



MAY 12 2004

2462 04 MAY 13 11:32

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

RE: Health Claim Petition – Lycopene, Tomatoes, Lycopene-Containing
Tomato-Based Products and Various Cancers (Docket No. 2004Q-0201)

Dear Mr. Emord:

This letter acknowledges receipt on April 28, 2004 by the Food and Drug Administration (FDA) of your letter dated April 27, 2004 regarding the above-referenced health claim petition you submitted on January 21, 2004 on behalf of American Longevity Inc. We understand that the petitioner has elected to have their health claim petition reviewed under the interim procedures for qualified health claims rather than under the standard health claim review process described in Section 403(r)(4)(A)(i) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(4)(A)(i)). 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 petition for qualified health claims about the relationship between lycopene, tomatoes and lycopene-containing tomato-based products and (1) cancer, (2) prostate cancer, (3) lung cancer, (4) gastric cancer, (5) colorectal cancer, (6) breast cancer, (7) cervical cancer, (8) endometrial cancer, (9) ovarian cancer, (10) and pancreatic cancer. The petition is posted at this web address: <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm> and we are requesting comment on it for 60 days. Interested persons may submit comments until July 12, 2004. Within 225 days of the filing date we will notify you of our final decision regarding the requested qualified health claims. We have calculated that date to be December 23, 2004.

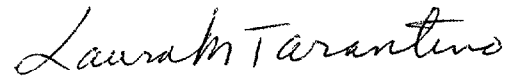
2004Q-0201

ACK 2

Page 2 - Jonathan W. Emord, Esq.

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

Sincerely yours,

A handwritten signature in cursive script that reads "Laura M. Tarantino".

Laura M. Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition