The Association of Food, Beverage and Consumer Products Companies

June 15, 2015

Mr. Michael Taylor, Deputy Commissioner
Division of Document Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852
Sent via E-mail: Mike.Taylor@fda.hhs.gov

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Division of Document Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852
Sent via USPS

RE: Docket No. FDA-2013-N-1317; Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information: Request for Correction of Information Disseminated to the Public that Improperly Attributed a Study to the Centers for Disease Control and Prevention (CDC)

Dear Mr. Taylor:

The Grocery Manufacturers Association (GMA)[1] is the voice of more than 300 leading food, beverage, and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

[1] Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policy makers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The 2.1 trillion food, beverage,

GMA hereby submits a request for correction of information 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 (HHS),[4] and the Food and Drug Administration (FDA)[5] that improperly attributed a study to the (CDC). Information that is disseminated to the public must meet the requirement of "objectivity." According to the HHS Guidelines, "'objectivity' involves a focus on ensuring that information is accurate, reliable and unbiased and that information products are presented in an accurate, clear, complete and unbiased manner." [6] The information identified below fails to meet this requirement because the FDA inaccurately and incorrectly attributed authorship of a study on the epidemiological effects of *trans* fats to the CDC.

Why the Information Is Inaccurate and Fails to Meet Objectivity Requirements

The FDA improperly attributes a two-page viewpoint on the epidemiology of *trans* fat consumption to the CDC, when it was in fact a viewpoint article authored by Dietz et al. (2012) [7], and is not a CDC study. The CDC did not estimate the alleged cardiovascular deaths due to *trans* fats that the FDA has widely promoted in numerous publications. Two authors who happened to work at the CDC published the viewpoint in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA). At the end of the published viewpoint, it expressly states: "The findings and conclusions in this report are those of the authors and do not necessarily reflect the official position of the US Centers for Disease Control and Prevention."[8] In its Tentative Determination, the FDA explains that the data comes from the CDC, and then cites the two-page JAMA viewpoint to support this claim—the same JAMA viewpoint that is expressly not a CDC study. The FDA clearly should have known that the report was not a CDC study, especially when it cited a JAMA viewpoint for the alleged CDC claim.

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and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to nation's economy.

[2] Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554.

[3] 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") available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf (accessed May 20, 2015).

[4] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, available at http://aspe.hhs.gov/infoquality/Guidelines/index.shtml (accessed May 20, 2015).

[5] Guidelines for Ensuring the Quality of Information Disseminated to the Public, Food and Drug Administration, available at http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml (accessed May 20, 2015).

[6] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public. http://aspe.hhs.gov/infoquality/Guidelines/index.shtml accessed June 9, 2015.

[7] Dietz WH, Scanlon, KS. 2012. Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation. JAMA. 2012;308(2):143-144.

[8] Ibid.

The CDC currently lists the estimates of cardiovascular deaths on their web site, and it specifically cites the source but does not claim that CDC authored these estimates.[9] There was one instance where the CDC referenced the data, but did not cite the study properly. In a previously posted document called "Winnable Battles Progress Report: 2010-2015,"[10] the CDC explained, "CDC has concluded that 10,000–20,000 heart attacks and 3,000–7,000 coronary heart disease deaths each year in the U.S. could be prevented by removing artificial *trans* fat from processed foods."

After an IQA Request for Correction was made by GMA to the CDC on October 9, 2014, and a follow-up Request for Reconsideration was submitted on January 15, 2015, the CDC edited its "Winnable Battles" report, which now states that

> "CDC **researchers** have concluded that 10,000–20,000 heart attacks and 3,000–7,000 coronary heart disease deaths each year in the U.S. could be prevented by removing artificial *trans* fat from processed foods. ***See* Dietz, WH, Scanlon, KS. Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation. *JAMA*; 308(2): 143-144.**"[11] (Emphasis added).

The CDC's correction confirms that the study is not properly classified as a CDC study. Although CDC failed to respond to GMA's follow-up Request for Reconsideration, in a response to Heritage Foundation's Request for Reconsideration that was received May 14, 2015, the CDC explains "To clarify that the numbers presented in the Winnable Battles report came from this paper [Dietz et al.], the report now indicates that the numbers are obtained from the paper by Dietz et al."[12] The letter concludes, "In response to your previous request, the *Winnable Battles Progress Report: 2010-2015* now provides the appropriate reference to the paper."

Locations of Inaccurate Information

In numerous publications listed below, and in its "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information,"[13] (Tentative Determination) the FDA improperly attributes a study on the epidemiology of *trans* fat consumption and the conclusions of the Dietz et al. JAMA viewpoint to the CDC.

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[9] "Nutrition for Everyone: Trans Fat," Centers for Disease Control and Prevention, available at http://www.cdc.gov/nutrition/everyone/basics/fat/transfat.html (accessed June 2, 2015); "Trans Fat: The Facts," Centers for Disease Control and Prevention, at http://www.cdc.gov/nutrition/downloads/trans_fat_final.pdf (accessed June 1, 2015).

