The Warning Letters presented in this chapter were chosen to provide examples of the types of Warning Letters issued for violations of FDA laws. A complete list of Warning Letters issued is available on FDA's web site at: http://www.fda.gov/foi/warning.htm.

Bakery Products

Court Ordered Injunction - Mid-Florida Bakeries, LLC

Firm Continued Insanitary Conditions Despite FDA Warnings

U.S. v. Mid-Florida Bakeries, LLC and Donald D. Metchick (M.D. Fla.). On July 18, 2005, U.S. District Judge Gregory Presnell issued an Order granting injunctive relief against the defendants for operating a wholesale bakery that had become infested with rodents and insects. During the course of the litigation, the company ceased doing business. The July 18 Order modified an earlier order which required defendants to comply with Current Good Manufacturing Practice regulations for food and to create a sanitation control program.

The July 18 Order included some limited prospective relief including requirements that defendants notify FDA of any intention to re-enter the business, hire an expert, and get written approval from FDA prior to resuming their operations. Further, it permitted FDA inspections to monitor compliance with the Order.

Warning Letter Issued to Just Fabulous Pastries, Inc., for Deviations from CGMP Regulations

On December 21, 2004, FDA's Los Angeles District Office issued a Warning Letter to Just Fabulous Pastries, Inc., San Diego, California. FDA's inspection on September 30 - October 1, 2004, showed that the firm did not follow Current Good Manufacturing Practice regulations. A number of gross insanitary conditions were present at the facility at the time of the inspection. FDA determined that these conditions caused the products manufactured in the facility to be adulterated, because they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

The following insanitary conditions included, but were not limited to, the following:

- Employees did not wash and sanitize their hands thoroughly in an adequate hand-washing facility after each absence from the work station and any time their hands may have become soiled or contaminated.

- Hand-washing and hand-sanitizing facilities were not provided at each location in the plant where needed.

- The facility and procedure used for cleaning and sanitizing equipment and utensils had not been shown to provide adequate cleaning and sanitizing treatment.

- Food was not stored under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

- Toilet facilities lacked self-closing doors.

Warning Letter Issued to Barney's Weir Cove Bakery for Misbranded Italian Bread

Warning Letter Issued for Failure to Bear Nutrition Labeling on Italian Bread Products

On April 27, 2005, FDA's Baltimore District Office issued a Warning Letter to Barney's Weir Cove Bakery, Weirton, West Virginia. FDA's inspection on May 10-12, 2004 and January 31-February 2, 2005, revealed a serious violation of the Federal Food, Drug, and Cosmetic (Act). An investigator observed significant deviations from the food labeling regulations, which caused the packaged Italian bread products to be misbranded.

FDA's review of the labeling of "DiCarlo's Italian Bread" and "The Real Italian Bread" bakery products revealed that the products were misbranded, because their labeling failed to bear nutrition labeling. Because of the amount of Italian bread the firm distributed, these products did not qualify for exemption from nutritional labeling as a low volume food of a small business.

Beverages

Warning Letter Issued to Old Path Natural Herbs Inc.,

On September 22, 2005, FDA's Florida District Office issued a Warning Letter to the Old Path Natural Herbs Inc., Pensacola, Florida. During FDA's inspection on March 21-25, 2005, the investigator collected labeling associated with the product God's Herbal Blessing Tea. In addition, FDA reviewed labeling on the website: http://www.oldpath.com. This review showed serious violations of the Act in the labeling of the products.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man are drugs. The labeling for the product on the website and in the literature packet provided to potential and actual customers included some, but not all, of the following claims:

- "…[T]heir son…was stricken with AIDS…He had pneumonia…Minister Jones instructed the parents to have the nurses to pour 5 cups of his tea every day into their son's feeder tube…Today…he does not have a trace of the AIDS virus in his system."

- "Thousands of individuals have used the tea and he [Minister Jones] says that he has not encountered the condition that the tea was not able to treat. He has successfully treated diabetes, emphysema, hypertension, heart conditions and over 135 other medical conditions."

- "He has also successfully treated cancer patients at the brink of death such as, a woman who was diagnosed with breast cancer who went home to die. She was also diagnosed with blood clots, silicone poisoning and as a borderline diabetic. When she took the tea, the cancer and all the other conditions were completely eliminated…"

In addition, the literature packet and website included a list of 183 serious diseases or medical conditions implying that the product was useful for the treatment or prevention of serious diseases, including but not limited to, pneumonia, diabetes, AIDS, sickle cell anemia, lupus, cancer and tumors anywhere in the body including breast cancer, colon cancer, and skin cancer, glaucoma, hepatitis B, Crohn's disease, leukemia, venereal disease, hepatitis C, cirrhosis of the liver, multiple sclerosis, and lymphoma.

Because the product is not generally recognized as safe and effective when used as labeled, it is also a "new drug." Under section 505 of the Act a new drug may not be legally marketed in the

U.S. without an approved New Drug Application (NDA). In addition, the product was misbranded because its labeling failed to bear adequate directions for use for the conditions for which it was offered.

Bottled Water

Warning Letter Issued to Halstead Springs, Inc., for Deviations from CGMP Regulations

On July 29, 2005, FDA's New Orleans District Office issued a Warning Letter to Halstead Springs, Inc., Speedwell, Tennessee. FDA's inspection on May 18, and 25-26, 2005, revealed deviations from CGMP regulations, and the Processing and Bottling of Bottled Drinking Water Regulations. The product processed at the facility was adulterated because it was prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Some examples of the deviations documented in the Warning Letter included the following:

- Failure to analyze samples of bottled drinking water for chemical testing at least annually.
- Failure to analyze samples of product source water for chemical, microbiological, and radiological purposes at defined frequencies and consistent with the minimum requirements.
- Lack of running water of a suitable temperature in hand-washing facilities.

Candy

Warning Letter Issued to Blake Street Manufacturing, LLC, for Misbranding of Seasonal Candy

On July 1, 2005, FDA's Denver District Office issued a Warning Letter to Blake Street Manufacturing, LLC, Denver, Colorado. During FDA's inspection in February and April 2005, labeling for the products was collected and a review of the labeling indicated serious violations of the Act and FDA regulations.

The products Petite Box, Small Ducks, Small Rubber Ducks, Large Rubber Ducks, Flower Pops, Decorated Eggs, Christmas Stocking, Gingerbread Man, and Snow Man were misbranded because the labels failed to bear nutrition labeling.

The products Christmas Stockings, Snowman, and Gingerbread Man were misbranded because they contained the color additives Red 3, Red 40, Blue 1 Lake, Yellow 5 Lake, and Yellow 6 Lake that are subject to certification, but the product labels failed to declare these colors by specific name.

FDA Issued Nationwide Alert for "Jelly Candy Pops Sour Zip Kids" Brand Halloween Candy, Which Contained an Undeclared Food Allergen

Product Found to Contain Undeclared Egg Protein, Which if Consumed by Allergic Person Could Cause Serious or Life-Threatening Injury

On October 29, 2004, FDA issued a Nationwide Alert warning consumers about the possibility that undeclared egg allergens may be present in "Jelly Candy Pops Sour Zip Kids" brand candy that had been marketed during the Halloween season. Preliminary analysis by FDA indicated that this product contained enough egg protein to cause serious or life-threatening injury to those who suffer from severe allergy to eggs.

The product consisted of individually wrapped lollipop candies in a cardboard display box. The label on the front of the display package read "JELLY CANDY POPS SOUR ZIP KIDS." The candy came in the form of gelatin-based lollipops with frosting made to look like various Halloween figures (e.g., ghosts, monsters, etc.). The lollipops were individually cellophane wrapped with the ingredient statement and the name of the distributor, Morris National, Inc. The ingredients statement did not list eggs.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/news/2004/NEW01128.html.

Canned Foods

Warning Letter Issued to California Natural Products for Adulteration of Low-Acid Canned Foods

Firm Failed to Obtain Evaluation of Potential Hazard to Public Health Due to Loss of Product's Sterility

On December 6, 2004, FDA's San Francisco District issued a Warning Letter to California Natural Products, Lathrop, California. FDA's inspection on July 19-23, 27, and August 2, 2004, showed that the firm had serious deviations from the Low-Acid Canned Foods (LACF) regulations. Specifically, the firm failed to adequately segregate and handle product packaged under conditions below those specified in the scheduled process. The firm experienced a loss of sterility and then shipped some of the product without first obtaining an evaluation by a competent processing authority that was adequate to detect any potential hazard to public health.

