



November 3, 2015

Leon Bruner, DVM, Ph.D.
Grocery Manufacturers Association
1350 I Street, NW
Washington, DC 20005

Re: Docket No. FDA-2013-N1317; Tentative Determination Regarding Partially Hydrogenated Oils; Request for Correction of Information Disseminated to the Public that Improperly Attributed a Study to the Centers for Disease Control and Prevention (CDC)".

Dear Dr. Bruner:

This is in response to your letter dated June 15, 2015, inquiring about request for correction of information disseminated by the Department of Health and Human Services (HHS) regarding a study that you allege was "improperly attributed to the (CDC)" in several publications available on the Food and Drug Administration's (FDA) website and in the FDA's Tentative Determination Regarding Partially Hydrogenated Oils (78 Fed. Reg. 67169 (November 8, 2013)). The study as referenced in FDA's tentative determination is "Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation" (the "Paper") published in *Journal of the American Medical Association* in July, 2012.

As described by Deborah Galuska's letter to GMA on behalf of CDC dated December 19, 2014 (the "CDC Letter")¹, the Paper was authored by William Dietz and Kelley Scanlon who were CDC employees at the time it was developed. The Paper was reviewed and approved by CDC following CDC's standard agency clearance protocol. As you noted, the Paper contained a disclaimer statement that "The findings and conclusions in this report are those of the authors and do not necessarily reflect the official position of the [CDC]." The Paper underwent external peer review as part of the CDC review process and then was subjected to peer review by the *Journal of the American Medical Association*, a widely respected, scientific refereed journal. This process conformed to both CDC's and FDA's Information Quality Guidelines. As noted in the CDC Letter, the presence of a disclaimer statement does not prevent CDC or any other HHS agency from subsequently using the information from such publications in progress reports and other publications. The CDC Letter explains that CDC used the information for its "Winnable Battles Progress Report: 2010-2015," and edited that report to clarify that the information was from the peer reviewed literature and to provide the appropriate reference.

¹ Available online at <http://aspe.hhs.gov/cdc-%E2%80%94trans-fats-study-b12>

I. FDA's Tentative Determination Regarding Partially Hydrogenated Oils

We did not rely on the Paper in making our tentative determination that partially hydrogenated oils are not GRAS. FDA's tentative determination discussed the scientific evidence identifying health risks associated with *trans* fat consumption as well as the opinions of expert panels and the 2005 recommendation of the Institutes of Medicine (IOM) regarding *trans* fat consumption, as well as the conclusions of the Paper. Rather, we only used the conclusions of the Paper to explain the potential impact of removing partially hydrogenated oils from the food supply. That is, we agree that the tentative determination inappropriately attributed the Paper's estimates to the CDC (78 Fed. Reg. 67169), but the Paper was not used or even mentioned in our safety discussion (Section IV of the tentative determination). The safety discussion, and the evidence we cited in the safety discussion, adequately supported our tentative determination that "based on current scientific evidence discussed in section IV of [the tentative determination] regarding the health risks associated with the consumption of *trans* fat, opinions of expert panels, as well as the IOM's recommendation to limit *trans* fat consumption as much as possible, "... there is not a consensus that PHOs, the primary dietary source of industrially-produced *trans* fatty acids, are safe for use in food" (id. at 67173).

We published our Final Determination Regarding Partially Hydrogenated Oils in the Federal Register on June 17, 2015 (80 Fed. Reg. 34650). To clarify the source of the information from the Paper that was included in the tentative determination, we noted in the final determination that our tentative determination cited "a peer reviewed, published estimate of deaths and coronary events that would be prevented annually in the United States from elimination of remaining uses of partially hydrogenated oils from the food supply (Ref. 15)" (id. at 34650-34651). Consistent with the tentative determination, we did not cite or even mention the Paper in our discussion of scientific issues in the final determination (id. at 34657-34667), nor did we rely on the Paper to support our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils are GRAS for any use in human food.

FDA takes steps to ensure that our regulatory and policy decisions are based on objective information. Among our many activities, we monitor peer-reviewed scientific journals to ensure the data used to inform our regulatory and policy decisions are accurate and timely. We have a number of regulations and guidances that set standards for the generation of information in support of regulatory decisions including reviews of existing information obtained primarily from peer-reviewed scientific literature. FDA understands that when we draw inferences from third-party information, including peer reviewed journal articles, we are implicitly endorsing the quality of the information. We reviewed the quality of the Paper before using it as the basis of our estimate of the impact of our final determination, and determined that the Paper meets FDA's Information Quality Guidelines.

Although your request was submitted before we published our final determination, we note that, under our Information Quality guidelines.

In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered prior to the final agency action or information product in those cases where in the agency's judgment issuing an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency or information

product. 2 Here, because the tentative determination did not cite or even mention the Paper as part of our safety evaluation, we do not believe that you have shown a “reasonable likelihood of suffering actual harm” based solely on the Paper’s mention in our tentative determination as a means of explaining the potential impact of removing partially hydrogenated oils from the food supply. As such, we find it unnecessary to take any further action relative to the tentative determination.

II. Other FDA Publications

We updated our consumer information web pages on *trans* fat after the final determination issued, and these updated web pages do not cite the Paper. The Consumer Update, “FDA Targets Trans Fat in Processed Food” (#1 in your list of locations) and the page “Questions and Answers Regarding Trans Fat” (#2 in your list of locations) are no longer active webpages.

Because our consumer information web pages have been updated and do not mention the Paper, we find it unnecessary to take further action regarding these documents you cited from our website.

You also listed two other publications that cite the estimates, the January 2014 issue of FDA/CFSAN’s News for Educators (#3 in your list of locations) and a section contained in FDA’s Fiscal Year 2015 Justification of Estimates for Appropriations Committees (#4 in your list of locations). These two documents remain posted on our website. The conclusions from the Paper were cited in these documents to explain the potential impact of removing partially hydrogenated oils from the food supply. We do not find it necessary to take action regarding these publications.

Thank you for your interest in the quality of information disseminated by HHS. If you do not agree with FDA’s decision about your complaint (including any corrective action), you may send a request for reconsideration within 30 days of receipt of our decision. You may use any of the Procedures for Submitting Complaints described in the FDA specific guidelines contained in the HHS Information Quality Guidelines available at: <http://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>. A request for reconsideration should state the reasons why you believe the response is inadequate, should be designated as an "Information Quality Appeal," and sent to the following address:

²Section II.F.VI.B (FDA specific guidelines) in HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (the “HHS Information Quality Guidelines”), available at: <http://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>

4 -Dr. Bruner

Food and Drug Administration
Office of the Ombudsman
10903 New Hampshire Avenue
WO Building 32, room 4260
Silver Spring, MD 29993
E-mail: Ombuds@OC.FDA.gov

A request for reconsideration should include a copy of your original request and the agency's decision. The agency will respond to all requests for appeals within the time frame specified in the procedure you use. Where a procedure does not specify a time frame for a response to your appeal, we will respond in a timely manner, in accordance with the OMB and HHS Guidelines.

Sincerely,

Dennis M. Keefe
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

5 -Dr. Bruner

2015-11-15

not a CTS number

R/D:HFS-200 DKeefe:11/3/15

Init: HFS-200:<SUPERVISOR>:<DATE>

Init:HFS-2XX:<Division Director>:<DATE>

Init:HFS-200:DMKeefe:<DATE>

F/T: HFS-200 DKeefe:11/3/15