[10] The text of report has changed, as discussed, but the original language was found at http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf

[11] http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf (accessed May 20, 2015).

[12] GMA requests and CDC's responses can be accessed on the HHS IQA requests web site, available at http://aspe.hhs.gov/infoquality/requests.shtml (accessed June 9, 2015).

[13] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67169 (November 8, 2013), available at https://www.federalregister.gov/articles/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for (accessed May 20, 2015).

1) "Questions and Answers Regarding *Trans* Fat," available at http://www.fda.gov/food/populartopics/ucm373922.htm, and http://www.fda.gov/downloads/Food/PopularTopics/UCM385846.pdf :

> "[T]he Centers for Disease Control and Prevention estimates that eliminating intake of *trans* fat from partially hydrogenated oils could prevent up to 20,000 cases of coronary heart disease (CHD) and up to 7,000 deaths annually."

2) "FDA Targets Trans Fat in Processed Food," available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm

> "The Centers for Disease Control and Prevention estimates that a further reduction of *trans* fat in the food supply can prevent an additional 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year."

3) "News for Educators" (January 2014), available at http://content.govdelivery.com/accounts/USFDA/bulletins/9e4a34

> "CDC estimates that removal of PHOs from the food supply could prevent an additional 7,000 deaths and up to 20,000 heart attacks *each year*." (Emphasis in original.)

4) "Narrative by Activity" at pages 30-31, available at http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm394622.pdf

> "The Centers for Disease Control and Prevention estimates that eliminating artificial trans-fat in processed foods could prevent up to 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year."

5) "Tentative Determination,"(November 2013), available at https://www.federalregister.gov/articles/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for

> "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." [p. 67169]

The Impact of Improperly Attributing the Data and Study to the CDC (Including the Impact on the Requester)

The improper and incorrect characterization of the data presented by FDA and CDC is important for several reasons. Of great significance is the impact of attribution on public perception of the issue. The FDA is incorrectly attributing the data to an official CDC study thereby improperly giving the data significantly greater legitimacy than is warranted due to the imprimatur of the United States federal government. It is important that the attributions be corrected to ensure the accuracy of information presented and, in turn, ensure all stakeholders are properly informed of data sources, opinion and significance of the information communicated.

GMA is also concerned about the timeliness and accuracy of the data presented in the opinion article published by Dietz et al. It is apparent that the epidemiological data are based on consumer consumption data that are dated and therefore irrelevant to the current situation. The reason for the change in relevance is that *trans* fat added to food products has decreased by approximately 86% in recent years. In order to gain a more correct understanding of the basis for the risk calculations presented in CDC and FDA communications and to verify the aforementioned presumptions, GMA submitted Freedom of Information Act (FOIA) requests to CDC for the source data used to make the morbidity and mortality figures presented in CDC and FDA communications. So far CDC has failed to respond. GMA similarly submitted FOIA requests to FDA for the data underlying the Dietz study. So far, FDA has not provided the source data that has been requested. We will make another request for this information with the expectation that the FDA will either provide the information necessary to verify the correctness of the morbidity and mortality figures or acknowledge the information does not exist. These non-validated numbers are being used to justify far-ranging government actions that will greatly impact consumers and industry. It is important that any decision involving far-ranging regulatory actions that will greatly impact consumers and the industry be made based on accurate, up-to-date exposure information with appropriate risk calculation methodologies.

Required Corrections

In order to ensure correct portrayal of the science and attribution of critical work, the FDA must correct or remove the documents and web pages identified in this Request.[14] The corrected information should also be communicated to the public and policymakers in a prompt manner before any action is taken on its Tentative Determination. Since 2013, the FDA has miscommunicated this critical information and the only way to rectify the problem is to prominently acknowledge the error in a manner that will promptly reach interested parties.

In addition, because FDA's Tentative Determination on the GRAS status of PHO itself included an inaccurate claim that the FDA was relying on a CDC study; the public's opportunity to provide comments was based on a critical misunderstanding. This mistake is not simply a clerical problem; the FDA improperly attributed the imprimatur of the government to a study critical to the safety assertions made in FDA's Tentative Determination. Interested parties may not have bothered to challenge the study in comments or were heavily influenced by the inaccurate claims (e.g., the CDC – a governmental agency dedicated to protecting America from health, safety and security threats – allegedly asserted health risks due to *trans* fats) thereby influencing comments.

Absent providing a new comment period for the Tentative Determination based on accurate information regarding this study, the public will be severely harmed.[15] Therefore, the FDA should allow the public to provide comments based on this accurate information.

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[14] FDA should make whatever edits are legally authorized to be made to the Tentative Determination as published in the Federal Register, noting any changes to readers.
[15] The proper action, regardless of the IQA, is to provide an additional comment period.

GMA appreciates your consideration of our request.

Sincerely,

Leon Bruner, DVM, PhD
EVP, Science and Regulatory Affairs & CSO
Grocery Manufacturers Association

cc: Susan Mayne, PhD – Director, FDA CFSAN
Dennis Keefe, PhD – Director, FDA OFAS