
Chapter 4 – Center for Food Safety and Applied Nutrition

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The Warning Letters presented in this chapter were chosen to provide examples of the types of Warning Letters issued for violations of FDA laws and regulations. The hyperlinks provided may change. To locate the archived Warning Letters go to: <http://www.fda.gov/foi/warning.htm>.

Allergens

Warning Letter for Spelt

On September 2, 2008, the Food and Drug Administration (FDA) issued a Warning Letter to Albert Batshon, President of Jerusalem Manufacturing Natural Foods & Wholesalers, Inc., of Dearborn, Michigan, for violations of the Federal Food, Drug and Cosmetic Act (the Act). FDA sample analysis and label review revealed significant violations of the regulations.

Analysis of the products revealed:

- Jerusalem World Pure Foods brand Turnip Pickle contains a color additive Rhodamine B that is unsafe; and
- Jerusalem brand Pita Bread, Spelt Wheat Free - the label fails to declare the presence of the major food allergen, wheat, as required.

A color additive is deemed to be unsafe unless its use is in conformity with a regulation listing the additive for such use. The chloride and stearate salts of Rhodamine B were formerly listed as D&C Red No. 19 and D&C Red No. 37, respectively. However, in 1983 FDA terminated the listings of these compounds for use in coloring ingested drugs and cosmetics based on the Agency's conclusion that they are carcinogens when ingested [21 CFR 81.10(q) (1)]. There is no regulation listing Rhodamine B as safe for use in coloring any food.

The Act defines "major food allergens" to include milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity, and it is or it contains an ingredient that bears or contains a major

food allergen not listed in the labeling. Spelt is *Triticum spelta* L. The term "wheat" in the Act means any species in the genus *Triticum*. Thus, wheat includes grains such as spelt. See Guidance for Industry, Questions and Answers Regarding Food Allergens, Section II, #27, located at:

<http://www.cfsan.fda.gov/~dms/alrguid4.html>.

The Jerusalem brand Pita Bread, Spelt Wheat Free, was manufactured with spelt, which is *Triticum spelta* L., a species of wheat. The labeling is false and misleading because the label claims the product is wheat free, but it contains spelt.

To view the full text of the Warning Letter, go to

http://www.fda.gov/foi/warning_letters/s6904c.htm

Recall: Allergy Alert on Undeclared Macadamia Nuts

On October 12, 2007, Dairy State Foods voluntarily recalled a limited quantity of 7 ounce Minnie's Bake Shop Chocolate Chunk Cookies. These cookies may contain undeclared macadamia nuts. People who have an allergy to macadamia nuts run the risk of serious or life-threatening allergic reaction if they consumed these products. The products in the recall did not declare macadamia nuts in the ingredient statement. Minnie's Bake Shop White Chocolate Chunk Macadamia Cookies were packed in Minnie's Bake Shop Chocolate Chunk packaging with the package code date of "Best if used by" March 2008.

The recall was initiated after discovery that the macadamia nut containing product was distributed in packaging that did not reveal the presence of macadamia nuts. An allergy warning was on the box, stating that it was manufactured on shared equipment with peanuts or tree nuts. Subsequent investigation indicated that a temporary break down in the packaging process caused the problem. The problem has been corrected, and current production runs are accurately labeled.

KFC Issues a Nationwide Recall

On April 18, 2008, the KFC Corporation, of Toledo, Ohio, issued a voluntarily recall of its Double Chocolate Chip Cakes because they contained eggs, milk, wheat, soy ingredients, and possibly traces of tree nuts, and were not

individually labeled with ingredient information.

The cakes were being recalled because people who have an allergy to eggs, milk, wheat, soy ingredients, or tree nuts run the risk of a serious or life-threatening reaction if they consume the product. There was no health risk for consumers who are not allergic to any ingredients in the product. The distributed cakes were recalled voluntarily by the restaurant chain nationwide from KFC restaurants.

Cracker Barrel Issues Allergy Alert

On April 9, 2008, Cracker Barrel Old Country Store®, Inc., of Lebanon, Tennessee issued a recall of 5 ounce bags of chocolate-covered almonds and 5 ounce bags of chocolate double-dipped peanuts because the packaging was labeled incorrectly. The product, labeled as containing chocolate-covered almonds, may have contained chocolate double-dipped peanuts, and the product labeled as containing chocolate double-dipped peanuts may have contained chocolate covered almonds. People who have an allergy or a severe sensitivity to peanuts or almonds run the risk of serious or life-threatening allergic reaction if they consume these products.

These products were available at all Cracker Barrel Old Country Store® locations in 41 states. No illnesses or allergic reactions had been reported to date. No other candies or packaged food items were a part of this recall, and there was no health risk for consumers who are not allergic to peanuts or almonds.

After the issue was reported to FDA by Cracker Barrel, management publicly announced the issue and initiated the recall. Subsequent investigation indicated the problem was caused by a temporary breakdown in the supplier's labeling and packaging processes. This labeling error was limited in scope, and no other food products were involved.

Canned Foods

Warning and Recall for Threat of Botulism in Canned French Cut Green Beans

FDA issued a warning on December 21, 2007, to consumers about a potential

Clostridium botulinum (*C. botulinum*) contamination of canned cut green beans manufactured by New Era Canning Company, New Era, Michigan. On January 18, 2008, FDA announced that New Era Canning Company was expanding the product recall because of potential *C. botulinum* contamination to all canned green beans and garbanzo beans distributed by the company nationwide over the last five years. On February 7, 2008, New Era broadened the nationwide recall of canned vegetable products for a third time because of the potential for the foods to be contaminated with *C. botulinum*



For information on specific brands and codes of green beans and garbanzo beans that were subject to the recall, consumers and retailers can access this information at the following link:

<http://www.fda.gov/oc/opacom/hottopics/newera.html>.