Failure to comply with all of the requirements of 21 CFR Part 108.35 and the mandatory portions of Part 113 constitutes a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the Federal Food, Drug, and Cosmetic Act (Act).* In addition, such failure rendered the products adulterated. Some of the almond-based, soy-based, and rice-based products were adulterated because these products were processed, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

* The emergency permit provisions are a powerful tool that the Commissioner of Food and Drugs has at his disposal to assure the public is protected from LACF, distributed in interstate commerce, which may have been inadequately or improperly manufactured or packed; and whose harmful nature cannot be adequately determined.

Caterers

Warning Letter Issued to Gate Gourmet, Inc., a Facility Providing Food to Airlines

On April 21, 2005, FDA's San Francisco District issued a Warning Letter to Gate Gourmet, Inc., Reston, Virginia, which provided food and beverage service to various airlines at Honolulu Airport. FDA's inspection on February 25-26, 2005, revealed that the facility was in violation of the U.S. Public Health Service Act (PHS Act), and the Interstate Conveyance Sanitation regulations.

Some examples of the violations documented in the Warning Letter included the following:

- The firm failed to hold perishable food at or below 50°F, except when being prepared or kept hot for serving.
- The firm failed to keep utensils used in the preparation of food and beverages clean.
- The firm failed to maintain equipment in a clean manner.

Based on the inspectional findings, FDA classified the facility as "Provisional" for interstate carrier use for a period of 30 days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. FDA noted on or about that date, a re-inspection of this facility would be conducted to assure that corrections met FDA requirements. If significant corrections were not made by the time of the next inspection, the facility would be reclassified as "Use-Prohibited" for carrier use. Assignment of "Use-Prohibited" status for food service facilities means that food and beverages from this facility may not be used by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

Cosmetics

Warning Letter Issued to Master's Miracle, Inc., for Adulteration of Skin Moisturizer

On June 9, 2005, FDA's Minneapolis District Office issued a Warning Letter to Master's Miracle, Inc., Maple Grove, Minnesota. FDA's inspections on December 2004, and January 2005, and a review of the Internet website at: www.themastersmiracle.com was conducted to determine the firm's compliance with the Act and applicable implementing regulations.

FDA's analysis of a sample of the Skin Moisturizer product collected during the inspection revealed bacterial contamination and aerobic plate counts at levels that posed a potential health risk for the uses recommended in the labeling. The product was adulterated because it contained a poisonous or deleterious substance that may render the product injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

Medline Industries, Inc., Recall of Mouthwash Because of Possible Contamination with *Burkholderia cepacia*

On August 29, 2005, FDA notified the public of a nationwide voluntary recall of alcohol-free mouthwash and hygiene kits containing mouthwash distributed by Medline Industries, Inc., Mundelein, Illinois, because of the potential contamination with *Burkholderia cepacia* (*B. cepacia*). The Medline labeled mouthwash packaged in 2 and 4 ounce bottles were recalled by the manufacturer, Carrington Laboratories, Inc, Irving, Texas. FDA advised that consumers and health care providers who had Medline brand alcohol free mouthwash should stop using the product immediately and check to see if it is being recalled. FDA advised that the mouthwash may also be found in certain Medline Personal Hygiene Hospital Admission Kits.

B. cepacia is a known cause of infections in hospitalized patients. The effects of *B. cepacia* on people vary widely, ranging from no symptoms at all, to serious respiratory infections, especially in patients with Cystic Fibrosis (CF). *B. cepacia* poses little medical risk to healthy people. However, people who have certain health problems such as weakened immune systems or chronic lung diseases, particularly CF, may be more susceptible to infections with *B. cepacia*. Of note, *B. cepacia* bacteria are often resistant to common antibiotics.

Products recalled would be identified by checking the lot code stamped on the bottom of the bottle. Product lot numbers beginning 0503 through 0508 are affected. Additionally, affected

product could be identified by checking for the identification code RA05CRR on the lower portion of back display panel of the product label.

The recall included the following products:

Description	Reorder Number
Alcohol-Free Mouthwash, Medline Label, 2 ounce	MDS095029
Alcohol-Free Mouthwash, Medline Label, 4 ounce	MDS095030

The product was distributed to hospitals, medical centers, and long term-care facilities nationwide. There was no known distribution through retail sales. The Centers for Disease Control and Prevention confirmed hospital illness associated with the use of the affected mouthwash in Texas and Florida.

For a complete list of admission kits involved, go to: www.medline.com or call Medline Industries at: 1-800-950-0128.

The full text of the Press Release is available at: http://www.fda.gov/bbs/topics/news/2005/NEW01225.html.

Dairy Products

Warning Letter Issued to White Egret Farm for Unpasteurized Goat Milk

FDA Inspection Disclosed Unpasteurized Goat Milk in Violation of PHS Act and FDA Regulations

On December 15, 2004, FDA's Dallas District Office issued a Warning Letter to White Egret Farm, Austin, Texas. During FDA's inspection on July 28-August 6, 2004, investigators documented violations of the PHS Act and a Federal regulation promulgated under the PHS Act.

FDA's inspection determined that the firm distributed unpasteurized goat milk in interstate commerce, in finished form for human consumption. Such distribution is a violation of the PHS Act and FDA regulations. The regulation bans the delivery, sale, or distribution in interstate

commerce of milk and milk products in final package form for human consumption unless they have been pasteurized. FDA noted that the goat milk was a "milk product" as that term is defined by FDA regulation. Further, the goat milk was shipped directly to customers for consumption without subsequent processing and pasteurization, and was in final package form for human consumption.

Warning Letter Issued to Paul Meserve Distributor for Misbranding of Sharp Cheddar Tub Cheese

On May 24, 2005, FDA's New England District Office issued a Warning Letter to Paul Meserve Distributor, Gorham, Maine. During FDA's inspection on February 2 and 9, 2005, physical samples and representative product labeling for the product "Original Squire Mountain Sharp Cheddar Tub Cheese" were collected. FDA's review of the labeling for the product showed serious violations of the Act and FDA regulations.

The "Original Squire Mountain Sharp Cheddar Tub Cheese" was misbranded because the ingredient statement failed to bear the common or usual name of each of the component ingredients of several main ingredients which themselves contain two or more ingredients. The declaration of the soy lecithin was of particular concern because soy is an allergenic substance. For sensitive individuals, the presence of allergens in food is potentially life-threatening.

FDA also noted that the statement of identity "SHARP CHEDDAR TUB CHEESE" did not adequately describe the product. The product did not satisfy the requirements for a "cheddar cheese." Further, the product did not appear to be a "cheese" at all. "Tub cheese" was not a sufficiently descriptive term for the statement of identity as required. FDA was not aware of "tub cheese" as a usual or common name for any food, nor is it a fanciful term commonly used by the public.

FDA noted that the ingredient statement on the product "Original Squire Mountain Sharp Cheddar Tub Cheese" listed "FLAVOR AND COLOR INGREDIENTS" and "PRESERVATIVE INGREDIENTS," but that listing did not comply with the regulations governing the listing of colors, flavors, and preservatives on ingredient labels.

Warning Letter Issued to Lifeway Foods, Inc., for Misbranding of Cream Cheese

On August 9, 2005, FDA's Philadelphia District Office issued a Warning Letter to Lifeway Foods, Inc., Morton Grove, Illinois. Inspections of the manufacturing plant, L.F.I. Enterprises, Inc., located at 5201 Harbison Avenue, Philadelphia, Pennsylvania, conducted by FDA between December 6-10, 2004, and April 11-14, 2005, revealed that the products were misbranded for reasons including but not limited to the following:

- The labels bore the nutrient content claim "Lite," but failed to include the additional information that is required to accompany a "Lite" claim. Additionally, the labels failed to contain the percentage or fraction by which the food had been modified and the amount of the nutrient, that is the subject of the claim, that is in the labeled food and in the reference food.

- Lifeway Brand Gourmet varieties of cream cheese were fabricated from two or more ingredients, but the labels failed to bear a complete list of all of the ingredients by common or usual name in descending order of predominance by weight.

- The labels of the Lifeway Brand varieties of cream cheeses failed to bear the name and place of business of the manufacturer, packer or distributor of this product.

FDA Issued Nationwide Alert on Possible Health Risk Associated with Cold Stone Creamery "Cake Batter" Ice Cream

Ice Cream Associated with *Salmonella* Infection in Several States

On July 1, 2005, FDA issued a nationwide alert that products containing "cake batter" ice cream sold at Cold Stone Creamery stores throughout the country may be associated with an outbreak of *Salmonella typhimurium* infection in several states. After being informed by FDA of the potential contamination problem, Cold Stone Creamery agreed to immediately remove all "cake batter" ice cream products from its stores throughout the country. FDA advised consumers who may have purchased take-home products from Cold Stone Creamery containing "cake batter" ice cream to not eat them, but instead dispose of them immediately.

Salmonella typhimurium is an organism, which can cause serious and sometimes fatal infections in small children, frail or elderly people, and others with weakened immune systems. Healthy

people may only suffer short-term symptoms, such as high fever, severe headache, vomiting, nausea, abdominal pain, and diarrhea. Long term complications can include arthritis.

The ice cream's possible contamination with this organism came to light after multiple cases of infection with this form of Salmonella were reported in late May and early June 2005, in Minnesota, Washington, Oregon and Ohio. At the time of FDA's notification, 14 people had become ill from this unusual strain of Salmonella. Many of the people reporting this illness also reported consuming "cake batter" ice cream at a Cold Stone Creamery shortly before the onset of their illness.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/NEWS/2005/NEW01200.html.

Class I Recall: Esh Foods LLC Recalled Cream Cheese Due to Undeclared Allergens

On August 12, 2005, FDA issued a Press Release notifying consumers that Esh Foods LLC, Gordonville, Pennsylvania, was recalling its 5 pound bulk packages and smaller unlabeled containers of Crabmeat Cocktail Cream Cheese, Shrimp Cream Cheese and Plain Whipped Cream Cheese spreads, because the products may have contained undeclared fish, eggs, wheat, milk, shrimp, soy and crab. FDA classified the recall as a Class I recall, which is the most serious type of recall, and involve situations in which there is a reasonable probability that use of the affected product will cause serious injury or death.

FDA advised that people who have allergies to these undeclared ingredients ran the risk of serious or life-threatening allergic reaction if they consumed the products. The spreads were distributed in New Jersey, Maryland and Pennsylvania.

The 5 pound bulk packages of the cream cheese spreads bore an Esh Foods LLC label on top of the container. Spreads from these large containers were transferred to smaller, unlabeled containers and sold at farmers markets.

The recall was initiated after it was discovered that the spreads were distributed in packaging that did not reveal the presence of fish, eggs, wheat, milk, shrimp, soy and crab. Subsequent investigation indicated the problem was caused by temporary breakdown in the company's production and packaging processes.

Esh Foods LLC stopped production of the cream cheese spreads until the company and FDA were certain that the labeling error had been corrected.

Consumers who purchased packages of unlabeled cream cheeses from retail outlets in New Jersey, Maryland or Pennsylvania were advised to contact the place of purchase to determine if their product was under recall.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/NEWS/2005/NEW01219.html.

Dietary Supplements

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA or get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety, e.g., voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

FDA Announced Major Initiatives for Dietary Supplements

Regulatory Strategy

On November 4, 2004, FDA announced three major regulatory initiatives designed to further implement DSHEA. These initiatives: a regulatory strategy; an open public meeting; and a draft guidance document for industry represented significant steps FDA has taken in the implementation of DSHEA.

FDA announced that the Agency intended to improve the transparency, predictability, and consistency of its scientific evaluations and regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA also noted that the Agency would continue its ongoing efforts of monitoring and

evaluating product safety, ingredient safety, and product labeling, as well as ensuring product quality. FDA published a *Federal Register* notice about the public meeting as well as two notices describing the other initiatives.

In the first initiative, a regulatory strategy, FDA announced that the Agency intended to work collaboratively with its Federal and other partners to improve the evidentiary base FDA uses to make safety and enforcement decisions about dietary ingredients and dietary supplements. Those partners include the National Institutes of Health's Office of Dietary Supplements and National Center for Complementary and Alternative Medicine, the National Toxicology Program in the Department of Health and Human Services, the University of Mississippi's National Center for Natural Products Research, FDA's National Center for Toxicological Research, and others.

FDA announced that the Agency would also implement a transparent, systematic, and predictable process to evaluate safety concerns about dietary ingredients and dietary supplements. The process begins with a "signal detection" (identifying an issue of concern). Signals of a possible safety concern can come from Federal, state and local counterparts; adverse event reports; foreign regulatory actions; media reports; information from consumer groups; and consultation with experts.

When the quality or quantity of these signals indicates that there may be a public health problem, FDA may then seek input from an independent third party review. FDA's regulatory actions will be based on the totality of the scientific evidence available, including the pharmacology of the substance, scientific literature, adverse event reports, and evidence-based reviews. FDA has a variety of options for pursuing its public health mission, including making a determination of unreasonable risk, issuing public health advisories, educating consumers, conducting research, and requiring labeling changes.

Open Public Meeting

Under DSHEA, dietary supplements do not need approval from FDA before they are marketed; however, in the case of some new dietary ingredients (i.e., dietary ingredients that were not marketed in the United States before October 15, 1994), a pre-market safety notification to FDA is required by law.

To further the effective implementation of this requirement, FDA announced its second initiative, a public meeting on November 15, 2004, that was designed to seek public comment on the type, quantity, and quality of evidence manufacturers should provide FDA in a new dietary ingredient notification.

The Agency is committed to taking action against unsafe products. For example, after determining that products containing androstenedione posed significant health risks and lacked NDI notifications, FDA sent Warning Letters to 23 companies in March 2004, asking them to

cease distributing products sold as dietary supplements that contain androstenedione and warning them that they could face further enforcement actions if they did not take appropriate measures.

Another aspect to the strategy is ensuring product quality. This initiative addresses the need to establish industry-wide standards to help ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition.

On March 13, 2003, FDA published a proposed rule on CGMP for dietary supplements. FDA reviewed and evaluated more than 1,600 pages of comments. Publication of a CGMP final rule is one of the Agency's highest priorities.

Because FDA is committed to protecting consumers against dietary supplements that make false or misleading claims, including unsubstantiated claims, the Agency will also continue to monitor and evaluate dietary supplement labeling and take enforcement action, as appropriate. This measure will include monitoring of labeling claims, including claims in accompanying literature such as flyers, brochures, and catalogs, and in Internet labeling.

Other measures included identifying and taking enforcement action against products whose labeling fails to reveal material facts, targeting those products that pose the greatest risk to consumers, obtaining and analyzing samples of dietary supplements in the marketplace to verify that the contents are consistent with the labeling; and reviewing Supplement Facts panels to determine whether the substances listed as dietary ingredients can be lawfully marketed in dietary supplements.

Draft Guidance Document for Industry

The third initiative reflected FDA's commitment to fully implement DSHEA by asking for comments on a draft guidance document on the amount, type and quality of evidence a manufacturer should have to substantiate a claim made under 403(r)(6) of the Act, e.g., a structure function claim. While the Act, as amended by DSHEA, requires substantiation for such claims, it did not define the term. The draft guidance document provides manufacturers flexibility in the precise amount and type of evidence that constitutes adequate substantiation.

Providing a standard for substantiation may also help to preserve consumer confidence in these products.

In preparing this draft guidance, FDA reviewed regulations, case law, the Federal Trade Commission (FTC) guidance on substantiating claims made for dietary supplements in advertising, as well as recommendations from the Commission on Dietary Supplement Labels.

FTC has typically applied a substantiation standard of "competent and reliable scientific evidence" to claims made for dietary supplements in advertising. FDA intends to apply a standard consistent with FTC's approach when it reviews label and other claims.

See the full text of the Press Release at:
http://www.fda.gov/bbs/topics/news/2004/NEW01130.html.

Seizure of Ephedra-Containing Dietary Supplements at Asia MedLabs, Inc.

Supplement Labeled as "Traditional Asian Herbal Formulation" Found to Contain Ephedra

On November 23, 2004, FDA investigators accompanied the U.S. Marshals Service in a seizure of more than 2.1 million VITERA-XT capsules in the possession of Asia MedLabs, Inc., Houston, Texas. Of the total products seized, one million were yet unpackaged capsules; the remainder was contained in more than 14,000 labeled bottles. The articles were seized, because they contained an ephedra-containing dietary supplement.

VITERA-XT capsules were represented and labeled as a "traditional Asian herbal formulation." However, the article was being marketed as a dietary supplement, as evidenced by the presence on the label of a "Supplement Facts" panel and the dietary supplement disclaimer statement, both of which are consistent with dietary supplement products. FDA's analysis of a sample of the article revealed the presence of six ephedrine alkaloids. The product was, therefore, adulterated because it is a dietary supplement that contains ephedrine alkaloids and, as such, presented an unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling, or, if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.

