Providing Over-the-Counter Monograph Submissions in Electronic Format

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Trang Tran at (240) 402-7945.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

September 2022
Electronic Submissions

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Providing Over-the-Counter Monograph Submissions in Electronic Format Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information on providing electronic submissions to FDA under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) (hereafter referred to as over-the-counter (OTC) monograph submissions). This guidance is intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On March 27, 2020, the president signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act added section 505G to the FD&C Act. Section 505G reforms and modernizes the framework for the regulation of OTC monograph drugs. OTC monograph drugs may be marketed without new drug applications approved under section 505 of the FD&C Act if they meet the requirements of section 505G of the FD&C Act, as well as all other applicable requirements.

The CARES Act also added section 744M to the FD&C Act authorizing FDA to assess and collect user fees dedicated to OTC monograph drug activities.

[1] This guidance has been prepared by the Office of Nonprescription Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

Section 505G(j) of the FD&C Act requires that all submissions under section 505G (also referred to herein as "OTC monograph submissions") must be in electronic format. Examples of OTC monograph submissions include, but are not limited to, the following:

- OTC monograph order requests (OMORs)[2]
- Public comments to a proposed administrative order (issued either on FDA's initiative[3] or at the request of one or more requestors[4]) or interim final administrative order[5]
- Formal meeting requests and meeting packages[6]
- Formal dispute resolution requests related to a final administrative order[7]
- Administrative hearing requests related to a final administrative order[8]
- Responses to record requests by FDA relating to minor changes[9]
- Updates to drug listing information for the drug in accordance with section 510(j) of the FD&C Act when a change is made to a drug subject to section 505G.[10]

Section 505G(l)(3) of the FD&C Act requires FDA to issue guidance that specifies the format of electronic submissions under section 505G.[11] This guidance is being issued to fulfill this requirement.

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[2] See section 744L(7) of the FD&C Act, which defines an OTC monograph order request as a request submitted under section 505G(b)(5) of the FD&C Act.

[3] See section 505G(b)(1) and (2) of the FD&C Act.

[4] See section 505G(b)(1) and (5) of the FD&C Act.

[5] See section 505G(b)(4) of the FD&C Act.

[6] See section 505G(h), (l)(1) of the FD&C Act. See also the draft guidance for industry *Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs* (February 2022). When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[7] See, for example, section 505G(b)(2)(A)(iv)(III) of the FD&C Act.

[8] See, for example, section 505G(b)(3) of the FD&C Act.

[9] See section 505G(c)(2)(A) of the FD&C Act.

[10] See section 505G(e) of the FD&C Act.

[11] See section 505G(l)(3) of the FD&C Act.

III. SUBMITTING ELECTRONIC OTC MONOGRAPH SUBMISSIONS

OTC monograph submissions must be submitted electronically,[12] and, depending on the type of submission, should be submitted to FDA through the CDER NextGen Portal[13] or as specified by instructions in the OTC Monographs@FDA portal.[14,15]

OMORs, formal meeting requests and meeting packages, formal dispute resolution requests related to a final administrative order, administrative hearing requests related to a final administrative order, and responses to record requests by FDA relating to minor changes should be electronically submitted through the CDER NextGen Portal.

Data, information, and public comments to a proposed order or interim final order should be electronically submitted as specified by instructions in the OTC Monographs@FDA portal.

Submissions related to updating drug listing information should be electronically submitted consistent with the Electronic Drug Registration and Listing System (eDRLS) process and instructions.[16]

A. CDER NextGen Portal

1. Presubmission Considerations for CDER NextGen Portal

FDA's CDER NextGen Portal is a website for users to report information to the FDA, including certain OTC monograph submissions. Submitters need to have a CDER NextGen Portal account to submit OTC monograph submissions in electronic format through the CDER NextGen Portal. For information on how to set up an account and other related questions, visit CDER NextGen Portal website and click the FAQs link.[17]

[12] See section 505G(j) of the FD&C Act.

