

April 12, 2022

Claudine Kavanaugh, Ph.D.  
Director, Office of Nutrition & Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740

Re: Clarification Request Compliance Date Under the Food Allergy Safety, Treatment, Education, and Research Act (“FASTER Act”)

Dear Dr. Kavanaugh

On behalf of our members, the undersigned organizations respectfully request that FDA clarify that the compliance date under the Food Allergy Safety, Treatment, Education, and Research Act (“FASTER Act”) means that food products containing sesame must be labeled (i.e., when the label is placed on the product) with a sesame allergen statement on or after January 1, 2023, and that products labeled before January 1, 2023 do not need to be in compliance with the FASTER Act, even if they make their way into commerce after that date. This clarification would be consistent with historical approaches to labeling compliance dates and would be amenable to food industry practices.

The FASTER Act makes sesame a major food allergen, requiring it to be labeled in a manner as prescribed by section 403(w) of the Food, Drug, and Cosmetic Act (“FDCA”), which was added to the FDCA by the Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”). The original compliance date for FALCPA applied to “any food that is labeled on or after January 1, 2006.”<sup>1</sup> This meant compliance was dependent on when the label was placed on the product. While the FASTER Act states that the new sesame labeling requirement “shall apply to any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023,”<sup>2</sup> there is no reason to believe that Congress intended the FASTER Act’s compliance date to be interpreted differently than FALCPA’s or FDA’s general approach to compliance dates for label changes, as described below.

When FDA revised the Nutrition Facts label, it initially provided guidance to manufacturers that they had to display the revised labels when the products were initially introduced into interstate commerce on or after the compliance dates, similar to the language used in the FASTER Act. FDA then revised its guidance to state:

Products that are labeled (i.e., when the label is placed on the product) on or after the applicable compliance date must bear a nutrition label that meets our new nutrition labeling requirements in 21 CFR 101.9 and 21 CFR 101.36. Products that are labeled before the applicable compliance date do not need to be in compliance

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<sup>1</sup> Section 203(d) of FALCPA.

<sup>2</sup> Section 2(b) of the FASTER Act.

with the new labeling requirements, and therefore, do not need to bear the new nutrition label.<sup>3</sup>

That is, compliance was dependent on when the label was placed on the product.

As the agency has recognized, the food supply chain presents unique challenges for implementing label changes. Any changes to labeling and manufacturing often require coordination with third parties, such as labelers and ingredient suppliers, and take many months to implement. For these reasons, FDA has often extended compliance dates for new or revised labeling rules, including the revised Nutrition Facts label and trans fat rules, to give manufacturers more time to comply with their requirements.<sup>4</sup> The agency also establishes uniform compliance dates for new food labeling requirements “to minimize the economic impact of labeling changes.”<sup>5</sup>

Moreover, it can be very difficult to determine in advance what the date of introduction or delivery for introduction into interstate commerce will be, whereas the date a product is labeled is certain. For example, food products that have stable shelf lives of 3 to 24 months, including frozen products, are often manufactured months in advance of introduction or delivery for interstate commerce. Particularly given the supply chain disruptions due to the pandemic, including difficulties in obtaining packaging and labeling materials, food manufacturers need both certainty regarding the compliance date for the FASTER Act and sufficient time to comply. If they must ensure that all products that might be “introduced or delivered for introduction into interstate commerce” on or after January 1, 2023, are compliant, they will need to label these products many months in advance of that date, significantly shortening the time frame for compliance since the passage of the Act.

While the FASTER Act became law last year, FDA has not yet released official guidance on this issue, nor revised its current major food allergen guidance. Thus far, the agency has only made some notes on its website regarding sesame labeling and released an educational video on January 31, 2022. To provide clarity to manufacturers, who need to begin planning their label changes now, we respectfully request that FDA make clear to stakeholders in a public manner that the January 1, 2023, date for compliance with the FASTER Act means that products labeled on or after that date must be labeled in compliance with that Act, and that products labeled before that date need not be compliant, even if they reach the marketplace after that date. This approach would not undermine the benefit of the Act to sesame-allergic consumers, for there will be a mix of products labeled and not labeled as containing sesame on January 1, 2023, under any interpretation. Rather, establishing the compliance deadline as the certain date a

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<sup>3</sup> FDA Guidance, Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (Revised December 2019), <https://www.fda.gov/media/117402/download>.

<sup>4</sup> With the revised Nutrition Facts label, FDA extended the compliance dates because it recognized that there were “significant concerns about [manufacturers’] ability to update all their labels by the compliance dates due to issues regarding (among other things) the need for upgrades to labeling software, the need to obtain nutrition information from suppliers, the number of products that would need new labels, and a limited time for reformulation of products.” 82 Fed. Reg. 45753, 45754. FDA extended the trans fat compliance date “to allow time for food manufacturers...to identify suitable replacement ingredients...and to reformulate and modify labeling of affected products.” 83 Fed. Reg. 23358.

<sup>5</sup> FDA, Uniform Compliance Date for Labeling Regulations, 86 Fed. Reg. 462 (January 6, 2021).

product is labeled would be well-understood by industry and consumers, as it would be consistent with the implementation of other label changes historically.

We thank you in advance for your consideration of this request.

Sincerely,



Cc: Dr. Susan Mayne, CFSAN