



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

MAY 27 2004

Food and Drug Administration
College Park, MD 20740

F. Kerr Dow, Ph.D.
Vice President Nutrition and Technical Affairs
H. J. Heinz Company
P.O. Box 57
Pittsburgh, PA 15230-0057

RE: Qualified Health Claim Petition –Tomato Products, which Contain Lycopene,
and Reduced Risk of Prostate Cancer

Dear F. Kerr Dow:

This letter acknowledges receipt on May 17, 2004 by the Food and Drug Administration (FDA) of your petition submitted on behalf of the Lycopene Health Claim Coalition pursuant to Section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. §§ 343(r)(4) or 343(r)(5)(D)). You requested that the FDA allow a qualified health claim concerning the relationship between consumption of tomato products, which contain lycopene, and reduced the risk of prostate cancer.

Your petition is undergoing initial FDA review and the agency will follow the interim procedures for qualified health claim petitions as described in the FDA publication entitled "Consumer Health Information for Better Nutrition Initiative" Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttfoc.html>). As such, the petition will be filed no later than 45 days after the petition has been received and will be available for comment for 60 days at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. FDA will issue a final decision concerning the petition no later than 270 days after the petition has been received. We have calculated the filing date, which is the date the petition will be available for comment, to be no later than July 1, 2004.

2004Q-0201

ACK3

Page 2 - F. Kerr Dow, Ph.D.

If you have any questions concerning this petition, please feel free to contact me at 301-436-1450.

Sincerely yours,

A handwritten signature in black ink that reads "Jilanne Kevala". The signature is written in a cursive style with a large initial "J".

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