FDA worked closely with Michigan Department of Agriculture state officials and New Era to identify all products that may be involved. FDA and the Michigan Department of Agriculture launched a joint investigation of New Era's processing plant. This investigation resulted in the identification of *C. botulinum* contamination in several lots of canned green beans and one lot of garbanzo beans, the identification of serious food violations that resulted in an expanded recall. Original findings of the investigation resulted in the company voluntarily recalling green beans in December 2007.

To view full text of FDA's Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01764.html>)

To view full text of FDA's Press Release for green beans, Mexican-style chili beans, and dark red kidney beans from January 2008 go to:

http://www.fda.gov/oc/po/firmrecalls/newera01_08.html).

FDA initiated the inspection at New Era, along with inspections of other low acid canned food (LACF) manufacturers, following four cases of botulism in consumers who had consumed canned hot dog chili sauce in the summer of 2007. In light of these botulism cases, FDA increased its inspection efforts to assure that manufacturers of all types of LACF products were adhering to applicable FDA requirements. These actions illustrate the need for companies to operate under adequate preventive control systems.

Because of the findings of the investigation, FDA issued an "Order of Need for Emergency Permit" (Order) to New Era. This Order prohibits the manufacture

and shipment of the company's LACF across state lines until the company demonstrated to FDA's satisfaction that the products were safe. In addition, the Michigan Department of Agriculture, under its state authority, embargoed New Era's entire inventory of LACF contained in the company's warehouses in Michigan. FDA granted an Emergency Permit to New Era on June 26, 2008. Under the terms of the Emergency Permit, New Era must obtain FDA approval prior to shipping any products that were manufactured prior to FDA's issuance of the Emergency Permit.

To view full text of FDA's Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01782.html>

To view full text of FDA's latest Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01795.html>

Cereal

Recalled Cereal may be Linked to *Salmonella* Outbreak

On April 12, 2008, the FDA announced that at least 21 people in 13 states have been diagnosed with salmonellosis that was caused by the same strain of *Salmonella* that was found in the recently recalled unsweetened Puffed Rice and unsweetened Puffed Wheat Cereals produced by Malt-O-Meal.

The recalled products were distributed nationally under the Malt-O-Meal brand name as well as under private label brands including Acme, America's Choice, Food Club, Giant, Hannaford, Jewel, Laura Lynn, Pathmark, Shaw's, ShopRite, Tops, and Weis Quality. The cereals have "Best If Used By" dates from April 8, 2008 (coded as "APR0808"), through March 18, 2009 (coded as "MAR1809").

On April 5, 2008, Malt-O-Meal voluntarily recalled the cereals because the company's routine testing found *Salmonella* in a product produced on March 24, 2008.

The FDA worked with Malt-O-Meal to determine the cause of the contamination and with the states and the Centers for Disease Control (CDC) to identify and prevent additional illnesses.

A full list of recalled products can be found at www.malt-o-meal.com/recallinfo.

To view the full text of the FDA Press Release for this recall, go to:
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01819.html>

Cosmetics

Warning For Botox®

Warning of adverse reactions to Botox® use

On February 8, 2008, FDA notified the public that Botox® and Botox® Cosmetic (Botulinum Toxin Type A) and Myobloc Botox® (Botulinum Toxin Type B) had been linked in some cases to adverse reactions, including respiratory failure and death, following treatment of a variety of conditions using a wide range of doses.

In an early communication based on the FDA's ongoing safety review, the Agency said the reactions may be related to overdosing. There was no evidence that these reactions are related to any defect in the products.



The adverse effects were found in FDA-approved and nonapproved usages. The most severe adverse effects were found in children treated for spasticity in their limbs associated with cerebral palsy. Treatment of spasticity is not an FDA-approved use of botulism toxins in children or adults.

The adverse reactions appear to be related to the spread of the toxin to areas distant from the site of injection, and mimic symptoms of botulism, which may include difficulty swallowing, weakness, and breathing problems.

The FDA did not advise health care professionals to discontinue prescribing these products. The Agency is currently reviewing safety data from clinical studies submitted by the drugs' manufacturers, as well as post-marketing adverse event reports and medical literature. After completing a review of the data, the FDA will communicate to the public its conclusions, recommendations, and any regulatory actions.

The notification is in keeping with the FDA's commitment to inform the public about its ongoing safety reviews of drugs. The early communication, which

includes background information and advice for health care professionals, can be viewed at:

http://www.fda.gov/cder/drug/early_comm/botulinium_toxins.htm

\$2 Million of Harmful “Cosmetic” Eye Product Seized

On November 16, 2007, the U.S. Attorney's Office in the Northern District of California filed a complaint requesting that United States (U.S.) Marshals seize 12,682 applicator tubes of Age Intervention Eyelash. The Age Intervention Eyelash, promoted to increase eyelash growth, was sold and distributed by Jan Marini Skin Research, Inc., of San Jose, California.

FDA considered the seized Age Intervention Eyelash to be an unapproved and misbranded drug. Before a new drug product may be legally marketed, it must be shown to be safe and effective and approved by FDA. The Agency takes seriously its responsibility to protect Americans from unapproved drugs.

The article is also considered to be an adulterated cosmetic. The Age Intervention Eyelash contains bimatoprost; an active ingredient in an FDA-approved drug to treat elevated intraocular pressure (elevated pressure inside the eye). For patients using the prescription drug, using the Age Intervention Eyelash in addition to the drug may increase the risk of optic nerve damage because the extra dose of bimatoprost may decrease the prescription drug's effectiveness. Damage to the optic nerve may lead to decreased vision and possibly blindness.

In addition, use of Age Intervention Eyelash may cause other adverse effects in certain people due to the bimatoprost, including macular edema (swelling of the retina) and uveitis (inflammation in the eye), which may lead to decreased vision.

The FDA recommended that consumers, dermatologists, and estheticians who may still have Age Intervention Eyelash discontinue using the product and discard any remaining product. FDA also recommended that consumers consult their health care provider if they have experienced any adverse events that they suspect are related to the product's use.

To read FDA's Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01746.html>

Dairy

Cream Cheese Companies Shut Down

On May 15, 2008, the FDA announced closure of the cream cheese and seafood operations at Lifeway Foods, Inc. and its subsidiary, LFI Enterprises, Inc., both Illinois companies, until they were found compliant with food safety laws. A consent decree of permanent injunction, signed by both corporations and two of their top executives, Julie and Edward Smolyansky (the defendants), halted cream cheese and seafood processing in facilities in Skokie, Illinois, and Philadelphia, Pennsylvania, until the defendants complied with the necessary requirements.

The FDA's enforcement action follows the defendants' extensive history of violations of the Act dating back to at least 2004. The complaint, filed by the U.S. Department of Justice, alleged that the defendants:

- Labeled and distributed cream cheese products with inadequate labeling, including labels that did not disclose major food allergens, trans fat levels, and complete ingredient lists;
- Processed and distributed products with seafood, including whitefish salad, ground nova salmon, lox cream cheese, and spreads without having adequate Hazard Analysis and Critical Control Point (HACCP) plans to ensure the safe and sanitary processing of seafood containing products; and
- Failed to document that they monitored sanitation conditions to keep food contact surfaces clean, to prevent cross-contamination from unsanitary objects, and to maintain hand washing, hand sanitizing, and toilet facilities.

Under the consent decree, operations may resume only after the FDA determines that the defendants have come into full compliance with all food safety and labeling requirements. The consent decree requires the defendants to hire a seafood-processing expert to prepare a HACCP plan and to submit the plan to the FDA.

To view the press releases, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01835.html>

Salmon Spread Recalled

On October 2, 2007, Jensen's Old Fashioned Smokehouse Inc. of Seattle, Washington, issued a recall of 936 tubs of Jensen's Seattle Style Wild Smoked Salmon Spread Lemon Dill and Onion made by Carso's Pasta, of Lynnwood, Washington, because it had the potential to be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

No illnesses have been confirmed to date. The recall was the result of testing by the FDA which revealed that the finished product contained the bacteria.

Kraft Foods Recalled Baker's Premium White Chocolate Baking Squares

On October 3, 2007, Kraft Foods issued a recall in the U.S. for Baker's Premium White Chocolate Baking Squares because the product may be contaminated with *Salmonella*, a bacterium that causes foodborne illness.

The potential for contamination was noted after testing by the FDA detected the presence of *Salmonella* in some packages of Baker's Premium White Chocolate Baking Squares. The company was aggressively investigating the source of the problem.

Warning Letter for Whey Powder

On November 7, 2007, the FDA's Florida District Office issued a Warning Letter to Marjon® Specialty Food, Inc., in Plant City, Florida. FDA inspected the firm on June 19 and 20, 2007, and found serious Current Good Manufacturing Practice (CGMP) and labeling violations.

The Warning Letter addressed several violations:

- Marjon® Tofu Grills Mesquite Pepper Rub was misbranded in that the label failed to declare the presence of the major food allergen milk;
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- Marjon® Tofu Grills Mesquite Pepper Rub is also misbranded because it was fabricated from two or more ingredients and failed to declare the common or usual name of each;
- Marjon® Tofu Grills Mesquite Pepper Rub was further misbranded in that the labeling was false and misleading. The term "NO PRESERVATIVES" was found on the finished product package when in fact the ingredient listing declared "sodium benzoate less than 1/10 of 1% as a preservative; and
- Marjon® Edamame in Pods and Marjon® Edamame Shelled products were misbranded because the labels had unauthorized health claims.

To view the full text of the Warning Letter, go to

http://www.fda.gov/foi/warning_letters/archive/s6593c.htm

Dietary Supplements

Consent Decree of Permanent Injunction Against Food Companies Making Health Claims

On February 22, 2008, the FDA announced the Brownwood Acres Foods Inc., Cherry Capital Services Inc. (doing business as Flavonoid Sciences), and two of their top executives signed a consent decree that prohibited the companies and their executives from manufacturing and distributing any products with claims in the label or labeling to cure, treat, mitigate or prevent diseases. Brownwood Acres Foods Inc., and Cherry Capital Services Inc., manufacture and distribute various products including juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules.

The consent decree of permanent injunction is a result of the companies and their executives making unapproved drug claims and unauthorized health claims about their products, such as "chemicals found in cherries may help fight diabetes." The companies are prevented from making these claims until the products are approved by the FDA as new drugs, exempt from approval as investigational new drugs, or until the claims on the products' label and labeling comply with the law.

Under the terms of the consent decree, the companies have agreed to remove

drug and unauthorized health claims from their labels, brochures, and Websites, as well as references to other Websites that contain such claims. They have also agreed to hire an independent expert to review the claims they make for their products and to certify that they have omitted all violative claims. The companies were also required to pay \$1,000 per violation per day in the event they fail to comply with the consent decree.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01800.html>

Warning Letter for a Food Storage Warehouse

On August 12, 2008, FDA's Baltimore District Office issued a Warning Letter to John Kunkel, President of Capitol Cake Co., in Baltimore, Maryland, after an inspection of their food storage warehouse from May 12 to May 30, 2008. FDA investigators observed that the ingredients and finished food products had been held in a facility under conditions that may have caused the products to be adulterated, in violation of the Act.

The violations listed were:

- Failure to ensure no pests were allowed in any area of a food plant. Further, effective measures must be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests;
- Failure to provide adequate screening or other protection against pests; and
- Failure to ensure the buildings, fixtures, and other physical facilities of the plant are maintained in a sanitary condition and are kept in repair sufficient to prevent food from becoming adulterated.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6880c.htm

Imports

High Level of Lead in Swad Brand Sindoor

On December 15, 2007, the FDA issued a warning to the public not to consume packages of SWAD brand sindoor, an orange or red powder applied to the face or scalp for some traditional South Asian Pacific ceremonies. The product is imported by Raja Foods LLC, of Skokie, Illinois. The warning indicated that the product contains high levels of lead and was not intended to be sold for food use. The labeling was confusing and implied that the product may be used as food. The Illinois Department of Public Health confirmed two cases of lead poisoning in consumers who used the product as an ingredient in home cooked meals. Other uses of the product, including as a cosmetic, can also be dangerous due to the high levels of lead.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01756.html>

Import Alert: *Salmonella* Risk with Cantaloupes

On March 2, 2008, the FDA issued an import alert regarding entry of cantaloupe from Agropecuaria Montelibano, a Honduran grower and packer, because cantaloupe from this company appeared to be associated with a *Salmonella* Litchfield outbreak in the U.S. and Canada. The import alert advised FDA field offices that all cantaloupes shipped to the U.S. by this company are to be detained. The FDA has contacted importers about this action and advised U.S. grocers, food service operators, and produce processors to remove from their stock any cantaloupes from this company.

The FDA received reports of approximately 50 illnesses in 16 states and nine illnesses in Canada linked to the consumption of cantaloupes. Although no deaths have been reported 14 people have been hospitalized. The states reporting illnesses are Arizona, California, Colorado, Georgia, Illinois, Missouri, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Tennessee, Utah, Washington, and Wisconsin.

This firm conducted several recalls related to cantaloupes. On March 27, 2008, Chiquita Brands International, Inc., announced a voluntary recall of cantaloupes

grown, packed and shipped by Agropecuaria Montelibano in Honduras. On March 28, 2008, Spokane Produce, Inc., of Spokane, Washington, recalled Garden Patch, Yokes, and Rosauers Classic labels of various products of fresh cut and cut fruits containing cantaloupe supplied from Agropecuaria Montelibano. On March 28, 2008, Dole Fresh Fruit Company, a subsidiary of Dole Food Company, Inc., voluntarily recalled all Honduran cantaloupes grown, packed, and shipped by an independent third-party grower, Agropecuaria Montelibano. Also on March 28, 2008, JARD Marketing, Lawrence, Massachusetts, issued a recall for selected fresh cut fruit products which contain cantaloupe from Agropecuaria Montelibano. On April 3, 2008, Taylor Fresh Foods, of Salinas, California, voluntarily recalled selected fresh cut fruit products which may contain cantaloupe from the Honduran grower Agropecuaria Montelibano.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01808.html>

***Salmonella* Saintpaul Outbreak**

Serrano and Jalapeño Peppers from Mexico

On June 3, 2008, the FDA alerted consumers in New Mexico and Texas that a salmonellosis outbreak initially appeared to be linked to consumption of certain types of raw red tomatoes and products containing raw red tomatoes. The bacteria causing the illnesses are *Salmonella* serotype Saintpaul, an uncommon type of *Salmonella*.

Since the middle of April, there have been 145 reported cases of salmonellosis caused by *Salmonella* Saintpaul nationwide, including at least 23 hospitalizations. States reporting illnesses linked to the outbreak include: Arizona, California, Colorado, Connecticut, Idaho, Illinois, Indiana, Kansas, New Mexico, Oklahoma, Oregon, Texas, Utah, Virginia, Washington, and Wisconsin.

On June 5, using traceback and other distribution pattern information, FDA published a list of states, territories, and countries where tomatoes are grown and harvested which **have not been associated with this outbreak**. This updated list includes: Arkansas, California, Georgia, Hawaii, North Carolina, South Carolina, Tennessee, Texas, Belgium, Canada, Dominican Republic, Guatemala, Israel, Netherlands, and Puerto Rico. The list is available at:

www.fda.gov/oc/opacom/hottopics/tomatoes.html#retailers.

Last year the FDA began a multi-year Tomato Safety Initiative to reduce the incidence of tomato-related foodborne illness. The Initiative is a collaborative effort between FDA and the state health and agriculture departments in Virginia and Florida, in cooperation with several universities and members of the produce industry.

On July 17, 2008, after extensive sampling the FDA announced it had determined that fresh tomatoes available in the domestic market were not implicated in the current outbreak. On July 25, 2008, the FDA advised consumers that jalapeño and serrano peppers grown in the U.S. were not implicated with the current *Salmonella* Saintpaul outbreak. The FDA continued to advise consumers to avoid raw jalapeño peppers and the food that contains them if they have been grown, harvested, or packed in Mexico.

On July 30, 2008, laboratory testing by the FDA confirmed that both a sample of serrano pepper and a sample of irrigation water collected by Agency investigators on a farm in the state of Tamaulipas, Mexico, contained *Salmonella* Saintpaul with the same genetic fingerprint as the strain of bacteria that caused the current outbreak in the U.S.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01869.html>

Information on safe handling of produce can be found at:

www.cfsan.fda.gov/~dms/prodsafe.html.

Updates from the CDC and Prevention can be found at: <http://www.cdc.gov/>

Juice

Warning Letter: Sugar Free Juice Not Sugar Free

On September 10, 2008, FDA's San Juan District issued a Warning Letter to San Mar Manufacturing Corporation, Guanabo, Puerto Rico, after an inspection of their facility from April 28 through May 12, 2008, revealed labeling violations. The labels of the San Mar's Cool River Fruit Punch beverage in 64 ounce



containers and its Cool River Grape beverage in 16 ounce containers were misbranded because their labels bear the claim "Sugar Free." The Nutrition Facts Panels for the Cool River Fruit Punch and Cool River Grape beverages stated that the products contain 2 grams and 10 grams of sugars, respectively, per labeled serving. Under the FDA's regulations, a food may not be labeled with a nutrient content claim using the term "sugar free" unless the product "contains less than 0.5 grams of sugars. The definition of "sugars" is not limited to added sugars, but also includes naturally occurring sugars like the fructose in fruit juice and fruit pulp.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6969c.htm

Consent Decree of Permanent Injunction Against Good Glow Honey and Juice Company

On May 6, 2008, in the U.S. District Court for the Western District of Texas, Thomas and Judith Crofut, doing business as Good Glow Honey and Juice Company agreed to enter into a consent decree of permanent injunction with the U.S. government.

Good Glow Honey and Juice Company produced unpasteurized, fresh-squeezed, juices and juice blends. The complaint stated the juice products were stored under insanitary conditions and that there was no HACCP plan for each type of juice processed.

As part of the decree, Good Glow Honey and Juice Company was ordered to develop a HACCP plan. The FDA approved the HACCP plan developed for Good Glow Honey and Juice Company. FDA may also, without prior notice, conduct inspections at the plant and take any other measures necessary to monitor and ensure continuing compliance the terms of the decree.

Prepared Foods

Warning Letter for Misbranded Peanut Butter Granola

On July 10, 2008, the FDA's Seattle District Office issued a Warning Letter after

an inspection of Baker's Breakfast Cookie in Bellingham, Washington. The inspection revealed violations of the Act regarding Erin Baker's Homestyle Peanut Butter Granola.

The FDA analyzed a sample of Homestyle Peanut Butter Granola to determine whether the nutrition information on the Nutrition Facts panel accurately reflected the nutrient content of the product. The product label stated that one serving (45 grams) contained 1 gram saturated fat. In the original analysis the granola was found to contain 1.32 grams saturated fat, or 32 percent in excess of the value for saturated fat declared on the label. In the analysis the granola was found to contain 1.42 grams saturated fat, or 42 percent in excess of the value for saturated fat declared on the label. The product was misbranded in that the labeling was false and misleading because the amount of saturated fat present was more than the amount declared.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6863c.htm.

Warning Letter to Soymilk and Tofu Manufacturer

On September 2, 2008, the FDA's Detroit District Office sent a Warning Letter to Roselife, LLC, dba Rosewood Products of Ann Arbor, Michigan, after an inspection of their soymilk and ready-to-eat tofu facility on June 3 through 6, 2008, revealed significant violations of the Act. The products manufactured were prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health.



The inspection revealed the following sanitation violations:

- Failure to have all plant equipment designed and of such material and workmanship as to be adequately cleanable and properly maintained;
 - Failure to have all food manufacturing, including packaging and storage, conducted under conditions and controls necessary to minimize the potential for the growth of microorganisms;
 - Failure to have plant buildings and structures constructed in such a manner that floors, walls, and ceilings may be adequately cleaned, kept clean and kept in good repair, failure to ensure drip or condensate from fixtures, ducts,
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and pipes does not contaminate food, food-contact surfaces, or food-packaging materials;

- Failure to have all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food conducted in accordance with adequate sanitation principles; and
- Failure to ensure all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of food, including washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable organisms) in an adequate hand-washing facility at any time when the hands may have become soiled or contaminated.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6905c.htm

Warning Letter to Acidified Food Manufacturer

On May 6, 2008, a Warning Letter was issued to Bella Cucina Artful Food, Inc., in Atlanta, Georgia, after an inspection conducted by the FDA's Atlanta District Office from February 12 through 21, 2008. During the inspection, FDA investigators documented deviations from the regulations.

The deviations of concern are as follows:

- Failure to file a scheduled process for acidified foods in each container size;
 - Failure to manufacture, process, and package acidified foods so that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods;
 - Failure to maintain processing and production records showing adherence to the scheduled processes, including records of critical factors intended to ensure a safe product;
 - Failure to have personnel involved in acidification, pH control, heat treatment, or critical factors under the operating supervision of a person who
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has attended and satisfactorily completed a Better Process Control school or an approved Acidified Food CGMP school; and

- Failure to adequately maintain instruments used for measuring conditions that control or prevent the growth of undesirable microorganisms.

Additionally, FDA had the following observations:

- The kitchen supervisor was observed pre-recording process end times on processing records.
- The Spinach and Artichoke Pesto had not been evaluated by a processing authority to determine appropriate levels of acidification.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6763c.htm

Warning Letter to Bottled Water Firm

On October 15, 2008, the FDA's Minneapolis District Office sent a Warning Letter to Stephen Knaus, co-owner of Valley Springs Artesian Gold, LLC, in Sun Prairie, Wisconsin, for deviations revealed during an inspection conducted June 23, 25, 27, and 30, 2008. The investigator found deviations from the "Processing and Bottling of Bottled Drinking Water" regulation.

Some of the deviations listed were:

- Failure to retain at the plant the current certificates or notifications of approval issued by the government agency or agencies approving the source and supply of product water and operations water;
 - Failure to sample and analyze the product source water obtained from other than a public water system for microbiological contaminants at least once each week;
 - Failure to take and analyze samples of product source water at least once every year for chemical contaminants and at least once every four years for radiological contaminants;
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- Failure to take and analyze a representative sample of bottled drinking water from a batch or segment of a continuous production run for bacteriological testing at least once a week for each type of bottled drinking water produced during a day's production; and
- Not all plant equipment and utensils are suitable for their intended use.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6980c.htm

Seafood



Company Failed to Follow Consent Decree

On May 16, 2008, the FDA directed Hope Food Supply Inc., a Pasadena, Texas, food processing company, to shut down and immediately recall all products manufactured from its Texas facility since 2007.

The company, under a different name, had manufactured dried smoked catfish steaks and other smoked seafood products and had been subject to a consent decree of permanent injunction requiring the company to develop and implement an adequate Hazard Analysis and Critical Control Point (HACCP) plan for the fish and fishery products. The firm had not developed this plan. The company cannot restart manufacturing until the company has implemented an FDA-approved HACCP plan.

The FDA's HACCP regulations require that all seafood processors develop and implement adequate HACCP plans that identify all food safety hazards that are likely to occur for each kind of seafood product that they process, and set forth preventative measures to control those hazards.

The HACCP violations documented by the FDA pose a public health hazard because, without adequate controls, Hope Food Supply's seafood products could harbor pathogenic bacteria such as *Staphylococcus aureus* and *Listeria monocytogenes*. Food products with these kinds of pathogens can cause serious illnesses in people who eat them.

To view the full text of the Press Release go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01836.html>

Permanent Injunction Against Seafood Processing Company & Executives

On June 6, 2008, the FDA filed a complaint for permanent injunction against seafood processor Captain's Select Seafood, Inc., Minneapolis, Minnesota, and two of its top officers for violating the Act.

The FDA's enforcement action follows the company's extensive history of violating the Act and the Agency's HACCP regulation.

The violations by Captain's Select Seafood as documented by the FDA posed a public health hazard because; the seafood could harbor pathogenic bacteria, such as *Staphylococcus aureus* and *Listeria monocytogenes*.

To view the full text of the FDA Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01846.html>.

Warning on Mussel Product from Bantry Bay Seafoods

On August 15, 2008, the FDA issued a warning to consumers against eating certain frozen cooked mussel products made by Bantry Bay Seafoods, imported from Ireland, because they may be contaminated with azaspiracid toxins. Azaspiracid toxins are odorless, tasteless, and cannot be destroyed or neutralized by freezing or cooking, including boiling.

In July, two people in Washington State became ill after eating the company's "Mussels in a Garlic Butter Sauce." FDA tested unopened product from the same production lot and found that it contained the azaspiracid toxins. Azaspiracid toxins are a group of naturally occurring marine toxins known to cause nausea, vomiting, diarrhea, and stomach cramps.

The FDA recommended that consumers, retailers and foodservice operators remove these products, and any food in which these products were used as an ingredient, from sale or service.

To view the full text of the Press Release go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01875.html>

Warning Issued for Consumption of Tomalley from *Homarus americanus*

July 28, 2008, the FDA warned consumers to avoid eating tomalley from American lobster, known as *Homarus americanus*, regardless of where the lobster was harvested, because of potential contamination with dangerous levels of the toxins that cause Paralytic Shellfish Poisoning (PSP).

The FDA advisory applied only to tomalley, the soft, green substance found in the body cavity of the lobster that functions as the liver and pancreas. Cooking does not eliminate the PSP toxins. Nonetheless, studies had shown that, even when high levels of PSP toxins were present in lobster tomalley, lobster meat itself was typically unaffected. There was no indication that consumers needed to be concerned about PSP toxicity in lobster meat. Lobster tomalley normally does not contain dangerous levels of PSP toxins. The current high levels of PSP toxins were likely associated with an ongoing red tide episode in northern New England and eastern Canada. Canadian authorities recommend limited consumption of lobster tomalley. However, authorities in Maine, Massachusetts, and New Hampshire have issued advisories cautioning against eating any tomalley.

To view the full text of the FDA Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01866.html>.

Warning Issued to Seafood Processors

On February 5, 2008, the FDA issued a letter to seafood processors, advising them of recent illnesses linked to consuming fish carrying the ciguatera toxin, which has led to cases of ciguatera fish poisoning (CFP) in consumers. The toxic fish were harvested in the Northern Gulf of Mexico, near the Flower Garden Banks National Marine Sanctuary, which is located in federal waters south of the Texas-Louisiana coastline.

FDA's letter urged seafood processors who purchase reef fish and other potentially ciguatoxic fish directly from fishermen to reassess their current hazard analysis and update their HACCP plans as necessary. FDA's seafood

HACCP regulation requires processors to have and implement written plans to control food safety hazards. This updated information differs from what is currently listed in FDA's *Fish & Fisheries Products Hazards & Controls Guidance, Third Edition*.

To view the full text of the FDA Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01790.html>.

Warning: Eating Raw Oysters Associated with Illness from Norovirus

On December 29, 2007, FDA issued a warning to consumers not to eat raw oysters harvested from West Karako Bay, a section of Growing Area 3 in Louisiana. On August 10 and August 24, 2007, FDA issued warnings about eating raw oysters from Growing Area 6 of Hood Canal, and Growing Area 5 of the southern tip of Hood Canal in Washington State. The oysters harvested from December 3 through 21, 2007, may also have been contaminated with norovirus.

FDA had received reports of norovirus infection in seven individuals who ate raw oysters on December 13th at a restaurant in Chattanooga, Tennessee. The Tennessee Department of Health's test results from two of the ill patients were positive for norovirus. FDA confirmed the presence of norovirus in shell oysters harvested from the West Karako Bay section of Growing Area 3, which were served at the restaurant. Louisiana Department of Health and Hospitals closed the affected growing area on December 21st. FDA is working with the states involved to determine if any additional actions may be necessary to ensure public health protection.

To view the full text of the FDA Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01767.html>.

Warning Letter to Seafood Importer

On September 4 through 10, 2007, FDA conducted an inspection of a fish and fishery products importer located in the U.S. (Nu-Wave Seafood Consultants, LLC in Barnegat Light, New Jersey) to assess the importer's compliance with HACCP. The importer was found to be importing various fish and fishery product from Trinidad Dock & Fishing Services, Ltd., Chaguaramas, Trinidad, West Indies. During the inspection, the firm provided the FDA with a copy of

Trinidad Dock & Fishing Services' HACCP plan.

The FDA evaluation of that HACCP plan revealed serious deviations from the requirements of the seafood HACCP regulation. FDA noted the following significant deviations from the seafood HACCP regulation:

- Failure to conduct or have conducted a hazard analysis for each kind of fish and fishery product that is produced to determine whether there are food safety hazards that are reasonably likely to occur and have an implemented written HACCP plan that, at a minimum, lists the critical control points.

For more information on the hazard of scombrototoxin (histamine) formation, as well as guidance in setting critical control points and critical limits, please refer to the "Fish and Fisheries Products Hazards and Controls Guidance: Third Edition," Chapter 7, found at: www.cfsan.fda.gov/~comm/haccp4.html.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6973c.htm

FDA Provided Advice on Safe Sources of Puffer Fish

On October 17, 2007, the FDA released consumer and industry advisories regarding safe sources of puffer fish. Many puffer fish, also known as fugu, bok, blowfish, globefish, swellfish, balloonfish, or sea squab, contain deadly toxins that affect the central nervous system.

