



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0099]

Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; and Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Final Guidance for Industry

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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry.” The draft guidance, when finalized, will explain FDA’s current thinking on a number of issues related to the labeling of food allergens, including requirements in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act). The draft guidance is a revision of a currently issued guidance, entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4).” This draft guidance is not final nor is it in effect at this time. In addition, the FDA is announcing availability of a final guidance entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Final Guidance for Industry.” This final guidance

includes the questions and answers from the currently issued guidance that remain substantively unchanged.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF THE PUBLICATION OF THE *FEDERAL REGISTER*].

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 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-2022-D-0099 for “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry.” 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.

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

Submit written requests for single copies of the guidance documents to the Office of Nutrition and Food Labeling, Division of Food Labeling and Standards, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: *With regard to the guidance documents:* Carol D'Lima, Office of Nutrition and Food Labeling (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Denise See, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

*With regard to the proposed collection of information:* Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

FALCPA (Pub. L. 108-282) was enacted in August 2004 and, in part, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by defining the term “major food allergen” and requiring that the presence of any major food allergen be declared on the labels of FDA-regulated foods. FALCPA defined a major food allergen as milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans and as a food ingredient that contains protein derived from these foods (section 201(qq) (21 U.S.C. 321(qq)) of the FD&C Act). In addition, the FASTER Act (Pub. L. 117-11) was enacted in April 2021 and, in part, amended the definition of major food allergen in the FD&C Act to include sesame, effective January 1, 2023. Exceptions to the definition include highly refined oil derived from a major food allergen and any ingredient derived from the highly refined oil. FALCPA also amended the FD&C Act to include provisions to request an exemption from the food allergen labeling requirements through a petition process when a food ingredient is demonstrated to not cause an allergic response that poses a risk to human health or through a notification process when processing of a food ingredient results in the removal of the allergenic protein (section 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7))).

Since the passage of FALCPA, FDA has received numerous questions about food allergen labeling requirements. To explain FALCPA’s requirements as well as FDA’s current thinking on issues relating to the regulation of food allergens, on October 5, 2005, FDA issued the first edition of a guidance entitled “Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004.” We subsequently updated the guidance in December 2005 (Edition 2), April 2006 (Edition 3), and October 2006 (Edition 4).

FDA is issuing a draft guidance for industry entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5).” The draft guidance is a revision of Edition 4 originally entitled

“Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004” that contains revised and new questions and answers relating to food allergens, including questions and answers about FALCPA and the FASTER Act. Editorial changes, such as renumbering and organizational changes have also been made in this revision.

FDA is also issuing a final guidance, “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5),” that contains the questions and answers from Edition 4 that remain unchanged, with the exception of editorial changes such as renumbering and organizational changes, and are therefore being reissued as final guidance. FDA is issuing the draft guidance document to receive comments on the new or revised questions and answers, and, as appropriate, will move the questions and answers to the final guidance document, after reviewing comments and incorporating any changes to the questions and answers, when appropriate. Note that some questions and answers that were in Edition 4 of the final guidance have been withdrawn and moved to the draft guidance document if FDA determined that the question and answer should be revised in some respect and reissued in draft for comment. For ease of reference, a question retains the same number when it moves from the draft guidance to the final guidance and we use the term “RESERVED” after some question numbers, where appropriate, to facilitate this process.

We are issuing these guidance documents consistent with our good guidance practices regulation (21 CFR 10.115). The guidance documents do not establish any rights for any person and are not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance (“Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)”) responds to new questions about food allergen labeling requirements, including, but not limited

to, the labeling of sesame, milk, eggs, incidental additives, highly refined oils, dietary supplement products, and certain specific packing and labeling situations (e.g., individual units within a multiunit package). For example, we have included draft questions and answers regarding our historical interpretation of the terms “milk” and “eggs;” for purposes of the definition of a “major food allergen” under section 201(qq) of the FD&C Act and complying with the food allergen labeling requirements of the FD&C Act. FDA has historically interpreted “milk” as milk from the domesticated cow and “eggs” as eggs from the domesticated chicken.

Since 2005, when we first issued the guidance document, there have been changes in our laws as well as in the overall food marketplace. For example, in 2011, the FDA Food Safety Modernization Act (FSMA) added new allergen control provisions for major food allergens. We are also aware that, while the market in the United States for milk and eggs from species other than domesticated cows and chickens remains limited, it has increased in recent years. Given that, we are considering whether we should modify our historical interpretations of “milk” and “eggs” for purposes of the definition of “major food allergen” under 201(qq) of the FD&C Act and complying with the food allergen labeling requirements of the FD&C Act as set forth in the guidance document.

