DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

Daren Bakst
Research Fellow in Agricultural Policy
Thomas A. Roe Institute for Economic
Policy Studies
The Heritage Foundation
214 Massachusetts Ave., NE
Washington, DC 20002-4999

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 Mr. Bakst:

This letter responds to your request, dated December 11, 2015, for reconsideration of the Food and Drug Administration's (FDA's) response to your Request for Correction of information disseminated by FDA to the public concerning a peer-reviewed journal article, "Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation," authored by William Dietz and Kelley Scanlon and which published in the *Journal of the American Medical Association* in July 2012 ("the Paper"). You claim that, contrary to FDA's response, this Paper was critical to FDA in reaching its tentative determination on partially hydrogenated oils, and that the public was harmed because FDA in its tentative determination inappropriately attributed the Paper that was written by two scientists working at the Centers for Disease Control and Prevention (CDC) to CDC itself. You contend that this inaccuracy may have improperly discouraged comments or influenced comments that were received, and may have altered the outcome of the final determination.

As Dr. Keefe explained in his letter to you dated November 3, 2015, information provided to you by CDC[1] makes clear that Drs. Dietz and Scanlon were CDC employees at the time the Paper was developed, and the Paper was reviewed and approved by CDC following a process that conformed to both CDC's and FDA's Information Quality Guidelines. The published article included the disclaimer recommended in the "OMB Final Information Quality Bulletin for Peer Review" indicating that the findings and conclusions of the paper were those of the authors and did not represent the official views of CDC.

[1] See letter from Deborah Galuska to The Heritage Foundation, dated December 19, 2014, available at http://aspe.hhs.gov/cdc-%E2%80%94trans-fats-b2.

The presence of the disclaimer statement does not prevent CDC or any other agency of the Department of Health and Human Services from subsequently using the information from such publications. Dr. Keefe's November 3, 2015 response explains that the Paper was not critical to FDA's Tentative Determination Regarding Partially Hydrogenated Oils (78 Fed. Reg. 67169 (Nov. 8, 2013)), but rather that the conclusions of the Paper (which you do not contest) explain the potential impact of removing partially hydrogenated oils from the food supply. FDA did not use or mention the Paper in the safety discussion set out in Section IV of the Tentative Determination. To clarify the source of the information, in the Final Determination Regarding Partially Hydrogenated Oils (80 Fed. Reg. 34650 (June 17, 2015), we noted that the 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" (citing the Paper). As Dr. Keefe explained, "[c]onsistent with the tentative determination, we did not cite or even mention the Paper in our discussion of scientific issues in the final determination …, 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."

Finally, I note that your request for reconsideration provides no basis for the conjecture that attributing the Paper to CDC, rather than to the individual authors, may have dissuaded interested parties from challenging the study in comments. To the contrary, thirteen major food trade associations sponsored a scientific report by Biofortis[2] in response to the Tentative Determination. This report reviewed expert panel reports and studies included in the Tentative Determination and was critical of the Paper. This report, like all submitted comments, was considered by FDA in reaching its final determination. However, as stated above, these estimates of coronary events and coronary deaths prevented had no bearing on FDA's determination that partially hydrogenated oils are not generally recognized as safe for any use in human food.

In conclusion, after reviewing your request for reconsideration, I find that no corrective action is required. Thank you again for your interest in the quality of information disseminated by the Department of Health and Human Services.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

[2] Biofortis is a research and consulting organization. Their report, "Assessment of Evidence Used to Determine Impact of Industrially-Produced Oils on Risk of Cardiovascular Disease," was authored by DeAnn Liska, Kristin Nieman, and Kevin Maki, and dated March 6, 2014.