modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Science Board to the Food and Drug Administration will consider challenges in evaluating the safety of dietary supplement and food ingredients with predicted pharmacological activity, utilizing cannabinoids as a case study. The Science Board to the Food and Drug Administration will also hear about the Agency's enhanced efforts to spur the development, qualification, and adoption of new alternative methods for regulatory use that can replace, reduce, and refine animal testing and have the potential to provide both more timely and more predictive information to accelerate product development and enhance emergency preparedness. The Science Board to the Food and Drug Administration will also hear about the Agency's enhanced efforts to ensure optimal organization, infrastructure, and expertise for data science efforts in alignment with its regulatory scope and evidence-based decision making, in support of FDA's public health priorities.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 7, 2022. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 1, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 7, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rakesh Raghuwanshi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10697 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–2013–D–0401]

Safety Considerations for Container Labels and Carton Labeling Design To Minimize Medication Errors; 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 ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' The guidance focuses on safety aspects of the container label and carton labeling design for human prescription drug and biological products. The guidance provides sponsors of new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and prescription drugs marketed without an approved NDA or ANDA with a set of principles and recommendations for ensuring that critical elements of product container labels and carton labeling are designed to promote safe dispensing, administration, and use of the product. This guidance finalizes the draft guidance of the same title issued on April 24, 2013.

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–2013–D–0401 for ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Irene Z. Chan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD 20993–0002, 301–796–3962; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Safety Considerations for Container Labels and Carton Labeling Design To Minimize Medication Errors.'' In Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), Congress reauthorized and expanded the Prescription Drug User Fee Act (PDUFA) program for fiscal years 2008 through 2012. As part of the performance goals and procedures set forth in an enclosure to the letter from the Secretary of Health and Human Services referred to in section 101(c) of FDAAA, FDA committed to certain performance goals and procedures. (See *https://wayback.archive-it.org/7993/20171115015358/https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*). In that letter, FDA stated that it would use fees collected under PDUFA to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed that, after public consultation with academia, industry, other stakeholders, and the general public, the Agency would publish a draft guidance describing practices for naming, labeling, and packaging drugs and biologics to reduce medication errors. On June 24 and 25, 2010, FDA held a public workshop and opened a public docket (Docket No. FDA–2010–N–0168) to receive comments on these measures. After reviewing public input, a draft guidance was subsequently published by FDA in April 2013 (Docket No. FDA–2013–D–0401). Additional public comment was provided through a docket. This guidance presents FDA's final recommendations and conclusions after having reviewed this public input and considered information learned through evaluating postmarketing medication errors.

This guidance is intended to help entities holding NDAs, BLAs, and ANDAs and entities manufacturing or distributing prescription drugs marketed without an approved application. This guidance focuses on safety aspects of the application holder's container label and carton labeling design, and it provides a set of principles and recommendations for ensuring that critical elements of a product's container label and carton labeling are designed to promote safe dispensing, administration, and use of the product.

The recommendations in this guidance are intended to provide best practices on how to improve the container label and carton labeling of prescription drug and biological products to minimize medication errors. The guidance also provides examples of container label and carton labeling designs that resulted in postmarketing medication errors.

This guidance finalizes the draft guidance entitled ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors'' published in the **Federal Register** of April 24, 2013 (78 FR 24211). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include revisions to clarify language that some commenters considered unnecessarily restrictive and emphasize that labeling statements should be considered within a risk framework. In addition, the guidance has been updated to reflect regulations and policy that have been established since the draft guidance was

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