



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305  
Public Health Service

Food and Drug Administration  
Washington DC 20204

NOV 22 2000

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Mr. Eliot Spitzer  
Attorney General  
New York State  
120 Broadway  
New York, New York 10271-0332

Docket No. 00P-1322/CP 1

Dear Mr. Spitzer:

This refers to your citizen petition, dated May 26, 2000, and filed May 30, 2000, requesting that the Food and Drug Administration (FDA) amend its food labeling regulations to:

1. Require that manufacturers inform consumers of the actual or possible presence of allergenic ingredients in foods, and to provide consumers a mechanism to obtain product information,
2. Require that flavorings containing allergenic substances be listed by their common or usual name,
3. Exclude allergens from the definition of incidental additives, and
4. Require manufacturers to adopt good manufacturing practices aimed at preventing cross-contamination of allergenic substances to non-allergenic foods.

The requested action seeks to amend 21 CFR 101.17, 21 CFR 101.22(h), 21 CFR 101.100(a), and 21 CFR Part 110.

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 within the first 180 days of its receipt because of the complexities of the issues raised in the petition and the limited availability of resources. As you may be aware, the Center for Food Safety and Applied Nutrition's (CFSAN) Program Priorities for FY 2000 (relevant sections enclosed), included priorities aimed at raising consumer and industry awareness to the presence of allergens in foods. We participated in meetings with consumer groups and industry and discussed labeling approaches that identify the presence of allergens in foods. As a result of these meetings and other information available to the agency, we are reviewing our entire approach on how to best address the issue of food allergens. As we continue to develop our policy, we will consider how to most appropriately address your petition in FDA's overall strategy to label allergenic substances in foods and to enforce good manufacturing practices that prevent cross-contamination of non-allergenic food with allergenic substances.

00P-1322

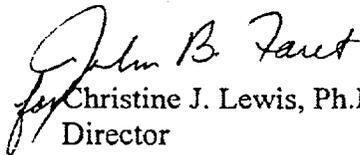
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Moreover, CFSAN is establishing program priorities for fiscal year FY 2001. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. We recognize the public health importance of informing consumers of the presence of allergenic substances in foods and the need for good manufacturing practices to prevent cross-contamination of foods. Therefore, we intend to further address your petition in this fiscal year.

Should you have additional questions, do not hesitate to contact us.

Sincerely,



Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and  
Applied Nutrition

Enclosure

### Strategy 3.4

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#### Emerging Areas

#### "A" List

1. **Biotechnology:** Develop and implement strategies based on public meetings held in fall 1999.
2. **Food Allergens:**
  - (a) Raise consumer and industry awareness to the presence of allergens in foods. Conduct meetings on labeling approaches to identify the presence of allergens.
  - (b) Develop a proposed rule to require declaration of carmine/cochineal extract on the ingredient statement of food products containing it.
3. **Adverse Event Reporting (AER):** Develop action plan for integrating all AER systems within CFSAN.

### Strategy 3.5

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#### Regulatory Processes

#### "A" List

1. **CFSAN-Field Relations:** Initiate development of an action plan to strengthen working relations between CFSAN and ORA in the areas of: (1) budget and work plan; (2) outbreaks and tracebacks; (3) inspections and field programs; (4) international programs; (5) enforcement; and (6) laboratories.
2. **Regulations Process:** Evaluate CFSAN regulations development process for quality and efficiency and make recommendations for improvement.
3. **Communications:** Develop a plan to improve responses to the Field Offices, the states and other federal agencies through better utilization of the internet and e-mail, improved correspondence control and improved telephone responsiveness.
4. **Bioterrorism:** In conjunction with ORA, and after consultation with other federal agencies, develop a CFSAN bioterrorism plan to address intentional chemical and biological contamination of foods and water associated with food production.