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The Honorable Jack Reed
United States Senate
Washington, D.C. 20510-3903

Dear Senator Reed:

Thank you for the letter of June 19, 2002, on behalf of your constituent, Ms. Barbara Ruth Dunbar of Barrington, Rhode Island. Your constituent is concerned about the Food and Drug Administration's (FDA or the Agency) enforcement of food allergen labeling under the Federal Food, Drug, and Cosmetic (FD&C) Act. Specifically, she is concerned that bread made with wheat starch is being labeled "gluten-free," which could be misleading to people with celiac sprue who must restrict their consumption of gluten. Persons with gluten intolerance need to avoid the protein component of the gluten found in wheat, rye, oats, and barley.

By way of background, FDA is responsible for assuring that foods sold in the United States are safe, wholesome and properly labeled. This applies to foods produced domestically, as well as foods from foreign countries. If a product contains wheat gluten and is labeled "gluten-free," that would be a violation of the FD&C Act. If your constituent has information about a specific product that is mislabeled, we would encourage her to report it. She can contact the local FDA Consumer Complaint Coordinator at (781) 279-1675 x188. Information about reporting problems to FDA is enclosed.

FDA appreciates the difficulties faced by persons with food allergies and food intolerance. In our continuing efforts to address allergens, FDA recently issued two food allergen guidance documents. First, 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. Second, on May 3, 2001, the Agency published a Compliance Policy Guide (CPG) on Allergens entitled, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (a copy is enclosed). This CPG provides guidance to the Agency's compliance staff, field investigators, and the regulated industry on Agency policy and regulatory action criteria for undeclared food allergens. While these guidance documents deal only with food allergens, the inclusion of wheat on the list of common allergens will enable persons with celiac sprue to avoid certain proscribed products.

FDA held a public meeting on August 13, 2001, to obtain input from the public on allergen labeling issues to determine what additional actions may be necessary to assist consumers in identifying products containing allergens and to assist manufacturers in producing food

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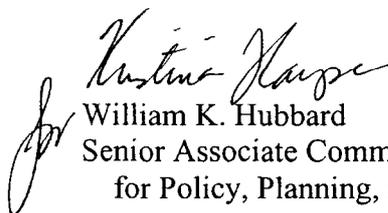
products that are safe for allergenic consumers. Specifically, the meeting focused on: (1) source labeling or plain English labeling; (2) advisory labeling such as “may contain wheat;” and (3) labeling of flavorings, spices, and colors and of incidental additives. FDA has received comments for consideration regarding this issue. Although the docket closed on October 29, 2001, we will forward your request and your constituent’s letter to the Dockets Management Branch to be included with other letters relating to allergens. Please be assured that we will consider all comments before making a final decision on this issue.

FDA has been working with industry and consumer groups to raise awareness about the presence of allergens in foods and to identify practical approaches for the labeling of allergens. Addressing food allergen issues was identified as a 2001 priority by FDA’s Center for Food Safety and Applied Nutrition. Food allergens are also specifically targeted in the 2002 priorities. Continuing consumer and industry outreach, developing and implementing an allergen strategy for cross-contact, informing Congress of Agency plans to issue regulations to prevent cross-contact, and developing a strategy to improve the labeling of the most common allergens are some of the many allergen-related goals included in the current list of Agency priorities. In addition, FDA is addressing the issue of cross-contact by common allergens through increasing inspections and by providing education on cross-contact during these inspections.

We have enclosed a recent article entitled, “Food Allergen Awareness: An FDA Priority,” that may be of interest to you and your constituent. This article, the guidance documents referred to earlier in this letter, and other allergen-related Agency information and initiatives are available at the Agency’s “Information about Food Allergies” website: www.cfsan.fda.gov/~dms/wh-alrgy.html.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,


William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

Enclosures

cc: Dockets Management Branch
(Docket #00P-1322)