Puffer fish can be safely consumed when special care is taken to ensure that the fish caught are free of toxins, or when they are processed to eliminate the toxins. Over the past year, several illnesses have been linked to puffer fish improperly processed and illegally imported into the U.S. If restaurateurs, retailers, and consumers follow the advice the FDA is providing, puffer fish can be safely enjoyed in the U.S.

The only safe sources for imported puffer fish are fish that have been processed and prepared by specially trained and certified fish cutters in the city of Shimonoseki, Japan. Additionally, puffer fish caught in the mid-Atlantic coastal waters of the U.S., typically between Virginia and New York, are safe to consume. Puffer fish from all other sources can either naturally contain deadly toxins or become toxic because of environmental factors and therefore are not

considered safe.

To view the full text of FDA's Press Release regarding the puffer fish, go to:
<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01727.html>.

Snack Foods

Warning Letter Sent to Glenn Foods For Food Mislabeling

The FDA sent a Warning Letter to Glenn Foods, Inc., of Freeport, New York, after reviewing a label for their Glenny's® Low Fat Soy Crisps (cheddar cheese flavor). The labeling said the product contained a food additive, folic acid. Any substance intentionally added to a conventional food such as soy crisps must be used in accordance with the food additive regulation approving the substance for that use, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety under the conditions of intended use, or is otherwise exempt from the food additive definition. The food additive regulation for folic acid does not provide for the addition of folic acid to snack products. The product also bears the health claims on the back of the label.

Although FDA has authorized a health claim for soy protein and a reduced risk of coronary heart disease, the Glenny's® Low Fat Soy Crisps label did not include all of the elements of the claim that are required by the regulation governing the use of this claim. This product also did not qualify for this health claim because the product was not low in fat.

Also, the FDA has not authorized a health claim associating a reduced risk of coronary heart disease with the consumption of soy isoflavones, folic acid, or calcium. Therefore, the use of hearts to highlight the presence of soy protein, soy isoflavones, folic acid, and calcium under the heading "HEALTHY BENEFITS" constitutes unauthorized health claims that are prohibited in food labeling.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6595c.htm.

Snack Food Manufacturer Received Warning Letter

On December 18, 2007, the FDA's Philadelphia District Office issued a Warning Letter to Keystone Food Products, Inc., of Easton, Pennsylvania, for significant deviations from the CGMP regulations found during an inspection on April 25 through 26, 2007.

FDA inspection of the facility revealed the following sanitation deviations:

- Failure of equipment to be maintained in an acceptable condition through appropriate cleaning and sanitizing;
- Failure of all food contact surfaces to be cleaned as frequently as necessary to protect against contamination of food; and
- Failure of all plant equipment to be so designed and of such material and workmanship as to be adequately cleanable and to be properly maintained.

As a result of these CGMP deviations, an undeclared allergen – milk, was found to adulterate the product.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/s6609c.htm.

Symptoms of Foodborne Illnesses

Azspiracid Toxins

Azspiracid toxins are a group of naturally occurring marine toxins known to cause nausea, vomiting, diarrhea, and stomach cramps. Azspiracid toxins are odorless, tasteless, and cannot be destroyed or neutralized by freezing or cooking, including boiling. Individuals who have experienced gastrointestinal symptoms such as those noted above should consult their health care professional. Symptoms typically occur within hours of consumption and persist for 2 to 3 days.

Ciguatera Toxin

Symptoms of ciguatera (*Gambierdiscus toxicus*) poisoning include nausea,

vomiting, diarrhea, joint pain, muscle pain, headache, reversal of hot and cold sensation (such that cold objects feel hot and vice versa), sensitivity to temperature changes, vertigo, muscular weakness, and numbness and tingling of the mouth, hands, or feet. There also can be cardiovascular problems, including irregular heartbeat and reduced blood pressure. Symptoms usually appear within hours after eating a toxic fish and go away within a few weeks. However, in some cases, neurological symptoms can last for months to years. There is no antidote for CFP; symptoms can be treated most effectively if diagnosed by a doctor with 72 hours. CFP is rarely fatal.

Clostridium Botulinum (Botulism)

Symptoms of botulism toxicity (*Clostridium botulinum*) can begin from six hours to two weeks after eating food that contains the toxin. The symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness that moves progressively down the body, affecting the shoulders first then descending to the upper arms, lower arms, thighs, and calves. Botulism also may cause paralysis of the breathing muscles, which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who show these symptoms and who may have recently eaten the product should seek immediate medical attention.

Cryptosporidium

Cryptosporidium is a protozoan that can cause gastro-intestinal illness with diarrhea in humans. Other symptoms can include dehydration, weight loss, stomach cramps or pain, fever, nausea and vomiting. Symptoms generally begin 2 to 10 days after becoming infected with the parasite and generally last 1 to 2 weeks. While most people with healthy immune systems will recover without treatment, the infection could be serious or life-threatening for certain individuals. Infants, children and pregnant women are susceptible to dehydration resulting from diarrhea, which can be life-threatening. Individuals with weakened immune systems are also at risk for a more serious and life-threatening form of illness.

Lead Poisoning

Lead occurs naturally in the environment. The main target for lead toxicity is the nervous system, both in adults and children. Children are more vulnerable to lead poisoning than adults. Due to the risks it poses, high levels of exposure can severely damage the brain and kidneys in adults or children and ultimately cause death. In pregnant women, high levels of exposure to lead may cause miscarriage. High-level exposure in men can damage the organs responsible for

sperm production. Symptoms of lead toxicity include: stomach aches, colic, nausea, vomiting, abnormal irritability, and insomnia. However, people with lead in their blood often do not exhibit symptoms.

Listeria Monocytogenes (Listeriosis)

Listeria monocytogenes is an organism which can cause illness, mild, moderate or even severe. Healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea. The disease affects primarily frail and elderly persons, pregnant women, newborns, and adults with weakened immune systems. Infected pregnant women may experience only a mild, flu-like illness; however, infections during pregnancy can lead to miscarriage or stillbirth, premature delivery, or infection of the newborn.

