4164-01-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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the request for information, published in the *Federal Register* of November 8, 2024. In that notice, FDA invited 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). We are extending the comment period to allow interested persons additional time to submit comments on FDA's approach.

DATES: FDA is extending the comment period announced in the notice for request for information published November 8, 2024 (89 FR 88785). Electronic or written comments must be submitted by February 21, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 21, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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, those filed in a timely manner (see ADDRESSES), 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: Lauren Ferguson Baham, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 8, 2024, we published a notice announcing a request for information. The notice explained our export

certification for human foods and that FDA is considering charging firms fees for our export list services to offset our costs. The notice also explained that, 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. Further, the notice explained that, to better inform the continuing development of our export list program for human foods, we invited 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 (89 FR 88785).

The docket for public comments was scheduled to close January 7, 2025.

We have received several requests to extend the comment period. In general, the requests explain that FDA's consideration to charge fees for its export list services to offset costs is a significant change from current Agency practice that will take firms time to fully evaluate the impacts of the proposed changes and to provide substantive comment that details firms' experiences and challenges with export lists. The requests also note that the comment period overlaps with the holiday season.

We have considered the requests and are extending the comment period until February 21, 2025. We believe that the extension will allow adequate time for interested persons to submit comments.

Dated: December 18, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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