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Acting Commissioner
Food and Drug Administration
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CITIZEN PETITION

I. Introduction

On behalf of the Center for Science in the Public Interest (CSPI) and our 900,000 members, we are submitting a petition to the Food and Drug Administration (FDA) urging the agency to issue standards and regulations to help ensure the safe production of fresh fruits and vegetables. These regulations are clearly needed, as demonstrated by recent multi-state outbreaks in produce, including the *E. coli* O157:H7 outbreak from spinach that sickened over 200 people and killed at least four and the more recent *Salmonella* outbreak caused by tomatoes that has sickened nearly as many. Many other outbreaks have been traced to produce, and these will continue to occur until FDA adopts enforceable standards for this important sector. CSPI urges the FDA to develop mandatory regulations and auditing programs for produce growers and processors to reduce the likelihood of microbial contamination. These regulations are authorized under the Federal Food, Drug and Cosmetic Act, section 402(a) and the Public Health Service Act, section 361.

We also hope that FDA will expedite development and publication of produce regulations, the way the agency did for regulations developed in response to the 2002 Bioterrorism Act. Regulations covering Administrative Detention, Registration of Food Facilities, Maintenance and Inspection of Records for Food, and Prior Notice of Imported Food Shipments were largely finalized within two years of the signing of the Act. In contrast, in 1997, CSPI petitioned FDA for a regulation to develop on-farm practices to reduce *Salmonella* in shell eggs, based on a successful pilot program in Pennsylvania. FDA's Proposed Rule was finally issued in September 2004 but has been pending without action since. We hope that mandating improved agricultural practices for growing and packing fresh fruits and vegetables will be done quickly to maximize consumer protection, ensure consumer confidence in these essential components of a healthy diet, and minimize the harm to the produce industry.

II. Action Requested

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that steps are taken to improve their safety. FDA should consider emergency regulations requiring all fruit and vegetable producers and processors to focus on the hazards associated with their products and have written plans in place to identify where contamination is likely to occur and how to address it. This approach is appropriate for both large and small growers and processors. It targets resources to critical areas and reduces risk by using prevention. The FDA should adopt mandatory hazard control programs for farms and fruit and vegetable processors. These programs should address all major sources of contamination, including the following areas:

Manure:

The grower must manage the application of manure to ensure that it does not contribute to the contamination of crops, including limitations on the crops where and the times when it may be applied. The use of raw manure on produce during the growing season should be prohibited. See 5 CFR Part 205.203(c) for manure application requirements under the National Organic Program.¹ Composting of manure intended for use on food crops should be monitored and records should be maintained to ensure effective controls are used to destroy pathogens. Domestic animals should be excluded from fields and orchards during the growing and harvesting season, and growing areas should have wildlife deterrents. Farmers and producers should ensure that animal waste from adjacent fields, pastures, or waste storage facilities do not contaminate growing areas. Manure treatment and storage sites close to fresh produce fields increase the risk of contamination; livestock producers should be required to move or otherwise control these sites.

Water:

Growers and producers should ensure that the water supply used for irrigation and in food processing plants is suitable for its intended use. The internationally agreed-upon Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Processors says that growers should assess the microbial and chemical quality of the water used in primary production.² Vegetable processors should use only potable water in the processing facility for cleaning or sanitizing the facility and equipment and for processing. Facilities should have an environmental monitoring program that includes sampling for pathogens to detect areas of harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. Sanitizers used for washing vegetables should be approved by FDA and continuously monitored by the facility to ensure they remain at effective levels in the wash water. If effective sampling programs can be developed, water used for washing produce should be monitored for the presence of pathogens at a rate adequate to ensure highly contaminated batches are identified and either destroyed or sent for further processing.

Hygiene:

Growers and processors should ensure that employees have close access to bathrooms and that handwashing facilities are visible to supervisors. Employees with direct and indirect access to the production areas should be trained in preventive controls that will help to eliminate or minimize contamination of produce.

