

OTC Drug Review Process | OTC Drug Monographs

OTC MONOGRAPHS @ FDA (<https://dps.fda.gov/omuf>)

A resource for the public to view OTC Monographs and their Administrative Orders (Proposed, Final, and Interim Final). OTC Monographs@FDA also facilitates the ability for the public to submit, search, and view comments and data for Proposed and Interim Final Administrative Orders, except if otherwise specified.

There are two regulatory pathways to bring a nonprescription drug to market in the US -- the drug application process and the Over-the-Counter (OTC) Drug Review (OTC drug monograph) process.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136) was signed into law. The CARES Act added section 505G to the Federal Food, Drug and Cosmetic (FD&C) Act. Section 505G reforms and modernizes the framework for the regulation of OTC monograph drugs.

OTC monograph drugs may be marketed without an approved drug application under section 505 of the FD&C Act if they meet the requirements of section 505G of the FD&C Act, including the OTC drug monograph (OTC monograph) and other applicable requirements.

An OTC drug monograph establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is generally recognized as safe and effective (GRASE) for its intended use.

Under the process set forth in section 505G(b) of the FD&C Act, FDA has the authority to issue an administrative order (proposed and final) that adds, removes, or changes generally recognized as safe and effective (GRASE) conditions for an OTC drug monograph. Either FDA or a requestor can initiate the administrative order process.

Administrative Order Process

The administrative order process to add, remove, or change a monograph can be initiated by either industry (any person or group of persons marketing, manufacturing, processing, or developing a drug) or FDA.

Industry-Initiated Order

Industry can request that FDA issue an administrative order by submitting an OTC monograph order request (OMOR) to FDA. FDA will determine if the OMOR is acceptable for filing. If FDA accepts the OMOR for filing, FDA will review the OMOR and issue a proposed order. The public will receive at least 45 calendar days to submit comments on the proposed order. After reviewing and considering the comments, FDA will issue a final order which is the final OTC monograph. All final orders are subject to dispute resolution, an administrative hearing, and judicial review.

FDA-Initiated Order

FDA issues a proposed order. The public will receive at least 45 calendar days to submit comments on the proposed order. After reviewing and considering the comments, FDA will issue a final order which is the final OTC monograph. All final orders are subject to dispute resolution, an administrative hearing, and judicial review.

Expedited Procedure for FDA-Initiated Order

FDA can initiate an expedited procedure for issuing an administrative order when:

- a drug poses an imminent hazard to public health; or
- a change in the labeling of a drug, class of drugs, or combination of drugs is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug

Under the expedited procedure, FDA issues an interim final order that becomes effective before the public has an opportunity to comment. After issuing the interim final order, the public will receive at least 45 calendar days to submit comments on the interim final order. FDA then issues a final order taking into account public comment.

Meet with FDA

FDA encourages all potential drug sponsors and requestors of OTC monograph drugs to examine the information available from FDA's website related to the OTC Drug Review process.

FDA issued a draft guidance titled “[Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs \(/media/164758/download?attachment\)](#)” regarding formal meetings between FDA and sponsors or requestors of OTC monograph drugs (hereinafter referred to as “meeting requesters”). Requests for formal meetings between FDA and sponsors or requestors of OTC monograph drug formal meetings (and their related meeting correspondences such as meeting packages) should be submitted via the [CDER NextGen Portal \(https://cdernextgenportal.fda.gov/Login_CDER?ec=302&startURL=%2Fs%2F\)](#).

For general question on the OTC Drug Review process, email druginfo@fda.hhs.gov (<mailto:druginfo@fda.hhs.gov>).

Additional Information

- [Over-the-Counter \(OTC\) Drug Review | OTC Monograph Reform in the CARES Act \(/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act\)](#)
- [Historical Status of OTC Rulemakings \(/drugs/over-counter-otc-nonprescription-drugs/historical-status-otc-rulemakings\)](#)
- [Small Business Assistance: Frequently Asked Questions on the Regulatory Process of OTC Drugs \(/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-regulatory-process-over-counter-otc-drugs\)](#)