U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
May 3, 2001

Questions and Answers on Allergen Guides

1. **What is a Compliance Policy Guide?**

   A Compliance Policy Guide (CPG) provides guidance to the Agency's compliance staff, field investigators, and the regulated industry on Agency policy and actions that the Agency may or may not take under the Federal Food, Drug, and Cosmetic Act (the Act) and regulations based on the Act. A CPG represents the Agency's current thinking on a specific regulatory issue.

2. **Where can I get a copy of the allergen CPG?**

   The CPG entitled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" is available on the Internet at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm. Copies of this CPG can also be obtained by faxing requests to 301-827-0482.

3. **When was the allergen CPG published?**

   A Federal Register Notice announcing the availability of the FDA's Compliance Policy Guide (CPG) on allergens, entitled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens," published in the Federal Register on May 3, 2001.

4. **Is the CPG effective immediately or will the public have an opportunity to comment?**

   FDA is making this compliance policy guidance document effective immediately. The guidance will help FDA identify problems that can result in serious allergic reactions in sensitive individuals. Although the guidance document is being implemented immediately, FDA is requesting comments on the guidance and comments may be submitted at anytime. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability of the revised guidance, if it is revised.

5. **What is FDA's policy on Allergens?**

   Products that contain an allergenic ingredient by design must comply with section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act), which requires each ingredient in a food to be declared. Processing aids that contain allergenic ingredients must be declared in accordance with 21 CFR 101.4(a)(1). Production practices that lead to unintentional addition of allergens to food may be considered insanitary conditions that may render the food injurious to health and cause the food product to be adulterated under section 402(a)(4) of the Act.

   The only exemption to labeling requirements is found in section 403(i)(2) of the Act and provides that spices, flavors, and certain colors used in food may be declared collectively without naming each. In some instances, these ingredients contain sub-components that are allergens. Therefore, FDA strongly encourages the declaration of any allergenic ingredient contained in a spice, flavor, or color. The Agency is considering whether to require, by regulation, declaration of an allergenic ingredient in a spice, flavor, or color, 403(i) notwithstanding. FDA will hold a public meeting on August 13 in Washington, DC to discuss the labeling of food allergens.

6. **Why did FDA publish a Compliance Policy Guide?**

   A recent review of FDA food recall actions based on undeclared allergens in food revealed an increase in such recalls during the last decade. Ten years ago, there were 35 recalls per year for undeclared food allergens. From FY 1996 to FY 1999, undeclared allergen recalls averaged 90 per year. In FY-2000, the number of recalls rose to 121. To provide guidance to the field about the increasing findings of undeclared allergens in food, FDA published the compliance policy guide. This CPG reiterates the information provided in a 1996 "Notice to Manufacturers" issued by the FDA. The CPG also addresses issues identified in the recent FDA / Minnesota & Wisconsin Partnership study on food allergens (see question #10 below).

7. **How does the guidance in the Compliance Policy Guide differ from guidance provided in the 1996 Notice to Manufacturers?**

   The 1996 Notice to Manufacturers provided guidance to the regulated industry to increase allergen awareness. The Compliance Policy Guide provides guidance to the Agency's compliance staff, field investigators, and the regulated industry on the Agency's policy on allergens and actions that the Agency may or may not take under the Federal Food, Drug, and Cosmetic Act (the Act) and regulations based on the Act.

8. **What are the food allergens of concern?**

The CPG focuses on the most common allergens that cause 90% of allergic reactions: milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, and soybeans.

9. **What legal violation will FDA charge for findings of undeclared allergens?**

   FDA will consider taking actions against products as misbranded or adulterated depending on the facts of a given case.

   Specimen Charges:

   Misbranding due to an undeclared allergen- The article was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of the section 403(i)(2) of the Act, in that it is fabricated from two or more ingredients, and its label fails to bear the common or usual name of each such ingredient, namely (specify the undeclared allergenic ingredient).

   Adulteration of a food through contamination by an undeclared allergen - The article was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the section 402(a)(4) of the Act, in that it has been prepared, packed and held under insanitary conditions whereby it may have been rendered injurious to health.

10. **Was the CPG developed in response to the FDA / Minnesota & Wisconsin State Partnership study results?**

    No, publication of the CPG was identified in the FY 2001 CFSAN Program Priorities prior to the release of the FDA / State Partnership results. The FY 2001 CFSAN Program Priorities identified the publication of a Compliance Policy Guide and the issuance of a field inspection guide as key goals to combat undeclared allergens. However, the CPG addresses the issues identified in the FDA / Minnesota & Wisconsin Partnership study, and so they should be considered complementary.

11. **What is an inspection guide?**

    The purpose of an Inspection Guide is to provide FDA Investigators/Inspectors with general or commodity specific guidance in the area of inspectional methods, techniques and procedures, and policy.

12. **Has the allergen inspection guide been issued to the FDA field offices?**

    Yes, the inspection guide entitled "Guide to Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients" was issued to the FDA field offices on April 9, 2001. FDA will be training field investigators on how to use the guide to conduct on-site inspections.

13. **Does the public have access to the inspection guide?**

    The "Guide to Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients" is available on the Internet at http://www.cfsan.fda.gov/~dms/wh-alrgy.html. You may also obtain a copy of this Guide by faxing a request to 301-443-6919.

Food Allergens

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