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

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to obtain 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 (REMS). The Agency would like information and comments on the issues to be discussed at the public workshop convened by the National Academies of Sciences, Engineering and Medicine's (NASEM'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.

DATES: Submit either electronic or written comments, data, or information by August 28, 2023.

ADDRESSES: You may submit data and comments as follows. Please note that late, untimely filed comments will not be considered. The docket will close on August 28, 2023. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 28, 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:

I. Background

Nonmedical use,[1] accidental exposure, and overdose associated with prescription opioid analgesics remain a serious problem in the United States. Patients commonly report having unused opioid analgesics after treatment of acute pain, such as pain following surgical procedures (Refs. 1 and 2). Opioid analgesics prescribed to treat chronic pain conditions can also result in unused drugs. When not properly disposed, these opioid analgesics provide opportunities for nonmedical use, accidental exposure, and overdose. Accordingly, FDA's efforts to address the opioid crisis include a focus on encouraging appropriate disposal of unused opioid analgesics (for additional information, see the *Federal Register* notice "Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments" (April 21, 2022, 87 FR 23869; Sec. I., Background (Docket No. FDA-2022-N-0165)). The Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271), signed into law on October 24, 2018, provides FDA authorities to address the opioid crisis. The SUPPORT Act authorized FDA to require through a REMS that a safe disposal packaging or safe disposal system be dispensed to certain patients with opioids or other drugs that pose a serious risk of abuse or overdose if, among other things, FDA determines that such safe disposal packaging or system may mitigate such risks and is sufficiently available (21 U.S.C. 355-1(e)(4)).

II. Topic for Public Input

This request for information is part of FDA's ongoing efforts to determine 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 these

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[1] We use the term "nonmedical" in this document to refer to misuse of a drug, abuse of a drug, or both. "Misuse" is the intentional use, for therapeutic purposes, of a drug in a manner other than prescribed. "Abuse" is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects.

products available to patients under a REMS. On June 26 and 27, 2023, NASEM's Forum on Drug Discovery, Development, and Translation will hold a public workshop entitled "Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics."

The purpose of the workshop is to provide an opportunity for stakeholders to examine in-home drug disposal systems, with a focus on removing unused opioid analgesics from the home. The workshop will feature invited presenters and discussions to explore the types of in-home drug disposal options, other than mail-back envelopes, which could be used to remove unused opioid analgesics from the home. This will include, among other things, a discussion of the scientific, behavioral, health equity, and policy considerations for assessing the safety, use, and effectiveness of in-home drug disposal options.

Workshop participants will address questions about the methods (e.g., sequestration, adsorption, absorption) used in in-home disposal options for rendering opioids unavailable for nonmedical use, assuming the in-home disposal product is used as intended. In addition, workshop participants will discuss approaches and methodologies needed to evaluate the safe and correct use of in-home drug disposal options in real-world settings. Finally, workshop participants will consider potential strategies for encouraging and assessing the development and use of in-home drug disposal options. Additional meeting information, including the briefing document, agenda, and presentations, will be made available at https://www.nationalacademies.org/our-work/advancing-regulatory-science-for-defining-and-evaluating-in-home-safe-disposal-systems-a-workshop closer to the workshop date. FDA is seeking information and comments on the topics discussed at this meeting.

III. References

The following references are not on public display at https://www.regulations.gov because they have copyright restriction. Some references may be available at the website address, if listed. The references below are available for viewing only at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

FDA has verified the web addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Bicket, M.C., J.J. Long, P.J. Pronovost, et al., "Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review," *JAMA Surgery*, vol. 152(11), pp. 1066-1071, 2017, https://doi.org/10.1001/jamasurg.2017.0831.

2. Mallama, C.A., C.A. Greene, A.A. Alexandridis, et al., "Patient-Reported Opioid Analgesic Use After Discharge from Surgical Procedures: A Systematic Review," *Pain Medicine*, vol. 23(1), pp. 22-44, 2022, https://doi.org/10.1093/pm/pnab244.

Dated: March 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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