includes: clarification that we are not asking sponsors to submit all raw data, addition of a link to CVM's Data Quality Resources website, and clarification on file format for data submitted in our eSubmitter platform. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 2024.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Raw Data for Safety and Effectiveness Studies.'' 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

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 part 514 have been approved under 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10262 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–1360]

Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs

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) (OTC000038) entitled ''Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs.'' This proposed order, if finalized, will permit minor dosage form changes, *i.e.,* from tablets or capsules to chewable tablets, orally disintegrating tablets, or films, of over-the-counter (OTC) monograph drugs that are in conformity with the requirements of the order, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and other applicable requirements, without the issuance of a separate order amending an applicable OTC monograph to add the new dosage form or otherwise finding the new dosage form to be generally recognized as safe and effective (GRASE).

DATES: Submit electronic comments on the proposed administrative order by October 3, 2025.

ADDRESSES: The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 3, 2025. Please note that late, untimely filed comments will not be considered. Instructions for submitting comments are contained in the proposed order OTC000038, 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 announcing the availability of the proposed order OTC000038 pursuant to section 505G(c) of the FD&C Act (21 U.S.C. 355h(c)), which specifies FDA's proposed requirements for making a minor change in the dosage form of certain OTC monograph drugs, without the issuance of a separate order under section 505G(b) of the FD&C Act amending an applicable monograph to add the new dosage form or otherwise finding the new dosage form to be GRASE. Section 505G(c) of the FD&C Act applies to drugs described in section 505G(a)(1) or (a)(2) of the FD&C Act or that are otherwise the subject of an order under section 505G(b). More specifically, section 505G(c)(3) of the FD&C Act directs FDA to issue one or more administrative orders specifying the requirements for determining whether a minor dosage form change to a drug made by a sponsor pursuant to section 505G(c) of the FD&C Act 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 in comparison to a suitable reference product.

This proposed order also fulfills a commitment made by FDA under the terms of 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* and the document with the updated goal dates for fiscal years 2021 to 2025 can be accessed at *https://www.fda.gov/media/146283/download*). The OMUFA commitment letter specifies goals and timelines mutually agreed upon by FDA and industry with respect to various OTC monograph drug activities conducted by FDA. FDA committed to issuing a proposed order outlining key requirements to clarify which types of minor changes to solid oral dosage forms are permissible without the issuance of an order finding the new dosage forms to be GRASE (when the applicable OTC monograph does not already provide for these types of changes), together with related draft guidance (FDA is publishing notice of the draft guidance for industry ''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'' elsewhere in this issue of the **Federal Register**).

Consistent with section 505G(c)(3) of the FD&C Act, FDA proposes to specify the requirements for determining whether a particular minor dosage form change to a drug made by a sponsor

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]

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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