December 11, 2015

Food and Drug Administration
Office of the Ombudsman
WO Building 32, room 4260
10901 New Hampshire Ave.
Silver Spring, MD 29993
Sent via E-mail: Ombuds@OC.FDA.gov

RE: Information Quality Appeal: Request for Reconsideration of FDA's Response to Request for Correction of Information Disseminated to the Public that Improperly Attributed a Study to the Centers for Disease Control and Prevention (CDC)

Dear Sir or Madam:

I am hereby submitting[1] this request for reconsideration pursuant to the Information Quality Act,[2] as implemented through the Office of Management and Budget (OMB),[3] United States Department of Health and Human Services,[4] and the Food and Drug Administration.[5]

On May 21, 2015, I submitted a Request for Correction (RFC) and on November 6, 2015, via email, I was informed that I would receive FDA's response and received the response shortly thereafter. Both of these documents have been attached to the email in which this document is being sent.

The FDA's response was insufficient and inadequate because it improperly claims "We did not rely on the Paper in making our tentative determination that partially hydrogenated oils are not GRAS." In fact, at the very start of the tentative determination (introduction), it makes it clear that the paper was used in making the tentative determination:

> The current scientific evidence, which is discussed in section IV of this document, identifies significant health risks caused by the consumption of *trans* fat. This evidence includes the opinions of expert panels and the 2005 recommendation of the Institute of Medicine (IOM) to limit *trans* fat consumption as much as possible while consuming a nutritionally adequate diet, recognizing that *trans* fat occurs naturally in meat and dairy

[1] This request is made on my own behalf. All views expressed are solely my own.
[2] Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554.
[3] Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," 67 Fed. Reg. 8452 (Feb. 22, 2002). ("OMB Guidelines") at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf (accessed December 11, 2015).
[4] U.S. Department of Health and Human Services, "HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public," https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public (accessed December 11, 2015).
[5] U.S. Department of Health and Human Services, "HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public," Food and Drug Administration, https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public (accessed December 11, 2015).

> products from ruminant animals and that naturally-occurring *trans* fat is unavoidable in ordinary, nonvegan diets without significant dietary adjustments that may introduce undesirable effects (Ref. 2). **In addition, according to the Centers for Disease Control and Prevention (CDC), elimination of PHOs from the food supply could prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths annually, if the marginal benefits of continuing to remove trans fats from food items remain constant (Ref. 3).** (See accompanying economic analysis for more information on this estimate.) **Given this evidence, we have tentatively determined that there is no longer a consensus among qualified scientific experts that PHOs, the primary dietary source of industrially-produced *trans* fatty acids, are safe for human consumption, either directly or as ingredients in other food products. [Emphasis added]**

The FDA's response goes on to say "that is, we agree that the tentative determination inappropriately attributed the Paper's estimates to the CDC, but the Paper was not used or even mentioned in our safety discussion." As mentioned by the FDA itself right at the start of the tentative determination, the paper was used in making the tentative determination. This, in and of itself, is sufficient to show the FDA's reliance on the paper and provides a clear indication to the public that the paper was critical in reaching the tentative determination. Further, the safety section discusses recent evidence and studies *in general*, without citing all of the sources; so a reader of the safety section, even if reading the section in isolation from the rest of the tentative determination, would not and could not assume that the only research relied upon by the FDA were those studies expressly mentioned in the safety section.

As it relates to FDA's comments regarding the final determination, those points are irrelevant to the concerns I expressed regarding the tentative determination. As I wrote:

> The Tentative Determination itself included an inaccurate claim that the FDA was relying on a CDC study; the public's lone chance to provide comments were based on this critical misunderstanding. This mistake is not simply a clerical problem; the FDA improperly attributed the imprimatur of the government to a study playing a central role in the Tentative Determination. Interested parties may not have even bothered to challenge the study in comments or were heavily influenced by the inaccurate claims (e.g. being swayed because the CDC allegedly asserted health benefits) thereby influencing comments.
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> Absent providing a new comment period for a Tentative Determination based on accurate information regarding this study, the public will be severely harmed.[6] Therefore, the FDA should allow the public to provide comments based on this accurate information.

The public was harmed because the FDA did convey to the public that the paper was critical in making the tentative determination. This may have improperly discouraged comments or influenced the comments that were received. These problems still exist even if the FDA ultimately did not use the paper in its final determination. In addition, the tentative

[6] The proper action, regardless of the IQA, is to have this new comment period.

determination may not have been made in the first place if the paper had not been used for support; and thus, the final determination would have never happened.

Conclusion

I appreciate the FDA's corrections to date. However, the incorrect information included in the tentative determination regarding the paper has created severe harm to me and to the public. The characterization of the data as coming from the CDC impacted public perception and the notice and comment process. This Tentative Determination, by the agency's own estimates, was supposed to result in billions of dollars in costs and benefits, which will impact me along with all Americans.

An ingredient in food that is available to me and to the public is effectively going to be banned because the FDA has decided to revoke GRAS status for PHOs, based on a flawed process. Some companies may not be able to transition away from PHOs, or if they do, it will come at great cost and altered product quality. This great cost to companies would also be incurred by employees (through lost jobs) and consumers (through higher prices).

As requested before, the FDA should allow the public to provide comments based on this accurate information in a new notice and comment period.

Sincerely,

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