• 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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Dunn, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4214, Silver Spring, MD 20993–0002, 240–402–8985; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications.'' This draft guidance provides information to applicants on how FDA intends to use alternative tools to assess manufacturing facilities identified in an NDA, an ANDA, a BLA, or a supplement to any of these types of applications. As part of the negotiations relating to the reauthorization of BsUFA and PDUFA, FDA agreed to issue guidance on the use of alternative tools to assess manufacturing facilities named in pending applications and to incorporate best practices from the use of such tools during the COVID–19 pandemic. This draft guidance, within the context of approval and licensure decisions by FDA, describes the use of alternative tools to assess manufacturing facilities identified in an NDA, an ANDA, or a BLA to establish that these facilities meet the applicable requirements, including under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) and either section 505 of the FD&C Act (21 U.S.C. 355) or section 351 of the PHS Act (42 U.S.C. 262).

During the pandemic, FDA expanded its use of alternative tools to evaluate drug manufacturing facilities to support regulatory decision making when facility inspections were not feasible. Given the success of these innovative approaches, FDA intends to continue risk-based use of these alternative tools and to apply certain virtual technological capabilities within a specific inspectional context defined within this draft guidance. When used in advance or in lieu of preapproval inspections (PAIs) and prelicense inspections (PLIs) or to support PAIs and PLIs, the appropriate use of these approaches will help FDA maintain operational flexibility to support timely facility evaluations and application decisions.

This draft guidance is being issued 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 ''Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice requirements and electronic records and signatures have been approved under OMB control numbers 0910–0139 and 0910–0303, respectively. The collections of information in 21 CFR part 314 pertaining to the submission of NDAs and ANDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to BLAs have been approved under OMB control number 0910–0338.

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/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: September 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20590 Filed 9–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0917]

In-Home Disposal Systems for Opioid Analgesics; Request for Information; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is reopening the comment period for the notice entitled ''In-Home Disposal Systems for Opioid Analgesics; Request for Information'' published in the **Federal Register** of April 4, 2023. FDA is reopening the comment period to allow interested persons additional time to develop and submit comments.

DATES: FDA is reopening the comment period on the notice published April 4, 2023 (88 FR 19959). Either electronic or written comments must be submitted by November 6, 2023.

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 November 6, 2023. 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–2023–N–0917 for ''In-Home Disposal Systems for Opioid Analgesics; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 4, 2023 (88 FR 19959), FDA published a notice requesting information and comments that will assist the Agency in assessing whether in-home disposal products can be expected to meet the public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make in-home disposal products available to patients under a risk evaluation and mitigation strategy. The Agency requested information and comments on the issues that were discussed at the public workshop convened by the National Academies of Sciences, Engineering, and Medicine's Forum on Drug Discovery, Development, and Translation entitled ''Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics'' on June 26 and 27, 2023. Interested persons were originally given until August 28, 2023, to submit comments on in-home disposal systems for opioid analgesics.

FDA is reopening the public docket to allow interested persons additional time to submit comments. We note that there is a listening session on October 5, 2023, with federally recognized American Indian and Alaska Native tribes on the safe disposal of opioid analgesics. The Agency believes that reopening the comment period for an additional 45 days will allow adequate time for interested persons to submit comments without significantly delaying Agency decision-making on these important issues. FDA is reopening the comment period for 45 days, until November 6, 2023.

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20516 Filed 9–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.