



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service

Food and Drug Administration
College Park, MD

JUL 25 2002

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Mr. William B. Schultz
Zuckerman Spaeder LLP
1201 Connecticut Avenue, N.W.
Washington, DC 20036

Dear Mr. Schultz:

This letter is in response to your citizen petition dated October 4, 2001, which was filed on October 10, 2001, under Docket Number 00P-1322/CP2. You requested that the Food and Drug Administration (FDA) amend its labeling regulations to require the declaration of allergenic ingredients on food labels, and to establish good manufacturing practices (GMPs) to prevent inadvertent introduction of allergenic ingredients into foods that do not contain allergenic ingredients.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition after the first 180 days of its receipt. As I am sure you are aware, FDA has been addressing allergen labeling issues over the past two years. As part of its allergen initiative, FDA issued the Allergen Inspection Guide to FDA field offices on April 9, 2001. The Allergen Inspection Guide provides field investigators and inspectors with specific guidance on inspection methods, techniques, procedures and policy relating to allergenic ingredients. On May 3, 2001, FDA published a Compliance Policy Guide (CPG) on Allergens, entitled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (enclosed). This CPG provides guidance to FDA's compliance staff, field investigators, and the regulated industry on our policy and regulatory action criteria for undeclared food allergens.

Because FDA recognizes that the labeling of food allergens is a concern of allergic consumers and additional measures may be needed to ensure that consumers obtain adequate information about the foods they eat, we held a public meeting on August 13, 2001, to discuss labeling foods containing allergens and the unintended addition of allergens to foods because of processing practices. The public meeting transcript is available on our website at <http://www.cfsan.fda.gov/~dms/alrgltr4.html>. Currently, we are reviewing comments on the public meeting.

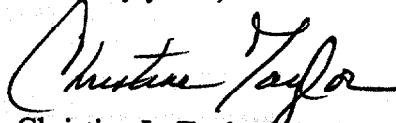
At this time, FDA's Center for Food Safety and Applied Nutrition (CFSAN)'s work on allergen issues has slowed because of other agency priorities and limited availability of resources. Currently, CFSAN is focused on food safety and, after the September 11, 2001, terrorist attacks, on counter-terrorism. However, we plan to continue to make progress on our efforts to address allergens. As stated in item 1.11.7, of our program priorities, we plan to

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develop a strategy to improve the labeling of the most common allergens to include responding to the "Nine States Attorneys General" petition that you mentioned in your letter. We will consider the points raised in your petition when we address better labeling of allergens.

Sincerely yours,



Christine L. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Enclosure

Copy to:

Mr. Carlos T. Angulo

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