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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Via https://www.regulations.gov/docket/FDA-2022-D-0099

RE: Docket Number: 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the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry; Draft Guidance*

On behalf of the more than 32 million Americans who suffer directly from life-threatening food allergies, and the 85 million that are directly and indirectly affected by food allergies and/or intolerances to one of the top nine food allergens, FARE (Food Allergy Research and Education) appreciates the opportunity to submit the following comments to the U.S. Food and Drug Administration (FDA) on its draft guidance, *Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5):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*, updating FDA's Q&As to address changes from the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act, P.L. 117-11) and other relevant updates and revisions.

FARE is the nation's leading non-profit engaged in food allergy advocacy as well as the largest private funder of food allergy research. FARE's innovative education, advocacy, and research initiatives transform the future of food allergy through the advancement of new and improved treatments and prevention strategies, effective policies and legislation, and novel approaches to managing the disease.

Overarching FARE Comments

The following outlines FARE's overarching comments on FDA's draft guidance referenced above. Detailed comments follow this section. While FARE believes the revisions to these Q&As adequately address requirements related to the FASTER Act, they should go further in several areas.

While the Food Allergen Labeling and Consumer Protection Act of 2024 (P. L. 108-282) amended the Federal Food, Drug, Cosmetic Act (FD&C Act) by defining the term "major food allergen" at 21 U.S.C. 321(qq) and listed the top eight food allergens requiring labeling and the FASTER Act adds sesame, FARE believes that tables and text should note which law is applicable to foods and food groups where relevant. The Q&As should be clearer to readers to understand which food allergens requiring labeling are from FALCPA and the FASTER Act.

Proposed New Questions

1) Address intentional addition of allergens in lieu of adequate food allergen controls and adherence to good manufacturing practices (GMPs) in light of current industry practice around sesame allergen labeling.
2) Significantly amend Q&A D.17 related to the 2022 edition of FDA's *Food Code* in the final guidance Edition 5 given expanded recommendations related to food allergy awareness, labeling, and information for retail and food service.
3) Explain FDA's draft guidance on evaluation of future food allergens requiring labeling.

Given actions taken by many companies in the U.S. baking sector in response to the FASTER Act, FARE urges FDA to add a Q&A that addresses intentional addition of a food allergen to sidestep adequate food allergen controls required by the Food Safety Modernization Act (FSMA). Those with sesame allergy in our community are being both placed at risk with intentional addition of sesame flour to plain bakery products and having vastly reduced "safe" options to consume by those with sesame allergy. This is critical while stakeholders are awaiting completion and publication of draft guidance for industry, *FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 11: Food Allergen Controls*.

FARE requests that FDA revise Q&A D.17 in the final set of Q&As to reflect the revisions related to food allergens contained in the 2022 edition of FDA's *Food Code*. FARE enthusiastically supports the greatly expanded information and recommendations related to food allergy awareness, labeling, and information for retail and food service. This is critical to communicate to stakeholders.

FARE requests that a new Q&A be added to reflect the draft guidance published in April 2022, Docket Number: FDA-2021-N-0553 – *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders*. This is critical as FDA's draft guidance is in effect now as a way for stakeholders to request evaluation of additional food allergens requiring labeling. See also FARE's comment on Section II, D.12. These additions and revision will make FDA's Q&As more holistic, clearer, and unified.

Technical Changes for Clarity

1) While this draft was published in November 2022, the notations related to the FASTER Act implementation date of January 1, 2023, now need to be changed to past tense in several areas or removed. FARE's detailed comments note where this is needed for specific Q&As.
2) FARE requests that FDA prepare and publish a unified version of Edition 5 of these draft Q&As and those finalized as Edition 5 from Edition 4 as soon as possible after the close of the comment period. This will greatly facilitate use of these Q&As by all stakeholders even though many remain draft (draft Q&As can be noted as such).

Detailed FARE Comments on Draft Q&As, Section II

FARE provides the following comments on the Draft Q&As Edition 5.

- Section II, A General Information
- Section II, A.1 What food and food groups are designated as "major food allergens"?
  - FARE agrees with the narrative above the table and supports this revision's detail.
  - FARE requests that the table in Q&A A.1 be modified by using two footnotes to note which foods and food groups were established by FALCPA and the FASTER Act, respectively. There is no distinction needed about the effective date of the FASTER Act as that date has passed and the FD&C Act section 201(qq) list has been amended and published. FARE offers a recommended revision below. Moving forward, additional food allergens requiring labeling can be added via legislation or a regulatory process following the framework required by the FASTER Act, published as draft guidance in April 2022. As proposed by FARE, the table below would be consistent over time with any new additions to describe with additional footnotes the legislative or regulatory source of a food allergen requiring labeling.

Foods	**Food Groups**
Milk [1]	Fish (such as bass, flounder, cod) [1]
Eggs [1]	Crustacean shellfish (such as crab, lobster, shrimp) [1]
Peanuts [1]	Tree nuts (such as almonds, walnuts, pecans) [1]
Wheat [1]	
Soybeans [1]	
Sesame [2]	

1. Included by FALCPA, 2004.
2. Added by the FASTER Act of 2021.

  - Note: FARE questions why Q&A A.2 in the final Edition 5 does not reflect sesame. FARE requests that question A.2 be updated to reflect the nine (9) foods and food groups requiring labeling under FALCPA and the FASTER Act.
- Section II, B.2 Are food ingredients and finished food subject to the food allergen labeling requirements of the FD&C Act?
  - FARE supports the new question and narrative related to food ingredients and finished foods and the detail.
- Section II, B.3 Do the food allergen labeling requirements of the FD&C Act apply to bulk containers, such as reusable totes or containers of bulk food shipped for further processing, labeling, or repacking between manufacturers, repackers or distributors? Can foods subject to these requirements be exempted through the use of a labeling agreement under 21 CFR 101.100(d)(2)?

- FARE agrees with and supports the narrative and graphic in this new question.

- Section II, B.4 I purchase spice mixes and seasoning mixes that might contain major food allergens in bulk for my food manufacturing facilities. Questions (a) and (b).
  - FARE supports and appreciates this new question and sub-questions and the clarity provided for stakeholders.
- Section II, B.5 How should sesame be declared if it is used in a spice blend?
  - FARE agrees with and supports this new question to provide clarity to those that have included or plan to include sesame in a spice blend. While information specific to sesame in spice or flavor blends is contemporary to 2023 as sesame food allergen labeling is newly required, FARE encourages FDA to consider integrating sesame along with the other eight (8) food allergens requiring labeling in the next Edition, as all food allergens requiring labeling must be addressed the same way when used in spice or flavor blends. Finally, FARE reminds FDA that with these new Q&As, its November 2020 voluntary guidance on labeling sesame as a food allergen now can be rescinded.
- Section II, B.6 Are foods, including dietary supplements, derived from roots, leaves, stems, or bark of the same plant that bears tree nuts subject to the food allergen labeling requirements of the FD&C Act? What about wheatgrass or coconut sugar?
  - FARE supports this new question and its answer that provides clarity on what parts of plants are not required to be labeled in the absence of allergenic proteins in other parts of the plant that produce an allergenic protein.
- Section II, B.8 Which species of "fish" does FDA consider allergenic?
  - FARE agrees with and supports the additional clarity of this new Q&A related to fish and types of fish that are required to be labeled related to food allergen labeling.
- Section II, B.11 Are pet foods or animal feeds subject to the food allergen labeling requirements of the FD&C Act?
  - FARE agrees with the language of this new Q&A related to pet food and animal feed. Further, FARE recommends that FDA consider noting that pet food and animal feed manufacturers could voluntarily provide food allergen information as pet food and animal feed are sometimes consumed by humans.
- Section II, B.12 Are prescription or over-the-counter drugs, cosmetics, or household cleaning products subject to the food allergen labeling requirements of the FD&C Act?
  - FARE supports this new question for the clarity it provides to address frequent questions from our food allergy community beyond FDA's regulatory scope of food.
  - The response could be clearer by mentioning that FDA does not regulate household cleaning products and that most are regulated by the Environmental Protection Agency (EPA). FARE recommends that FDA advance work to provide allergen labeling information in these cases (prescription drugs, and cosmetics) and consider interagency collaboration with EPA on allergen labeling for household cleaning products.