Sanitation:

Processors should establish mandatory sanitation standard operating procedures, including cleaning procedures for equipment, storage areas, air systems, and water storage areas. Facilities should be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. There should be limited access to the facility and to its processing areas; adequate space for operations; adequate drainage of processing and wash water; food contact surfaces that are easy to clean and maintain; and areas and structures designed to protect the product and equipment from contamination.

Traceback:

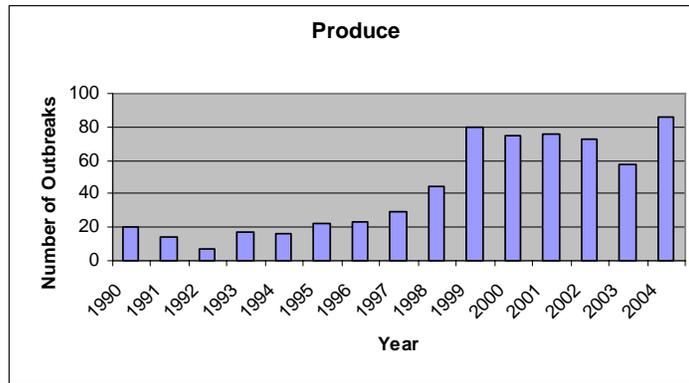
Processors should mark packaging to ensure easy traceback when fruits and vegetables are implicated in an outbreak. Package markings should be specific enough to extend all the way back to the farm/farms of origin. The ability to identify the source of a product is a critical component of food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation can help limit the impact of an outbreak of foodborne illness and help to identify and eliminate conditions that may have contributed to product contamination.

Adoption of mandatory, regulatory requirements is the best way to ensure that growers and others in the produce supply chain address the risks inherent in the production of fresh produce. FDA should also regularly conduct random inspections of farm fields and facilities that process produce, prioritizing by size and risk potential. Where states or third party auditors are being used, FDA should oversee audits and exercise more rigorous enforcement actions, including product seizure and criminal sanctions whenever adulterated products are sold.

Foodborne illness outbreaks related to fresh produce are a major public health problem. Prevention, early detection, and control measures must be in place at every step of fresh produce production to help minimize food safety risks. Voluntary guidelines are not an effective public health response to address the food safety problems related to fruits and vegetables.

III. Statement of Grounds For Petition**A. Factual Grounds****1. Produce outbreaks are increasing in frequency**

The Center for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick and 5,000 die from foodborne hazards each year in the United States. Many health-conscious Americans consume fresh produce as part of a balanced diet. But in the last decade, the number of foodborne illnesses from outbreaks associated with fruits and vegetables has doubled in the United States. According to CSPI's database of 5,000 foodborne illness outbreaks, 639 outbreaks with nearly 31,500 cases have been linked to produce and produce dishes between 1990 and 2004. In fact, produce is responsible for more cases linked to outbreaks than any other specific food type and the size of the average outbreak is larger, thus affecting more people.³



Source: Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006).

In recent years, a variety of pathogens have been implicated in produce outbreaks. *Salmonella* illnesses have been traced back to lettuce, salads, melons, sprouts, tomatoes, and other fruit- and vegetable-containing dishes. Numerous outbreaks have also been traced to *E. coli* 0157:H7. In addition to the recent spinach outbreak, this devastating pathogen has also been linked to at least 35 other produce outbreaks between 1990 and 2004, traced to lettuce, salads, melons, sprouts, and spinach.

CDC epidemiologist Christopher Braden at the National Center for Infectious Diseases in Atlanta, Georgia, recently said, "Fruit and vegetable produce is now a major source of outbreaks, at the same level as we used to see in meat." and attributed the rise in part to increased international trade, which lets people eat produce year-round rather than when in season locally.⁴

2. Studies show numerous multistate outbreaks linked to produce and minimal understanding of FDA's Good Agricultural Practices

Produce outbreaks in the U.S. have been documented from both imported produce and domestically grown produce. The changes we recommend would protect both U.S. consumers eating imported and domestically grown produce and consumers in other countries eating U.S. grown produce.

