

SEP 8 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 August 29, 2003 by the Food and Drug Administration (FDA) of your petition submitted on behalf of North American Olive Oil Association. You requested that the FDA authorize a health claim for monounsaturated fatty acids from olive oil and coronary heart disease.

Your petition is undergoing initial FDA review as an unqualified health claim petition. In accordance with Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)(A)(i)) and 21 C.F.R. 101.70(j)(2), within 100 days of receipt of your petition, the petition will be filed for comprehensive review or denied. The 100-day period ends on December 7, 2003, and FDA will notify you by letter on or before that date of the disposition of your petition.

In addition, we would like to inform you that your petition does not contain information required in 21 C.F.R. 101.70(c) with respect to non-clinical trials or 21 C.F.R. 101.70(d) with respect to clinical or other human investigations. This minor problem can be remedied by submitting to FDA a statement that declares to the best of the Petitioner's knowledge, all non-clinical studies relied upon were conducted in compliance with the good laboratory practice regulations as set forth in 21 C.F.R. Part 58, and all clinical or other human investigations relied upon were either conducted in accordance with the requirements for institutional review set forth at 21 C.F.R. Part 56 or were not subject to such requirements in accordance with 21 C.F.R. 56.104 or 56.105, and were conducted in conformance with the requirements for informed consent set forth in 21 C.F.R. Part 50.

2003Q-0559

ACK1

Page 2 - Bob Bauer

Please feel free to contact me at 301-436-1848 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink that reads "Jilanne Kevala". The signature is written in a cursive style with a large initial 'J' and a long, sweeping tail on the 'a'.

Jilanne Kevala, Ph.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition