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Food and Drug Administration College Park, MD 20740-38

DEC 1 9 2003

**Bob Bauer** North American Olive Oil Association 3301 Route 66 Suite 205, Building C Neptune, NJ 07753

> RE: Health Claim Petition - Monounsaturated fatty acids from olive oil and coronary heart disease

Dear Mr. Bauer:

This letter acknowledges receipt on December 5, 2003 by the Food and Drug Administration (FDA) of your faxed letter regarding the health claim petition you submitted on August 29, 2003 on behalf of the North American Olive Oil Association. We understand that the petitioner has elected to have their health claim petition reviewed under the new process for qualified health claims rather than under the standard health claim review process described in Section 403(r)(4) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(4)). We will follow the interim procedures for qualified health claims described in the FDA publication entitled "Consumer Health Information for Better Nutrition Initiative" Task Force Final Report (http://www.cfsan.fda.gov/~dms/nuttftoc.html).

Accordingly, today we are filing your qualified health claim for monounsaturated fatty acids from olive oil and reduced risk of coronary heart disease. The petition is posted on Dockets web page (http://www.fda.gov/ohrms/dockets/dockets/dockets.htm) and we are requesting comment on it for 60 days. Interested persons may submit comments until February 17, 2004. Within 225 days of the filing date, December 19, 2003, we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be July 31, 2004.

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Please feel free to contact Dr. Jillonne Kevala at 301-436-1450 if you have any questions concerning this petition.

Sincerely yours,

Jugme Z Wilking

Christine L. Taylor, Ph.D. Director Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition