Estimated Total Annual Burden Hours: 10,800.

Authority: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) (Title IV, Sec. 412 of the Act) and 45 CFR 400.28(b).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–27767 Filed 12–21–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0756]

Validation and Verification of Analytical Testing Methods Used for Tobacco Products; Draft Guidance for Industry; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Validation and Verification of Analytical Testing Methods used for Tobacco Products'' and requesting comments, including scientific and other information, concerning the recommendations set forth in the draft guidance. The draft guidance, when finalized, would provide information and recommendations related to the validation and verification of analytical test methods, including analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of tobacco products. This draft guidance would help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products.

DATES: Submit either electronic or written comments on the draft guidance by February 22, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–0756 for ''Validation and Verification of Analytical Testing Methods used for Tobacco Products.'' 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 the draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, 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 guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft document entitled ''Validation and Verification of Analytical Testing Methods used for Tobacco Products; Draft Guidance for Industry.'' This draft guidance, when finalized, provides information and recommendations on how tobacco product manufacturers can produce validation and verification data for the analytical procedures and

methods used to support regulatory submissions for finished tobacco products including substantial equivalence (SE) applications, premarket tobacco product applications (PMTA), and modified risk tobacco product applications (MRTPA). These recommendations include analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of finished tobacco products. The principles in this guidance may also be used for finished tobacco product testing and reporting of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

The FD&C Act requires, among other things, premarket review for new tobacco products and modified risk tobacco products (see sections 910 and 911 (21 U.S.C. 387j and 21 U.S.C. 387k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and also reporting of HPHCs under section 904 of the FD&C Act (21 U.S.C. 387d). Information about constituents, for example, might be required by law or otherwise support the findings for premarket authorization. Regulatory submissions often contain data from analytical testing, such as data about ingredients, constituents, and additives. In standard practice, analytical testing is done through validation of the analytical method. In these cases, the applicant will want to use analytical methods that are sufficiently precise, accurate, selective, and sensitive. Validation involves documenting, through the use of specific laboratory investigations, that the performance characteristics of the method are suitable and reliable for the intended analytical applications, in terms of precision, accuracy, selectivity, and sensitivity. When finalized, this guidance is intended to help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products, such as SE applications, PMTAs, MRTPAs, and for finished tobacco product testing and reporting of HPHCs in tobacco products and tobacco smoke.

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 ''Validation and Verification of Analytical Testing Methods used for Tobacco Products.'' 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 of 1995

We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the recordkeeping provisions are part of usual and customary business practice. Tobacco manufacturers would have in-house analysts or contractual agreements with outside analytical laboratories and suppliers, as applicable for the type of tobacco product, to address all these information collection provisions.

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673; and the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684, the collections of information in section 904(a)(3) of the FD&C Act have been approved under OMB control number 0910–0732.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27719 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 21, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Program

OMB Control Number 0910–0718—Revision

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological