

3158 5 AUG 17 PT 39
1050 SEVENTEENTH STREET, N.W., SUITE 600
WASHINGTON, DC 20036
202.466.6937 • FAX 202.466.6938
www.emord.com

August 11, 2005

VIA EMAIL Jillone.Kevala@cfsan.fda.gov

AND US MAIL

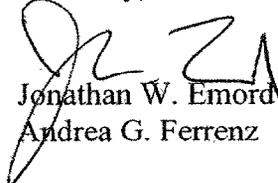
Jill Kevala, Ph.D.
Food and Drug Administration
Harvey W. Wiley Federal Building
HFS-830
Room 4A035
5100 Paint Branch Pkwy
College Park, MD 20740

Re: Qualified Health Claim Petition: Tomatoes, Lycopene and Various Cancers

Dear Dr. Kevala:

You have asked American Longevity (AL), petitioner for the above-referenced health claims, to agree to an extraordinary fifth extension of time to complete agency review of AL's pending claims. The AL petition has been pending for 567 days, in excess of the maximum time specified in 21 U.S.C. § 343(r)(4). Having endured four extensions, each one said to represent a deadline for agency action, AL cannot be faulted now for questioning the reliability of the proposed fifth. Public awareness of nutrient-disease relationships are indispensable to the exercise of informed consumer choice. AL's pending claims cannot lawfully be suppressed consistent with the First Amendment. See, Pearson v. Shalala, 164 F.2d 650, 658 (D.C.Cir. 1998). Despite constitutional law compelling prompt evaluation of private speech (Elrod v. Burns, 427 U.S. 347, 373-374 (1976)), FDA has maintained its prohibition on the utterance of the pending claims through inaction on them spanning over a year and seven months. While AL gives its consent to the requested fifth time extension (until October 11, 2005), it does so with great reluctance. If that deadline proves fictive yet again, AL will have no choice but to seek judicial review of the agency's maintenance of a speech ban in violation of AL's First Amendment rights.

Sincerely,


Jonathan W. Emord
Andrea G. Ferrenz

2004Q-0201

LET8