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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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.

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