



JAN 29 2004

Food and Drug Administration  
College Park, MD 20740-38

*Rec'd 5/12/04  
ib*

Jonathan W. Emord, Esq.  
Emord & Associates, P.C.  
5282 Lyngate Court  
Burke, VA 22015

RE: Health Claim Petition – 1) Lycopene and the following: Cancer, Prostate Cancer, Lung Cancer, Gastric Cancer, Colorectal Cancer, Breast Cancer, Cervical Cancer, Endometrial Cancer, and Pancreatic Cancer; 2) Tomatoes and the following: Cancer, Prostate Cancer, Lung Cancer, Gastric Cancer, Colorectal Cancer, Breast Cancer, Cervical Cancer, Endometrial Cancer, and Pancreatic Cancer; and 3) Lycopene-Containing Tomato-Based Products and the following: Cancer, Prostate Cancer, Lung Cancer, Gastric Cancer, Colorectal Cancer, Breast Cancer, Cervical Cancer, Endometrial Cancer, and Pancreatic Cancer

Dear Mr. Emord:

This letter acknowledges receipt on January 21, 2004 by the Food and Drug Administration (FDA) of your petition submitted on behalf of American Longevity, Inc. pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. §§ 343(r)(4) and 343(r)(5)(D)). You requested that the FDA authorize health claims or allow qualified health claims concerning the relationship between lycopene, tomatoes, lycopene-containing tomato-based products and reduction in the risk of cancer, prostate cancer, lung cancer, gastric cancer, colorectal cancer, breast cancer, cervical cancer, endometrial cancer, and pancreatic cancer.

Your petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act (21 U.S.C. § 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the 100-day period, which ends on April 30, 2004, or by a lack of FDA action within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

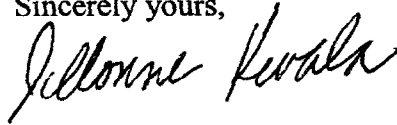
*2004Q-0201*

*ACK 1*

Page 2 - Jonathan W. Emord

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink that reads "Jillette Kevala". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

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