4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-1188]

Over-the-Counter Monograph Order Requests: Format and Content; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Over-the-Counter Monograph Order Requests (OMORs): Format and Content." This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an over-the-counter (OTC) monograph order request (OMOR) and identifies relevant guidance documents to assist requestors in preparing their OMORs.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2023-D-1188 for "Over-the-Counter Monograph Order Requests (OMORs): Format and Content." 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: Trang Tran, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Over-the-Counter Monograph Order Requests (OMORs): Format and Content." This draft guidance is intended to assist requestors in preparing OMORs for submission to FDA under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h). This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an OMOR and identifies relevant guidance documents to assist requestors in preparing their OMORs.

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 required by section 505G(l) of the FD&C Act, this draft guidance, when finalized, will discuss the format and content of data submissions, specifically OMORs, to FDA.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document "Over-the-Counter Monograph User Fee Program Performance Goals and Procedures--Fiscal Years 2018-2022," 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 updated goal dates for fiscal years 2021-2025 can be accessed at https://www.fda.gov/media/146283/download). In the OMUFA Commitment Letter, FDA committed to issuing this draft guidance under specific timelines.

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 "Over-the-Counter Monograph Order Requests (OMORs): Format and Content." 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.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. The information collections described in this guidance implement the following provisions of section 505G:

(1) Section 505G(b)(5) of the FD&C Act, which allows submission of administrative orders, OMORs, initiated at the request of a requestor.

(2) Section 505G(b)(6) of the FD&C Act, which allows requestors to provide certain information regarding safe nonprescription product marketing and use as a condition for filing a generally recognized as safe and effective request.

(3) Section 505G(d) of the FD&C Act confidentiality of information submitted to the Secretary, which requires FDA to make information submitted in support of an OMORs available to the public no later than the date of the proposed order unless it meets certain limitations on public availability.

(4) Section 505G(j) of the FD&C Act, which requires that all submissions under section 505G must be in electronic format.

(5) Section 505G(l)(1) of the FD&C Act, which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to section 505G.

(6) Section 505G(1)(2) of the FD&C Act, which requires FDA to issue guidance that specifies the format and content of data submissions to the Secretary under section 505G.

(7) Section 505G(1)(3) of the FD&C Act, which requires FDA to issue guidance that specifies the format of electronic submissions to the Secretary under section 505G.

Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for these collections of information. In addition, this guidance refers to previously approved FDA

collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for OTC monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910-0340. The information collections for submission of new drug applications and abbreviated new drug applications in 21 CFR part 314 are approved under OMB control number 0910-0001. The collections of information used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses under 21 CFR part 25 have been approved under OMB control number 0910-0322.

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: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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