The outbreaks below help illustrate that although the FDA's voluntary guidance for fresh produce has been in place for eight years, many growers and producers are either unaware of or not complying with the guidance. While most of these examples involve imported produce, many outbreaks are also traced to domestic growers:

- In 1996, approximately 850 cases of laboratory-confirmed *Cyclospora* infection were reported to CDC and Health Canada and traced to raspberries grown in Guatemala.⁵ *Cyclospora* infects the small intestine and typically causes watery diarrhea, loss of appetite, substantial loss of weight, and persistent fatigue. If untreated, illness may last for a few days to a month or longer, and may follow a remitting-relapsing course.⁶
- In 1997, approximately 1000 laboratory-confirmed and clinically defined cases of *Cyclospora* infections were reported in 14 states and Ontario, including an outbreak originating on a cruise ship.⁷ Fresh raspberries from Guatemala were again identified as the culprit.

- In 1997, over 150 cases of Hepatitis A associated with the consumption of frozen strawberries were reported in Michigan, most of whom were students or staff of schools in four different school districts. The strawberries associated with illness were reportedly from Mexico and were processed and frozen in southern California. These strawberries were distributed to U.S. Department of Agriculture (USDA)-sponsored school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.⁸ In all, over 256 cases were reported to CDC.
- Three multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations of cantaloupe purchased by patients in all three outbreaks. In each instance, point-of-sale sources of cantaloupe were traced back to shippers and then to farms in Mexico. FDA conducted on-farm investigations in Mexico and concluded that measures were not in place to minimize microbial contamination in the growing, harvesting, packaging, and cooling of cantaloupe. Possible sources of contamination include irrigation of fields with water contaminated with sewage, processing (cleaning and cooling) produce with *Salmonella*-contaminated water, poor hygienic practices of workers who harvest and process the cantaloupe, pests in packing facilities, and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.⁹
- In 2003, a major Hepatitis A outbreak sickened 555 people in Pennsylvania, including 13 restaurant food service workers and 75 residents of six other states who dined at the restaurant. The Food and Drug Administration (FDA), CDC, and state health departments investigated the source of the green onions associated with this outbreak and how they became contaminated with Hepatitis A virus. Preliminary traceback information indicated that green onions supplied to the restaurant were grown in Mexico. This outbreak followed three other ones, in Georgia, Tennessee, and North Carolina that were linked to the same green onions.¹⁰
- In February 2004, following fourteen outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes reminding them to review their current operations in light of the agency's guidance.¹¹ FDA sent another letter specifically to California lettuce firms in November 2005 expressing concern over continuing outbreaks of foodborne illness and outlining actions the industry should take in order to ensure lettuce safety.¹²
- At the June 29, 2004 public meeting to discuss the proposed Product Action Plan, Dr. Robert Gravani of Cornell University's Food Science Department reported that a Good Agricultural Practices Survey of Farm Workers in New York State showed that approximately 30% of producers were unaware of Good Agricultural Practices (GAPs) for their particular crop. The numbers show the need for a mandatory regulatory program for fresh produce and the same should go for fresh-cut produce.
- A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Producers were conscious of product safety, but levels of awareness about risk varied.

Areas that needed improvement included improved hand washing facilities and practices; provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.¹³

3. Voluntary guidelines are not sufficient to address on-farm sources of produce contamination

Over the past decade, the federal government has focused on reducing foodborne illness from all sources. Despite these efforts, foodborne outbreaks associated with fresh produce persist at a high rate. Given the importance of produce consumption and its central role in a healthy diet, it is imperative that FDA take concrete steps to reduce the incidence of foodborne illness cases associated with fresh produce.

FDA's reliance on voluntary compliance with existing guidelines, education, and awareness has not been effective in preventing foodborne illness from fresh produce. The best way to minimize or prevent contamination is through implementation of hazard identification and process control systems. FDA should mandate these systems starting with the highest-risk products first – like leafy green vegetables that have been repeatedly linked to illness outbreaks.

