data submissions, amended data submissions, and annual tax records from TTB and CBP. After performing any necessary individual market share percentage recalculations based on such information, FDA makes corresponding assessment adjustments for the subject fiscal period, which it includes in the quarterly user fee assessment notifications to companies.[8] Under 21 CFR 1150.15(a), a company may dispute an assessment

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by using "gross domestic volume," and defines "gross domestic volume" as based on federal excise tax amounts owed, rather than federal excise tax amounts paid. *See* 7 U.S.C. §§ 518d(a)(2) (defining "gross domestic volume") & 518d(c), (e)–(h) (process for determining percentages).

[7] *See supra* section III.E. (explaining that tobacco product user fee assessments are based, in part, on "gross domestic volume").

[8] *See* 21 C.F.R. § 1150.11(b)(4).

adjustment (as an assessment), provided it does so within 45 days of the date on the assessment adjustment.[9]

FDA generally does not intend to further revise individual market share percentages for a fiscal period after it completes the three-year reconciliation for such fiscal period. The only instances in which FDA anticipates potentially further revising individual market share percentages after a three-year reconciliation are when:

- FDA determines, in reviewing a timely (i.e., received by FDA no later than 45 days after the date on the notification) dispute of an assessment adjustment stemming from such reconciliation, that there was an error related to the assessment adjustment; or
- FDA is made aware that a company was found liable for criminal activity that impacted its individual market share percentage (e.g., trafficking in contraband cigarettes or contraband smokeless tobacco).[10]

In these instances, FDA may adjust the individual market share percentage(s) of the impacted company and companies with products in the relevant class(es), and either issue revised invoices to the necessary companies that reflect corresponding assessment adjustments or include such adjustments in the next assessment.[11]

H. How are tobacco product user fee invoices distributed to industry?

FDA distributes tobacco product user fee invoices primarily via email, based on the email address listed on page one of the Form FDA 3852. If the email address is undeliverable or otherwise unavailable (and no other email addresses are associated with the company), invoices are distributed via mail to the mailing address listed on page one of the Form FDA 3852. Companies should provide the most current contact information in these fields when submitting the monthly Form FDA 3852. Companies should also take steps to ensure tobaccouserfees@fda.hhs.gov and tobaccouserfeesupport@fda.hhs.gov are not blocked by email spam filters.

I. Who should a company contact if they have questions or need further guidance with supporting documents?

For questions about or assistance with TTB 5210.5, TTB 5000.24, and TTB 5220.6 forms, please visit: https://www.ttb.gov/contact-nrc.

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[9] FDA must receive the dispute no later than 45 days after the date on the assessment notification and the dispute must include the basis for the dispute, be in writing, legible, in English, and sent to the address found on FDA's tobacco products website (http://www.fda.gov/tobaccoproducts). *See* 21 C.F.R. § 1150.15.

[10] *See* 18 U.S.C. §§ 2341–46. Please note that CTP generally does not intend to independently seek out this information.

[11] As a reminder, a domestic manufacturer or importer may contest an assessment, including an assessment adjustment issued in either of the instances described above, by submitting a written dispute that, among other things, is received by FDA no later than 45 days after the date on the assessment notification. *See* 21 C.F.R. § 1150.15(a); *see also supra* note 9.

For questions related to filling out the CBP 7501 forms, please visit: https://www.cbp.gov/trade/programs-administration/entry-summary/cbp-form-7501.