4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-7606]

Process for FDA Data Requests to Inform Certain Over-the-Counter Monograph Drug Activities; Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the process for FDA to issue Data Requests for the submission of data from the public to help inform certain future over-the counter (OTC) monograph drug activities, including development of FDA-initiated proposed orders to modify conditions described in an OTC monograph. FDA is issuing this notice to inform the public and interested parties of the process that FDA is implementing to issue these Data Requests.

DATES: The announcement of the process is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Michael Boblitz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-002, 301-837-7651.

SUPPLEMENTARY INFORMATION:

I. Background

Section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) sets forth the framework for the regulation of OTC monograph drugs.[1] OTC monograph drugs may be marketed without a new drug application approved under section 505 of the FD&C

[1] Per section 744L(5) of the FD&C Act, an ‘‘OTC monograph drug’’ is defined as a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act, as well as other applicable requirements. An OTC monograph set forth in a final order under section 505G for a therapeutic category of drugs describes the conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which OTC monograph drugs within such therapeutic category are generally recognized as safe and effective (GRASE) for their intended use. The conditions described in an OTC monograph may be amended, revoked, or otherwise modified in accordance with a final order issued under section 505G(b) of the FD&C Act.[2] Either FDA or a requestor[3] can initiate the order process in section 505G(b). A requestor can initiate the order process by submitting an OTC monograph order request[4] with respect to certain drugs, classes of drugs, or combinations of drugs.[5] FDA may opt to announce Data Requests described in this notice to help inform certain future OTC monograph drug activities, including development of FDA-initiated proposed orders.

II. Procedures for Data Requests

When FDA seeks data and information from the public to help inform certain OTC monograph drug activities, such as development of a potential FDA-initiated proposed order to add a GRASE condition to an OTC monograph, FDA intends to announce a Data Request on the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/. The Data Request will include instructions on the submission of the data and information to FDA, including with respect to confidential information. The Data Request will also include instruction on how submissions may be viewed by the public. Additionally, interested parties and the public generally may sign up for FDA email mailing lists on the OTC Monographs@FDA portal to

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[2] Under section 505G(b)(1) of the FD&C Act, "The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be…(i) not subject to section 503(b)(1) [i.e., nonprescription]; and (ii) generally recognized as safe and effective under section 201(p)(1)".

[3] Under section 505G(q)(3) of the FD&C Act (21 U.S.C. 355h(q)), the term *requestor* refers to any person or group of persons marketing, manufacturing, processing, or developing an OTC monograph drug.

[4] An OTC monograph order request means a request for an order submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

[5] See section 505G(b)(5) of the FD&C Act.

receive messages and alerts when FDA announces a Data Request described in this notice or other OTC monograph drug activities. FDA also intends to list future planned Data Requests of the type described in this notice in its Annual Forecast for Planned Monograph Activities, which is a nonbinding list issued each year of planned OTC monograph drug activities that FDA intends to initiate over the ensuing 3 years. It is available on the OTC Monographs@FDA portal.

This notice is not intended to announce the process with respect to requests for data to inform finalization of GRASE determinations for drugs described in section 505G(a)(3) of the FD&C Act (GRASE finalizations). The process FDA will use to request data packages to support GRASE finalizations will be announced in a future notice before any related crowdsourcing on that process, as described in the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures – Fiscal Years 2026–2030 document (OMUFA II commitment letter)[6]. In addition, this notice is unrelated to the following:

- any future *Federal Register* notice to solicit stakeholder feedback on test methods described in OTC monographs and the Test Methods Crowdsourcing described in section I.H of the OMUFA II commitment letter;
- the submission of relevant data and other information by a requestor (including a group of joint requestors) in an OTC monograph order request (OMOR)[7] submitted under section 505G(b)(5) of the FD&C Act;
- the requirement under section 505G(b)(2) of the FD&C Act to provide for a public comment period on a proposed order; and
- the requirement under section 505G(b)(4) of the FD&C Act, addressing certain expedited safety orders, to provide for a public comment period on an interim final order.

[6] The OMUFA II commitment letter can be accessed at https://www.fda.gov/media/182750/download.
[7] OTC monograph order request (OMOR) is defined in section 744L(7) of the FD&C Act for purposes of user fees supporting FDA activities under section 505G of the FD&C Act and refers to a request for FDA to issue an administrative order pursuant to a request submitted under section 505G(b)(5) of the FD&C Act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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