On December 30, 2003, FDA sent an advisory letter addressed MaxLabs, Inc., located at the same address as Asia MedLabs, Inc., advising that some of the products that the firms marketed, such as Max Ten, Max Fifty, or Sports Fuel, were labeled to contain the botanical ingredient, Ma Huang, a source of ephedrine alkaloids. FDA advised that it intended to publish a rule in the *Federal Register* in the near future that would affect dietary supplements containing ephedrine alkaloids and would declare dietary supplements containing ephedrine alkaloids to be adulterated because they present an unreasonable risk of illness or injury. FDA stated the purpose of the advisory letter was to give firms advance notice of the publication of this rule to facilitate their earliest compliance. Moreover, FDA indicated that it intended to begin enforcing the rule when it became effective.
On February 11, 2004, FDA announced the issuance of the final rule (69 FR 6788) declaring dietary supplements containing ephedrine alkaloids adulterated under 21 U.S.C. 342(f)(1)(A). Manufacturers and distributors were advised that this rule would become effective 60 days from the date of publication (April 12, 2004). Moreover, FDA advised that it may take enforcement action without further notice if firms did not cease distribution of adulterated products.

On April 12, 2004, the final rule prohibiting the sale of dietary supplements containing ephedrine alkaloid became effective (69 FR 6787). The rule, which was published on February 11, 2004, in the *Federal Register*, declared dietary supplements containing ephedrine alkaloids adulterated because such supplements present an unreasonable risk of illness or injury. Under DSHEA, FDA may remove a dietary supplement from the market if it presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/news/2004/NEW01140.html.

Seizure of Ginseng with Potentially Risky Pesticide Residues at FCC Products, Inc.

On December 15, 2004, FDA investigators accompanied the U.S. Marshals Service in a seizure of imported ginseng held for sale at FCC Products, Inc., Livingston, New Jersey. The product was seized due to the presence of pesticides. FDA issued a nationwide warning to those who may have used this product. FCC Products, Inc., is a manufacturer and repacker of bulk dietary supplements that are packaged in bulk and shipped for further processing or repacking.
FDA analysis of samples of ginseng collected at FCC Products, Inc., disclosed procymidone and quintozene.

The articles were adulterated because they contained a pesticide chemical residue for which no tolerances has been set.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01334.html.

Seizure of Dietary Supplement Containing Ephedrine Alkaloids at ATF Fitness Products, Inc.

FDA Lab Analysis of Dietary Supplements Revealed Presence of Ephedrine Alkaloids

On February 25, 2005, FDA announced that the Agency had requested the U.S. Attorney's Office for the Western District of Pennsylvania to file a Complaint for Forfeiture against adulterated and misbranded dietary supplement containing ephedrine alkaloids that were located at ATF Fitness Products, Inc., Oakmont, Pennsylvania. The U.S. Marshals Service seized the products in response to a warrant issued by the court. The products seized included several lots of SciFit Procut and one Thermogen II lot in an assortment of cases and bottles.

The seizure followed an FDA investigation that determined the products either contained prohibited ephedrine alkaloids or claimed to contain ephedrine or ephedrine alkaloids but did not.

These articles were, therefore, adulterated because they are dietary supplements that contained ephedrine alkaloids and, as such, present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling, or, if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use. Under DSHEA, FDA may remove a dietary supplement from the market if it presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use.

The products were misbranded because the labels represented that the product contained ephedrine or ephedrine alkaloids. In fact, FDA's laboratory analysis disclosed that the articles contain no ephedrine or ephedrine alkaloids.

On February 11, 2004, FDA published in the *Federal Register* the final rule (69 FR 6788) declaring dietary supplements containing ephedrine alkaloids adulterated. Manufacturers and distributors were advised that this rule would become effective 60 days from the date of publication (April 12, 2004). Moreover, FDA advised that once the rule became effective it might take enforcement action without further notice if parties did not cease distribution of adulterated products.

On April 12, 2004, the final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids became effective (69 FR 6787).

From October to November 2004, FDA inspected ATF Fitness Products, Inc., because the firm appeared to be marketing dietary supplements containing ephedrine alkaloids. On November 19, 2004, FDA issued a Warning Letter to ATF Fitness Products, Inc., to advise that dietary supplements containing ephedrine alkaloids were adulterated. The letter also noted that adulterated dietary supplements cannot be exported unless certain statutory requirements are met.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01342.html.

FDA Issued "Cyber" Letters

FDA Issued "Cyber" Letters Via the Internet to Websites Selling Products that May be Illegal

In 2000, FDA began issuing "Cyber" Letters, (letters sent electronically via the Internet), to websites whose online sales of products 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.

These "Cyber" Letters, sorted by month, are supplied by CFSAN and the Center for Drug Evaluation and Research. 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. In Fiscal Year 2005, FDA issued approximately 70 Cyber Letters.

Matters described in all FDA Cyber Letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the Letter.

A list of Cyber Letters is available on FDA's website at:
http://www.fda.gov/cder/warn/cyber/cyber2005.htm.

Warning Letter Issued to Bionutricals International, Inc., for Misbranding of CarboGetic™, Metabo Fat Blocker™, and Extreme Carb Blocker

On October 22, 2004, CFSAN issued a Warning Letter to Bionutricals International Inc., Kissimmee, Florida. FDA reviewed the website at the Internet address: http://www.bionutricals.com and concluded that claims on this website caused the products CarboGetic™, Metabo Fat Blocker™, and Extreme Carb Blocker to be misbranded under the Act.

Under the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading.

The labeling of CarboGetic™, Metabo Fat Blocker™, and Extreme Carb Blocker bore structure/function claims. Examples of these claims included but were not limited to the following:

- CarboGetic™
  - "[A] product that inhibits the absorption of carbohydrates while increasing your energy levels to burn more fat and carbs."
  - "Blocks carb absorption via alpha-amylase inhibition."
  - "Helps reduce sugar cravings."

- Under "Ingredients" for CarboGetic™
  - "CarboVal™-Phaseolus Vulgaris (extract): is a starch blocker that has been proven to neutralize the starch (carbs) consumed in a meal."
  - "Korean Ginseng...a good appetite suppressant."
- Under "FAQs" for CarboGetic™
  - "CarboGetic™…help[s] to reduce cravings, while preventing carbohydrates from being digested and converted into sugar that eventually gets stored in the body as fat."

FDA reviewed these claims and concluded that they were not supported by competent and reliable scientific evidence. Because these claims lacked substantiation, they were false or misleading, and caused the product to be misbranded. It is a violation of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement that is misbranded.

Androstenedione

Androstenedione is produced naturally in humans during the production of testosterone and estrogen. It is considered an anabolic steroid precursor because it can be converted in the body to testosterone. Scientific evidence shows that when androstenedione is taken over time and in sufficient quantities, it may increase the risk of serious and life-threatening diseases.

Warning Letter Issued to Sanapac Co., Inc., for Dietary Supplements Containing Androstenedione

On December 10, 2004, FDA's Philadelphia District Office issued a Warning Letter to Sanapac Co., Inc., Dallas, Pennsylvania. During FDA's inspection on October 7-8, 2004, an investigator collected labels and information pamphlets for the products. FDA reviewed the labels for several of the products and found that they violated the Act and FDA's regulations.

The product labeling for Vee 2000 for Men identified the product as a dietary supplement and declared androstenedione (among other names, also called 4-androstenedione or 4-androstene-3,17-dione) as an ingredient.

The firm labeled the Vee 2000 for Men product as a dietary supplement. Assuming that androstenedione was a "dietary ingredient," it would also be a NDI for which a notification is required under the Act and FDA regulations.

FDA law requires that a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the U.S. before October 15, 1994) must be deemed adulterated unless certain criteria are met.

FDA was not aware of any information demonstrating that androstenedione: (1) Was lawfully marketed as a dietary ingredient in the U.S. before October 15, 1994; or (2) Had been present in the food supply as an article used for food in a form in which the food had not been chemically altered. FDA determined that androstenedione was subject to the notification requirement for a new dietary ingredient. Because the firm had not submitted the required notification, the product was adulterated.

The product was misbranded as a dietary supplement because it contained a NDI for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited. The product was adulterated because FDA was aware of no history of use or other evidence of safety establishing that androstenedione would reasonably be expected to be safe as a dietary ingredient.

Warning Letter Issued to Cytodyne LLC for Misbranding of Xenadrine CarboCurb

Misleading Claim "…Helps Reduce Carbohydrate Absorption…" Resulted in Warning Letter

On October 22, 2004, CFSAN issued a Warning Letter to Cytodyne LLC, Lakewood, New Jersey. FDA reviewed the product labeling, including the website at the Internet address: http://www.cytodyne.com and concluded that claims in the labeling caused the product "Xenadrine CarboCurb" to be misbranded under the Act.

The labeling of Xenadrine CarboCurb included structure/function claims, such as the following:

- "Helps Reduce Simple & Complex Carbohydrate Absorption."
- "Helps reduce the amount of potential carbohydrates absorbed by your body…also helps limit the amount of carbs that turns into glucose, and help burn body fat."

FDA reviewed these claims and concluded that they were not supported by competent and reliable scientific evidence. Because these claims lacked substantiation, they were false or misleading, and caused the product to be misbranded.

Warning Letter Issued to Chi Machine International for Misbranding of BetaLoe Immune System Defense Supplement

On January 7, 2005, CFSAN issued a Warning Letter to Chi Machine International, Studio City, California. FDA reviewed the website at the Internet address: http://www.chimachine4u.com and concluded that claims in the labeling caused the product "BetaLoe Immune System Defense Supplement" to be a drug.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs. The website claimed that the product was useful in the prevention and treatment of influenza and other diseases.

The Internet labeling of the product included the following claims:

- "Protection for defense against flu, SARS, and Anthrax"(Testimonial) "The usual dose of 2 tablets, taken on an empty stomach will substantially lower the risk of developing Influenza & other infections. I have several patients on BetaLoe . . . no one has come down with Influenza."

- "Why would a person want to use BetaLoe? . . . Look around you . . .SARS outbreaks, deadly flu outbreaks, Anthrax threats . . "

- The website also made claims about ingredients in the product for the prevention and treatment of other diseases, including arthritis, coronary heart disease, and cancer.

These claims caused the product to be a drug because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug which may not be legally marketed in the U.S. without an approved NDA. This drug was also misbranded, because its labeling was false and misleading because it suggested that the drug is effective for the prevention and treatment of influenza and other serious diseases, when, in fact, these claims were not supported by competent and reliable scientific evidence. This drug was also misbranded because its labeling failed to bear adequate directions for use.

Warning Letter Issued to Beck & Beck, Inc., for Website Promoting Unapproved "New Drug"

On July 19, 2005, FDA's New Orleans District Office issued a Warning Letter to Beck & Beck, Inc., Coral Springs, Florida. The New Orleans District Office issued the Warning Letter based on a review of the firm's websites at the Internet addresses: http://www.aacstore.net; http://www.viusid.net; http://www.oncoxin.net; and http://www.bluecapusa.net. Based on this review, the Agency determined that the products Viusid, Diamel, Oncoxin, Alzer, Asbrip, Adrenal Cortex Glandular Extract, Kalsis, Relaxnova, and Herpigen were being promoted for conditions which cause these products to be drugs.

The Warning Letter advised the firm that the marketing of these products with these claims violated the Act, and may subject the firm, or the products, to regulatory action without further notice.

Examples of some of the claims, including claims in the form of testimonials, observed on these websites included, but were not limited to, the following:

- Viusid (http://www.aacstore.net; http://www.viusid.net; and http://www.bluecapusa.net)

  "What can VIUSID do for me?"

  - Will help reduce infections.
  - Helps with the prevention of many viral and bacterial infections.
  - Acts as an analgesic.

- Diamel (http://www.aacstore.net; and http://www.bluecapusa.net)

  "Diamel. Specifically formulated for Diabetic patients."

- Oncoxin (http://www.aacstore.net; http://www.oncoxin.net; and http://www.bluecapusa.net)

  "Nutritional Supplement to help fight Cancer."

The Warning Letter advised the firm that Viusid, Diarnel, Oncoxin, Alzer, Asbrip, Adrenal Cortex Glandular Extract, Kalsis, Relaxnova, and Herpigen products were not generally recognized as safe and effective for the above referenced conditions, and, therefore, these products were also "new drugs." New drugs may not be legally marketed in the United States without prior approval from FDA. FDA noted that the Agency approves a new drug based on scientific data submitted by a drug sponsor to demonstrate the drug is safe and effective.

Viusid, Diamel, Oncoxin, Alzer, Asbrip, Adrenal Cortex Glandular Extract, Kalsis, Relaxnova, and Herpigen were also misbranded because the labeling for these drugs failed to bear adequate directions for use.

Warning Letter Issued to Berkeley Premium Nutraceuticals for Unapproved New Drugs

On October 14, 2004, FDA's Cincinnati District Office issued a Warning Letter to Berkeley Premium Nutraceuticals, Cincinnati, Ohio, following an inspection from May 12-17, 2004. Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. The labeling of the firm's products Rovicid and Rogisen promoted these products to treat or prevent serious diseases. For example:

Web pages and product brochures for Rovicid promoted the product for prevention of heart disease and cancer, and for treatment of hypercholesterolemia with the following claims, among others:

- "May help reduce the risk of heart disease and help lower cholesterol.
- "Rovicid can help lower cholesterol levels, [and] prevent heart disease . . ."

Web pages and product brochures for Rogisen promoted the product for prevention and treatment of macular degeneration with the following claims, among others:

- "The once-daily caplet to fight macular degeneration and support improved night vision."
- "The leading cause of blindness among white Americans is age-related macular degeneration (AMD) . . .Coupled with annual comprehensive eye examinations, Rogisen may be your best defense against AMD.
- "Rogisen is the once-daily caplet to help prevent macular degeneration."

These claims caused the products Rovicid and Rogisen to be drugs as defined in section 201(g)(1)(B) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they were also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved NDA.

FDA Issued Nationwide Alert Regarding "Liqiang 4"

FDA Warned Consumers that Dietary Supplement Contained Glyburide - a Potentially Dangerous Drug

On July 1, 2005, FDA issued a Nationwide Alert warning consumers not to take Liqiang 4 Dietary Supplement Capsules because they contained glyburide – a drug that could have serious, life-threatening consequences in some people.

Glyburide is a drug used to lower blood sugar, and is safe and effective when used as labeled in FDA-approved medications. People who have low blood sugar or those with diabetes can receive dangerously high amounts of glyburide by consuming Liqiang 4. FDA advised that consumers should immediately stop using these products and seek medical attention, especially if they were being treated with diabetes drugs or if they had symptoms of fatigue, excessive hunger, profuse sweating, or numbness of the extremities. FDA advised that consumers who had this product should dispose of it immediately.

The product was sold as part of a shrink-wrapped two bottle set. One of the 90 capsule bottles was labeled Liqiang 4 Dietary Supplement Capsules, the other bottle was promoted as a "bonus pack" of Liqiang 1. FDA evaluated Liquang 1 and other versions of this line of products to determine their composition and safety. The product was manufactured by Liqiang Research Institute, China, and marketed throughout the United States in herbal stores and by mail order.

FDA learned of the potential problem through a consumer complaint and followed up with testing that revealed the presence of glyburide in this product. The product had also been termed "Liqiang Xiao Ke Ling" (Liqiang Thirst Quenching Efficacious) in ads in Chinese language publications, which also promoted it as useful for the control of diabetes and being derived from only natural ingredients.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01363.html.

Food Storage

Seizure of Multiple Foods at Northwest Trading & Spice Company

FDA Inspection Revealed Widespread Insect and Rodent Infestation

On October 6-9, 2004, FDA investigators from FDA's Seattle District Office accompanied the U.S. Marshals Service in a mass seizure of multiple foods at Northwest Trading & Spice Company located in Tukiwa, Washington.

Northwest Trading & Spice Company is a multi-food warehouse, repacker, and retail distributor of various foods. FDA's inspection of Northwest Trading & Spice Company from August 4 - 17, 2004, revealed a widespread insect infestation in the building, as well as significant rodent activity and limited bird activity. Live and dead insects, insect larvae, and insect cocoons were observed in and on assorted food items in the warehouse, repacking, and retail sales sections of the facility.

FDA's laboratory analyses of samples collected during the inspection confirmed the presence of adult insects, insect larvae, insect pupae, and insect excreta, as well as rodent excreta pellets, rodent urine, rodent gnawed material, and bird droppings.

All articles of food in susceptible containers, excluding articles in the firm's freezer, at Northwest Trading & Spice Company, that had been prepared, packed, and held under insanitary conditions were seized.

Seizure of Food at G.P.R. Company, Inc.

Widespread and Active Rodent and Insect Infestation Found in Food Storage and Manufacturing Areas Resulted in Seizure

On December 1-2, 2004, the U.S. Marshals Service in Royersford, Pennsylvania, seized the contents of G.P.R. Company, Inc., due to insect and rodent infestation. The firm is a manufacturer of powdered drink mixes, chocolate chips, chocolate covertures and sweetened coconut.

FDA's inspection on September 20-29, 2004, disclosed widespread and active rodent and insect infestation throughout the food storage and manufacturing area. FDA investigators observed the

firm's pest control records showing at least nine rodents had been trapped since the previous FDA inspection in June 2004. They also observed rodent-gnawed packages, dead rodents, rodent excreta, live and dead adult and larval insects, and insect gnawings in, on, and around stored lots of food. Rodent harborage areas and entryways were noted in the facility.

FDA's laboratory analyses of samples collected during the inspection confirmed the presence of rodent excreta pellets, rodent gnawed material, and rodent hairs, as well as live and dead insects in various stages of their lifecycle.

One of the articles was adulterated, because it consisted in whole or in part of a filthy substance by reason of the presence therein of insects, insect excreta, and insect webbing. All of the articles in susceptible containers, excluding articles in the firm's freezer(s), that were prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth were seized.

Seizure of Various Articles of Food at Purity Foods, Inc.

On December 29, 2004, at the request of FDA, the U.S. District Court for the Southern District of Ohio issued a warrant for the seizure of various articles of food located at Purity Foods, Inc., Clayton, Ohio. The U.S. Marshals Service, accompanied by an FDA investigator, seized the articles of food.

FDA's inspection of Purity Foods, Inc., during the period of October 20-25, 2004, revealed evidence of widespread insect infestation throughout the facility in some of the firm's production lines. Live and dead insects, insect larvae, and insect pupae were found on, in, and around various lots of food in the firm's storage area.

FDA's laboratory analyses of samples collected during the inspection confirmed the presence of insects in finished products of oats and farina (cream of wheat) and throughout the production facility.

The articles were seized because they were held under insanitary conditions whereby they may have become contaminated with filth.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01338.html.

Seizure of Food at LAO Trading Company

On March 14, 2005, at the request of FDA, the U.S. Marshals Service seized various articles of food at LAO Trading Company, Nashville, Tennessee. The U.S. Marshals Service seized all FDA-regulated items susceptible to rodent contamination.

An FDA inspection of Lao Trading Company on January 24-28, 2005, found evidence of widespread and active rodent infestation in all areas of the warehouse. During the course of the inspection, the FDA investigator sighted live rodents. Rodent excreta pellets too numerous to count were seen in the food storage areas throughout the building in, on, and around articles of food. Food products were observed to be directly contaminated with rodent excreta, rodent urine, and rodent gnawed holes. The building also had various potential rodent entryways.

FDA's laboratory analysis of samples collected during the inspection confirmed the presence of rodent urine, rodent excreta pellets, and rodent gnawed holes in bags.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/news/2005/field03_14.html.

Seizure of Basmati Rice at POF International, Inc.

FDA Lab Analysis of Basmati Rice Revealed Extensive Insect Infestation, Including Weevils, Beetles and Larvae

On July 25, 2005, at the request of FDA, the U.S. District Court for the District of New Jersey issued a seizure warrant for the seizure of over $80,000 worth of basmati rice at POF International, Inc., (POF), Irvington, New Jersey. POF is an importer, repacker, and wholesale distributor of basmati rice from Pakistan. The U.S. Marshals Office executed the seizure warrant on July 26, 2005.

The seized basmati rice, which had been imported from Pakistan, was adulterated because of insect contamination. Specifically, laboratory analysis of the rice revealed that it contained substantial numbers of weevils, beetles and insect larvae, which rendered it unfit for human consumption.

Prior to the seizure, the basmati rice had been placed under embargo by the New Jersey Department of Health and Senior Services to ensure that the product was not distributed to consumers. FDA initiated the seizure after POF declined to destroy the rice or recondition it in an appropriate manner.
The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/news/2005/field07_28.html.

Warning Letter Issued to Gulf Marine & Industrial Supplies, Inc., for Adulteration of Multiple Food Warehouse

On April 27, 2005, FDA's New Orleans District Office issued a Warning Letter to Gulf Marine & Industrial Supplies, Inc., New Orleans, Louisiana. FDA's inspection on January 25-26, 2005, was conducted to determine compliance with CGMP regulations. An investigator observed numerous insanitary conditions, which caused the ingredients and finished food products packed, and/or held at the facility, to become adulterated. The adulterated ingredients and finished food products violated the Act. The food products were adulterated since they consisted in whole or in part of filthy substances and/or had been held under insanitary conditions whereby they may have become contaminated with filth.

Some examples of the violations documented in the Warning Letter included the following:

- Failure to take effective measures to exclude pests from the facility and protect against contamination of food on the premises by pests.

- Failure of the facility to provide, where necessary, adequate screening or other protection against pests.

Warning Letter Issued to Great & Best Co., Inc., for Adulteration of Warehouse Facility

Firm Failed to Store Cleaning, Sanitizing and Pesticide Products so as to Protect Food Against Contamination

On May 19, 2005, FDA's New Orleans District Office issued a Warning Letter to Great & Best Co., Inc., Kenner, Louisiana. FDA's inspection on February 14-16, 23, and 25, 2005, was conducted to determine compliance with CGMP regulations. The food was adulterated because the food had been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

During the inspection, an investigator documented numerous insanitary conditions demonstrating the ingredients and finished food products packed, and/or held at the facility were adulterated.

The deviations were as follows:

- Failure to exclude pests from any area of a food plant.

- Failure to properly store equipment and assure the construction of the plant is suitable to conduct sanitary operations.

- Failure to construct the ceilings, floors and walls in the facility in such a manner where as the drip or condensate from fixtures, ducts and pipes do not contaminate food or food packaging materials.

- Failure to store toxic cleaning, sanitizing compounds and pesticide chemicals in such a way to protect against contamination of food or food packaging material.

- Failure to clean non-food contact surfaces as frequently as necessary to protect against contamination of food.

Fruit

Warning Letter Issued to Euro-USA Trading Co., Inc., for Misbranding of Organic Fruit Spread

"No Sugar Added" Claim Caused Organic Fruit Spread with Apple Juice Concentrate To Be Misbranded

On December 21, 2004, FDA's New England District Office issued a Warning Letter to Euro-USA Trading Co., Inc., North Franklin, Connecticut. During FDA's inspection on October 12, 2004, samples were collected of the product "Bionaturae Organic Fruit Spread" in various flavors: strawberry, bilberry, peach, apricot, wild berry, and plum to determine the company's compliance with the Act and its implementing FDA regulations.

The varieties of Bionaturae Organic Fruit Spread products were misbranded because the labels bore the claim "No Sugar Added," but did not meet the criteria established by FDA's regulations for such a claim. FDA's regulation defines "sugar" as all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose).

The Bionaturae Organic Fruit Spread products identified "Organic Apple Juice Concentrate" as an ingredient. Because apple juice concentrate was added to the Bionaturae Organic Fruit Spread products and contained sugars that functionally substituted for added sugars, the products did not meet the requirements for a "No Sugar Added" nutrient content claim and were therefore misbranded under the Act.

Warning Letter Issued to Sunrise Orchards, Inc., for Deviations from Juice HACCP Regulations

On September 22, 2005, FDA's Detroit District Office issued a Warning Letter to Sunrise Orchards, Inc., Goshen, Indiana. During FDA's inspection on February 21 and 23, 2005, an investigator collected two samples of "Kercher's October Gold...APPLE CIDER." Laboratory analysis of this product showed that both samples contained patulin. Patulin is a toxic substance produced by molds that may grow on apples.

The apple cider was adulterated when introduced into and while in interstate commerce and was adulterated while held for sale after shipment in interstate commerce because it contained an added poisonous or deleterious substance; patulin, which may render the article of food injurious to health.

The inspection of the firm found that the firm had serious deviations from the juice Hazard Analysis and Critical Control Point (HACCP) regulations. These deviations caused the product to be adulterated.

Some of the observations were as follows:

- Failure to have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur.
- Failure to have a HACCP plan that lists the critical limits that must be met
- Failure to have sanitation control records that document monitoring and corrections.

Warning Letter Issued to Sunshine Packing & Noodle Co., Inc., for Misbranding of Lo Cal Grape Jelly

On September 28, 2005, FDA's Florida District Office issued a Warning Letter to Sunshine Packing & Noodle Co., Inc., Jacksonville, Florida. During FDA's inspection on February 16-18, 2005, FDA collected samples of the "IPP Lo Cal Grape Jelly" product for laboratory analysis and labels to determine the firm's compliance with the Act and its implementing regulations.

The laboratory analysis and review of the product label found the "IPP Lo Cal Grape Jelly" product to be misbranded because the labeling was false or misleading. The amounts of total

calories and total carbohydrates were significantly higher than the values declared for these nutrients on the label. The label declared that the product provides 20 calories and 6g of total carbohydrate per serving, the serving being the entire one ounce packet of IPP Lo Cal Grape Jelly product. FDA's analysis found the calories to be 371% of the value on the label, and the

total carbohydrates to be 358% of the value on the label.

The product was also misbranded because the label bore the term "Lo Cal," which is synonymous with the nutrient content claim "Low Calorie," but was not qualified to make this claim. The term "low calorie" has been defined by regulation and may be used to describe a food that has 40 calories or less per reference amount customarily consumed (RACC) and per 50g when a food has a RACC of 30 g or less, or of two tablespoons or less. Based on the laboratory analysis of this product, the product did not comply with these requirements.

Furthermore, the "IPP Lo Cal Grape Jelly" product was misbranded because the nutrition information was not provided in one of the required formats. FDA also noted that the serving size for this single serving container was not properly declared.

Grains

Warning Letter Issued to Goya Foods, Inc., for Deviation from Standard for Enriched Corn Meal

Corn Meal Label Stated 17% Daily Value of Iron - FDA Analysis Found 8.5% Daily Value of Iron

On December 7, 2004, FDA's New Jersey District Office issued a Warning Letter to Goya Foods, Inc., Secaucus, New Jersey. During FDA's inspection on June 25, 2004, an investigator collected a sample of Goya Fine Yellow Enriched Corn Meal for nutrient content analysis to determine compliance with the Act and its implementing regulations.

FDA's analysis found the product to be adulterated because a valuable component, iron, had been in part omitted. The product was also misbranded because the labeling was false or misleading. The amount of iron was not at least equal to the value for that nutrient declared on the label. The label declared that the product provides 17% of the Daily Value (DV) of iron per serving. However, FDA's analysis found the iron content to be 8.5% of the value declared in the nutrition information on the label.

The product was also misbranded because it purported to be a food for which a definition and standard of identity has been prescribed by regulations, but it did not conform to such definition and standard for enriched corn meal.

In reviewing the label, FDA noted that the Nutrition Facts panel failed to declare the amount of riboflavin in the product. Riboflavin is a nutrient that has minimum and maximum levels in the

standard of identity for enriched corn meal, and the nutrition information must include the listing of riboflavin when it is added as a nutrient supplement.

Warning Letter Issued to Cafeteria Adelita for Imported Cheese

FDA Laboratory Analysis Found *E. Coli* and Alkaline Phosphatase in Imported Cheese Caused Product to be Adulterated

On March 30, 2005, FDA's Florida District Office issued a Warning Letter to Cafeteria Adelita, Miami, Florida. On December 22, 2004, the firm offered for import (imported) into the U.S. a shipment of cheese. After product review, FDA issued a written Notice of FDA Action, designating the entire shipment to be held for examination.

On January 6, 2005, FDA representatives attempted to examine the product covered by the Notice of FDA Action and found that the product was partially unavailable for examination, because a portion of the cheese shipment had already been distributed for consumption without an FDA release. This was a violation of FDA regulations which require the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Notice of Release" from FDA. FDA requested CBP to require redelivery of the missing portion of the cheese product that the firm failed to hold for FDA examination.

Failure to redeliver the missing portion to CBP custody may result in a penalty action at a later date. Furthermore, FDA representatives collected an import sample from the portion of cheese available at the time. The cheese sample was analyzed to determine compliance with the Act. FDA analysis of the cheese found it to contain high levels of *E. coli* and Alkaline Phosphatase, which caused the cheese to be adulterated.

Prepared Foods

Warning Letter Issued to Adelines Wholesale, Inc. for Misbranding of Sandwiches

On October 5, 2004, FDA's New Orleans District Office issued a Warning Letter to Adelines Wholesale, Inc., Nashville, Tennessee. During FDA's inspection on August 19-20, 2004, copies of the labeling were collected. Review of the labels revealed the firm's sandwiches were not labeled in compliance with FDA's food labeling regulations, which caused the sandwiches to be misbranded.

FDA's review of the labels revealed the following products were misbranded as follows:

- Sandwiches - the labels did not declare the components of the ingredients, which consist of two or more ingredients.
- The sausage and biscuit, and egg, sausage, and biscuit sandwiches -- the sandwiches contained the chemical preservative, sorbic acid, but it was not declared on the label.
- The sandwiches with sausage -- the sausage contained monosodium glutamate, which was not declared by its common and usual name "monosodium glutamate."
- The ham and Swiss sandwiches, and chicken cheese sandwiches, both on a poppy bun -- the poppy bun contained FD&C Yellow #5 and FD&C Yellow #6, which were not declared on the label by specific name in the list of ingredients.

Warning Letter Issued to Upscale Foods, Inc., for Misbranding of Mixed Dishes

On November 15, 2004, FDA's Minneapolis District Office issued a Warning Letter to Upscale Foods, Inc., New Hope, Minnesota. During FDA's inspection on March 29 and April 1, 2004, copies of labels for several of the food products were collected for review. The labels caused the products to be misbranded.

- "Old City Cafe Macaroni & Cheese Dinner" was misbranded because the label did not bear the correct location of the manufacturer, packer, or distributor.
- "Old City Cafe Vegetarian Beef & Bean Burrito" was misbranded because the label included the word "beef" in the statement of identity. However, beef was not used in this product, and therefore the use of the term was false and misleading. The product

was also misbranded because the ingredient statement on the product label failed to declare all of the ingredients in the product by their common or usual names.

- "Old City Cafe New York Style Cheese Pizza" was misbranded because the ingredient statement on the product label failed to declare all of the ingredients in the product by their common or usual names. The product was also misbranded because the serving size and servings per container on the Nutrition Facts panel were not declared in accordance with the requirements for serving size.

- "Old City Cafe Cheese Enchilada" and "Old City Cafe Bean & Cheese Burrito" were misbranded because the ingredient statement for each product label failed to declare all of the ingredients in the product by their common or usual names.

Warning Letter Issued to Field Roast Grain Meat Company for Misbranding of Meat Substitute

On April 20, 2005, FDA's Seattle District Office issued a Warning Letter to Field Roast Grain Meat Company, Seattle, Washington. During FDA's inspection on August 5, 2004, an investigator collected a sample of the Original Field Roast Brand Vegetarian Grain Meat Sliced Smoked Tomato. FDA analyzed the sample to determine whether the information in the Nutrition Facts panel accurately reflected the nutrient content of the product. The label stated that the product contained 25% of the % DV of Vitamin C per serving. The analyzed content of Vitamin C in the product was 2.6% of the amount of Vitamin C declared on the label.

Additional misbranding of the product included: The amount of Vitamin C present was less than 80 percent of the amount declared on the label; the product label bore a "Hi Protein" claim but it failed to include the %DV of protein in the Nutrition Facts panel; and the Nutrition Facts format did not meet the FDA requirements because the subheading "Amount/serving" was in the wrong location and was not separated from serving size information by a bar.

Also, the label bore the claim "GMO free." As explained in the FDA Draft Guidance for Industry regarding "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering," the claim "GMO free" is not technically accurate and may be misleading. This Draft Guidance may be viewed through the following link on FDA's web page: http://www.cfsan.fda.govhdmslbiolabgu.html.

FDA Issued a Safety Alert Regarding Smoked Salmon, Skinless Sliced Sides

***Listeria monocytogenes* Found in "Smoked Salmon Skinless Sliced Sides"**

On July 20, 2005, FDA issued a Safety Alert to consumers about the recall of SMOKED SALMON SKINLESS SLICED SIDES packaged in various 2 to 4 pound weight packages because they may be contaminated with *Listeria monocytogenes.* The products are sold under the brand names: Imperial Salmon House, Superior Brand Norwegian Cure, and Golden Eagle Smoked Salmon.

FDA's Alert extended to packages produced on June 13, 2005 with a shelf life of 3-4 months if maintained in an un-opened frozen state, four days if kept refrigerated. They were sold in individual 2 to 4 lb. packages labeled as: "Processed by Hickory House, Hialeah, FL 33016", "21555, Product of the USA", "keep frozen until ready to use." The product was sold in Florida, Georgia, New York and Virginia.

Listeria monocytogenes is an organism which can be serious and sometimes cause 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.

The contamination was noted after routine testing by the Florida Department of Agriculture and Consumer Services revealed the presence of *Listeria monocytogenes*.

FDA urged consumers who had purchased this product destroy it.

[FDA classified this recall as a Class I Recall.]

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/NEWS/2005/NEW01208.html.

