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MEMORANDUM

From: Martin J. Hahn
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Re: **Developments Related to the Compliance Date for FDA's Final Determination on the GRAS Status of Partially Hydrogenated Oils**

As the June 18, 2018 compliance date for the Food and Drug Administration's (FDA's) final determination that partially hydrogenated oils (PHOs) are no longer generally recognized as safe (GRAS) approaches, the food industry has undertaken efforts to obtain clarification and flexibility from FDA on several issues related to the compliance date, including (1) clarifying the regulatory status of PHO-containing products on the market after the compliance date, (2) requesting an extension of the compliance date to accommodate the time needed for the agency to respond to the pending food additive petition on PHOs, and (3) seeking enforcement discretion to use existing label inventory that declares PHOs as an ingredient after the ingredient has been removed from product formulations.

This memorandum summarizes recent developments and statements from the agency on these issues. In particular, Dr. Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), recently stated the agency will not consider it necessary to recall PHO-containing products that are in commerce prior to the compliance date and remain on the market past the compliance date, and that FDA will be providing written clarification on this issue in the near future. Additionally, we have learned that FDA is accepting requests for enforcement discretion on a case-by-case basis to allow companies to use existing labels that declare PHOs as an ingredient when the PHO has been removed from the product formulation. And we remain optimistic FDA will extend the compliance period for minor uses of PHOs covered by the food additive petition.

Background

There had been considerable confusion on how FDA is interpreting the compliance date for FDA's determination that PHOs are no longer GRAS – specifically, whether FDA considers the compliance date to apply to the date the food is shipped into interstate commerce, the date the food is manufactured, or the date the food is on the market. The agency made seemingly inconsistent statements on how the compliance date is interpreted, which resulted in some retailers and distributors questioning whether they should accept PHO-containing products after the compliance

date, and whether they must remove such products from store shelves. 1/ In order to address this confusion, a coalition of food industry trade associations 2/ submitted a letter to FDA Commissioner Dr. Scott Gottlieb on April 30, requesting that FDA:

(1) Clarify that the compliance date applies to the date products are shipped into interstate commerce and that PHO-containing products already in commerce on the compliance date will not be considered adulterated and will not need to be removed from store shelves; and

(2) Extend the compliance date for the final determination on the GRAS status of PHOs to provide additional time for the agency to respond to the Food Additive Petition submitted by the industry that would cover certain uses of PHOs in a wide number of food products across the industry and at varying levels.

A subset of these trade associations also requested a meeting with Dr. Gottlieb to discuss the letter.

Recent FDA Statements on the Compliance Date

FDA officials have provided a number of helpful clarifications about the compliance date. On May 3, at the Food and Drug Law Institute (FDLI) annual conference, Dr. Susan Mayne stated clearly and unequivocally that the agency will not require recalls for products containing PHOs that were introduced in commerce prior to the compliance date. 3/ Dr. Mayne noted that the agency is aware of the industry concerns, and stated that FDA will be providing written clarification on this specific issue in the near future. Companies should consult with legal and regulatory counsel to make certain PHO-containing products are introduced into commerce before the compliance date.

Dr. Gottlieb was recently asked during a Senate Appropriations subcommittee meeting about the agency actions on PHOs. Dr. Gottlieb expressed a positive outlook about whether the agency would afford food companies some flexibility in reformulating products in the event FDA issues a food additive regulation authorizing certain uses of PHOs, stating:

1/ Statements from FDA have alternatively suggested that the compliance date applies to the date the food is formulated or manufactured – or that it applies to the date the food is on the market. *See e.g.,* Dr. Susan Mayne, *Protecting Consumers from* Trans *Fat*, June 15, 2015, https://blogs.fda.gov/fdavoice/index.php/2015/06/protecting-consumers-from-trans-fat/ ("…PHOs may no longer be added to food after June 18, 2018, unless they are otherwise approved by FDA."); *see also* Final Determination Regarding Partially Hydrogenated Oils (Removing Trans Fat), last updated Feb. 27, 2018, https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm449162.htm ("By June 18, 2018, human food must no longer contain partially hydrogenated oils…").

2/ Signatories to the letter included the American Bakers Association, American Frozen Food Institute, Food Marketing Institute, Grocery Manufacturers Association, Independent Bakers Association, Institute of Shortening and Edible Oils, International Dairy Foods Association, International Foodservice Distributors Association, National Automated Merchandising Association, National Confectioners Association, National Grocers Association, National Restaurant Association, North American Millers' Association, Peanut and Tree Nut Processors Association, and SNAC International.

3/ *See* Ingrid Mezo, *FDA won't recall foods with PHOs already on shelves, Mayne says,* Food Chemical News, May 8, 2018.

> I think the question relates to whether or not the agency is going to allow a de minimis level of PHOs to persist, because most food manufacturers have reformulated to remove the partially hydrogenated oils. What we do in this area, I can tell you, is going to be mindful that if food manufacturers do need to remove even de minimis levels and have to contemplate reformulating the food, we would provide them with sufficient time to do that and be mindful of the disruption issues and the cost of compliance. 4/

Opportunity to Request Enforcement Discretion to Use up Labels Declaring PHOs as an Ingredient

We have received numerous requests from companies about the possibility of using old label inventory that declares PHOs as an ingredient after the company has reformulated the product to remove PHOs. We contacted FDA staff and they advised the agency will consider requests that FDA exercise enforcement discretion to permit, on a case-by-case basis, the continued use of old labels that declare PHOs as an ingredient after the product has been reformulated to remove PHOs. The agency would need the information, below.

1. The number of labels implicated
2. The dollar value of the labels implicated
3. The expected timeframe to exhaust the labels
4. An example of the existing label
5. An example of the new label

FDA will consider granting such requests where there are no other "major concerns" with the label. Given the fast-approaching compliance date and the likelihood that the agency will receive a large number of requests, we are encouraging companies to submit requests for enforcement discretion as soon as possible.

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We will continue to monitor developments regarding FDA's implementation of its final determination that PHOs are no longer GRAS as the compliance date nears. Unless an extension is granted, the compliance date will be June 18, 2018. Please contact us if you have any questions regarding this or any other matter.

4/ *Hearing to Review the FY2019 Budget Request for the Food & Drug Administration*: Hearing Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, April 24, 2018, *available at* https://www.appropriations.senate.gov/-hearings/hearing-to-review-the-fy2019-budget-request-for-the-food-and-drug-administration.