

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-6729]

U.S.-Origin Statements on Seafood; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “U.S.-Origin Statements on Seafood.” The draft guidance, when finalized, will provide examples of U.S.-origin statements in seafood product labeling that FDA would consider to be truthful and not misleading.

DATES: Submit either electronic or paper comments on the draft guidance by December 28, 2026 to ensure that FDA considers your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments, including attachments, submitted electronically 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 want 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 want to be made available to the public, submit the comment as a paper submission as specified in “Paper Submissions” and “Instructions.”

Paper Submissions

Submit paper comments by mail/hand delivery/courier to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2026-D-6729 for “U.S.-Origin Statements on Seafood.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” be 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 want to be made publicly available, submit your comment only as a paper submission. You should submit two copies total. In one copy, include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in our consideration of comments. In the second copy, redact/black out the claimed confidential information; this copy will be available for public viewing and will be posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not want your name and contact information to be made publicly available, provide this information on the cover sheet and not in the body of your comments and 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 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 or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit paper requests for single copies of the draft guidance to the Division of Food Labeling/Office of

Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to help that office process your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Pedro Cruz, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Deirdre Jurand, Office of Regulations and International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

With regard to the proposed collection of information: Chris Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-2093, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “U.S.-Origin Statements on Seafood.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In general, FDA-regulated food products may bear truthful and not misleading statements, including U.S.-origin statements, in their labeling. This draft guidance, when finalized, will provide examples of U.S.-origin statements in seafood product labeling that we would consider truthful and not misleading.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, as relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

U.S.-Origin Statements on Seafood: Draft Guidance for Industry

OMB Control Number 0910-0381—Revision

This draft guidance, if finalized, would provide examples of U.S.-origin

statements in seafood product labeling that FDA would consider truthful and not misleading. These products include both single-ingredient seafood and the seafood components of multi-ingredient foods. Respondents that choose to use U.S.-origin statements on their seafood products should be able to substantiate the statements to show that they are truthful and not misleading.

Description of respondents: Respondents to this information collection are manufacturers, packers, and distributors of seafood. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RELABELING BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs ¹
Relabel for U.S.-origin statement	1,150	5	5,750	1	5,750	\$7,664,750

¹ There are no operating and maintenance costs associated with this collection of information.

The burden estimates in Table 1 are based on FDA's institutional experience and knowledge of the seafood industry. We assume there are two scenarios where seafood products would be relabeled. The first scenario would involve a product currently labeled with a U.S.-origin statement, where the respondent chooses to remove such statement. The second scenario would involve a product not currently labeled with a U.S.-origin statement, where the respondent chooses to add such statement. Both instances involve relabeling. Because these statements are voluntary, we do not know how many respondents would make labeling changes. For the purpose of this analysis, we estimate that there are about 2,300 domestic manufacturers, packers, and distributors of seafood. Further, we estimate that approximately half of them (1,150 firms) would change their labels to either add or remove a U.S.-origin statement. We estimate that each firm would change 5 labels with each label taking about an hour to revise for an annual third-party disclosure burden of 5,750 hours (1,150 firms × 5 labels × 1 hour). Based on our experience with other relabeling policies, we estimate relabeling each product that respondents choose to relabel would cost \$1,333 assuming a three-year adoption period. That calculates to an annual capital cost of \$7,664,750 (\$1,333 × 5,750 labels). This

is the cost of designing revised labels and incorporating them into the manufacturing process. We believe that this would be a one-time capital cost.

This estimate also does not include maintaining records to substantiate a statement as respondents already maintain records as a usual and customary business practice.

III. Electronic Access

You may obtain the draft guidance at: <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval: Public Comment Request; Organ Procurement and Transplantation Network Board of Directors and Committee Member Applications and Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than October 27, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent