FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT ("ALLERGEN ACT")

On August 3, 2004, President Bush signed into law the Food Allergen Labeling and Consumer Protection Act of 2004, Title II of Pub.L.No. 108-282, 118 stat. 905 (2004) ("Allergen Act"). The Allergen Act will require both foreign and domestic food and dietary supplement manufacturers to revise labeling to include declaration of major food allergens after January 1, 2006, and provides the Food and Drug Administration (FDA) additional authority over food and dietary supplement manufacturing facilities. The Allergen Act will become effective and subject to FDA enforcement for any foreign or domestic food and dietary supplement product marketed in the U.S. that is labeled on or after January 1, 2006. (See Allergen Act of 2004, Section 203(d). The Allergen Act includes dietary supplements because they are regulated as foods under the FDC Act. This new legislation does not affect the Meat, Poultry and Egg Inspection Acts that are administered by the US Department of Agriculture (USDA). USDA intends through rule making to harmonize the labeling of meat, poultry, and egg products with the requirements of the Allergen Act.

The Allergen Act amends Section 403 of the Federal Food, Drug, and Cosmetic Act (FDC Act) concerning the misbranding provisions for food and dietary supplements. A food/dietary supplement will now be considered misbranded if does not declare that it contains an ingredient containing a "major food allergen." (See Allergen Act Section 203(a) and new Section 403(w) of the FDC Act). The Allergen Act further amends Section 201 of the FDC Act by adding a definition of "major food allergen[s]." The eight major food allergens include "milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp) tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans," (See Section 203(c) of the Allergen Act and Section 201(qq)(1) of the FDC Act). In addition, a food ingredient that contains protein derived from one of these eight major food allergens is also considered a "major food allergen," except highly refined oils or any ingredient derived from such highly refined oils. (See Section 203(c) of the Allergen Act and Section 201(qq)(2) of the FDC Act). However, the Allergen Act does not define the term "highly refined oils." Industry usage would suggest that the term would define oils that have been refined (e.g., heat extracted), deodorized and bleached to remove protein. But this is a term that FDA will have to define legally in future guidance. The term "tree nuts" will also need further clarification from FDA because without clarification it might be inclusive of foods such as coconuts and almond oil.

The new section 403(w)(1) of the FDC Act as amended by the Allergen Act states that a food/dietary supplement will be adulterated if it contains an ingredient that is or contains a major food allergen, unless the label identifies the major food allergen.

The Allergen Act provides several options for identifying the food allergens on a product label. For the first option, the label can state "Contains" followed by the name of the food source from which the major food allergen is derived (i.e., the name described in new section 201(qq)(1) of the FDC Act: "milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.") For the second option, the common or usual name of the major food allergen can be contained in parentheses following the common or usual name of the food source from which the major food allergen is derived (e.g., walnuts (tree nuts)). Neither of these label options is required if the common and usual name of the ingredient uses the name of the food source from which the major food allergen is derived, or if the allergen appears elsewhere in the label ingredient list unless it appears as part of the name of a food ingredient that is not defined as a major food allergen. (See Section 403(w)(1)(B)(i) and (ii) of the FDC Act). Flavoring, coloring, or incidental additive ingredients that are or contain a major food allergen will be subject to the Allergen Act label requirements. (See Section 403(w)(4) of the FDC Act).

The Allergen Act provides two methods for obtaining an exemption from the Allergen Act for a food ingredient that contains a protein derived from a major food allergen. First, a person may petition FDA to exempt a food ingredient that contains protein derived from a major food allergen. In this case the burden is on the petitioner to provide scientific evidence that demonstrates that the food ingredient does not cause an allergic response or pose a risk to public health. The submitted petition must be reviewed by FDA and either approved or denied within 180 days.

The second option allows a person to file a notification with FDA to exempt a food ingredient that contains protein derived from a major food allergen from the Allergen Act label requirements. The notification is different from the petition process in that it is never explicitly approved or denied by FDA. In the notification process, the person submitting the notification may introduce the food ingredient into interstate commerce as a food ingredient that is not a major food allergen 90 days after the notification is filed with FDA, unless the agency objects. The notification to FDA should contain scientific evidence (including the analytical method used) that demonstrates the food ingredient does not contain allergenic protein or FDA makes a determination that the ingredient does not cause an allergic response that poses a risk to public health. (See Section 403(w)(7)(A) of the FDC Act.

In addition to the new food/dietary supplement label requirements, the Allergen Act provides FDA the authority, consistent with authority under Section 704 of the FDC Act, to inspect facilities in which food/dietary supplements are manufactured, processed, packed, or held. The new inspectional authority allows FDA to determine whether a company is manufacturing products that comply with the good manufacturing practices that reduce or eliminate cross-contact of a food with residues of a major food allergen. Additionally, FDA will determine in this inspection activity whether major food allergens are correctly labeled on the food/dietary supplements produced by that company. (See Allergen Act of 2004 Section 205.)

The Allergen Act also required FDA to issue a proposed rule to define and permit the use of the term "gluten free" on food/dietary supplement labels. FDA conducted a public meeting on August 19, 2005 to obtain expert comment and consultation to assist the agency in defining and permitting the use of this term on food/dietary supplement labeling.

FDA has promised to issue guidance concerning the threshold level of proteins derived from a major food allergen that would trigger the Allergen Act label requirements. For example, if a company uses soya lecithin as an ingredient or as a processing agent in manufacturing a food/dietary supplement product, what level of protein from the soybeans contained in soya lecithin would trigger allergen labeling? FDA has authored a document entitled "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food that can be found at **http://www.cfsan.fda.gov/~dms/alrgn.html** that should be reviewed for the scientific issues which must be revolved by the agency to address the threshold levels of protein that are allergenic. Companies marketing food/dietary supplements products in the US should do a careful review of the ingredients used in their products to determine if any of the ingredients used will require the labels of the finished products to comply with the new Allergen Act requirements. If you have any questions concerning this new legislation, please contact me.