pursuant to section 505G(c) will affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug product in comparison to a suitable reference product. This proposed order specifies these requirements for when the minor dosage form change is from a tablet or capsule dosage form to one of the following dosage forms: chewable tablet, ODT, or film. The proposed order, if finalized, will permit these minor changes in the dosage form of OTC monograph drugs that are both highly soluble and highly permeable and in conformity with the requirements of the order, section 505G(c) of the FD&C Act, and other applicable requirements, without the issuance of a separate order under section 505G(b) of the FD&C Act to amend the applicable OTC monograph to add the new dosage form or otherwise find the new dosage form to be GRASE.

FDA plans to separately consider minor changes in dosage form under section 505G(c) of the FD&C Act from tablets or capsules to chewable tablets, ODTs, or films for OTC monograph drugs with active ingredients that are not both highly soluble and highly permeable (*i.e.,* drugs that have: (1) low solubility and high permeability; (2) high solubility and low permeability; and (3) low solubility and low permeability). In the future, FDA plans to issue a separate notice announcing a request for information that would seek comments on minor changes in dosage form under section 505G(c) of the FD&C Act for these types of drugs. Any comments on minor changes in solid oral dosage forms under section 505G(c) for OTC monograph drugs that are not both highly soluble and highly permeable that are submitted to the docket for this proposed order (OTC000038) will be considered outside the scope of this proposed order and will not be considered as part of a finalization of proposed order OTC000038.

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

This proposed order contains no collections of information that are subject to clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The proposed order is issued under section 505G(c) of the FD&C Act. Under section 505G(o) of the FD&C Act, the PRA does not apply to collections of information made under section 505G of the FD&C Act. Moreover, the labeling changes proposed in this order are excluded from the definition of ''collection of information'' under the PRA by 5 CFR 1320.3(c)(2), which states that ''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 this definition.'' 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. 2025–10252 Filed 6–4–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1359]

Over-the-Counter Monograph Condition B001: Single-Unit or Unit-Dose Containers for Over-the-Counter Monograph Drugs in Orally Disintegrating Tablet and Film Dosage Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on its website of the proposed administrative order (proposed order) (OTC000037) entitled ''Over-the-Counter Monograph Condition B001: Single-Unit or Unit-Dose Containers for Over-the-Counter Monograph Drugs in Orally Disintegrating Tablet and Film Dosage Forms.'' This proposed order, if finalized, will require over-the-counter (OTC) monograph drugs in an orally disintegrating tablet (ODT) or film dosage form that are subject to specified OTC monographs to be packaged in single-unit or unit-dose containers.

DATES: Submit electronic comments on the proposed administrative order by August 4, 2025.

ADDRESSES: The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 4, 2025. Please note that late, untimely filed comments will not be considered. Instructions for submitting comments are contained in the proposed order OTC000037, which can be viewed in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* Comments must be submitted electronically.

FOR FURTHER INFORMATION CONTACT: Shannon Liu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–2484.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing the proposed order OTC000037 pursuant to section 505G(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(2)), which permits the Agency to issue an administrative order at its initiative. Section 505G(b)(7) of the FD&C Act (21 U.S.C. 355h(b)(7)) explicitly permits an administrative order issued under section 505G(b)(2) to include requirements for the packaging of a drug to encourage use in accordance with labeling, such as through requirements for unit-dose packaging, requirements for products intended for use by pediatric populations, and requirements to reduce risk of harm from unsupervised ingestion.

This proposed order, if finalized, establishes packaging requirements for OTC monograph drugs in an ODT or film dosage form that are subject to an OTC monograph listed in the proposed order. In addition to meeting the applicable OTC monograph conditions and other applicable requirements under section 505G of the FD&C Act, these OTC monograph drugs in ODT or film dosage forms would, if the proposed order is finalized, be explicitly required to be packaged in single-unit or unit-dose containers in order to be

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]

BILLING CODE 4164–01–P

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.