Providing Over-the-Counter Monograph Submissions in Electronic Format

Guidance for Industry

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

July 2024
Electronic Submissions

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TABLE OF CONTENTS

Contains Nonbinding Recommendations

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

This guidance represents 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 the Food and Drug Administration (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 of the FD&C Act 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 (CDER) 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[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]

Submissions related to updating drug listing information must be electronically submitted[16] and should be submitted consistent with the Electronic Drug Registration and Listing System process and instructions.[17]

A. CDER NextGen Portal

FDA's CDER NextGen Portal is a website for users to submit information to FDA, including certain OTC monograph submissions. The following OTC monograph submissions should be electronically submitted through the CDER NextGen Portal[18]:

- OTC monograph order requests
- Formal meeting requests and related meeting correspondence (e.g., meeting packages)
- Formal dispute resolution requests related to a final administrative order
- Administrative hearing requests related to a final administrative order
- Responses to record requests by FDA relating to minor changes

1. Presubmission Considerations for the CDER NextGen Portal

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

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

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

[14] The 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 the submission 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] See sections 510(p)(1) and 505G(j) of the FD&C Act.

[17] The 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.

[18] In the future, the CDER NextGen Portal may be expanded to enable the submission of additional OTC monograph submissions. FDA intends to inform stakeholders about the expansion of the CDER NextGen Portal to enable additional OTC monograph submissions as these updates occur.

set up an account and other related questions, visit the CDER NextGen Portal website and click the FAQs link.[19]

After submitters create a CDER NextGen Portal account, CDER NextGen Portal will ask submitters to take certain steps before they can submit an OTC monograph submission. Submitters will need to establish a monograph file (MGF) before submitting an OTC monograph submission through the CDER NextGen Portal. The CDER NextGen Portal is structured so that a new MGF is needed for each new OTC monograph submission. To establish an MGF, submitters need to submit a Pre-Assignment Request through the CDER NextGen Portal. After submitters submit the Pre-Assignment Request, an MGF number is assigned. Once an MGF number is assigned, submitters can submit a new OTC monograph submission through the CDER NextGen Portal.

For additional information about submitting a Pre-Assignment Request, refer to the CDER NextGen Portal Reference Guide titled Over-the-Counter (OTC) Monograph Pre-Assignment Request.[20]

For additional presubmission considerations for submitting OTC monograph submissions through the CDER NextGen Portal, submitters should refer to the appropriate CDER NextGen Portal Reference Guide for the corresponding OTC monograph submission.[21]

2. Transmitting Electronic Submissions in the CDER NextGen Portal

CDER's NextGen Portal provides for the secure submission of OTC monograph submissions.

For information related to file naming conventions, acceptable file formats, and file size limitations for OTC monograph submissions submitted through the CDER NextGen Portal, refer to the appropriate CDER NextGen Portal Reference Guide for the corresponding OTC monograph submission.[22]

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 the CDER NextGen Portal.[23] After an OTC monograph submission has been successfully

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

[20] Available in the CDER NextGen Portal, accessible at https://edm.fda.gov.

[21] Available in the CDER NextGen Portal, accessible at https://edm.fda.gov.

[22] Available in the CDER NextGen Portal, accessible at https://edm.fda.gov.

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

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 and has been validated. 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).[24]

4. Contact Information

For questions related to providing electronic submissions in the CDER NextGen Portal according to the recommendations in this guidance, contact the 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.

The following OTC monograph submissions should be electronically submitted as specified by the instructions in the OTC Monographs@FDA portal:

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

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

Instructions on how submitters should 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

When a change is made to a drug subject to 505G of the FD&C Act, submissions related to updating drug listing information must be submitted in accordance with section 510(j) of the FD&C Act and must be electronically submitted.[25] Such submissions should follow the general

[24] 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.

[25] See section 510(p) of the FD&C Act.

process for providing updated listing information and instructions that can be found on FDA's Electronic Drug Registration and Listing System web page.[26]

IV. ELECTRONICALLY 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 remain confidential after submission to FDA in connection with a proposed order.

A. CDER NextGen Portal

The CDER NextGen Portal provides instructions for electronically submitting information in an OTC monograph submission.[27] Although the CDER NextGen Portal accepts certain OTC monograph submissions in electronic format, the public cannot view information submitted by a submitter in the CDER NextGen Portal. However, if the submitted information is required to be made publicly available pursuant to section 505G(d) of the FD&C Act or other applicable federal law governing disclosure of information, FDA will make such information publicly available consistent with those provisions.

B. OTC Monographs@FDA portal

FDA intends for proposed orders and interim final orders posted in the OTC Monographs@FDA portal to include information related to the confidentiality of data and information in public comments submitted on proposed orders or interim final orders.

[26] The 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. See also 21 U.S.C. 360 and 21 CFR part 207 (for requirements related to drug registration and listing). More information also is available at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls.

[27] For information on confidential information with respect to certain OTC monograph submissions, see the draft guidances for industry *Over-the-Counter Monograph Order Requests (OMORs): Format and Content* (April 2023) and *Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs*. When final, these guidances will represent the FDA's current thinking on these topics.