

December 19, 2013

Leslie Kux, Assistant Commissioner for Policy Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

RE: Tentative Determination Regarding Partially Hydrogenated Oils

Dear Assistant Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 110,600 family physicians and medical students across the country, I write in response to the FDA's request for comments about the tentative determination regarding partially hydrogenated oils (PHOs) as published in the November 8, 2013, Federal Register.

Citing new scientific evidence and findings from expert scientific panels, the U.S. Food and Drug Administration (FDA), in this regulation, tentatively determines that PHOs, which are the primary dietary source of industrially produced trans fatty acids, or trans-fat, are not generally recognized as safe (GRAS) for any use in food and therefore are food additives. The FDA has not listed the most commonly used PHOs, but acknowledges PHOs have been used in food for many years based on self-determinations by industry that such use is generally recognized as safe. If the FDA's tentative determination is finalized, food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, unless the manufacturer received prior FDA approval. According to the Centers for Disease Control and Prevention, elimination of PHOs from the food supply could prevent up to 20,000 coronary events and as many as 7,000 coronary deaths annually.

The AAFP reviewed the scientific evidence cited and we are pleased to wholeheartedly support the FDA's determination that PHOs are not generally safe for use in food. Our support also stems from input received f from family physicians serving on a medical advisory panel as part of the AAFPs initiative named Americans In Motion-Healthy Interventions (AIM-HI). This AAFP advisory panel found that PHOs:

- Contribute to obesity in children and adults;
- Have adverse effects on blood cholesterol levels;
- Put the population at risk for coronary heart disease; and
- Contribute to insulin resistance, a precursor to diabetes.

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While there are many other health risks, these reasons allow us to fully support the FDA's determination. The AAFP's AIM-HI initiative was conceived to address the serious problems that result when people become more sedentary, reduce physical activity and grow increasingly obese, and to emphasize the nation's need for better preventive services. Family physicians are uniquely positioned to teach patients and their families to become physically and emotionally fit and practice healthy eating.

In closing, we again offer our support to FDA and make ourselves available for any questions you might have or clarifications you might need. Please contact Janet Ann McAndrews, MPH, at 913-906-6000, Ext. 3132 or imcandrews@aafp.org.

Sincerely,

Jeffrey J. Cain, M.D., FAAFP Board Chair

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CC: Mical Honigfort, FDA Center for Food Safety and Applied Nutrition