Chapter 4 – Center for Food Safety and Applied Nutrition

Contents

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. A list of Warning Letters issued by FDA is available at: http://www.fda.gov/foi/warning.htm.

Allergens

Warning Letter for Undeclared Milk Protein

On July 13, 2007, FDA's New Jersey District Office issued a Warning Letter to the President and Chairman of Quality Formulation Laboratories, Inc., Paterson, New Jersey. FDA concluded a seven day inspection of this manufacturing facility in February 2007. The FDA inspection found serious Current Good Manufacturing Practices (CGMP) and labeling violations at the firm.

The Warning Letter addressed two of the firm's products: Egg Protein III Vanilla powder mix and American Sports Nutrition™ MAJOR EGG™ powder mixes (in Double Chocolate, Vanilla and Wildberry flavors). FDA analyzed samples of the Egg Protein III Vanilla powder mix collected during the inspection. Although the product was not labeled to contain milk, analytical testing found that some lots of the product did contain milk protein. This bulk ingredient was shipped to one customer, Vitalabs of Jonesboro, Georgia, who conducted a recall of all products containing the bulk ingredient. These products had been further distributed under a variety of names, including Jay Robb's, Carlsbad, California.

In addition, on January 31, 2007, Quality Formulation Laboratories issued a Press Release announcing a voluntary recall of its American Sports Nutrition™ MAJOR EGG™ powder mixes due to undeclared milk.

To view the full text of the Warning Letter, go to http://www.fda.gov/foi/warning_letters/s6421c.htm.

Canned Foods

FDA's Investigative Efforts
Recall: Chili Products (Botulism)

On July 18, 2007, FDA warned consumers not to eat 10 ounce cans of Castleberry's Hot Dog Chili Sauce (UPC 3030000101), Austex Hot Dog Chili Sauce (UPC 3030099533), and Kroger Hot Dog Chili Sauce (UPC 1111083942) with "best by" dates from April 30, 2009 through May 22, 2009 due to possible botulism contamination. Castleberry's Food Company, ("Castleberry's") of Augusta, Georgia, announced a recall of these products after receiving notification from FDA and the Centers for Disease Control and Prevention (CDC) of the possible botulism contamination. Exposure to botulinum toxin can be fatal.

On July 17, 2007, FDA initiated a joint inspection with the U.S. Department of Agriculture (USDA), at Castleberry's Augusta, Georgia facility. The inspection disclosed problems that could have caused under-processing of the implicated products.

On July 21, 2007, FDA expanded its July 18th warning to consumers. This latest expansion was for consumers and pet owners regarding canned food products and dog food produced by "Castleberry's" due to the risk of botulinum toxin. "Castleberry's" expanded the recall to include all of the following FDA-regulated canned products with all "best by" and code dates, and FDA warned consumers not to purchase or eat any of the canned products listed in the table below.

Hot Dog Chili Sauces	SIZE	UPC CODES
Castleberry's Austex Onion Hot Dog Chili Sauce	10 OZ	30300-97101
Castleberry's Austex Hot Dog Chili Sauce	10 OZ	30300-99533
Castleberry's Hot Dog Chili Sauce	10 OZ	30300-00101
Castleberry's Onion Hot Dog Chili Sauce	10 OZ	30300-07101
Castleberry's Bunker Hill Hot Dog Chili Sauce	10 OZ	75266-04152
Kroger Hot Dog Chili Sauce	10 OZ	11110-83942

Meijer Hot Dog Chili Sauce	10 OZ	41250-85862
Food Lion Hot Dog Chili Sauce	10 OZ	35826-06911
Bloom Hot Dog Chili Sauce	10 OZ	25439-92448
Thrifty Maid Hot Dog Chili Sauce	10 OZ	21140-21367
Natural Balance Eatables dog food varieties:		
Irish Stew with Beef Dog Food	15 OZ	23633-59860
Chinese Take Out with Sauce with Vegetables and Chicken Dog Food	15 OZ	23633-59861
Southern Style Dumplings with Gravy with Chicken and Vegetables Dog Food	15 OZ	23633-59862
Hobo Chili with Chicken Pasta Dog Food	15 OZ	23633-59863

The agency expanded its warning based in part on FDA test results and information obtained during a joint FDA and USDA inspection of Castleberry's facility in Augusta, Georgia.

While the previous recall and the known illnesses were linked to "best by" dates of April 30 to May 22, 2009, on August 1, 2007, the firm extended the recall to include all products listed regardless of the "best by" date. "Castleberry's" cooperated with FDA in the recall of these products and ceased processing and distribution.

In addition, "Castleberry's" recalled other products containing meat, which are regulated by the USDA. The USDA also warned the public not to eat certain brands of Castleberry's products containing meat. The list of these USDA-regulated products can be viewed at this link to the USDA website: http://www.fsis.usda.gov/News_&_Events/Recall_033_2007_expanded/index.asp.

Consumers who may have had any of these products or any foods made with these products were instructed to throw them away immediately. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm.

Retailers that had any of these products were asked to assure that they were removed from use and did not accidentally get reintroduced for sale, service or donation.

Symptoms of botulism poisoning in humans can begin from six hours to two weeks after eating food that contains the toxin. For additional information on botulism, go to "Symptoms of Foodborne Illness" at the end of the chapter.

FDA, in collaboration with the USDA's Food Safety and Inspection Service (FSIS) and numerous state agencies, completed visits to thousands of retail establishments to ensure that canned food and pet food products manufactured and distributed by "Castleberry's" that may contain the botulism toxin were removed from store shelves and safely disposed.

Although the products had been recalled by "Castleberry's", FDA investigators found potentially contaminated product still being sold in a total of 1,303 out of the 12,989 stores visited. FDA's food safety partners at FSIS and state agencies also visited thousands of retail stores. State agency inspectors identified an additional 1,192 stores that were still selling potentially contaminated product out of 10,073 stores visited.

This collaborative approach among the USDA, state agencies, and the FDA was implemented due to the size of the recall and the severity of the hazard, and was initiated early in the recall process to augment the efforts of the recalling firm, which bears responsibility for conducting an effective recall. This unique, effective method resulted in the removal of harmful product from the market, prevention of further injuries, and public health protection.

Information on Botulism in Animals:

Botulism has only been seen occasionally in dogs. Ferrets are highly susceptible to botulinum toxin. The incubation period can be two hours to two weeks; in most cases, the symptoms appear after 12 to 24 hours. Botulism is characterized by progressive motor paralysis. Typical clinical signs may include muscle paralysis, difficulty breathing, chewing and swallowing, visual disturbances and generalized weakness may also occur. Death usually results from paralysis of the respiratory or cardiac muscles. Pet owners who may have used these products and whose pets exhibited these symptoms were instructed to contact their veterinarian immediately. At the time of the recall, FDA was not aware of pet illnesses associated with these products although the agency recommended that these products be discarded.

"Castleberry's" recommended that consumers with any questions or concerns about this recall go to Castleberry website (www.castleberrys.com) or call Castleberry's consumer hotline at 1-800-203-4412 or 1-888-203-8446. Consumers with questions could also call FDA at 1-888-SAFEFOOD.

The products included in the voluntary recall have not changed since the recall was expanded on July 21st. To view the full list of recalled products, which includes both human and pet foods, go to: http://www.fda.gov/oc/po/firmrecalls/castleberry08_07.html.

To view full text of FDA's Press Release, go to:
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01670.html

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

FDA issued a warning on August 3, 2007, to consumers not to eat certain brands of French Cut Green Beans in 14.5 ounce cans manufactured by Lakeside Foods Inc, of Manitowoc, Wisconsin. The warning was based on the fact that the product may not have been processed adequately to eliminate the potential for the botulism toxin.

The canned green beans were the recalled because they may cause botulism if consumed. FDA provided this warning to make consumers aware of the possible risk of serious illness from eating these products. FDA warned that the botulism toxin is very potent, and botulism is a life-threatening illness. (To read the full description and incidence of this illness, see the Foodborne Illness section at the end of this chapter.)

The affected Lakeside cut green beans were sold nationwide under the following labels: Albertson's, Happy Harvest, Best Choice, Food Club, Bogopa, Valu Time, Hill Country Fare, HEB, Laura Lynn, Kroger, No Name, North Pride, Shop N Save, Shoppers Valu, Schnucks, Cub Foods, Dierbergs, Flavorite, IGA, Best Choice and Thrifty Maid. The specific codes (top line of can code) involved were: EAA5247, EAA5257, EAA5267, EAA5277, EAB5247, EAB5257, ECA5207, ECA5217, ECA5227, ECA5297, ECB5207, ECB5217, ECB5227, ECB5307.