Regulations should require growers and processors in the produce supply chain to have written plans that identify hazards associated with their products and the steps, interventions, and programs taken to address those hazards. Documentation of procedures is critical to ensure that producers and processors are doing everything possible to reduce microbial risks associated with fresh and fresh-cut fruits and vegetables. Random third party and state auditing, especially of large farms, based on consistent standards can play an important role in helping FDA to monitor that the regulations are being fully enforced. Auditors should be subject to state oversight and approval to ensure that they provide consistently reliable services.

Hazard control programs should be based on the best management practices developed for various sectors of the produce industry together with other guidance codes that have been adopted by the FDA, World Health Organization, and others. These programs should address all stages of fresh produce production, including growing, harvesting, sorting, processing, packaging, shipping, and storage.

The most important benefit of a mandatory regulatory program is that it would assure that all growers and processors implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is clearly not universal.¹⁴

In the past, the FDA has unsuccessfully tried to minimize microbial food safety hazards in produce by publishing a series of a draft “guidance” documents for farmers and processors. But the all-too-frequent produce-related outbreaks demonstrate that simply issuing guidance documents is insufficient to protect consumers from the threat of foodborne hazards. Equally important is the fact that the federal agencies' food safety expenditures are disproportionate to the percentage of foodborne illnesses caused by the foods they regulate. USDA-regulated foods account for only about 32 percent of reported foodborne outbreaks with known sources while FDA-regulated products account for roughly 68 percent of these outbreaks. However, USDA's food safety expenditures are about 49 percent more than FDA's.¹⁵ While USDA has the

resources to inspect meat and poultry plants daily, the FDA inspects food facilities it regulates on average just once every five to ten years. And neither agency has adopted on-farm food-safety regulations.

B. Legal Grounds

1. The Federal Food, Drug, and Cosmetics Act (FDCA) authorizes the FDA to establish a mandatory government program for on-farm sanitation

The Federal Food, Drug, and Cosmetic Act (FDCA) was enacted to safeguard public health and prevent deceit of the purchasing public.¹⁶ Indeed, the Supreme Court has established that “the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.”¹⁷ FDCA section 402(a)(1) establishes certain classes of food adulterants, depending on whether or not the substances are “added.”¹⁸ A food containing an “added” substance is adulterated if the substance “may render it injurious to health.”¹⁹ A food containing a naturally occurring (hence, not “added”) substance is adulterated only if the quantity of the substance in the food would “ordinarily render it injurious to health.”²⁰ A food is also deemed adulterated if it has been “prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”²¹ Through these provisions, Congress empowered the FDA to set requirements to assure that firms are producing foods that are safe, unadulterated, and wholesome, including the authority to control conditions at the earliest stages of food production.

Both FDA regulations and legal precedent have defined “added” substance broadly for the purposes of the adulteration standard under section 402(a)(1). Under FDA’s regulations, the “added”-substances adulteration standard applies where a naturally occurring substance “is increased to abnormal levels through mishandling or other intervening acts.”²² A substance is “added” to a food even if it derives in part from man and in part from nature.²³ The FDA is only required to show some portion of the substance is attributable to the acts of man and that the total amount may be injurious to health.²⁴ In *United States v. Anderson Seafoods, Inc.*, the Fifth Circuit held that mercury in swordfish is an “added” substance because at least some of the mercury present in the swordfish was present in the ocean because of “the acts of man.”²⁵

Just like mercury in seafood, *Salmonella* or *E. coli* 0157:H7 are not natural constituents of fruits or vegetables. Pathogens that occur on fruits or vegetables as a result of human actions, such as applications of manure, compost, sewage, or irrigation waters would meet the “added”-substance provision. Farmers apply these constituents to the growing environment or they may occur through pollution of the water table. Hence, an “intervening act” is responsible for the presence of these pathogens on these raw agricultural food products. Once contaminated, however, processing may spread them or a lapse in the cold chain may cause them to grow. Either results in pathogens on products through an “act of man.”

Under FDCA section 402(a)(1), a naturally occurring substance also may be considered an adulterant where it is in a quantity sufficient to cause the food to be “injurious to health.”²⁶ CSPI has provided numerous examples of outbreaks that demonstrate that the presence of *E. coli*, *Salmonella* and other pathogens on fruits or vegetables cause them to be “injurious to health.”

Under FDCA section 402(a)(4), food that is prepared, packed or held under unsanitary conditions whereby it may become injurious to health also is considered adulterated. This section gives broad authority to control conditions in food production and food processing because it does not require proof of actual contamination.²⁷ When this section was being deliberated in Congress, then-FDA chief Walter Campbell testified:

We are aware of a great many instances where we think public health is placed in jeopardy. At least, people are permitted to consume products that are possibly filthy, potentially dangerous, and which unquestionably they would not consume if they were conscious of the conditions of production . . . Now, a provision of the kind in this bill will make it necessary for those who enjoy the profits that come from the production of that food to observe, it seems to me, a reasonable concern about the freedom of the product from contamination.²⁸

Inspections and audits would help the FDA to verify that hygienic practices are being followed and effective methods are used to control hazards in the harvesting, preparation, packing, and holding of fruits or vegetables. If such hazard controls are lacking or are ineffective, the potential exists that the food may be rendered injurious to health and thus would be deemed “adulterated” under section 402(a)(4).

FDCA case law is in accord with this interpretation. In *United States v. Nova Scotia Food Products Corp.*, a smoked-fish processor challenged the FDA’s good manufacturing practices regulations, which provided that the failure to eliminate *Clostridium botulinum* through adequate processing created unsanitary conditions that rendered the fish adulterated under section 402(a)(4). The *Nova Scotia* court specifically rejected arguments by the seafood processor that “unsanitary conditions” were limited to conditions in the plant itself and not conditions that inhibit the growth and spread of organisms already in food when it enters the plant.²⁹

Under the broad authority of the FDCA, the agency can issue regulations that are reasonably related to the purposes of the Act.³⁰ Establishing a mandatory government hazard control program for fruits and vegetables would be a reasonable exercise of the FDA’s authority to ensure that these products are not “prepared, packed or held under unsanitary conditions.”³¹ Moreover, it would advance the purposes of the FDCA – to ensure that consumers are protected from unsafe food.

2. The Public Health Services Act (PHSA) authorizes the FDA to establish a mandatory on-farm hazard control program for fruits and vegetables.

Section 361 of the Public Health Service Act (PHSA) authorizes the FDA, by delegation, to adopt and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases into or within the U.S.³² “Communicable diseases” have been defined by the agency as follows:

Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.³³

Illnesses caused by tainted fruits or vegetables clearly fall within this ambit.

In implementing its PHSa mandate, the FDA is authorized to provide for the inspection, disinfection, and sanitation of animals and articles that are so infected or contaminated as to be sources of infection to humans and other necessary measures.³⁴ Thus, the agency has wide latitude to issue regulations and develop inspection programs to ensure that foods are manufactured, processed, packed or held under sanitary conditions to be safe, wholesome, and otherwise fit for food. In this instance, establishing a mandatory on-farm hazard control program for produce would be a reasonable exercise of the agency's PHSa authority to prevent the spread of communicable disease.

IV. Environmental Impact

The action requested in this petition does not fall within the categories of actions requiring an environmental impact statement under 21 C.F.R. § 25.21 or an environmental assessment under 21 C.F.R. § 25.22. The action requested is of a type that does not individually or cumulatively have a significant effect on the human environment, as required under 21 C.F.R. § 25.23. The action also is subject to categorical exclusion under 21 C.F.R. § 25.24 because it will not result in the introduction of any substance into the environment.

V. Economic Impact

An economic impact statement under 21 C.F.R § 10.30(b) is not necessary at this time.

