regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Device Exemption	0910–0332
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
822	Postmarket Surveillance of Medical Devices	0910–0449

Dated: May 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11215 Filed 5–26–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0373]

Tobacco Product User Fees: Responses to Frequently Asked Questions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' This draft guidance provides information in response to frequently asked questions related to tobacco product user fees assessed and collected under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by July 26, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0373 for ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Eric C. Mandle, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov,* 1–877–287–1373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' This draft guidance provides information in response to frequently asked questions related to tobacco product user fees assessed and collected under section 919 of the FD&C Act (21 U.S.C. 387s). In particular, this draft 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 current Form FDA 3852, ''Report of Tobacco Produce Removals Subject to Tax for Tobacco Product User Fee Assessments,'' discussed in this draft guidance, is available at *https://www.fda.gov/media/88957/download.*

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing 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), FDA is 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 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 proposed rule to add part 1150 (21 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 part 1150. In the **Federal Register** of May 10, 2016 (81 FR 28707), FDA finalized a rule that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act.

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the responses to the frequently asked questions set forth in the guidance. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in part 1150 have been approved under 0910–0749.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.regulations.gov*, *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm*, or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: May 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11222 Filed 5–26–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–Z–2200]

Termination of the Food and Drug Administration's Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective; Withdrawal

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing this document to withdraw a legally and factually inaccurate notice and request for information published in the **Federal Register** on November 25, 2020, entitled ''Termination of the Food and Drug Administration's Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective.'' This notice also ends the period for submission of responses to Part II of the November 25, 2020, notice and request for information.

DATES: The notice and the request for information are withdrawn as of May 27, 2021.

FOR FURTHER INFORMATION CONTACT: Anuj Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993, 301–796–2246.

SUPPLEMENTARY INFORMATION: On November 25, 2020, HHS published a notice and a request for information in the **Federal Register** entitled ''Termination of the Food and Drug Administration's Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective'' (the HHS Notice) (85 FR 75331). The HHS Notice stated that it was ''terminating'' the FDA's Unapproved Drugs Initiative (UDI) effective 30 days from publication of the HHS Notice in the **Federal Register**, by withdrawing FDA's ''Marketed Unapproved Drugs Compliance Policy Guide'' (CPG