- There are many different types of establishment listing and certification procedures for establishments that produce human food products. Please share your experience with other countries' establishment listing, certification, and registration requirements.
- FDA requires those on export lists to reapply regularly if they wish to remain listed. Do reapplicants experience any challenges with the renewal process? If you have experienced challenges, how were those challenges resolved?
- For those included on export lists, please describe any challenges you have experienced with exporting human food products included on the export lists.
- FDA is authorized to collect up to $175 per certification for each company and its human food products that FDA certifies through inclusion on an export list. For those that would be charged a fee, do you have any specific suggestions about how FDA should approach the implementation of fees? Please provide details relating to any suggestions you might have.

Dated: November 4, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26040 Filed 11–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4734]

Amending Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on its website of the proposed administrative order (proposed order) (OTC000036) entitled ''Amending Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.'' This proposed order, if finalized, will amend Final Administrative Order OTC000026, to remove orally administered phenylephrine hydrochloride and phenylephrine bitartrate in an effervescent dosage as nasal decongestant active ingredients because they are not effective.

DATES: Submit electronic comments on the proposed administrative order by May 7, 2025.

ADDRESSES: The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 7, 2025. Please note that late, untimely filed comments will not be considered. Instructions for submitting comments are contained in the proposed order OTC000036, which can be viewed in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* Comments must be submitted electronically.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0578.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this proposed order OTC000036 to amend the requirements for cold, cough, allergy, bronchodilator, and antiasthmatic drug products for over-the-counter (OTC) human use, as currently described in Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (OTC Monograph M012), as set forth in the Final Administrative Order OTC000026. FDA is issuing the proposed order pursuant to section 505G(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(1)).

OTC Monograph M012 describes the conditions under which OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products are generally recognized as safe and effective. OTC Monograph M012 is set forth in Final Administrative Order OTC000026, which was deemed established by section 505G(b)(8) of the FD&C Act, and was effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136) on March 27, 2020. The conditions described in OTC Monograph M012, as set forth in final order(s), may be amended, revoked, or otherwise modified in accordance with the procedures of section 505G(b) of the FD&C Act.

The proposed order, if finalized, will amend the conditions described in OTC Monograph M012 as set forth in the Final Administrative Order OTC000026 to remove orally administered phenylephrine hydrochloride and phenylephrine bitartrate in an effervescent dosage from OTC Monograph M012 as nasal decongestant active ingredients because they are not effective. This proposed order also includes minor stylistic and formatting changes to improve the readability and presentation of OTC Monograph M012, including removing references to historical **Federal Register** documents because OTC monographs are no longer modified through notice and comment rulemaking.

The proposed order can be viewed in the OTC Monographs@FDA portal at *https://dps.fda.gov/omuf.* The proposed order contains instructions for commenting on the proposed order. Comments to the proposed order must be submitted electronically to the Federal eRulemaking Portal at *https://www.regulations.gov.*

OTC Monographs@FDA provides a resource for the public to view Administrative Orders (Proposed, Final, and Interim Final Orders) for OTC Monograph Drugs and view OTC Monographs. In the future, OTC Monographs@FDA will facilitate the public's ability to submit, search, and view comments and data for Proposed and Interim Final Orders.

II. Paperwork Reduction Act of 1995

The proposed order is issued under section 505G(b)(1) of the FD&C Act. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) (Chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the PRA is not required for collections of information, if any, in a final order issued under section 505G of the FD&C Act that results from this proposed order.

Dated: October 31, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25910 Filed 11–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.