



FDA NEWS RELEASE

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FDA Takes Enforcement Action Against Three New Jersey Dietary Supplement and Protein Powder Manufacturers ***Companies failed to declare allergens in products and correct filthy conditions***

The U.S. Department of Justice, on behalf of the U.S. Food and Drug Administration, has filed a complaint for permanent injunction against Quality Formulation Laboratories, Inc., American Sports Nutrition Inc., Sports Nutrition International LLC and Mohamed S. Desoky, who oversees operations at all three companies.

The companies, located in Paterson, N.J., manufacture dietary supplements and protein powders and distribute them throughout the United States. The companies also export powder mixes and dietary supplements for sale by private label customers.

The government's complaint, filed July 1, 2009 in the U.S. District Court of New Jersey, alleges that the companies have failed to follow current Good Manufacturing Practice (GMP) by manufacturing and storing food under filthy conditions and in conditions that may cause major food allergens to enter into products not intended to contain them.

The complaint also alleges that the companies failed to disclose major food allergens on the product labels and have other labeling problems.

During a recent inspection, FDA investigators found that several of the companies' products contained milk ingredients that were not declared on the product labels. In addition, the company failed to clean processing equipment between batches and control allergens in the facility.

FDA investigators also discovered live and dead rodents and rodent urine, feces and gnaw holes on bags of product.

In three inspections, FDA investigators noted deviations from GMP standards. The companies promised to make corrections, but they failed to do so. The complaint requests a court order to stop the companies and its officer from manufacturing and distributing the products until needed corrections are made.

“This company has consistently failed to correct filthy conditions in their plants and to make sure that allergens are appropriately declared on the labels, despite frequent warnings to do so,” said Michael Chappell, the FDA’s acting associate commissioner for regulatory affairs. “The FDA will not tolerate companies that fail to provide adequate safeguards.”

Consumers with allergies to milk ingredients who have used these products and are experiencing any symptoms should contact their health care professional.