published. Furthermore, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' 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

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 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 203 described in the final rule entitled ''Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Policies'' have been approved under OMB control number 0910–0435. The collections of information in part 201 (21 CFR part 201) described in the final rule entitled ''Bar Code Label Requirement for Human Drug Products and Biological Products'' have been approved under OMB control number 0910–0537. The collections of information for prescription drug product labeling in § 201.56 and 201.57 (21 CFR 201.56 and 201.57) have been approved under OMB control number 0910–0572. The collections of information described in the FDA guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' have been approved under OMB control number 0910–0806.

In addition, the inclusion of warning statements on labels for certain drug products would be exempt from review by OMB under the PRA because the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within the definition of ''collection of information'' (see 5 CFR 1320.3(c)(2)).

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov*.

Dated: May 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10699 Filed 5–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0880]

Assessing User Fees Under the Generic Drug User Fee Amendments of 2017; 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 final guidance for industry entitled ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' This guidance provides stakeholders information regarding the implementation of the Generic Drug User Fee Amendments of 2017 (GDUFA II) and policies and procedures surrounding its application. This guidance is finalizing FDA's draft guidance for industry ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017,'' published in November 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on May 18, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2012–D–0880 for ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' 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 guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Keith F. Verrett Jr., Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2179, Silver Spring, MD 20993–0002, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' GDUFA II (Pub. L. 115–52, Title III), was signed into law on August 18, 2017. GDUFA II extends FDA's authority to assess and collect generic drug user fees from fiscal year (FY) 2018 through FY 2022. The extension of this user fee authority under GDUFA II continues FDA's and industry's ability to meet the goals of improving public access to safe and effective generic drugs and enhancing the predictability of the review process.

The guidance announced in this notice replaces the draft guidance for industry on ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017,'' dated October 2019 and published in November 2019. This guidance addresses changes in user fee assessments from GDUFA I, user fees incurred by industry under GDUFA II, payment procedures, reconsideration and appeals, and other additional information to assist industry in complying with GDUFA II. This guidance also describes how FDA determines affiliation for purposes of assessing generic drug user fees.

FDA has reviewed the comments submitted to the docket and determined that the comments do not require substantive changes from the draft guidance. Clarifying language was, however, added to this final guidance largely based on the public comments and to update the Agency's treatment of sponsor requests for ''transfer'' of certain user fee payments eligible for refund toward applicable user fee liabilities.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' 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

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 Form FDA 3913 (User Fee Payment Refund Request) have been approved under OMB control number 0910–0805 and the collections of information in Form FDA 3914 (User Fee Payment Transfer Request) have been approved under OMB control number 0910–0805.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10702 Filed 5–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–xxxx]

Agency Father Generic Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 18, 2022.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Strategy for a Resilient Public Health Supply Chain Paper Reduction Act Clearance.

Type of Collection: Father Generic ICR.

OMB No. 0990–XXXX—Assistant Secretary for Preparedness and