in occupational safety and health; (2) address currently relevant needs in the fields of occupational safety and health either alone or in conjunction with other known activities inside and outside of NIOSH; and (3) produce their intended results in addressing important research questions in occupational safety and health, both in terms of applicability of the research findings and dissemination of the findings.

Purpose: The BSC, NIOSH National Firefighter Registry Subcommittee (the Subcommittee) provides scientific expertise to the Board of Scientific Counselors that will assist the BSC in advising the Director about NIOSH's efforts to establish and operate the National Firefighter Registry. Specifically, the Subcommittee advises the Board of Scientific Counselors on the following issues pertaining to the ''required strategy'' as mandated by the Firefighter Cancer Registry Act of 2018 (the Act): (1) Increase awareness of the National Firefighter Registry and encourage participation among all groups of firefighters; (2) consider data collection needs; (3) consider data storage and electronic access of health information; and (4) in consultation with subject matter experts, develop a method for estimating the number and type of fire incidents attended by a firefighter. Additional responsibilities of the Subcommittee are to provide guidance to the BSC regarding inclusion and the maintenance of data on firefighters as required by the Act.

Matters To Be Considered: The agenda for the meeting addresses issues related to: The National Firefighter Registry project overview and status, protocol updates, enrollment system demonstration, project launch, and future planning applicable to stakeholders. Agenda items are subject to change as priorities dictate.

The agenda is posted on the NIOSH website at *https://www.cdc.gov/niosh/bsc/nfrs/.*

Public Participation

Written Public Comment: Written comments will be accepted per the instructions provided in the **ADDRESSES** section above. Comments received in advance of the meeting are part of the public record and are subject to public disclosure. They will be included in the official record of the meeting. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written comments received by August 30, 2022, will be provided to the Subcommittee prior to the meeting.

Oral Public Comment: The public is welcome to participate during the public comment period, from 3:15 p.m. to 3:30 p.m., EDT, September 6, 2022. Each commenter will be provided up to 5 minutes for comment. A limited number of time slots are available and will be assigned on a first-come, first-served basis. Members of the public who wish to address the Subcommittee are requested to contact Designated Federal Officer for scheduling purposes (see **FOR FUTHER INFORMATION CONTACT** above).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–17476 Filed 8–12–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1633]

Soliciting Public Comment on Appendix A of the Food and Drug Administration's July 2018 Guidance Entitled ''Abbreviated New Drug Application Submissions—Amendments To Abbreviated New Drug Applications Under Generic Drug User Fee Amendments;'' Notice; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the establishment of a docket to solicit comments on the content of Appendix A in the July 2018 guidance for industry entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA'' (ANDA Amendments Guidance). We are soliciting comments on the content of Appendix A. The Agency is taking this action to fulfill the Agency's commitment described in section IX.B. of the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 Commitment Letter (GDUFA III Commitment Letter).

DATES: Either electronic or written comments must be submitted by October 14, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2022–N–1633 for ''Soliciting Public Comment on Appendix A of FDA's July 2018 Guidance Entitled 'ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA'; Notice; Establishment of a Public Docket; Request for Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA I) into law. GDUFA must be reauthorized every 5 years so FDA can continue to assess and collect GDUFA fees, and was most recently authorized in the FDA Reauthorization Act of 2017, Public Law 115–52 (GDUFA II) on August 18, 2017, for fiscal years 2018–2022. In a joint effort in anticipation of GDUFA reauthorization in 2022, the Agency and representatives from the generic drug industry negotiated the draft agreement reflected in the GDUFA III Commitment Letter.[1] Specifically, FDA agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on the GDUFA program established and enhanced through previous authorizations. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitating timely access to quality, affordable, safe, and effective generic medicines.

In the GDUFA III Commitment Letter, FDA agreed to issue a **Federal Register** notice on or before April 30, 2023, to solicit public comment on the content of Appendix A in the ANDA Amendments Guidance.[2] The ANDA Amendments Guidance describes amendment classifications (''major'' or ''minor'' amendments) and categories (amendments subject to ''priority'' or ''standard'' review goals) and explains how amendment submission classification and category may affect an amendment's performance goal date. The guidance superseded a 2001 guidance entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications'' (2001 guidance), which contained descriptions of major and minor amendments; however, these descriptions were considered during GDUFA II negotiations and were incorporated into the GDUFA II Commitment Letter.[3] Accordingly, the ANDA Amendments Guidance incorporates the descriptions from the 2001 guidance, and provides further description of these amendments, including general descriptions and examples of the types of deficiencies that would classify an applicant's response to these deficiencies as a major or minor amendment. Appendix A in the ANDA amendments guidance (Appendix A: Major Deficiencies) is a non-exhaustive list of examples of deficiencies that the FDA may consider major.

With this notice, FDA is seeking comments on the examples of major deficiencies listed in Appendix A of the ANDA amendments guidance, as well as comment on how any proposed revisions to that list could be beneficial to industry in understanding ANDA amendment classification.

II. Paperwork Reduction Act of 1995

This notice contains no new collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft 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: August 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17414 Filed 8–12–22; 8:45 am]

BILLING CODE 4164–01–P

[1] See ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027,'' available at *https://www.fda.gov/media/153631/download.*

[2] See the guidance for industry entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA,'' available at *https://www.fda.gov/media/89258/download.*

[3] See ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022,'' available at *https://www.fda.gov/media/101052/download.*