Seafood

Consent Decree of Injunction - Best Fish Company d/b/a Crab Fresh

Inadequate HACCP Plan Could Result in Formation of *C. botulinum*

On October 14, 2004, Best Fish Company d/b/a Crab Fresh, Seattle, Washington, signed a Consent Decree of Permanent Injunction. The firm manufactured refrigerated ready-to-eat cooked Dungeness crabmeat in vacuum-sealed five pound metal cans. The product was not thermally processed. The firm failed to: conduct a hazard analysis; verify that the HACCP plan was adequate; adequately implement HACCP plan monitoring procedures; keep and review records properly; calibrate process monitoring instruments; take corrective action following deviations from critical limits; and properly monitor sanitation conditions.

This injunction involved a product in an oxygen-impermeable container, where the oxygen has been removed, but the product had not been thermally processed. Even though this process extends the shelf life of the product, it relies on the product remaining refrigerated from manufacture to consumption to prevent the formation of *C. botulinum* toxin.

Consent Decree of Injunction - SeaSpecialties, Inc., d/b/a/ Florida Smoked Fish Company

On April 15, 2005, U.S. District Judge James Lawrence King entered judgment against SeaSpecialties, Inc., d/b/a Florida Smoked Fish Company and several of its officers. The judgment and consent decree signed and agreed to by all defendants prevented the defendants from distributing food that was unsafe for human consumption and required them to cease operations at their Miami facility until it was properly cleaned-up and they otherwise complied with the terms imposed by FDA in the Consent Decree.

SeaSpecialties, Inc., produced and distributed, in Florida and nationwide, several ready-to-eat smoked salmon and other fish products to wholesalers, cruise ships, restaurants, and retailers, including major grocery store chains such as Publix and Giant Foods. The fish products were distributed under several brand names, including SeaSpecialties, Mama’s, Marshall’s, and the Boy’s Farmer’s Market.

In the civil complaint filed on March 30, 2005, against SeaSpecialties, Inc., and the individually-named officers, the U.S. alleged that inspections conducted by FDA revealed significant deficiencies in SeaSpecialties, Inc., operations, causing its food to be adulterated in violation of the Act, and FDA regulations. Laboratory tests conducted by the State of Florida’s Department of

Agriculture and Consumer Services and by SeaSpecialties, Inc.'s contracted laboratory, revealed the presence of *Listeria monocytogenes* in a variety of fish products produced at the Miami facility. Based on the laboratory results, SeaSpecialties Inc., publicly identified 53 of its products that tested positive for *Listeria monocytogenes*. No illnesses were reported in connection with this problem.

Seizure of Dried Whole Sea Cucumbers at Hoo Come Corporation

FDA Examination Found Product Heavily Infested with Live and Dead Insects, Larvae, and Insect Filth

On October 4, 2004, FDA's Los Angeles District Office investigators accompanied the U.S. Marshals Service in a seizure of various types of dried and vacuum packed frozen seafood products, including whole sea cucumbers at Hoo Come Corporation, Industry, California. The products at Hoo Come Corporation were imported from Hong Kong.

FDA's examination of the sea cucumbers revealed that the product consisted in part of a filthy substance because it was heavily infested with live and dead insects, insect larvae, and other insect filth. In addition, the product had been held under insanitary conditions whereby it may have become contaminated with filth.

Seizure of Tuna at E. Frank Hopkins Company and Philadelphia Warehousing and Cold Storage Company

On November 23, 2004, FDA investigators accompanied the U.S. Marshals Service in a seizure of frozen tuna loins located at E. Frank Hopkins Company, and Philadelphia Warehousing and Cold Storage Company, Philadelphia, Pennsylvania.

FDA's sensory and chemical examination of the articles revealed that they (both lots) consisted in part of decomposed tuna loins. FDA's chemical (histamine) analysis confirmed the decomposition and also found that one lot of tuna loins contained histamine at levels that constitute a risk of scombrotoxin poisoning to consumers of the product.

Seizure of Shrimp at Atzlan Cold Storage, Inc.

FDA Initiated Seizure to Prevent Export of Decomposed Shrimp

On September 2, 2005, FDA investigators from the Los Angeles District Office accompanied the U.S. Marshals Service in the execution of a seizure of decomposed shrimp. The seizure took place at Atzlan Cold Storage, Inc., located in Commerce, California. The decomposed shrimp were imported from a foreign source to a Los Angeles, California firm who sold the product to a customer in another state. The customer performed quality control testing, found the product was decomposed, and shipped the product back to California.

An independent sample was collected and analyzed by FDA which confirmed the decomposition. The California firm refused to have the decomposed shrimp destroyed. As a result, a seizure was necessary to prevent the export of adulterated shrimp, which could have allowed for the possibility of re-entry into the U.S.

Warning Letters for Deviations from the Seafood HACCP Regulation

In Fiscal Year 2005, FDA issued 55 Warning Letters for violations of the Seafood HACCP Regulation. The following Warning Letter was chosen to provide an example of the types of violations that may result in a Warning Letter.

Warning Letter Issued to Boston Seafood Wholesale LLC for Violations of Seafood HACCP

On September 29, 2005, FDA's Florida District Office issued a Warning Letter to Boston Seafood Wholesale LLC, Gainesville, Florida. FDA's inspection on June 7-9, 2005, showed serious violations of the seafood HACCP regulation, and the CGMP regulation for foods.

The processor of fish or fishery products failed to have and implement a HACCP plan that complies with FDA regulations. Thus, the histamine-forming fish were adulterated, because they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

The significant violations noted during the inspection were as follows:

- Failure to have a HACCP plan that, at a minimum, lists the critical limits that must be met.

- Failure to conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and must have a HACCP plan to control any food safety hazards that are reasonably likely to occur.

- Failure to implement the record keeping system that is listed in the HACCP plan.

FDA Extended Nationwide Health Alert on Mama's and King Salmon Brands of Smoked Salmon Product

On April 15, 2005, FDA extended a previous alert of possible *Listeria monocytogenes* contamination of SeaSpecialities, Inc., smoked nova salmon Nationwide Alert products. This second nationwide alert applied to SeaSpecialities product packaged in 8-oz vacuum-packed bags under the "Mama's" and "King Salmon" brands. The Mama's brand products were sold in individual 8-ounce packages marked: "SELL BY AUG 22 2005 32178." They also may have been shipped in cartons labeled: "08/22/05 SELL BY 32178." No coding or packaging information on the King Salmon brand product was available.

Both FDA and the State of Florida issued public alerts about other potentially contaminated products from the firm. The contamination was noted after routine testing by the Florida Department of Agriculture and Consumer Services revealed the presence of *Listeria monocytogenes.*

Listeria monocytogenes is an organism which sometimes causes 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 a high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea. *Listeria* infection can cause miscarriages and stillbirths among infected pregnant women.

Consumers who purchased this product were urged to return it to the place of purchase for a full refund.

The full text of the Press Release is available at:
http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01351.html.

Soy Products

Warning Letter Issued to Denver Tofu Company, Inc., for Misbranding of Tofu

On December 21, 2004, FDA's Denver District Office issued a Warning Letter to Denver Tofu Company, Inc., Denver, Colorado. During FDA's inspection on September 13, 2004, samples of the product Kinugoshi Silken Tofu, packaged in 16-ounce trays with cellophane lids, were collected to determine the firm's compliance with the Act and its implementing regulations. FDA's analysis of the Kinugoshi Silken Tofu showed that the product was misbranded because the labeling was false or misleading. The amount of calcium present was less than the amount declared. The label declared that the product provided 15% of the DV of calcium per serving. FDA's analysis showed the calcium content to be 29.3% of the value declared in the nutrition information on the label.

Vessel Watering Points

Warning Letter Issued to Reid's Bus Service

On November 2, 2004, FDA's Kansas City District Office issued a Warning Letter to Reid's Bus Service, Creighton, Missouri. The facility was used as a service area for waste disposal. FDA's inspection on September 23, 2004, revealed a significant deviation from the Interstate Conveyance Sanitation Regulations (21 CFR 1250) issued under the authority of the PHS Act.

During the inspection the following significant deficiency was noted:

- Failure to have a backflow prevention device installed on the hydrant used to flush and clean out the toilet wastes from buses serviced at the station.

The deficiency found at the bus servicing facility may cause contamination of the potable water supply with human sewage and contribute to the spread of communicable disease. This deficiency had been observed at the facility during prior inspections. Based on the inspectional findings, FDA classified the facility as "Provisional" for interstate carrier use.

A “Provisional” classification means that the facility may continue to operate; however, correction of deficiency must be made by the time the facility is re-inspected. If significant corrections are not made by the time of the next inspection, the facility will be reclassified as “Use Prohibited” for carrier use. A classification of “Use Prohibited” prohibits the use of the facility by interstate conveyances until the deficiency has been corrected and the facility has been re-inspected by FDA.