FDA advised consumers who had any of these products or any foods made with these products to dispose of them immediately. If the code on an affected can was missing or unreadable, consumers were also advised to safely dispose of the product.

Warning: Contaminated Olives with Threat of *Clostridium botulinum*

On April 13, 2007, FDA issued an urgent warning to consumers regarding possible serious health risks from eating olives that may be contaminated with the deadly bacterium, *Clostridium botulinum*. The olives were made by Charlie Brown di Rutigliano & Figli S.r.l, of Bari, Italy, and were being recalled by the manufacturer. No illnesses had been reported at the time of this recall.

FDA advised that the olives should not be eaten alone or in other foods, even if they did not appear to be spoiled. Consumers were instructed to discard these products or return them to the point of purchase. If in doubt, consumers were told they should contact the retailer and inquire whether its olives were part of the recall.

The first notification of a problem occurred in December 1, 2006, after the Canadian Food Inspection Agency issued a warning for Saroli brand Green Bella Di Cerignola Olives to advise of a *Clostridium botulinum* potential risk. Based on the manufacturer's process filings with CFSAN, these foods are considered "acidified foods."

On January 8, 2007, CFSAN issued a sampling assignment to determine whether the products presented a potential for the growth and production of *C. Botulinum* toxin in the product.

Analysis revealed that some samples of the products were violative in that the pH and water activity were high, indicating that the products may not have been adequately processed to prevent the growth of *C. botulinum*.

On March 27, 2007, Charlie Brown di Rutigliano & Figli S.r.l, initiated a recall of its olives sold under the following brands: Bonta di Puglia, Cento,

Corrado's, Dal Raccolto, Flora, Roland and Vantia, and had codes that started with the letter "G" and were followed by 3 or 4 digits. All sizes of cans, glass jars and pouches of Cerignola, Nocerella and Castelvetrano type olives were affected.

The recalled olives were distributed to wholesalers, who marketed them nationally to restaurants and retail stores. FDA concluded that additional warnings were needed because the company had not contacted importers with specific instructions on the recall.

In addition, FDA required olives, as well as all other food products manufactured by Charlie Brown di Rutigaliano & Figli S.r.l. to be subject to import restrictions to prevent entry of violative products into the United States.

To view the full text of the FDA Press Release for this recall, go to: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01608.html.

Cosmetics

Warned Letter For Illegal Sale of Melanotan II

Warning Letter Issued for Sale and Marketing of Injectable Tanning Agent

On August 30, 2007, FDA issued a Warning Letter to the owner of Melanocorp, Inc., located in Hendersonville, Tennessee, for the illegal sale and marketing of the product Melanotan II, which is not FDA-approved. Melanocorp, Inc., was promoting the product on its web site as an injectable tanning product, with additional claims that it was effective in protecting against skin cancer and rosacea (a flushing and redness of the skin). These claims cause Melanotan II to be classified as a drug under the Federal Food, Drug, and Cosmetic Act, as well as a new drug because this product does not have an approved new drug application. In addition, there is no evidence that the product is generally recognized as safe and effective for its labeled uses. The web site also made false and misleading statements. The introduction and delivery of the product into interstate commerce, therefore, violated federal law.

The risks run by patients who use unapproved new drugs could include adverse

side effects from inappropriately prescribed medications, dangerous drug interactions, and harm from contaminated, counterfeit or outdated drugs. FDA cautioned consumers about injecting any substance, particularly products that are not FDA-approved, into their bodies without the oversight of a licensed health care provider.

Issuance of the Warning Letter is consistent with FDA's focus on fraudulent products marketed on the internet for serious and life-threatening diseases.

The Warning Letter is available on FDA's Web site at:
http://www.fda.gov/foi/warning_letters/s6491c.htm.

Warning Letter to Cosmetics Distributor About Drug Claims

On April 24, 2007, FDA's New Jersey District Office issued a Warning Letter to Fusion Brands International, the distributor of LiftFusion brand cosmetics. The firm is an own-label distributor located in Ottawa, Canada. The Warning Letter was in reference to the firm's marketing and distribution of LiftFusion TM brand products, Micro-injected M-Tox TM Transdermal Face Lift, Mini Micro-injected M-Tox TM Transdermal Face Lift, and Micro-injected M-Tox TM Transdermal Eye Lift.

In January 2007, FDA conducted an inspection at the firm's co-packer, Cosmetic Essence Inc. in Ridgefield, New Jersey. This inspection revealed that Fusion Brands provided the labeling for their LiftFusion Transdermal Facelift and Eyelift cosmetic creams, which bore drug claims. FDA also reviewed the firm's Internet web site and the labeling for these products, including the literature that accompanied the products when shipped to customers.

The labeling claimed the products were more effective than Botox injections, repaired deep facial lines and furrows, relaxed facial muscles, and blocked muscle contractions. The products were also misbranded in that the packaging failed to accurately identify the manufacturer or distributor of the products.
To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6371c.htm.

Dairy

Guilty Plea by Milk Distributor

On November 2, 2006, Gary Oaks, owner of Double O Farms, Verona, Kentucky, pled guilty to two charges of violating Ohio statutes regarding the regulation of dairy products. The charges included acting as a raw milk dealer without a valid state license and for sale of a dairy product that was not labeled in accordance with the "Nutrition Labeling and Education Act of 1990."

Oaks was fined $415 and court costs. Oaks had previously been issued a Warning Letter by FDA in June 2006, for his delivery in interstate commerce of raw (unpasteurized) milk for direct human consumption. The action was part of a joint investigation by the Ohio Department of Agriculture, the Commonwealth of Kentucky and FDA's Cincinnati District Office.

Milk Plant Shut Down

On June 25, 2007, at the request of the Indiana Board of Animal Health (IBOAH) CFSAN removed the Goshen, Indiana Plant owned by Dairy Foods of America from the Interstate Milk Shippers' List, causing the firm to be unable to ship Grade 'A' milk. An inspection completed on June 21, 2007, found a number of sanitation deficiencies. In accordance with the procedures of the National Conference of Interstate Milk Shippers, the firm was required to make corrections and request re-inspection from IBOAH before it would be allowed to resume shipping Grade 'A' milk products.

Recall/Market Withdrawal: Raw Cream with *Listeria monocytogenes*

On September 7, 2007, the California Department of Food and Agriculture (CDFA) issued an order to Organic Pastures Dairy Company to withdraw Grade

'A' raw cream manufactured at the firm's facility in Fresno, from the retail marketplace due to detection of *Listeria monocytogenes* bacteria.

The quarantine order came following laboratory confirmation of *Listeria monocytogenes* bacteria. CDFA inspectors found the bacteria as a result of product testing conducted as part of its routine inspection and sampling collection at the facility.

The withdrawal order involved removal of raw cream from grocery stores, retail outlets and farmers' markets throughout California.

The firm also voluntarily recalled product that had been distributed outside of the state of California. Under the recall, Organic Pastures brand Grade A raw cream with code dates September 14th through September 21st, was to be pulled immediately from retail shelves and consumers were strongly urged to dispose of any product remaining in their refrigerators.

As of September 20, 2007, CDFA had permitted Organic Pastures to sell and distribute raw cream within the state of California.

Pasteurization eliminates the risk of bacterial illness. The great majority of cream consumed in California is pasteurized; raw cream is not.

Recall: Soups with Undeclared Milk Ingredient

On September 12, 2007, Harry & David Operations Corp., Medford, Oregon, recalled approximately 1,440 bags of Harry and David Hearthside Soups, Southwestern Chicken Chili Mix, because the product might contain different chili soup mix which contained a milk ingredient (whey). The milk ingredient (whey) was not declared in the ingredient statement.

People who have an allergy or severe sensitivity to dairy products run the risk of serious or life-threatening allergic reaction if they consume these products.

Harry & David recalled all Harry and David Hearthside Soups, Southwestern Chicken Chili Mix with a 8221-1 lot code. These products included: Clear plastic bags of soup mix, 12 to 16 oz. in weight, tied at the top with a cream and red

colored ribbon. The lot code could be found on the price sticker on the bottom of the bag. This product was made for Harry & David by Conifer Specialty, Inc., a co-packer.

Complete details of the recall may be found online at: http://www.fda.gov/oc/po/firmrecalls/harrydavid09_07.html.

Dietary Supplements

Seizure of Dietary Supplements
Charron Nutrition

On August 23, 2007, U.S. Marshals, at the request of FDA, seized the following articles of drug: Glucobetic, Neuro-Betic, Ocu-Comp, atri-oxi, super-flex, msm-1000 and atri-e-400. The products were located at the distributor, Charron Nutrition, Tallahassee, Florida. The articles were seized because they were in violation of the new drug and misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

Although these articles were represented as "dietary supplements," they were being promoted as drugs based on claims made in their labeling, including promotional literature, which was distributed with the articles by Charron Nutrition.

Previously on October 12, 2006, FDA had sent a Warning Letter to Charron Nutrition advising the firm that it was distributing unapproved new drugs because of the therapeutic claims contained on the firm's website. The website promoted the products for use in the cure, mitigation, treatment, and prevention of disease. The Warning Letter requested that the firm take corrective action to remove the therapeutic claims. The firm did not respond. Subsequent FDA inspections conducted in March 2007 and again in April 2007, revealed that the firm's operations were unchanged and that the violations continued.

FDA reviewed the firm's website in May and again in July 2007, and found that,

while some changes were noted, drug claims were still being used to promote the firm's products.

Seizure of Dietary Supplements
Vitality Products Co., Inc.

On January 17, 2007, the U.S. Marshals Service, accompanied by FDA investigators, seized approximately 38 cases of Highest Potency Acidophilus Capsules, Idebenone Capsules, MSM Powder & Capsules, Dietary Supplements. The goods were seized at Vitality Products Co., Inc., located in Olympia, Washington.

Although the goods were represented as "dietary supplements," they were being promoted as drugs based on the claims in their labeling. The labeling included promotional literature distributed with the articles by Vitality Products. The firm also operated an internet website that was used for marketing and promoting the firm's products for drug uses. Vitality Products promoted and marketed these articles for serious diseases including Alzheimer's, ischemic heart disease, congestive heart failure, stroke, multiple sclerosis, and colon cancer.

Previously, on June 17, 2005, FDA had issued a Warning Letter to Vitality Products advising that, among other things, the firm was distributing unapproved new drugs because therapeutic claims contained in the labeling (such as product literature) and on the firm's website promoted the products for use in treating serious health conditions. The Warning Letter requested that the firm take corrective action to address the therapeutic claims. The firm responded to the Warning Letter and submitted revised product labels. However, the firm's response did not address the therapeutic claims made in the firm's labeling, such as the promotional material that accompanied each product order. A subsequent FDA inspection conducted in September 2006, revealed that the firm continued to distribute the labeling containing the drug claims. FDA reviewed the firm's website in October 2006, and found that drug claims was still being used to promote the firm's products.

Warning Regarding Arsenic in "Jermuk" Mineral Water

On March 7, 2007, FDA issued a warning to consumers not to drink certain brands of mineral water imported from Armenia due to the risk of exposure to arsenic, a toxic substance and known cause of cancer in humans. The products were distributed nationwide.

The warning was a result of FDA analysis of the product, which revealed 500-600 micrograms of arsenic per liter. This exceeds FDA's 10 microgram of arsenic per liter standard of quality for bottled water. As a result, four brands were recalled:

- Zetlian Bakery, Inc., Pico Rivera, CA recalled product labeled as "Jermuk Original Sparkling Natural Mineral Water Fortified With Natural Gas From The Spring***2006 Jermuk Mayr Gortsaran CJSC***Imported by: Zetlian Bakery Inc."
- Zetlian Bakery, Inc., Pico Rivera, CA recalled product labeled as "Jermuk,1951, Natural Mineral Water, Jermuk Mayr Gortsaran CJSC***Imported by: Zetlian Bakery Inc."
- Importers Direct Wholesale Company Los Angeles, CA recalled product labeled as "Jermuk Sodium Calcium Bicarbonate and Sulphate Mineral Water***Bottled by ARPI Plant, Republic of Armenia***Exclusive US importer and distributor: Importers Direct Wholesale Co., Los Angeles, CA".
- Kradjian Importing Company, Glendale, CA recalled product labeled as "Jermuk, Natural Mineral Water Sparkling***Bottled by Jermuk Group CJSC***"Sale Agent Kradjian Importing Co. Inc."

On March 16, 2007, one of the product's distributors, Andreas Andreasyan DBA Arnaz & Nelli Co., North Hollywood, California, initiated a recall of product labeled as "Jermuk Natural Mineral Water Fortified with Gas from the Springs *** Produced by Sam-Har Co. Republic of Armenia *** Exclusive Distributor in USA: Arnaz & Nelli Inc., CA 91605."

On March 24, 2007, FDA re-issued its warning to consumers not to drink "Jermuk" brand mineral water due to the risk of exposure to arsenic. The agency provided this information for a second time due to the expansion of the recall "Jermuk" water was imported from Armenia and distributed under different labels in California.

On May 31, 2007, FDA issued a warning for consumers in the West Chester, Pennsylvania area not to drink any "Jermuk" brand mineral water due to the risk of exposure to arsenic, a toxic substance and a known cause of cancer in humans. This action was taken after Jermuk Classic Medicinal Table Natural Sparkling Mineral Water in 0.5 liter, green translucent glass bottles under the Jermuk Group brand label was recalled on May 1, 2007, by AA Impex Group, Philadelphia, Pennsylvania. Approximately 200 bottles of the product were sold at the Great Pumpkin Corporation, West Chester, Pennsylvania, a retail store.

FDA sampled the product and had found that it contained 536 - 539 micrograms of arsenic per liter of water, in excess of FDA's allowable limit. Consumers who drank this water and had concerns were encouraged to contact their health care provider.

Although arsenic is a well known human poison, there is little chance that someone would become seriously ill after consuming the recalled products over a brief period of time (days to weeks). However, it is likely that the person would experience nausea, abdominal pain and possibly vomiting, which are indicators of arsenic toxicity.

To view the press releases, go to:
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01594.html and
www.fda.gov/bbs/topics/NEWS/2007/NEW01581.html.

Warning Issued Regarding *Cryptosporidium* Illness in Baby's Bliss Gripe Water

On September 20, 2007, FDA issued a warning to consumers not to consume Baby's Bliss Gripe Water, apple flavor, with a code of 26952V and expiration date of October 2008 (shown as "10/08" on the label), distributed by MOM Enterprises, Inc., of San Rafael, California. After investigating the illness of a six-week-old infant in Minnesota who consumed the product, FDA confirmed the presence of *Cryptosporidium* through laboratory analysis. *Cryptosporidium* is a parasite that can cause intestinal infections.

FDA advised parents and caregivers who had given Baby's Bliss Gripe Water, apple flavor to their infants/children to be alert for diarrhea and other signs of the *Cryptosporidium* infection, and to seek immediate medical attention if necessary.

Approximately 17,600 bottles of the product were distributed nationwide in retail stores and sold over the Internet between November 2006 and September 2007. A code of 26952V with an expiration date of 10/08 appeared on the bottle's carton. The product was sold in a four-ounce plastic bottle packaged inside of a cardboard carton which was labeled with the following:

> Baby's Bliss. Pediatrician Recommended Gripe Water. Apple Flavor. An herbal supplement used to ease the gas and stomach discomfort often associated with colic, hiccups, and teething. Dietary Supplement. 4 fl. oz. (120 ml). Ginger Extract. Fennel Extract. Other ingredients: Deionized Water, Vegetable Glycerin, Fructose, Natural apple flavor, Citric acid, Bioflavonoid Extract, and Grapefruit Seed Extract. Distributed by: MOM Enterprises, Inc., San Rafael, CA 94903 USA.

FDA advised consumers to throw away bottles of the product described above. MOM Enterprises, Inc. recalled all potentially contaminated products.

To view the full text of the FDA Press Release, go to http://www.fda.gov/bbs/topics/NEWS/2007/NEW01707.html.

New Initiative Against Fraudulent Vendors of Diabetes Cures and Treatments

FDA, FTC and Foreign Countries Launch Drive to Stop Illegal Sale of Deceptive Products for Diabetes

On October 19, 2006, the Federal Trade Commission (FTC) and FDA, announced that both agencies were working with foreign government agencies in Mexico and Canada, and had launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign included approximately 180 Warning Letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web search for "hidden traps" by the International Consumer Protection and Enforcement Network (ICPEN), an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices in Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products.

Using the results of the Internet sweep, FTC sent Warning Letters for deceptive ads to domestic and Canadian Web sites targeting U.S. consumers, and referred an additional 21 sites to foreign governments.

FDA also announced it had issued Warning Letters to 24 firms marketing dietary supplement products with claims to treat, cure, prevent or mitigate diabetes (see link to Warning Letters at http://www.cfsan.fda.gov/~dms/dialist.html).

FDA developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy is designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. Within the last twelve months, the agency has sent more than 100 Warning Letters and other advisories to Internet firms.

To view the full text of the Press Release, go to:
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01494.html.

"Cyber" Letters

In 2000, FDA began issuing "cyber" letters, (letters sent electronically via the Internet), to web sites whose online sales of prescription drugs may be illegal. The letters warn these website operators that they may be engaged in illegal activities and informs them of the laws that govern prescription drug sales. FDA also issues cyber letters to firms marketing products purported to be dietary supplements on the internet with disease claims.

"Cyber" letters are issued by CFSAN and the Center for Drug Evaluation. Cyber letters issued from CFSAN are to Internet website operators promoting dietary supplement products that claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. Matters described in all FDA Cyber Letters may have been subject to subsequent interaction between FDA and the recipient of the letter. As a result, the regulatory status of the issues discussed in the letters may have subsequently changed.

A list of the Cyber Letters is available on CDER's Internet Website at: http://www.fda.gov/cder/warn/cyber/cyber2002.htm.

Recall: Shark Cartilage Capsules
Due to Possible *Salmonella* Contamination

On May 16, 2007, NBTY, Inc., of Bohemia, New York, recalled 3 lots of Shark Cartilage Capsules manufactured in 2004. The product had the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. (To read the full description and incidence of this illness see Foodborne Illness at the end of this chapter.)

The Shark Cartilage Capsules were distributed to consumers through mail orders, internet orders, and retail stores throughout the United States.
To view the full text of the Press Release, go to:
http://www.fda.gov/oc/po/firmrecalls/nbty05_07.html.

Warning Letter Issued to Mother Soy

On October 24, 2006, FDA's Detroit District Office issued a Warning Letter to MotherSoy Inc., Evansville, Indiana, for misbranding its Essential IsoFlavones and Essential Protein shake products. FDA conducted an inspection at MotherSoy on June 26 – 29, 2006. The inspection disclosed that the firm was offering dietary supplements online with health claims that claimed to cure, mitigate, treat or prevent cancer, heart disease, chronic fatigue syndrome and

other diseases and conditions.

Previously in March 2000, the firm received a Warning Letter for similar violations with its Essential Pro Plus and California Joe Drink protein shakes. The firm discontinued the marketing and sales of these products. However, the compliance follow-up inspection found the firm continued to make health claims for its dietary supplements, making their products unapproved drugs.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/g6093d.htm.

Warning Letter: Bee Pollen Products with Drug Claims

On March 2, 2007, FDA's Minneapolis District Office issued a Warning Letter to Beehive Botanical, Hayward, Wisconsin. FDA conducted an inspection of the firm on November 14 and 15, 2007, which disclosed that several products were labeled with unapproved health claims. In addition, FDA reviewed the firm's web site.
The above-referenced inspection and FDA's review of the firm's web site revealed serious violations of the Act in the labeling of the firm's Standardized Bee Propolis Dietary Supplement, PropolPom™ Bee Propolis Pomegranate Dietary Supplement, Bee Pollen Whole Grain Dietary Supplement (capsules, tablets and granules), Royal Jelly Dietary Supplement (1000 mg), Propolis & Herb Throat Spray, Propol-Guard Lip Balm, Therapeutic Derma Cream and Propolis 50% and 65% Tinctures. The therapeutic claims made for these products caused them to be unapproved new drugs. In addition, the firm promoted the Propolis Tincture and a Propolis Extract for use as a liquid bandage, which caused them to be unapproved medical devices.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/b6276d.htm

Food Storage

Mass Seizure at Warehouse
N&F Logistic, Inc.

On July 14, 2007, at the request of FDA, U.S. Marshals seized 260/100 pound bags of rice and all other articles of food (excluding food in metal and glass containers) at N&F Logistic, Inc., located in Harahan, Louisiana. FDA conducted an inspection of this facility from June 6 - 22, 2007. The inspection disclosed widespread rodent infestation. In addition, FDA laboratory analyses of samples collected during the inspection confirmed the presence of rodent excreta pellets and rodent urine in and on food articles, and rodent urine stains through all layers of food bagging.

FDA's inspection also documented poor employee practices as evidenced by coffee cups and an employee lunch plate in the warehouse. These insanitary conditions rendered the food in containers susceptible to contamination by rodents, birds and insects; and adulterated because these foods may have become contaminated with filth.

Liquid Damages Assessed against Happy Valley Food Corp.

On March 13, 2007, FDA's Baltimore District Office issued a letter assessing $2,000 in liquidated damages to Happy Valley Food Corporation and $5,000 against SBC Food Corporation (SBC) under a Consent Decree of Condemnation and Injunction entered on March 30, 2006. The Consent Decree allows for the assessment of $1000 per day for each day that the firm is found to be out of compliance with the Consent Decree and an additional $1000 for each violation. Happy Valley was cited for violating the Consent Decree on two documented occasions:

- for receiving and distributing articles of food in interstate commerce in violation of the Consent Decree; and

- failing to notify the agency prior to selling the firm to SBC Food Corporation.

SBC Food Corporation, a successor corporation, was also cited for violating the Consent Decree on two documented occasions:

- for adulterating articles of food, evidence of rodent activity within the facility was documented during four days of an inspection concluding on September 11, 2006; and

- for failing to maintain a written sanitation control procedure required under the Consent Decree.

Consent Decree of Condemnation
Beef Brands, Inc.

On March 19, 2007, Detroit District Officials and the U.S. Marshals Service witnessed the destruction of approximately over $100,000 worth of seized food products at Reef Brands, Inc., Detroit, Michigan, a wholesale warehouse. As a result of a Consent Decree of Condemnation ordered on January 6, 2006, Reef Brands, Inc., agreed to the voluntary mass destruction of food products seized at its facility on October 2, 2005. The Consent Decree of Condemnation was based on rodent infestation.

Imports

Importer Sentenced for Failure to Provide Prior Notice

On September 5, 2007, the Co-Owner and Vice-President of North Fish Co., Etobicoke, Ontario, Canada, was fined $2,500. The fine was based on a plea agreement entered on May 29, 2007, in the U.S. District Court for the Western District of New York; a one-count Information charging a violation of 21 U.S.C. 331(ee) and 333(a)(1) -- failure to submit prior notice of the importation of food. This case was the culmination of an investigation by FDA's New York District Office, U.S. Customs and Border Protection (CBP), the OCI Buffalo Domicile

Office, CBP ICE (Immigration and Customs Enforcement), and the Canadian Food Inspection Agency (CFIA).

The investigation involved a shipment of salmon roe which had been rejected by CFIA and entered at the Peace Bridge in Buffalo, New York, on March 21, 2006, by North Fish. CFIA had notified FDA's New York District of the rejection of the cans of Pacific salmon roe at North Fish due to potential pathogen growth based on low salt in the water phase of the product.

CBP conducted a Vehicle and Cargo Inspection System examination of the truck upon entry and noted anomalies in the cans. Examination of the truck by agencies including FDA and CBP, revealed a pallet of unlabeled loose cans in the nose of the truck containing 35 full cans of salmon roe on the top portion of the pallet. The rest of the pallet was layered with full unlabeled cans of tuna on the perimeter of each layer, and empty upside down cans of salmon roe within each layer. CBP seized the entire pallet of various cans (salmon roe, tuna, and empty cans). CFIA was notified and conducted an immediate inspection of the North Fish facility in Canada, and found 336 cans of the previously rejected salmon roe on a shrink wrapped pallet, presumably for shipment.

Nationwide Import Alert: Farm-Raised Chinese Seafood
Contained Potentially Harmful Residues

On June 28, 2007, FDA announced the need for broad import controls of all farm-raised catfish, bass, shrimp, dace (related to carp), and eel from China and put an Import Alert in place covering these products. FDA said it will detain these products at the border until the shipments are proven to be free of residues from drugs that are not approved in the United States for use in farm-raised aquatic animals. This action by FDA will protect American consumers from unsafe residues that have been detected in these products.

"We're taking this strong step because of current and continuing evidence that certain Chinese aquaculture products imported into the United States contain illegal substances that are not permitted in seafood sold in the United States," said Dr. David Acheson, FDA's Assistant Commissioner for Food Protection. "We will accept entries of these products from Chinese firms that demonstrate compliance with our requirements and safety standards."

During a targeted sampling period from October 2006 through May 2007, FDA repeatedly found that farm-raised seafood imported from China was contaminated with chemical agents that are not approved for this use in the United States.

