



**Council for Responsible Nutrition**  
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**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information.  
Docket No. FDA-2013-N-1317  
78 Fed. Reg. 67169 (November 8, 2013)**

The Council for Responsible Nutrition (CRN)<sup>1</sup> and the Consumer Healthcare Products Association (CHPA)<sup>2</sup> take this opportunity to share our views on the Food and Drug Administration's (FDA's) November 2013 *Federal Register* notice entitled, "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information." CRN is a leading trade association for the dietary supplement industry, representing manufacturers of dietary ingredients

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org).

<sup>2</sup> CHPA is the 133-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements ([chpa.org](http://chpa.org)).

and of national brand name and private label dietary supplements. We are joined in these comments by CHPA, a leading U.S. trade association for manufacturers and distributors of nonprescription medicines and dietary supplements.

CRN and CHPA applaud the agency's efforts to improve public health and we agree that reducing Americans' consumption of *trans* fatty acids (*trans* fats) is a valuable goal. FDA has tentatively determined that partially hydrogenated oils (PHOs), the primary source of industrially-produced *trans* fats, are not generally recognized as safe (GRAS) for any use in food and that PHOs are food additives. In the case that PHOs are food additives, food and dietary supplement manufacturers would no longer be permitted to use PHOs in food without prior FDA approval. However, there are several scientific and technical issues the agency should consider prior to issuing a final determination on PHOs.

FDA noted that in addition to industrially-made PHOs, hydrogenation of unsaturated fatty acids also occurs in the digestive tract of ruminant animals and can result in some *trans* fats in dairy and meat products, comprising a small percent (typically around 3%) of the total fatty acids in these types of products. FDA excluded naturally-occurring *trans* fats in meat and dairy products from ruminant animals from the scope of the notice. It is important to note that naturally-occurring *trans* fats also arise from plant sources, but these sources are not addressed in FDA's tentative determination on PHOs. CRN and CHPA request FDA to exclude naturally-occurring *trans* fats from plant sources from the scope of its final determination on PHOs. Moreover, FDA does not exclude fully hydrogenated oils (such as from soy) from the scope of the notice. CRN and CHPA request FDA to clarify whether fully hydrogenated oils are also outside the scope of the notice. In addition, CRN and CHPA request FDA to provide a formal definition of PHOs and fully hydrogenated oils in the final determination to ensure that the scope of ingredients that are the subject of the determination is clear. Furthermore, the length of the *trans* fat chain

(short, medium or long) and degree of unsaturation are important factors that can determine the impact on human health. FDA should clarify these aspects of PHOs in the scope of the agency's final determination as generalizations may unintentionally call into question the GRAS status for other ingredients which are saturated fats by chemical definition, yet have well documented health benefits.

Evidence suggests that consuming PHOs, the primary dietary source of industrially-produced *trans* fats, as a part of the diet contributes to increased risk of coronary heart disease; however, it is not clear if an increased risk applies when trace amounts are consumed from the use of PHOs as a food processing aid considering that FDA is excluding the small percent of *trans* fat naturally occurring in dairy and meat products from the scope of its tentative determination. There are many food applications that use trace amounts of PHOs and a complete ban of the ingredient will result in challenges for the industry. FDA's final determination should take into consideration whether there is a maximum amount of PHOs that can be used without negative health effects. CRN and CHPA suggest that FDA consider establishing a threshold for levels of PHOs or *trans* fats that may be present in a finished food product from the use of PHOs as a processing aid, production aid, adjuvant or secondary food additive.

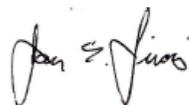
Respectfully submitted,

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