[13] CDER NextGen Portal is accessible at https://edm.fda.gov.

[14] OTC Monographs@FDA portal is accessible at https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.

[15] For OTC monograph submissions not explicitly described in this guidance, interested parties should check the OTC Monographs@FDA portal to see whether FDA has provided instructions on how they should be submitted electronically. If FDA has not provided instructions on how an OTC monograph submission not explicitly described in this guidance should be submitted, contact FDA at druginfo@fda.hhs.gov.

[16] Electronic Drug Registration and Listing System web page is accessible at https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions).

[17] CDER NextGen Portal is accessible at https://edm.fda.gov.

2. Transmitting Electronic Submissions in CDER NextGen Portal

CDER's NextGen Portal provides for the secure submission of OTC monograph submissions. CDER NextGen Portal does not provide a means to edit OTC monograph submissions once they have been submitted.

For information related to file size limitations for OTC monograph submissions, contact CDER at EDMSupport@fda.hhs.gov.

3. Receipt Date for CDER NextGen Portal Submissions

The receipt date for an electronic OTC monograph submission is determined only after the files in the submission have been validated (e.g., following successful file size verification and virus scan) in CDER NextGen Portal.[18] After an OTC monograph submission has been successfully submitted, a confirmation will appear in the portal. Submitters will also receive an email notification from the portal confirming the submission is successful and establishing the submission's receipt date. The receipt date for an OTC monograph submission is the date on which the request is deemed to have arrived at FDA. The receipt date should not be confused with the date of FDA's subsequent decision to file a request. Additional information on receipt dates for electronic submissions is available in the guidance for industry *Providing Regulatory Submissions in Electronic Format — Receipt Dates* (February 2014).[19]

4. Contact Information

For questions related to providing electronic submissions in CDER NextGen Portal according to the recommendations in this guidance, contact CDER electronic submission coordinator at EDMSupport@fda.hhs.gov.

B. OTC Monographs@FDA Portal

FDA's OTC Monographs@FDA portal is a website that provides a resource for the public to view proposed, final, and interim final orders for OTC monograph drugs. This portal also facilitates the submission of comments and data from the public for proposed and interim final administrative orders.

Data and information submissions in response to an FDA data request and public comments to a proposed order or interim order should be electronically submitted as specified by the instructions in the OTC Monographs@FDA portal.

[18] CDER NextGen Portal is similar to the Electronic Submissions Gateway. Therefore, the receipt date policy for submissions submitted via CDER NextGen Portal is identical to the policy for receipt of electronic submissions via the Electronic Submissions Gateway.

[19] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Instructions on how to submit data and information submissions will be found in the FDA data request posted in the OTC Monographs@FDA portal.

Instructions on how to submit public comments to a proposed order or interim final order are contained in the proposed order or interim final order posted in the OTC Monographs@ FDA portal.

C. Electronic Drug Registration and Listing System

Sponsors electronically submitting updates to drug listing information for a drug subject to section 505G in accordance with section 510(j) of the FD&C Act based on changes they have made to the drug should follow the general process for providing updated listing information and instructions that be can be found on FDA's Electronic Drug Registration and Listing System (eDRLS) web page.[20]

IV. SUBMITTING CONFIDENTIAL INFORMATION IN AN OTC MONOGRAPH SUBMISSION

The OTC monograph order process is generally a public process. Under this order process, section 505G(d) of the FD&C Act limits the information that can be confidentially submitted to FDA in connection with proceedings on an order.

The CDER NextGen Portal provides instructions for identifying confidential information included in OTC monograph submissions and submitted electronically to the CDER NextGen Portal. Proposed orders or interim final orders posted in OTC Monographs@FDA portal provide instructions for how to submit public comments, on proposed orders or interim final orders, that include confidential information.

[20] Available at https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions. See also 21 U.S.C. 360 and 21 CFR part 207.