The chemicals found during sampling were the following: nitrofuran, malachite green, gentian violet, and fluoroquinolone. Nitrofuran, malachite green, and gentian violet have been shown to be carcinogenic after long-term exposure in lab animals. The use of fluoroquinolones in food animals may also increase antibiotic resistance to this critically important class of antibiotics.

None of these substances is approved for use in farm-raised seafood in the United States. Chinese officials have acknowledged however, that fluoroquinolones are used in Chinese aquaculture and are permitted for use in China. FDA is concerned about long term exposure as well as the possible development of antibiotic resistance.

FDA's Import Alert includes conditions under which an exporter can be exempted from FDA's detention action by providing specified information to FDA. This information must demonstrate the exporter has implemented steps to ensure that its products do not contain these substances and that preventive controls are in place. The additional import controls placed on seafood from China will last as long as needed.

FDA may allow the entry into the United States and subsequent distribution into the marketplace of individual shipments of the Chinese farm-raised seafood products if the company provides documentation to confirm the products are free of residues of these drugs.

FDA's Import Alert can be found at:
http://www.fda.gov/ora/fiars/ora_import_ia16131.html.

FDA has created a web page entitled, "Questions and Answers on FDA's Import Alert on Farm-Raised Seafood From China." The web page is on CFSAN's website at:
http://www.cfsan.fda.gov/~frf/seadwpe.html.

Warning Letters to Seafood Importers

- On May 8, 2007, FDA's Florida District Office issued a Warning Letter to El Reglano Seafood Corporation, Miami, Florida. An FDA inspection of the firm on April 4 and 16, 2007, revealed serious violations of the seafood HACCP regulation. The firm failed to perform an affirmative step for fresh whole imported Spanish Mackerel in that it had not obtained a written guarantee or a copy of their HACCP plan in English, as required by the firm's written verification procedures. In addition, product specifications and HACCP documents from the foreign processor were inadequate in that they failed to include a HACCP plan, failed to identify specific fishery products with food safety hazards and lacked an adequate written guarantee.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6372c.htm.

- On April 26, 2007, FDA's Florida District Office issued a Warning Letter to the President of FAVPEP, LLC, d/b/a/ Queenmar LL, Miami, Florida. FDA conducted an inspection of this seafood import establishment on March 6 - 7, 2007. The FDA inspection disclosed a serious violation of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation. As an importer of fish or fishery products, the firm must comply with the HACCP requirements contained in 21 CFR Part 123.

  The Warning Letter advised that the firm must implement an affirmative step that will ensure that the fish and fishery product(s) that the firm imports are processed in accordance with the seafood HACCP regulation. Although the firm stated that the foreign processor was inspected on a monthly basis, the firm had no such records of these inspections to ensure the crabmeat was being processed in accordance with the regulation requirements.

  To view the full text of the Warning Letter, go to:
  http://www.fda.gov/foi/warning_letters/s6378c.htm.

- On June 25, 2007, FDA's Florida District Office issued a Warning Letter to the Owner and President of J & J Seafood, Inc., Miami, Florida, for seafood HACCP violations found during an inspection of the firm on April 18 and 20, 2007. The firm failed to implement written verification procedures for

ensuring that its fish products were processed in accordance with the seafood HACCP regulations. Specifically, the firm failed to perform an affirmative step for imported whole fresh yellowfin tuna, causing the tuna to be adulterated.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6416c.htm.

Honey Labeled as Apple Juice Concentrate Detained

In July 2007, FDA's Seattle District detained drums of Honey shipped from Quebec because they were violative for lead-based paint chips. The lead concentration in the paint chips was 84,700 ppm. The honey was shipped in drums that were labeled as pure Chinese apple juice concentrate.

Also in July 2007, FDA's Seattle District detained a second shipment of honey that was found violative for lead-based paint chips. The lead concentration in the paint chips for this shipment of honey was 128,000 ppm. The honey was shipped in drums which were also labeled as pure Chinese apple juice concentrate.

Juice

Warning: Do Not Drink Bolthouse Farms Carrot Juice Due to Botulism Concerns

In late September 2006, FDA issued a warning to consumers not to drink Bolthouse Farms Carrot Juice, 450 mL and 1 liter plastic bottles, with "BEST IF USED BY" dates of NOV 11 2006 or earlier. FDA issued this warning in response to a fourth case of botulism poisoning that was linked to Bolthouse Farms, Bakersfield, California brand carrot juice. FDA advised that consumers should discard this product. FDA also reiterated its advice to

consumers to keep carrot juice — including pasteurized carrot juice — refrigerated.

The fourth case of botulism poisoning involved an adult female in Florida. One link between the illness and the consumers who became ill appeared to be that the juice they drank was not properly refrigerated once it was in the home, which allowed the *Clostridium botulinum* spores to grow and produce toxin.

Clostridium botulinum is a bacterium commonly found in soil. Under certain conditions these bacteria can produce a toxin that if ingested can result in botulism, a disease that may cause paralysis or death. Cases of botulism from processed food are extremely rare in the U.S. To read the full description and incidence of this illness see Foodborne Illness at the end of this chapter.

Adequate refrigeration is one of the keys to food safety and is essential to preventing bacterial growth. Refrigerator temperatures should be no higher than 40°F and freezer temperatures no higher then 0°F. Consumers should check the temperatures occasionally with an appliance thermometer.

Consumers should look for the words "Keep Refrigerated" on juice labels so they know which products must be kept refrigerated. FDA is looking into whether industry's current juice labels provide clear refrigeration instructions.

Nuts

Recall: Peanut Butter Recalled
Due to Contamination with *Salmonella*

On February 14, 2007, FDA issued the first of four press releases warning consumers not to eat certain jars of Peter Pan peanut butter or Great Value peanut butter due to the risk of contamination with *Salmonella* Tennessee (a bacterium that causes foodborne illness). The affected jars of Peter Pan and Great Value peanut butter had a product code located on the lid of the jar that began with the number "2111." Both the Peter Pan and Great Value brands were

manufactured in a single facility in Georgia by ConAgra. Great Value peanut butter made by other manufacturers was not affected.

On February 13th, FDA contacted ConAgra officials. On February 14th, ConAgra agreed to initiate a product recall.

FDA also took the following actions:

- Notified the public of the findings related to the *Salmonella* outbreak and advised consumers not to eat peanut butter from jars with a certain product code.

- Notified its counterpart agencies in Canada and Mexico, the World Health Organization's INFOSAN Food Safety reporting program, and the food safety authority at the European Commission.

- Sent a team of microbiologists and experienced field investigators to begin its inspection of ConAgra's manufacturing plant in Georgia. The inspection included collecting environmental, raw ingredient and product samples, and reviewing manufacturing and quality assurance records.

- Analyzed samples collected from the manufacturing plant.

- FDA conducted a thorough inspection and assessed its own investigators' observations of the manufacturing plant for any necessary follow up actions.

FDA learned that the ConAgra plant in Sylvester, Georgia, sent bulk Peter Pan peanut butter to its plant in Humboldt, Tennessee. The bulk peanut butter was used to make the following toppings:

- Sonic Brand Ready-To-Use Peanut Butter Topping in 6 pound 10.5 oz cans. Sonic outlets used the topping until 2/16/07, when the product was recalled.
  The topping was used in the following Sonic products:
  - Peanut Butter Shake
  - Peanut Butter Fudge Shake

- Peanut Butter Sundae
- Peanut Butter Fudge Sundae

- Carvel Peanut Butter Topping in 6 pound 10 ounce cans. Carvel used the topping until 2/16/07, when the product was recalled.
  The topping was used in the following Carvel ice cream products:
  - Chocolate Peanut Butter
  - Peanut Butter Treasure
  - Peanut Butter & Jelly
  - Reese's Peanut Butter Cup Sundae Dasher
  - Any other customized products containing the Peanut Butter Topping, including peanut butter flavored ice cream in ice cream cakes

- J. Hungerford Smith Peanut Butter Dessert Topping in 6 pound 10 ounce cans: This topping could be used by retail and restaurant outlets throughout the United States but was not available for direct purchase by the public.

- TCBY Peanut Butter Topping, Net Contents 6 lbs, 10 oz (3.01 kg), Distributed by TCBY Systems, LLC, 2855 East Cottonwood Parkway, Salt Lake City, Utah 84121-7050

In late February 2007, tests by several states identified *Salmonella* in many open jars of Peter Pan and Great Value peanut butter recovered from consumers. In these instances, the *Salmonella* found in the plant and in the open jars matched the outbreak strain recovered from consumers who became ill.

On March 1, 2007, as a follow-up to the recent *Salmonella* outbreak linked to peanut butter, FDA conducted an extensive inspection of ConAgra's Sylvester, Georgia processing plant. Samples collected by FDA revealed the presence of *Salmonella*. The fact that FDA found *Salmonella* in the plant environment further suggested that the contamination likely took place in the plant before the product reached consumers.

To view the full text of the Press Release go to:
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01574.html.

Oil

Seizure of Olive Oil
Krinos Foods of Long Island City
Sayreville, New Jersey

On April 5, 2007, FDA investigators accompanied the U.S. Marshals Service in a seizure of approximately 31,000 liters of adulterated and misbranded olive pomace oil from a storage facility located in Sayreville, New Jersey. The storage facility was rented by Krinos Foods of Long Island City, New York. The seized oil was packed in 3-liter tins and had an estimated retail value of $77,000. Although the labels on the tins represented that the product was olive pomace oil, FDA investigators determined that the tins actually consisted primarily of soybean oil, which is significantly less expensive than olive oil.

Seizure of Olive and Pomace Olive Oil
Krinos Foods of Long Island City
Long Island City, New York

On May 22, 2007, New York District investigators accompanied the U.S. Marshals Service in the seizure of a total of 10,939 cases of Extra Virgin Olive Oil and Pomace Olive Oil, valued at approximately $628,000. The seizure took place at Krinos Foods Inc., Long Island City, New York. This seizure was based on the results of an inspection initiated during July 2005, as a follow-up to a news alert that oil being sold as Extra Virgin Olive Oil and Pomace Olive Oil was actually soybean oil. FDA Northeast Regional Laboratory analysis of the samples subsequently collected by New York District investigators confirmed the products were adulterated in that soybean oil was substituted in whole or in part for the olive oil and olive pomace oil.

Prepared Foods

Warning Letter for Misbranded Pizza

On October 27, 2006, FDA's Minneapolis District Office issued a Warning Letter to Bonita's Pizza, Inc., Hatton, North Dakota. An FDA inspection of the Hatton facility was conducted on July 24, 2006. This inspection verified that this firm manufactures and distributes ready-to-bake food products. An FDA review of the firm's product labels and other evidence collected during the investigation found several violations of the Federal Food, Drug, and Cosmetic Act (the Act).

The warning letter relayed the following findings:

- Bonita's Garlic Cheese Pizza product was misbranded because it was fabricated from two or more ingredients and the label failed to declare the common or usual name of each ingredient;
- The ingredient statement on Bonita's Garlic Cheese Pizza product label failed to declare that wheat, a major food allergen, and malted barley were components of the flour;
- The product label failed to declare the vegetable shortening ingredient in the pizza crust by its specific common or usual name, which must identify the type of shortening; and
- The label falsely stated that the product had been inspected and passed by the (USDA). However, this product is not regulated by USDA.

The firm was also cited for failure to register in accordance with the Act. To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/archive/g6111d.htm.

Restaurants

Taco John Restaurants
E. coli O157:H7 Outbreak at Taco John Restaurants

On January 12, 2007, FDA announced that it agency was close to identifying the source of illness for an *E. coli* O157:H7 outbreak associated with Taco John restaurants. FDA and the State of California, working in conjunction with state health officials in Minnesota, Iowa, and Wisconsin, were able to DNA-match the strain of *E. coli O157:H7* bacteria associated with the outbreak with two environmental samples gathered from dairy farms near a lettuce growing area in California's Central Valley.

The outbreak sickened approximately 81 individuals in November and December of 2006. Illnesses were reported in Minnesota (33), Iowa (47), and Wisconsin (1). Twenty-six people were hospitalized, and two suffered hemolytic uremic syndrome, a serious complication of *E. coli* O157:H7 infection that can cause permanent kidney damage and death.

Taco John's is headquartered in Cheyenne, Wyoming, and has franchises in more than 25 states; however, the outbreak was associated only with Taco John's restaurants located in Iowa and Minnesota.

Epidemiological studies by Minnesota and Iowa health officials had previously identified shredded iceberg lettuce served in the restaurants as the likely vehicle of transmission in the outbreak. FDA was able to focus on specific lettuce growing regions based on the traceback from records obtained from the lettuce processor. The DNA match provided a clue as to one possible source of the contamination for the lettuce.

In the wake of recent outbreaks of consumer illness connected with fresh produce, FDA accelerated its efforts to address produce safety, including consideration of new regulations, if appropriate, to reduce risk of contamination by pathogens.

Taco Bell
***E. coli* O157:H7 Outbreak at Taco Bell Restaurants**

Locations of Outbreaks in Taco Bell Restaurants: Delaware (2 cases), New Jersey (33 cases), New York (22 cases), Pennsylvania (13 cases) and South Carolina (1 case)

On December 14, 2006, the Centers of Disease Control and Prevention (CDC) reported that the *E. coli O157:H7* outbreak linked to Taco Bell restaurants in the Northeastern states appeared to be over. Based on a number of factors, iceberg lettuce was considered overall to be the single most likely source of the outbreak.

The peak of the outbreak occurred from the last week of November until the beginning of December 2006. A total of 71 cases in five states were reported to the CDC: Delaware (2 cases), New Jersey (33 cases), New York (22 cases), Pennsylvania (13 cases) and South Carolina (1 case – this person ate at a Taco Bell in Pennsylvania). Fifty-three hospitalizations and 8 cases of Hemolytic Uremic Syndrome (HUS) were reported. For the latest details about these cases, see the CDC website at http://www.cdc.gov/ecoli/.

FDA expedited its review of Taco Bell's records in order to trace the distribution channels of the iceberg lettuce and identify the farm or farms where the lettuce was grown, as well as all firms and facilities that handled the product.

FDA also monitored the outbreaks of *E. coli O157:H7* at Taco John restaurants in Iowa and Minnesota, in cooperation with health authorities in those states. Based on genetic fingerprinting of the *E.coli,* these outbreaks did not appear to be related to the Taco Bell outbreak.

Earlier FDA Press Releases regarding the Taco Bell E. Coli outbreak can be found on FDA's Web site as follows:
UPDATE: FDA Narrows Investigation of E. Coli O157:H7 Outbreak at Taco Bell Restaurants *(Dec. 13, 2006)*

Update: FDA Continues Investigation of *E. coli* O157:H7 Cases Associated with Taco Bell Restaurants *(Dec. 12, 2006)*

Update: FDA Investigates *E. coli* O157 Cases Associated with Taco Bell Restaurants *(Dec. 8, 2006)*

FDA Investigating *E. coli* O157 Infections Associated with Taco Bell Restaurants in Northeast *(Dec. 6, 2006)*

Seafood

Consent Decree of Permanent Injunction
Worldwide Fish & Seafood, Inc. d/b/a Coastal Seafood

On April 18, 2007, Worldwide Fish & Seafood, Inc., Minneapolis, Minnesota (doing business as Coastal Seafood), a seafood processor, and three of its officers entered into a Consent Decree of permanent injunction due to violations of the Federal Food, Drug and Cosmetic Act (the Act). The decree was entered in the U.S. District Court for the District of Minnesota. The Consent Decree requires the company to come into compliance with the Act by developing and implementing adequate Hazard Analysis and Critical Control Point (HACCP) plans.

Over six years, seven FDA inspections revealed that the defendants' HACCP plans were not adequate to prevent conditions that could pose a potential public health risk. In particular, the defendants' HACCP violations related to their failure to ensure that their seafood products were transported and continuously stored at adequate refrigeration temperatures to prevent bacterial growth and pathogen development.

The defendants agreed to come into compliance with the Act and its implementing regulations by, among other requirements: obtaining an expert consultant to evaluate the HACCP plans for all of the defendants' products and the defendants' implementation of the plans; and submitting to FDA inspection to ensure that the HACCP plans are adequately implemented.

The defendants received FDA approval of the HACCP plans prepared by their expert. The decree allows FDA to order a shutdown, recall, or other corrective action in the event of future violations, and requires the defendants to pay the costs of inspections performed pursuant to the decree.

Consent Decree of Permanent Injunction
Scandinavian Smoke House, Inc.

On December 1, 2006, a U.S. Magistrate Judge entered a Consent Decree of Permanent Injunction between the United States and Odd Anders Holm, the owner and operator of Scandinavian Smoke House, Inc., a cold-smoked fishery products processor in San Francisco, California. FDA inspections revealed the presence of *Listeria monocytogenes* (*Listeria)* on Scandinavian Smoke House's processing equipment and fish, and persistent insanitary conditions. Under the Consent Decree, Mr. Odd Anders Holm represented to the Court that he and Scandinavian Smoke House are no longer operating.

If the firm intends to resume any aspect of their business, it must receive written notice from FDA and start their operations only to the extent authorized in that notice. Additionally, Mr. Odd Anders Holm and Scandinavian Smoke House are prohibited from processing, preparing, packing, holding, or distributing food, including any cold-smoked fishery products, until they have, among other things, hired a *Listeria* expert, developed an environmental microbial monitoring program, and a sanitation standard operating procedure plan, and received written acknowledgement from FDA that their programs and plans are acceptable.

Warning Letter Issued to Fish Market

On June 6, 2007, FDA's New England District Office issued a Warning Letter to the president of Number One Fish Market, Inc., Hamden, Connecticut, for serious violations of the seafood HACCP regulations. An FDA inspection of the firm conducted on May 2-3, 2007, determined that the firm receives, stores, and ships canned pasteurized crabmeat. The inspection disclosed that the firm did not have a written HACCP plan. In addition, the firm failed to maintain sanitation monitoring records for the safety of water that comes in contact with food.
To read the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6434c.htm.

Florida District Office Issues Warning Letters to Seafood Facilities

On May 8, 2007, FDA's Florida District Office issued a Warning Letter to Ocho Rios Miami Inc., Miami, Florida. An FDA inspection of the firm conducted on April 2 – 3, 2007, revealed serious violations of the seafood HACCP regulation. The firm failed to conduct a hazard analysis for any of the seafood products it distributed and did not have HACCP plans to control the food safety hazards in refrigerated seafood products such as vacuum packed pickled split mackerel and salted mackerel fillets in brine.

The firm also failed to maintain sanitation and monitoring records. In addition, the inspection disclosed that that the firm did not monitor the eight areas of sanitation to ensure compliance with the CGMP requirements as evidenced by the observation of a dead rodent, rodent excreta pellets, and possible harborage areas for pests.

The Warning Letter also reminded the firm that it should use insecticides as permitted only under appropriate precautions to protect against contamination of the food, food contact surfaces, and food packaging materials to comply with 21 CFR 110.35(c).

To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/s6380c.htm.

Warning Letter Issued for Smoked Salmon

On November 6, 2006, FDA's New England District issued a Warning Letter to New England Smoked Seafood, Rutland, Vermont. FDA conducted an inspection on August 29 – 31, 2006, which revealed serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation. The finished product was a vacuum-packed, refrigerated smoked salmon.

The inspection disclosed that the firm was not using a continuous recording thermometer, nor was it monitoring the hot smoking process continuously to ensure that it controlled a toxin and pathogen hazard. Failure of a processor of

fish or fishery products to have and implement a HACCP plan that complies with FDA regulations renders the fishery or fishery products adulterated. To view the full text of the Warning Letter, to go: http://www.fda.gov/foi/warning_letters/archive/g6136d.htm.

Warning Issued to Seafood Processor and Importer

On March 1, 2007, FDA's San Francisco District Office issued a Warning Letter to Pacific International Seafood, LLC, Honolulu, Hawaii. FDA conducted an inspection of the firm on November 21 and 29, 2006. The inspection disclosed serious violations of the seafood HACCP regulations by the firm both as a processor of fish and fishery products and as an importer of seafood. Pacific International Seafood did not have a HACCP plan:

a) to control the food safety hazard of histamine formation as a result of time/temperature abuse during the receipt, re-packing, and storage of the product at the facility; and

b) to control the food safety hazard of histamine formation and *Clostridium botulinum* toxin formation as a result of time/temperature abuse during the receipt, re-packing, storage, and distribution of the product.

The Warning Letter advised the firm that it must implement an affirmative step which ensures that the fish and fishery products the firm imports are processed in accordance with the seafood HACCP regulations.

In addition, the firm was warned for failure to register its facility as required by the Public Health Security and Bioterrorism Act.

To view the full text of the Warning Letter, go to: http://www.fda.gov/foi/warning_letters/archive/g6136d.htm.

Warning: Eating Raw Oysters is Associated with Illness from *Vibrio parahaemolyticus*

On August 24, 2007, FDA issued a second warning to consumers not to eat raw oysters harvested from an additional part area (growing area 5) of the southern tip of Hood Canal in Washington State due to a foodborne illness outbreak caused by *Vibrio parahaemolyticus* bacteria. This followed an earlier outbreak and a warning on August 10, 2007, about oysters harvested from growing area 6 of Hood Canal.

Symptoms of the illness, vibriosis, include watery diarrhea, often with abdominal cramping, nausea, vomiting, fever, and chills. To read the full description and incidence of this illness see Foodborne Illness at the end of this chapter.

Raw oysters harvested from growing area 5 in Hood Canal from July 31 through August 20, 2007, caused at least six people to become ill in Washington State. Records indicated that raw oysters from the area were domestically distributed to Arizona, California, Colorado, Delaware, Florida, Idaho, Minnesota, New York, Oregon, Pennsylvania, Utah, Washington, and to foreign locations in Canada, Bali, Hong Kong, Singapore, and Thailand.

The Washington State Department of Health closed the growing area associated with the illness and asked commercial oyster harvesters and dealers who obtained oysters from this area to recall them.

To view the full text of the FDA Press Release, go to: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01688.html.

Warning: Monkfish May be Puffer Fish
Puffer Fish Contain Deadly Toxin

On May 23, 2007, Hong Chang Corporation, Santa Fe Springs, California, recalled product labeled as monkfish because it may have contained tetrodotoxin, a potent toxin. Although the product was identified as monkfish, it

may have been pufferfish because this toxin is usually associated with certain types of pufferfish. Consumption of foods containing tetrodotoxin can result in life-threatening illness or death. The recall was a result of two people in the midwest area becoming ill after consuming homemade soup containing the fish. One was hospitalized due to severe illness.

FDA's analysis of the fish confirmed the presence of potentially life-threatening levels of tetrodotoxin. On May 24, 2007, FDA issued a warning to consumers not to buy or eat imported fish labeled as monkfish, because the monkfish may actually be puffer fish, which may contain tetrodotoxin. Tetrodotoxin is not destroyed by common food preparation or storage, such as cooking or freezing. Monkfish do not contain tetrodotoxin.

The product was imported and distributed by Hong Chang Corp., Santa Fe Springs, California. Consumers concerned that they may have purchased this fish were instructed to contact their retailer and ask if the product was received from Hong Chang Corporation.

FDA advised that the product should not be eaten, and should be thrown away. FDA also instructed consumers to exercise care when handling the fish, and to wash their hands thoroughly after handling the fish.

To view the full text of FDA's Press Release regarding the monkfish, go to: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01639.html.

Snack Foods

Recall: Tainted Veggie Booty Snack Food
FDA Testing Confirms Presence of Salmonella Contamination

On June 28, 2007, FDA issued a warning to consumers not to eat Veggie Booty Snack Food, marketed by Robert's American Gourmet, Sea Cliff, New York, due to possible contamination with *Salmonella* Wandsworth, bacteria that causes gastrointestinal illness.

The warning was based on 52 reports of illness across 17 states, beginning in March 2007. Almost all the illnesses occurred in children under 10 years old, with the most cases in toddlers. FDA learned of the illnesses on June 27, 2007, from the Centers for Disease Control and Prevention, which conducted an investigation of the illnesses with state and local health officials.

On June 28, 2007, Robert's American Gourmet Food, Inc., of Sea Cliff, New York, announced a recall of the Veggie Booty Snack Food, all lots and sizes. Veggie Booty was distributed nationwide and also in Canada through local distributors, internet sales, phone orders, mail orders and retail outlets.

The company also voluntarily recalled all lots and sizes of Super Veggie Tings Crunchy Corn Sticks snack food because the same potentially contaminated seasoning may have been used in making that product.

On July 13, 2007, FDA confirmed that a strain of *Salmonella* Wandsworth bacteria found in Veggie Booty snack food was responsible for a disease outbreak that occurred between March and June 2007.

Laboratory testing conducted by the Minnesota Agricultural Laboratory confirmed initial epidemiologic evidence that implicated Veggie Booty Snack Food as the source of the outbreak. The results of FDA's own testing added further confirmation.

FDA 's advisory instructed consumers not to eat any Veggie Booty and to throw away any product they may have had. FDA also advised consumers not to eat Super Veggie Tings Crunchy Corn Sticks, and to throw out any supplies they had, because this product also may also have been contaminated.

FDA advised that individuals who had eaten Veggie Booty or Super Veggie Tings Crunchy Corn Sticks and who had experienced any of the symptoms of illness to contact a doctor or other health care provider immediately. Both products may appeal to children, so FDA advised that parents should be especially vigilant and seek medical care if they observed signs of illness.

FDA, various states, and the CDC conducted the investigation. Preliminary testing suggested that the seasoning mix used in Veggie Booty could have been the source of the contamination. FDA continued to trace back the ingredients and

processing methods used for the seasoning mix, seeking to determine whether the seasoning actually was the source of the problem.

Veggie Booty is sold in a flexible plastic foil bag in four ounce, one ounce and one-half ounce packages. Some gift baskets available for purchase on the internet included Veggie Booty or Super Veggie Tings Crunchy Corn Sticks.

Vegetables

Recall: 'Dole Hearts Delight' Packaged Salads

On September 17, 2007, Dole Fresh Vegetables, a division of Dole Food Company, Inc., announced that it was voluntarily recalling all salad bearing the label "Dole Hearts Delight" sold in the United States and Canada with a "best if used by (BIUB)" date of September 19, 2007, and a production code of "A24924A" or "A24924B" stamped on the package. The "best if use by (BIUB)" code date was located in the upper right hand corner of the front of the bag. The salad was sold in plastic bags of 227 grams in Canada and one-half pound in the United States, with UPC code 071430-01038.

Dole initiated this recall because a sample in a grocery store in Canada was found through random screening to contain *E. coli O157:H7* by the Canadian Food Inspection Agency. No other Dole salad products were involved.

The notice advised consumers who may have had any of the "Dole Hearts Delight" salads with a "best if used by date" of September 19 and a production code of "A24924A" or "A24924B" to dispose of the product. This product was sold in Ontario, Quebec and the Maritime Provinces in Canada and in Illinois, Indiana, Maine, Michigan, Mississippi, New York, Ohio, Pennsylvania, Tennessee and neighboring states in the United States. The Dole Consumer Center toll-free for consumers to call is 800-356-3111. Consumers were reminded that products should not be consumed after the "best if used by" date.

To read the full press release for this recall, go to:
http://www.fda.gov/oc/po/firmrecalls/dole09_07.html.

Recall: Bagged Spinach Found Positive for *Salmonella enteriditis*

On August 28, 2007, Metz Fresh, LLC, Salinas, California, announced it was voluntarily recalling bagged spinach as a result of a positive test for S*almonella* found during routine company testing.

The spinach was distributed under the label Metz Fresh, in both retail and food service packages. These included 10 and 16 ounce bags as well as 4-2.5 pound and 4 pound cartons. The only Metz Fresh product affected was spinach that bore the tracking codes 12208114, 12208214 and 12208314. It was distributed in the continental United States and Canada. Consumers were advised to discard the product or return it to the place of purchase for a refund.

The positive test came during independent lab testing that Metz Fresh conducts on all of its products. Through its labeling and numbering system, Metz Fresh had already tracked, located and put 'holds' on the vast majority of the cartons of spinach affected. That spinach was not to be released into the marketplace.

While the positive test came from only one sample of many on three packing lines, Metz Fresh, as a precaution, chose to recall all of the spinach from the 'field lot' packed that day on all three lines.

Recall: Turnip Greens Found with Trace Amounts of Diesel Fuel

On May 18, 2007, McCall Farms of Effingham, of Raleigh, South Carolina, announced it was voluntarily recalling more than 2,500 cases of Margaret Holmes Seasoned Turnip Greens after tests by the North Carolina Department of Agriculture and Consumer Services confirmed trace amounts of diesel fuel in product samples.

The recall affected 27-ounce cans of Margaret Holmes Seasoned Turnip Greens with the product code TURN3 K10GY and a "best-by" date of November 2009. The recalled product was distributed to retail stores in Florida, Georgia, North Carolina, South Carolina, Tennessee and Virginia.

State public health officials said the level of diesel fuel detected in the samples of turnip greens should not pose a health risk. The North Carolina Department of Agriculture and Food and Drug Protection Division launched an investigation after a consumer complained that the product had a chemical taste. Testing confirmed trace amounts of diesel fuel in the turnip greens.

To view the full text of the Press Release, go to: http://www.fda.gov/oc/po/firmrecalls/mccallfarm05_07.html.

Final Report on 2006 Spinach Outbreak

On March 23, 2007, FDA and the California Department of Health Services (CDHS) released a joint report of an extensive investigation into the causes of an *E. coli O157:H7* outbreak in the fall of 2006. This outbreak was associated with contaminated Dole brand Baby Spinach and resulted in approximately 205 confirmed illnesses and three deaths. The inquiry was conducted by the California Food Emergency Response Team (CalFERT), a team of experts from FDA's district office in San Francisco and CDHS. They were assisted by experts from the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) of the USDA.

The investigators successfully identified the environmental risk factors and the areas that were most likely involved in the outbreak, but they were unable to definitely determine how the contamination originated. The report describes the painstaking detective work of the investigators following the first reports from CDC in September 2006, of an apparent outbreak of *E. coli O157:H7* linked to the consumption of bagged spinach. The probe initially focused on the processing and packaging plant of Natural Selection Foods, LLC in San Juan Bautista, California, where the contaminated products had been processed.

The next focus of the inquiry was the source of the spinach in 13 bags containing *E. coli O157:H7* isolates that had been collected nationwide from sick customers. Using the product codes on the bags, and employing DNA fingerprinting on the bacteria from the bags, the investigators were able to match environmental samples of *E.coli O157:H7* from one field of spinach to the strain that had caused the outbreak. Potential environmental risk factors for *E.coli O157:H7* contamination at or near the field included the presence of wild pigs, the

proximity of irrigation wells used to grow produce for ready-to-eat packaging, and surface waterways exposed to feces from cattle and wildlife.

Because the contamination occurred before the start of the investigation, and because of the many ways that *E.coli O157:H7* can be transferred -- including animals, humans, and water -- the precise means by which the bacteria spread to the spinach remains unknown.

The report on the probe of the Dole spinach contamination, entitled: "Investigation of an E. coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach, is posted at http://www.DHS.ca.gov.

Report of FDA/CDC/State Investigation:
Tomatoes in Restaurants Linked to *Salmonella Typhimurium* Outbreak

On November 3, 2006, FDA announced the results of an investigation by state and CDC investigators, which found consuming tomatoes in restaurants as the cause of illnesses in the *Salmonella Typhimurium* outbreak. By November 3, 2006, 183 cases were reported in 21 states.

Based on information currently available from the CDC, the investigation showed a peak in cases of illness in late September 2006. FDA believed that the tomatoes that caused the illnesses had at that point been consumed, destroyed or thrown out because they are perishable. Therefore, FDA did not believe a consumer warning about tomatoes on store shelves was warranted at that time.

FDA initiated a traceback of these tomatoes and the Agency continued its close collaboration with the CDC and state and local authorities to identify the source of contamination on tomatoes in this outbreak. In particular, FDA worked closely with the states of Minnesota, Massachusetts, and Connecticut, since groups of illnesses were specifically reported in these states.

To view the full text of the Press Release, including tips for buying and storing produce, go to:
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01504.html.

Additional information on the outbreak of *Salmonellosis Typhimurium* is also available on CDC's Web site located at the following URL: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2006/outbreak_notice.htm.

In March 2007, FDA Issued "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables." The full text of this guidance is available online at: http://www.cfsan.fda.gov/~dms/prodgui3.html.

Symptoms of Foodborne Illnesses

Clostridium Botulinum (Botulism)

Symptoms of botulism 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

The most common symptom of infection is watery diarrhea. Other symptoms can include dehydration, weight loss, stomach cramps or pain, fever, nausea and vomiting. Symptoms generally begin two to ten days after becoming infected with the parasite and generally last one to two 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.

Listeria Monocytogenes (*Listeria*)

Listeria monocytogenes is an organism which can cause illness, mild, moderate or even severe. 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 more serious illness in young children, frail or elderly people and may even cause miscarriages or stillbirths.

Salmonella

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 *Salmonella* 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.

There are 28 serotypes of Salmonella. To view the full list of serotypes, go to: http://www.fda.gov/cvm/Documents/Table5b2004.pdf.

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 2-3 days following exposure, but may occur as soon as 1 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 (Virbriosis).

Symptoms of vibriosis 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 three days. Severe disease is rare and occurs most commonly in people with weakened immune systems and is most often associated with eating raw oysters.