- Section II, B.13 Are foods packaged for airline and other transportation carriers subject to the food allergen labeling requirements of the FD&C Act?
  - FARE enthusiastically supports this new Q&A given the concerns from our food allergy community about food allergen information on foods sold or served on airlines and other transportation carriers.
- Section II, B.14 Are proteins from major food allergens, produced in other sources through the use of genetic engineering, subject to the food allergen labeling requirements of the FD&C Act?
  - FARE appreciates addition of this new question and the wording to cover the genetic engineering example and other technologies included in the "e.g." parenthetical in the answer – "through chemical, biochemical, mechanical, fermentation, or bioengineering." FARE encourages FDA to modify the wording of the question to state "use of genetic engineering 'and other technologies,'" to make the question and answer more durable over time going forward. FARE also notes that post January 1, 2023, the effective date of the FASTER Act is no longer necessary and footnote 1 on page 11 with Q&A B.14 is no longer needed as the requirements and implementation date of the FASTER Act related to food allergen labeling are clearly explained in Section I, Introduction.
- Section II, C. Food Sources
  - In the introduction to this section, FARE agrees with the narrative about the nine (9) food allergens requiring labeling, but the parenthetical about effective date for sesame is no longer needed in the next Edition since we are now beyond the January 1, 2023, statutory deadline for labeling sesame as a major food allergen. As stated earlier, FARE recommends using footnotes as recommended for question A.1.
- Section II, C.1 For purposes of complying with the food allergen labeling requirements of the FD&C Act, what is "milk"?
  - FARE agrees with response to new question C.1 and appreciates the cross reference to question B.14.
- Section II C.2 For purposes of complying with the food allergen labeling requirements of the FD&C Act, what are "eggs"?
  - FARE agrees with response to new question C.2 and appreciates the cross reference to question B.14. Further, as there is cross reactivity to other eggs (e.g., quail) to those with allergy to eggs from the domesticated chicken, FARE believes that the question could provide additional clarity.
- Section II, C.5 For the purpose of complying with the food allergen labeling requirements of the FD&C Act, what are tree nuts?
  - FARE concurs with the revised and updated narrative of Question C.5 and the detailed Table 1 of tree nuts that follows.

- Section II, D. The Food Allergen Labeling Requirements of the FD&C Act
- Section II, D.1 Where are the major food allergens required to be declared on the food label?
  - FARE agrees with and supports the narrative of this new question that specifies requirements and options for food allergen labeling within the ingredient declaration or a "Contains: [X allergen(s)]" statement immediately adjacent to the ingredient declaration.
  - While FARE agrees with the description of the three ways that food allergens can be labeled in Figure 4, FARE does not support the graphic examples in Figure 4 and requests that FDA be clear about the presence of peanut in the "bar." Our rationale is that the inclusion of "Natural Peanut Flavor" could imply endorsement of intentional addition of a food allergen to a "bar" that does not include "Peanut" in its common or usual name. FDA has been clear that it does not support the practice of intentional addition of food allergens to avoid food allergen control measures at the manufacturing level, and should avoid this tacit endorsement. One alternative is to rename the bar "Peanut Flavored Cocoa Crispers Bar."
- Section II, D.3 Under the food allergen labeling requirements of the FD&C Act, must individual units within a multiunit package have a "Contains" statement if each unit is not fully labeled?
  - FARE supports this new Q&A.
- Section II, D.4 If an ingredient that contains a major food allergen is derived from several different species of the allergenic source, does each source need to be declared on the label?
  - FARE supports this new Q&A.
- Section II, D.5 Is the name of the food source required to be declared in the ingredient list more than once if the food contains multiple ingredients that are or contain the same major food allergen?
  - FARE supports this new Q&A.
- Section II, D.8 Lactose is a milk sugar and ghee is a milk-derived fat. As a manufacturer, do I have to declare milk on the label if I use these ingredients?
  - FARE supports this new Q&A and appreciates its clarity and specific examples.
- Section II, D.9 When is a food ingredient derived from a major food allergen not subject to the food allergen labeling requirements of the FD&C Act?
  - FARE supports this new Q&A and appreciates its clarity.
- Section II, D.10 As a manufacturer, how do I label a major food allergen that is also an incidental additive?
  - FARE supports this new Q&A and appreciates its clarity.

- Section II, D.11 As a manufacturer, how do I label oils derived from a major food allergen?
  - FARE supports this new Q&A and appreciates its clarity.
- Section II, D.12 May a "Contains" statement be used to alert consumers to the presence of: (a) food allergens other than the major food allergens defined in the Act; and (b) food substances that are not food allergens to which individuals may be sensitive?
  - FARE supports this new Q&A and appreciates its detail.
  - FARE recommends FDA clarify that preferred industry best practice should be to utilize a "Contains: [x allergen]" statement, over food allergen disclosure in the ingredient declaration alone, when a manufacturer elects to use a "Other Allergen Information: [x allergen]" statement. This will help ensure consumer understanding. Graphic examples of "a" and "b" would greatly assist understanding of this new Q&A, and FDA should consider inclusion of precautionary allergen labeling that also may appear on a label in graphic examples.
  - FARE recommends removing "or in the ingredient list" at the end of D.12(b).
  - FARE believes that following this question FDA should add a new Q&A related to its draft guidance, *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act*. This is an appropriate location to describe the draft guidance related to future food allergens requiring labeling. This will provide a holistic approach to reflect FDA's guidance documents related to food allergy and food allergen labeling.

- **Proposed New Question:** Section II, D.XX How can future food allergens be evaluated for required labeling beyond the existing food allergens defined in the FD&C Act at 21 U.S.C. 321(qq)?