For example, for “milk,” we note that our regulation, at 21 CFR 131.110, defines “milk” as the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, and our historical interpretation of “milk” in the context of a major food allergen under the FD&C Act has been consistent with this definition. However, we are aware that foods from ruminant species such as goat’s milk, sheep’s milk and buffalo’s milk are sold or used in human food, and that allergic reactions associated with consumption of milk from other ruminants have been reported in some individuals. While consumption of such foods in the United States is limited, in light of the risk of allergic reactions associated with consumption of milk from other ruminants, we invite comment on whether we should revise our interpretation of

“milk” for this guidance, what a revised interpretation should be, and the potential implications or impact of a revised interpretation.

Similarly, some FDA documents interpret “eggs” as coming solely from chickens, and our historical interpretation in the context of a major food allergen under the FD&C Act has been to consider eggs as coming from chickens. However, we are aware that eggs from various bird species (such as turkey, duck, goose, and guinea) can be purchased and are used as human food. In addition, we are aware that allergic reactions associated with eggs from birds other than chickens have been reported in some individuals. Thus, we invite comment on whether we should revise our interpretation of “eggs” for this guidance, what a revised interpretation should be, and the potential implications or impact of a revised interpretation.

We also have revised several questions and answers to update and clarify information presented in previous editions, including, among other things, questions related to the labeling of tree nuts, fish, and crustacean shellfish. We also invite comments on these draft questions and answers.

## 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.

Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry  
OMB Control Number 0910-0792--Revision

The draft guidance, when finalized, will explain FDA’s current thinking on the labeling requirements in FALCPA and the FASTER Act. The draft guidance will assist food manufacturers to comply with new requirements under the FASTER Act for treating sesame as a major allergen and declaring sesame on the label of food products, effective January 1, 2023.

*Description of respondents:* The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States.

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

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

FD&C Act Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs
403(w)(1) (FALCPA); Review labels to comply with sesame labeling requirements pursuant to the FASTER Act	77,500	1	77,500	1	77,500	0
403(w)(1) (FALCPA); Redesign labels to comply with sesame labeling requirements pursuant to the FASTER Act	775	1	775	16	12,400	\$1,414,375
<b>Total</b>					<b>89,900</b>	<b>\$1,414,375</b>

<sup>1</sup> There are no operating and maintenance costs associated with this collection of information.

We base these estimates from our experience with our food allergen labeling program and our labeling cost model. We estimate that there are approximately 775,000 Universal Product Codes (UPCs) of FDA-regulated foods. Using FDA’s labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 ×10 percent). Thus, we estimate that 77,500 new or reformulated products are sold annually in the United States. Assuming an association of one respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify the need to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 1 percent of the reviewed labels of new or reformulated products, or 775 labels (77,500 × 1 percent) would need to be redesigned to comply with the labeling requirements of the FASTER Act. Assuming an association of one respondent to each of the 775 labels, we estimate that 775 respondents will each redesign one label. Using our labeling cost model, we estimate that it will take an average of 16 hours to complete the administration and internal design work for the redesign of a label to comply with the labeling requirements of the FASTER Act. Consequently, the burden of redesigning the 775 labels of new or reformulated products is 12,400 hours, as reported in table 1, row 2. Thus, the total third-party disclosure burden would be 89,900 hours.

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

FD&C Act Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(w)(6) (FALCPA); petition for exemption for sesame	1	1	1	100	100
403(w)(7) (FALCPA); notification for sesame	1	1	1	68	68
Total					168

<sup>1</sup> There are no operating and maintenance costs associated with this collection of information.

Based on the number of petitions and notifications under FALCPA received in recent years, we estimate that we will receive one additional petition and one additional notification annually for sesame, over the next 3 years. We base our estimate of the average burdens per response reported in table 2 on our experience with the existing FALCPA petition process. We estimate that a petition would take, on average, 100 hours to develop and submit.

The burden of a notification involves collecting documentation that a food ingredient does not pose an allergen risk. Either we can make a determination that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409 of the FD&C Act (21 U.S.C. 348), or the respondent would submit scientific evidence demonstrating that the ingredient when manufactured as described does not contain allergenic protein. Based on the existing FALCPA notification process, we estimate that the average time to prepare and submit a notification for sesame is approximately 68 hours. Thus, the total annual reporting burden would be 168 hours over the next 3 years.

### III. Electronic Access

Persons with access to the internet may obtain the guidance documents at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/FoodGuidances>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidances.

Dated: November 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.