VI. Certification

The undersigned parties certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,



Caroline Smith DeWaal
Director, Food Safety
Center for Science in the Public Interest

Endnotes

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- ¹ National Organic Program. 5 CFR pt.205.203(c).
- ² United Nations Codex Alimentarius Commission (2003). *Codex Code of Hygienic Practice for Fresh Fruits and Vegetables*.Section 3.2.1.1.1. November 15, 2006.
<http://www.codexalimentarius.net/download/standards/10200/cxp_053e.pdf>. See also: Beuchat LR (1998). “Surface decontamination of fruits and vegetables eaten raw: A review.” *Food Safety Issues*. World Health Organization.
- ³ Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006).
- ⁴ “Fruity hitchhikers leave you heaving.” *New Scientist*, August 12, 2006 (2564): 16.
<<http://www.newscientist.com/article/mg19125644.900.html>>.
- ⁵ J Hoffman *et al* (1996). “Update: Outbreaks of *Cyclospora cayetanensis* Infection – United States and Canada, 1996.” July 19, 1996. *MMWR* 45(28): 611-612.
- ⁶ CDC Division of Parasitic Diseases (2004). *Fact Sheet: Cyclospora Infection—Information for Healthcare Providers*. April 19, 2004. November 14, 2006.
<http://www.cdc.gov/ncidod/dpd/parasites/cyclospora/healthcare_cyclospora.htm>.
- ⁷ E DeGraw *et al.* (1997). “Update: Outbreaks of Cyclosporiasis—United States and Canada, 1997.” June 13, 1997. *MMWR*, 46(23): 512-523.
- ⁸ Centers for Disease Control (1997). “Hepatitis A Association with Consumption of Frozen Strawberries—Michigan, March 1997.” *MMWR*, 46(13): 288,295.
- ⁹ SM Anderson *et al.* (2002) “Multistate Outbreaks of Salmonella serotype Poona Infections Association with Eating Cantaloupe from Mexico—United States and Canada, 2000-2002.” November 22, 2002. *MMWR*, 51(46);1044-1047.
- ¹⁰ V Dato *et al.* (2003) “Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003.” *MMWR*, 52(47): 1155-1157.
- ¹¹ FDA, CFSAN (2004). *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes*. Feb. 5, 2004. November 14, 2006. <<http://www.cfsan.fda.gov/~dms/prodltr.html>>.
- ¹² FDA, CFSAN (2005). *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce*. November 4, 2005. November 14, 2006. <<http://www.cfsan.fda.gov/~dms/prodltr2.html>>.
- ¹³ J Ellis, et al. (2005). “Assessing On-farm Food Handling Practices of Iowa-grown Produce and Eggs in Regard to Food Safety.” *Food Protection Trends*, 25(10): 758-61.
- ¹⁴ USDA, FDA, CDC (1998). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. October 26, 1998. Commodity-specific guidelines are available at <www.foodsafety.gov/~dms/fs-toc.html>.
- ¹⁵ LJ Dyckman (2004). *Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap*. GAO-04-588T: 10. Washington, D.C.: March 30, 2004.
<<http://www.gao.gov/new.items/d04588t.pdf>>.
- ¹⁶ Dunn, Federal Food, Drug, and Cosmetic Act 997 (1987) (Conference Report) [hereinafter *FDCA Legislative History*].
- ¹⁷ *U.S. v. Park*, 421 U.S. 658, 671 (1975).

¹⁸ 21 U.S.C. § 342(a)(1).

¹⁹ 21 U.S.C. § 342(a)(1).

²⁰ 21 U.S.C. § 342(a)(1).

²¹ 21 U.S.C. § 342(a)(4).

²² 21 C.F.R. § 109.3(d).

²³ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 160-62 (5th Cir. 1980).

²⁴ *Anderson Seafoods*, 622 F.2d at 162.

²⁵ *Anderson Seafoods*, 622 F.2d at 161-62.

²⁶ 21 U.S.C. § 342(a)(1).

²⁷ *See, e.g., United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 247 (2d Cir. 1977).

²⁸ *FDCA Legislative History*, at 1144 (S. Hearing on S. 2800).

²⁹ *Nova Scotia*, 568 F.2d at 245-46.

³⁰ *Nova Scotia*, 568 F.2d at 246.

³¹ 21 U.S.C. § 342(a)(4).

³² 42 U.S.C. § 264.

³³ 21 C.F.R. § 1240.3(b).

³⁴ 42 U.S.C. § 264.