Norovirus

Symptoms of norovirus infection include nausea, vomiting, diarrhea and stomach cramping. Affected individuals often experience low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. Most people show symptoms within 48 hours of exposure to the virus, with the illness lasting 1 to 2 days. However, the illness can become serious for the very young, the elderly and people with weakened immune systems.

Paralytic Shellfish Poisoning (PSP)

Symptoms of PSP include tingling and/or numbness of the mouth, face or neck; muscle weakness; headache; and nausea. In extreme cases, when large amounts of the toxin are consumed, these symptoms can lead to respiratory failure and death. Symptoms usually occur within 2 hours of exposure to the toxin. Anyone experiencing these symptoms should seek medical attention.

Puffer Fish

Symptoms of ingesting the toxins found in puffer fish include tingling around the lips and in the extremities followed by problems speaking, loss of balance, muscle weakness and paralysis, vomiting, and diarrhea. In extreme cases, there may be respiratory paralysis that can lead to death.

Salmonella (salmonellosis)

Salmonella is an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with Salmonellosis often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into

the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis.

E. coli O157:H7

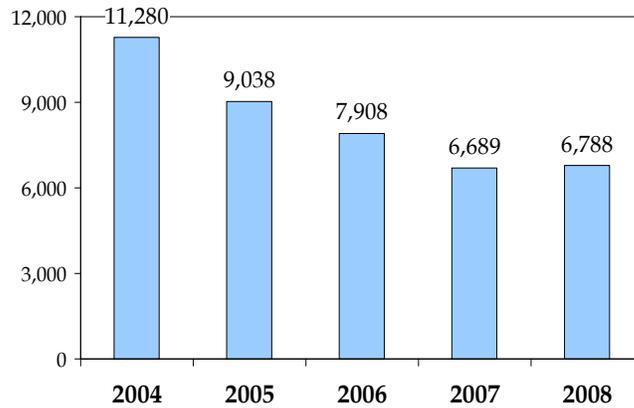
E. coli O157:H7 is a bacterium that causes diarrhea that is often bloody. The diarrhea can be accompanied by abdominal cramps. Fever may be absent or mild. Symptoms usually occur within 2 to 3 days following exposure, but may occur as soon as one day following exposure or up to one week following exposure. Healthy adults can typically recover completely from *E. coli O157:H7* exposure within a week. However, some people, especially young children and the elderly, can develop Hemolytic Uremic Syndrome (HUS) as a result of exposure to *E. coli O157:H7*, a condition that can lead to serious kidney damage and even death.

Vibrio Parahaemolyticus (vibriosis)

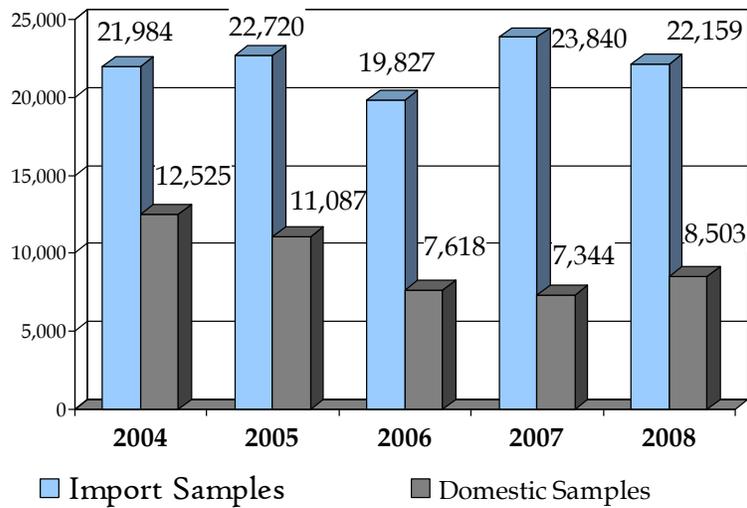
Symptoms of this bacterial infection include watery diarrhea, often with abdominal cramping, nausea, vomiting, fever, and chills. Usually these symptoms occur within 24 hours of ingestion and last no more than 3 days. Severe disease is rare and occurs most commonly in people with weakened immune systems and is most often associated with eating raw oysters.

Enforcement Statistics

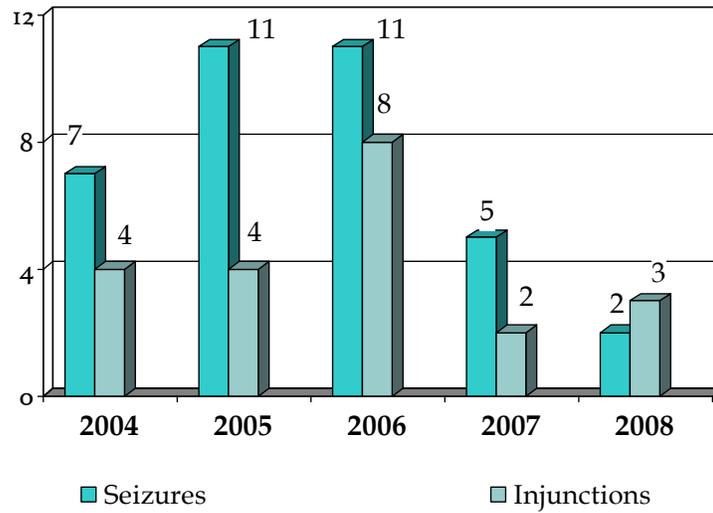
Center for Food Safety and Applied Nutrition
 FDA Foreign and Domestic Inspections
 Fiscal Years 2004 - 2008



Center for Food Safety and Applied Nutrition
 Surveillance: Import and Domestic Samples
 Fiscal Years 2004 - 2008



Center for Food Safety and Applied Nutrition
 Enforcement Statistics
 Fiscal Years 2004 - 2008



Center for Food Safety and Applied Nutrition
 Five-Year Total Product Recall Statistics
 Fiscal Years 2004-2008