- **Proposed Response**: While this guidance addresses major food allergens requiring labeling defined in the FD&C Act at 21 U.S.C. 321(qq), the FASTER Act required FDA to establish "a regulatory process and framework that would allow for the timely, transparent, and evidence-based modification of the definition of 'major food allergen' included in section 201(qq) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(qq))," In April 2022, FDA issued draft guidance for industry, *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act*. The draft guidance outlines the framework the Agency proposes to use to evaluate evidence, prevalence, severity, and potency toward additional food allergens requiring labeling.

- Section II, D.13 Is a major food allergen that has been unintentionally incorporated in a food as the result of cross-contact subject to the food allergen labeling requirements of the FD&C Act?
  - FARE supports the revision to this question and additional clarity, with one recommendation. FARE believes that the answer would be clearer if it used the

language “precautionary allergen labeling statements” which is more recognized and understood by our food allergy community instead of “allergen advisory statements.”
  - NOTE: FARE requests similar language change in the final guidance Q&A D.14.

- **Proposed New Question**: Section II, D.XX A small amount of a specific major food allergen is **intentionally incorporated** into a food due to the probability of cross-contact during production with this major food allergen. Is this an acceptable practice and is the food item subject to the food allergen labeling requirements of the FD&C Act?

- **Proposed Response**: Any intentional addition of a major food allergen to a food would be subject to the food allergen labeling requirements of the FD&C Act. FDA does not support the practice of intentionally adding a small amount of a major food allergen to a product in cases where there is a potential for cross-contact with a major food allergen. Manufacturers should, whenever possible, follow current good manufacturing practices to prevent allergen cross-contact (21 CFR part 117.10(b), 117.20(b)(2), 117.35 (d)-(f), 117.40(a)-(b) 117.80(a)-(c), 117.93)). Food facilities that are subject to the preventive control requirements in 21 CFR part 117 must conduct a hazard analysis and implement a food safety plan that may include allergen controls for proper labeling and the prevention of allergen cross-contact (see 21 CFR 117.135(c)(2) in the Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food). FDA will be monitoring and evaluating this issue and working with stakeholders to address this concern.

- Section II, D.15 I repackage bulk ingredients for retail sale. Sometimes I package spices and peanuts on the same equipment. Can I label my product “may contain peanuts”?
  - FARE supports this new question that underscores the importance of good manufacturing practices over the use of precautionary allergen labeling statements.
  - As with question D.13, FARE recommends the use of “precautionary allergen labeling statements” instead of “advisory labels.”
- Section II, E Dietary Supplements, Questions E.1 through E.7
  - FARE greatly appreciates this new section and set of questions related to dietary supplements. Many in our food allergy community ask questions about food allergen labeling for dietary supplements in addition to foods.
  - As the responses to these new questions and answers are similar to those related to conventional foods, FARE supports these Q&As and has no further comments.

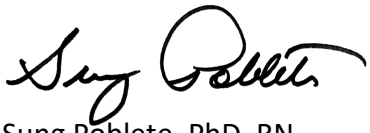
Conclusion

FARE thanks FDA for the opportunity to provide comments on the Agency’s draft guidance on new and revised questions and answers regarding food allergens and food allergen labeling requirements of the FD&C Act. FDA’s Q&As are an extremely important tool for the food and dietary supplement industry and for our food allergy community. To summarize, in addition to specific comments on individual Q&As, FARE is requesting that FDA revise the draft guidance to clarify or include:

- Add a new Q&A related to intentional addition of a food allergen in lieu of food allergen controls required by FSMA.
- Thorough revision to Q&A D.17 in the final guidance Edition 5 detailing the food allergy awareness, labeling, and information for retail and food service content in the 2022 edition of FDA's *Food Code*.
- Add a new Q&A describing its draft guidance, *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act*. These additions will make FDA's Q&As more holistic, clearer, and unified.
- Eliminate the effective date of sesame labeling required by the FASTER Act after the Section I, Introduction, as the top nine food allergens requiring labeling are now codified in 21 U.S.C. 321(qq).
- Issue a single set of the draft and final guidance Q&As for ease of use and reading by all stakeholders.

If you have any questions, please contact Robert Earl, Vice President of Regulatory Affairs, at rearl@foodallergy.org or 571-771-8582. FARE looks forward to our ongoing dialogue with FDA on all food allergy issues.

Respectfully submitted,



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Additional organizations and individuals supporting FARE's comments:

Allergy & Asthma Network

Allergy Advocacy Association

AllergyStrong

Additional organizations and individuals supporting FARE's comments (continued):

American Partnership for Eosinophilic Disorders

Asthma and Allergy Foundation of America

Campaign Urging Research for Eosinophilic Disease

Elijah-Alavi Foundation Inc.

Food Allergy & Anaphylaxis Connection Team (FAACT)

Food Equality Initiative

The FPIES Foundation

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