considered generally recognized as safe and effective and not misbranded.

As we develop any final order on this topic, FDA will consider comments on the applicability of Executive Order 14192, in particular, on any costs or cost savings.

The proposed order can be viewed in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* The proposed order contains instructions for commenting on the proposed order. Comments to the proposed order must be submitted electronically to the Federal eRulemaking Portal *https://www.regulations.gov.*

OTC Monographs@FDA provides a resource for the public to view administrative orders (proposed, final, and interim final orders) for OTC Monograph Drugs and view OTC Monographs. In the future, OTC Monographs@FDA will facilitate the public's ability to submit, search, and view comments and data for proposed, final, and interim final orders.

II. Paperwork Reduction Act of 1995

The proposed order is issued under section 505G(b)(2) of the FD&C Act. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the PRA is not required for collections of information, if any, in a final order issued under section 505G of the FD&C Act that results from this proposed order.

Dated: June 2, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10253 Filed 6–4–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1358]

Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry titled ''Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' The purpose of this guidance is to provide recommendations for how requestors can comply with the requirements described in the Proposed Administrative Order (OTC000038) titled Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs (hereinafter referred to as C001).

DATES: Submit either electronic or written comments on the draft guidance by October 3, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2025–D–1358 for ''Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' 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 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. 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: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 301–796–6341, *CDER-Quality-Policy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled ''Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' This draft guidance is being issued pursuant to section 505G(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(c)) as a companion to proposed C001, which specifies the requirements for making a minor dosage form change from a tablet or capsule to a chewable tablet, orally disintegrating tablet, or film for over-the-counter (OTC) monograph drugs without an order issued under section 505G(b) (21 U.S.C. 355h(b)) amending an applicable monograph to add the new dosage form (or otherwise finding such change to be generally recognized as safe and effective).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), which was enacted on March 27, 2020. As described in section 505G(c)(3) of the FD&C Act (21 U.S.C. 355h(c)(3)), the Agency will issue one or more administrative orders under 505G(c) specifying requirements for making a minor dosage form change, together with guidance for applying such requirements to specific dosage forms. In the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures, commonly referred to as the OMUFA Commitment Letter (the document can be accessed at *https://www.fda.gov/media/106407/download?attachment,* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download?attachment*), FDA and industry agreed to specific performance goals and timelines for various OTC monograph drug activities conducted by the Agency. In the OMUFA Commitment Letter, FDA committed to issuing a proposed administrative order regarding minor changes to solid oral dosage forms (along with a draft guidance) specifying requirements for determining when such changes are permissible without the issuance of an order finding the new dosage forms to be generally recognized as safe and effective (when the applicable OTC monograph does not already provide for these types of changes). Issuance of proposed C001 and this draft guidance fulfills this commitment.

C001 proposes requirements for a minor change in dosage form of an OTC monograph drug from a capsule or tablet to a chewable tablet, orally disintegrating tablet, or film when the drug meets the requirements under sections 505G(c) of the FD&C Act, C001, and all other applicable requirements. This draft guidance provides recommendations for how requestors can comply with the requirements described in C001. Specifically, this guidance provides recommendations for complying with the order to demonstrate that a minor change in solid oral dosage form from a tablet or capsule to a chewable tablet, orally disintegrating tablet, or film will not affect the safety or effectiveness of a drug. It also provides recommendations for complying with the order to demonstrate that such a change will not materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product. These recommendations include procedures for demonstrating that the active ingredient has high solubility and high permeability and that the drug product is rapidly dissolving. The draft guidance also provides additional dosage form–specific considerations for the dosage forms that are subject to C001 and recommendations regarding recordkeeping requirements.

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 ''Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' 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, administrative orders, and regulations.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act (21 U.S.C. 355h(o)), the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) does not apply to collections of information made under section 505G of the FD&C Act. This draft guidance is issued pursuant to section 505G(c), which requires FDA to issue guidance for applying the requirements in an administrative order to specific dosage forms. Information collection in this draft guidance for this purpose is covered under section 505G(o). Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for this collection of information.

In addition, this draft guidance refers 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 relating to current good manufacturing practice requirements have been approved under OMB control number 0910–0139. The collections of information for OTC monograph drug products have been approved under OMB control number 0910–0340.

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: June 2, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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