



## NORTH AMERICAN OLIVE OIL ASSOCIATION

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September 20, 2003

Dr. Jillonne Kevala  
Office of Nutritional Products, Labeling and  
Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740

Dear Dr. Kevala:

This letter pertains to the health claim petition entitled, "Monounsaturated fatty acids from olive oil and coronary heart disease" dated August 28, 2003 that was recently submitted to your office by the North American Olive Oil Association (NAOOA).

In accordance with 21 C.F.R. § 101.70(c) and 21 C.F.R. § 101.70(d) the NAOOA declares that to the best of our knowledge, all non-clinical studies relied upon in our petition 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.

Sincerely,

*Bob Bauer / BT*

Bob Bauer  
President

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