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**VIA UPS OVERNIGHT MAIL**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

***Re: Docket No. 2004Q-0201***

Dear Sir or Madam:

We represent American Longevity, Inc. (Petitioner). The Petitioner filed its petition with FDA on January 21, 2004 for the approval of health claims associating lycopene, tomatoes and lycopene-containing tomato-based products with a reduction in the risk of certain kinds of cancer. Since that filing the Petitioner has agreed to FDA's review of the claims as qualified health claims pursuant to Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), reh'g denied en banc, 172 F.2d 72 (D.C. Cir. 1999). On May 17, 2004, H.J. Heinz ("Heinz") filed a similar petition requesting that FDA allow qualified health claims linking the consumption of lycopenes with a reduction in the risk of prostate cancer. In a letter dated July 8, 2004 and a second letter dated August 26, 2004, Campbell's Soup Company responded to those petitions. It is in response to Campbell's comments that we submit this letter on behalf of the Petitioner.

American Longevity's petition and the Heinz petition, and Campbell's comments each acknowledge the well studied and scientifically supported association between lycopene, tomatoes and tomato-based products and cancer risk reduction.

In its August 26, 2004 letter, Campbell's states that Heinz's proposed claims mislead because the proposed claims imply that lycopenes as opposed to tomato-based products (that contain lycopenes) are responsible for cancer risk reduction. Campbell's operates on the assumption that conclusive proof is needed to support the lycopene claims. As shown in both the American Longevity and Heinz petitions, scientific evidence does support the proposition lycopenes, including food products that contain them, do reduce the risk of some cancers. Campbell's admits that there is considerable evidence to support the relationship, but perceives an absence of conclusive proof.

2004Q-0201

RC 1

Following Pearson and Whitaker v. Thompson 248 F.Supp.2d 1, 23-24 (D.D.C. 2002), a misleading claim would be one where there is no scientific evidence to support it and where the claim could not be cured of its misleadingness through use of a disclaimer. That is not the case here. The proposed claims are backed by sound scientific evidence and are not misleading (at worst they harbor a potential for misleadingness, a potential capable of being eliminated through use of a properly worded disclaimer).

The Petitioner, Heinz and Campbell's all agree that scientific evidence supports an association between the consumption of lycopene, tomatoes, and lycopene-containing tomato-based products and a reduction in the risk of certain forms of cancer. Petitioner believes that the truthful and succinct health information conveyed by its proposed claims will enable consumers to make prudent and effective dietary choices. It is the agency's duty to satisfy the demands of the First Amendment and allow the claims relying, to the extent necessary, on reasonable disclaimers to avoid potential misleadingness.

Respectfully submitted,



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