

ORIGINAL PETITION
COVER LETTER

Petition for Qualified Health Claim



Date: February 11, 2004

Name of petitioner: Lycopene Health Claim Coalition

Post office address: C/O H. J. Heinz Company, P.O. Box 57, Pittsburgh, PA 15230-0057

Subject of the petition: Tomato Lycopene Consumption

Food and Drug Administration

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)

5100 Paint Branch Pkwy.

College Park, MD 20740

The undersigned, representatives of the H. J. Heinz Company, LycoRed Natural Products Industries, Ltd., The Morningstar Company, and The Prostate Cancer Foundation submit their petition pursuant to section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to a qualified health claim indicating the association between consumption of lycopene in tomato products and a reduced risk of prostate cancer.

Prostate cancer is the second-leading cause of cancer-related death for adult males in the United States. Lycopene, commonly found in tomatoes, in tomato-based foods, and in tomato extract, has potent antioxidant properties and is commonly found in prostate tissue. Research suggests a protective role for lycopene in tomatoes and tomato products with respect to prostate cancer. Therefore, increased consumption of tomato lycopene may prove to be beneficial for a significant number of individuals. A coalition consisting of the H. J. Heinz Company, LycoRed Natural Products Industries, Ltd., The Morningstar Company, and The Prostate Cancer Foundation asked the Center for Food and Nutrition Policy (CFNP or "the Center") at Virginia Tech to form a third-party review panel to evaluate a qualified health claim informing consumers that lycopene from tomato products may reduce the risk of prostate cancer. The Center developed a systematic process by which to evaluate the relationship between lycopene, tomatoes and tomato-based foods, and the risk of prostate cancer and the results of this evaluation are attached.

The petition contains the results of the comprehensive scientific literature review. In addition, we have included consumer research data that assessed if consumers understand the proposed qualified health claims, if consumers interpret the health claims as truthful and not misleading, and how much consumers would change their consumption of tomatoes and tomato products based on the health claims. Based on the results of the consumer research, the Center estimated the possible reduction of prostate cancer as a result of increased tomato product consumption due to proposed claims.

The members of the coalition are excited about the positive impact that qualified health claims will have on consumer health.

- Attachments (Scientific review, Consumer research, Article assessments, Copies of Core and Background Articles)

2004 Q-0201

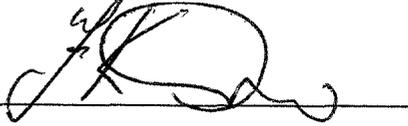
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- Environmental Impact
("The requested health claims listed in this petition are excluded from the environmental impact statement under 21 C.F.R. § 25.24")

Yours very truly,

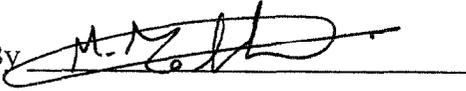
Petitioner: Lycopene Health Claim Coalition – C/O H.J. Heinz Company

1. By



Dr. F. Kerr Dow, Vice President, Chief Scientist H. J. Heinz Company

2. By



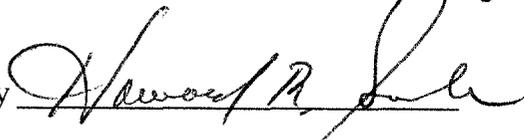
Mr. Morris Zelkha, CEO and General Manager, Lyco Red Natural Products Industries Ltd.

3. By



Mr. Chris J. Rufer, The Morning Star Company

4. By



Dr. Howard R. Soule, Executive Vice President/Chief Science Officer, The Prostate Cancer Foundation

April 28, 2004

Name of Petitioner: H. J. Heinz Company; LycoRed Natural Products Industries, Ltd.;
The Morning Star Packing Company; Prostate Cancer Foundation (CaP CURE)

Post Office Address: P.O. Box 57, Pittsburgh, PA 15230-0057

Subject of the Petition: The Relationship Between Consumption of Tomato Products,
Which Contain Lycopene, and Reduced Risk of Prostate Cancer: An Evidence-based
Review of the Scientific Literature Based on the Food and Drug Administration's
Guidance for Qualified Health Claims

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, MD 20740

The undersigned, F.K. Dow, representing, H. J. Heinz; LycoRed; Morning Star; Prostate
Cancer Foundation, submits this petition pursuant to section 403(r)(4) or 403(r)(5)(D) of
the Federal Food, Drug, and Cosmetic Act with respect to a qualified health claim
concerning the association between consumption of tomato products, which contain
lycopene, and reduced risk of prostate cancer.

Attached hereto, and constituting a part of this petition, are the following:

- A. Preliminary Requirements
- B. Summary of Scientific Data
- C. Analytical Data
- D. Model Health Claim
- E. Attachments
- F. Environmental Impact Statement

All communications and correspondence related to the enclosed qualified health claim
petition should be directed to:

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

Yours very truly,

Petitioner



VICE PRESIDENT,

H. J. HEINZ COMPANY

By for THE COALITION OF PETITIONER (indicate authority)
COMPANIES AS LISTED ABOVE.