



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUN 21 2004

Mr. Koichi Hata  
Vice President  
Aska Corporation  
1860 W. 220<sup>th</sup> Street, #440  
Torrance, California 90501

Dear Mr. Hata:

This is in response to your letter to the Food and Drug Administration (FDA), dated February 25, 2004, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual who is certifying that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject your product to regulation under the drug provisions of the Act.

Your submission states that Aska Corporation is making the following statement, among others, for the product **Aska Botanical Enzyme Plus**:

“Lecithin is added and known to...reduce cholesterol.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely, hypercholesterolemia and coronary heart disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim

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suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "SIL", written in a cursive style.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204

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To Whom it may concern:

February 25, 2004

Aska Corporation, 1860 W. 220th St. #440 Torrance, CA 90501, has commenced Marketing of Aska Botanical Enzyme Plus, supplement containing Botanical Enzyme Extract.

The following nutritional support statements are being made with respect to this dietary supplement:

1. Encapsulated enzymes help boost metabolism and maintain optimal health.
2. Lecithin is added and known to promote fat metabolism and reduce cholesterol.

The undersigned certifies that the information contained herein is accurate and complete and that the notifying firm has substantiation that the statements are truthful and not misleading.

Very truly yours,

Koichi Hata  
Vice President  
Aska Corporation  
1860 W. 220 th St. #440  
Torrance, CA 90501

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