disability networks will be analyzed to determine resource needs in legal subject matter areas and systems development topics indicated by the target audience. The information collected will be used by ACL and the Contract Officer Representative (COR) to tailor the resource support provided through the NCLER contract to the ongoing and emerging priority needs of aging and disability networks.

To determine effectiveness in reaching intended target audience: The NCLER contract and OAA section 420(a) requires that support services are provided to specific groups of providers within the aging and disability networks. The audience in need of comprehensive resource support through NCLER includes a broad range of legal, elder rights, and aging/disability services professionals, advocates, and organizations. These include legal assistance providers, legal assistance developers, long-term care ombudsmen, adult protective services, state units on aging, area agencies on aging, aging and disability resource centers, and others involved in protecting the legal rights of older persons. The information collected on requests for resource support from aging and disability networks will be reviewed and analyzed by ACL and the COR to determine whether the appropriate target audiences are requesting and receiving resource support through NCLER. ACL and the COR will also use the information to determine if the use of resource support through NCLER by intended target audiences is increasing at a set percentage annually in compliance with contractual performance indicators.

To determine the quality of legal resource support provided: The NCLER contract performance indicators require that the quality of resource support provided be measured through voluntary recipient feedback. The Contractor is required to assure that a set percentage of recipients of resource support responding to evaluative tools will rate the quality of the assistance provided as good to excellent. The Contractor will have processes in place to ensure the integrity of information received by target audience. The information collected on quality of resource support received by target audiences will be analyzed by ACL and the COR to determine whether minimum performance standards are met and whether necessary actions need to be taken to improve the quality of resource support provided through NCLER.

To determine the usefulness of resource support provided: The NCLER contract performance indicators require the anticipated usefulness of resource support provided be measured through voluntary recipient feedback. The Contractor is required to assure that a set percentage of recipients of resource support responding to evaluative tools will agree or strongly agree that the assistance provided contributed to the successful resolution of a specific legal issue.

The information collected on the usefulness of resource support received by target audiences will be analyzed by ACL and the COR to determine whether minimum performance standards are met and whether necessary actions need to be taken to improve the practical usefulness of resource support provided through NCLER.

The data collected will be reviewed by the COR on monthly basis through contractually required monthly reports provided by NCLER. Review of the data will be the focus of monthly calls with the Contractor to guide ongoing program improvements and adjustments as directed by the COR. The data will also be incorporated into the contractually required Summary of Stakeholder Input Document (SSID) designed to guide the ongoing evolution and improvement of NCLER into subsequent contract option years. The data will also be compiled in a final annual report provided by the Contractor and reviewed by the COR against the QUASP to determine contractual compliance.

This IC does not collect demographic data from grantees receiving programs and services funded by HHS. This includes guidance specific to the collection of sexual orientation and gender identity items that align with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, and Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation, and the updated Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (effective March 28, 2024).

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimates of Burden: Burden calculation for each category of information:

Respondent/data collection activity	Number of respondents	Minutes per response	Annual burden hours
Resource Support Requests	80	2	2.53
Legal Training, Case Consultation, Technical Assistance Requests-User Satisfaction.	14,000	2	397
Total	14,080	4 min 39 sec	399.53 hours

Dated: November 4, 2024.

Maura Calsyn,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–25931 Filed 11–7–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4776]

Export Lists for Human Food: Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) invites comment relating to the listing requirements of other countries and FDA's approach to facilitating U.S. industry compliance with these requirements through the issuance of export certification for human food products provided in the form of lists (export lists).

DATES: Submit either electronic or written comments on the request for

information by January 7, 2025 to ensure that the Agency considers your comment.

ADDRESSES: You may submit comments in the following way:

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–2024–N–4776 for ''Export Lists for Human Food: Request for Information.'' 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.'' We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Peter Fricke, Human Foods Program, Office of International Engagement, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2307.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 801(e)(4)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e)(4)(A)), any person who exports a food, drug, animal drug, or device may request that FDA:

- certify in writing that the exported food, drug, animal drug, or device meets the requirements of section 801(e)(1) or section 802 of the FD&C Act (21 U.S.C. 382) or
- certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of the FD&C Act upon a showing that the food, drug, or device meets the applicable requirements of the FD&C Act.

If we issue a written export certification within 20 days, we may then charge a fee up to $175 for each certification (see section 801(e)(4)(B) of the FD&C Act). The statute also authorizes us to issue certifications on a basis and in a form that we determine to be appropriate and expressly mentions publicly available listing as a form of certification (see section 801(e)(4)(C) of the FD&C Act).

Regarding export certification for human foods, FDA issues various types of export certificates and certification in the form of export lists. (For more information on the types of export certificates we issue for human foods, see *https://www.fda.gov/food/exporting-food-products-united-states/food-export-certificates.*) To request inclusion on an export list, parties can use our Export Listing Module, which can be accessed through our website at *https://www.access.fda.gov/.* Certification in the form of export lists is an intensive process due to both the development of a mutually acceptable listing procedure with foreign countries and then the maintenance of the export lists. FDA provides such certification to help ensure foreign market access for U.S. exporters of FDA-regulated food products. FDA export certification provides information concerning a product's regulatory status, often including information about the establishment in which the product was manufactured, packaged, prepared and/or held, based on available information at the time FDA issues the certification (including, as appropriate, attestations provided by the person seeking the export certification). In many cases, foreign governments are seeking official assurance that products exported from the United States to their countries can be marketed in the United States or that the products meet specific U.S. regulations, for example, as applicable, current good manufacturing practice regulations. A foreign government may also require export certification as part of the process to register or import a product into that country.

FDA does not currently charge firms to be included on export lists for human food, but as authorized by the FD&C Act, we are considering charging fees for our export list services to offset our costs. As of August 2024, we provide certification in the form of export lists that cover 19 categories of products for six destinations: Chile, China, the European Union, Saudi Arabia, Taiwan, and the United Kingdom.

To better inform the continuing development of our export list program for human foods, we invite public comment on the following:

- 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.