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## **Chapter 9 – Operations in a Global Environment**

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## Introduction

Increasing globalization of trade is a reality of the 21st century. The resulting impact is that United States (U.S.) markets are now composed of approximately \$2 trillion worth of imported goods annually and is continuing to steadily increase. In the past five years alone, the volume of imported products has doubled, with 60 percent of these imports consisting of food or food related products.<sup>1</sup> Experts predict this volume will triple by 2015.<sup>2</sup> As the volume of imported products has increased, greater challenges in the maintenance of consumer safety and protection of the public health through Food and Drug Administration (FDA) regulatory oversight have become evident. FDA regulates approximately 25 percent of the Gross National Product in the U.S. and roughly one third of all commercial lines of entry declared at U.S. ports of entry fall under FDA's regulatory oversight<sup>3</sup> with over 17 million lines reviewed for entry in fiscal year (FY) 08 alone.

To ensure the safety of marketed products, FDA investigators perform inspections of domestic and foreign manufacturers, conduct timely reviews of import entry information, carry out selected high priority physical examinations upon arrival of some imported products, and where indicated, collect and test product samples for signs of contamination. In FY08 this included 14,298 domestic and 947 foreign inspections, review of over 16 million lines of products requesting entry into the U.S., and the identification of over 17,907 lines of violative imports. The increases in the volume of imported finished products, components for domestically manufactured products, and the accompanying flow of import information is staggering. The need for careful review and assurance of safety at our borders and beyond is essential to meet the demands of consumers, the market place, and to effectively protect the public health.

Advances in science, technology, and manufacturing processes, both in the U.S. and overseas, have resulted in products which are more complex requiring greater attention from today's and tomorrow's regulators. Products that were once manufactured domestically are now being produced abroad. It is more difficult and costly for FDA to ensure that domestic standards are being met by foreign manufacturers of domestically marketed products, thereby ensuring the safety of U.S. consumers.

For example, recent problems with the contamination of heparin, a blood-thinning drug that has been in common use for over 60 years, have highlighted some of the challenges

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<sup>1</sup> Ibid.

<sup>2</sup> Statement of Randall Lutter, Ph.D., Deputy Commissioner for Policy, FDA, before the Committee on Energy and Commerce, Subcommittee on Health, U.S. House of Representatives, on "Regulation of Imported FDA-Regulated Products," September 26, 2007.

<sup>3</sup> <http://www.fda.gov/oc/opacom/fda101/fda101text.html> 12/3/08

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FDA faces. From this and other recent experiences with melamine, and serious Current Good Manufacturing Practices (CGMP) violations of producers of generic drug products, the FDA has recognized that value could be derived from leveraging the activities and resources of trusted foreign counterpart scientific and regulatory authorities, and from establishing an FDA presence overseas. In FY08, FDA identified China, India, the Middle East, Europe, and Latin America as areas in which to establish an in-country presence. FDA developed several initiatives intending to improve the sharing of information and understanding of FDA's regulatory standards and how these standards protect the safety of consumers.

This chapter describes some of FDA's global accomplishments in FY08.

## Foreign Inspections

FDA performs hundreds of foreign inspections per year (See Chapter 10 Enforcement Statistics). Most of these foreign inspections are pre-approval, CGMP inspections designed to evaluate the capability of manufacturing facilities to generate a safe and high-quality product or involve inspections for compliance with Good Clinical Practices (GCP) for the studies submitted in applications for regulatory review.

Exercising FDA's regulatory and inspectional authorities overseas can be challenging. In most countries, we need authorization from that government to enter and inspect manufacturing facilities. In some cases, the U.S. Department of State issues travel alerts and travel warnings that require FDA to appropriately take special precautions to ensure the safety of our investigators in these locations. Foreign inspections are more costly than similar inspections of domestic facilities because of travel costs and special needs associated with travel abroad. There are approximately 800 FDA investigators trained to conduct foreign inspections in all program areas, and 335 specifically for the drug program area. FDA relies on assistance from the firms' U.S. agents and representatives to provide translation services, if needed, and to provide assistance with logistical challenges that arise in traveling to foreign facilities. FDA is committed to increasing the number of foreign inspections, establishing a foreign presence, and enhancing interactions between ourselves and our foreign counterparts to ensure the safety of consumers.

## FDA's Food Protection Plan

The Food Protection Plan (FPP) is an integrated strategy for protecting the nation's food supply. The FPP addresses both food safety and food defense for domestic and imported products. FDA regulates \$417 billion worth of domestic food and \$48 billion worth of imported food each year—everything we eat except for meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture (USDA).

The FPP addresses the global expansion of food sources, production, and consumption that Americans face in today's world. Building upon and improving an already comprehensive food safety protection capability, the new plan presents an expanded strategy to protect the nation's food supply from both unintentional contamination and deliberate attacks on our food supply. FDA's FPP sets safety goals, building prevention first, intervention, and finally, response. This new strategy helps to ensure that Americans will continue to benefit from one of the safest food supplies in the world.

FDA's Integrated Plan provides three elements of protection:

1. PREVENT Foodborne Contamination
2. INTERVENE at Critical Points in the Food Supply Chain
3. RESPOND Rapidly to Minimize Harm

The following is a list of selected FY08 FPP accomplishments related to FDA's expanding global operations:

### **Prevention**

- **FDA Protected American Consumers from Potentially Harmful Products.**
  - In FY08, Health and Human Services (HHS)/FDA refused admission of over 16,000 entry lines, each line representing a distinct product type, that appeared to be adulterated, misbranded, processed under insanitary conditions, or was an unapproved new drug. The refusal of these potentially harmful products prevented them from being distributed to the American public.

### **Intervention**

- **Upgraded eLEXNET Portal Collaboration and User Interface Tools.**
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- FDA has upgraded the Electronic Laboratory Exchange Network (eLEXNET) user interface to more effectively provide information and stimulate interactive information exchange amongst federal, state and local governments. eLEXNET is a seamless, integrated, Web-based information network that allows health officials at multiple government agencies engaged in food safety activities to compare, share and coordinate laboratory analysis. This network provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends.
- **Completed PREDICT Pilot.**
  - The PREDICT prototype for improved, risk-based electronic screening of imports was successfully piloted using seafood entries at five ports in metropolitan Los Angeles during May 2008. The project is being assessed for further development and application to other product types.

### **Import Safety Action Plan (ISAP)**

The FDA collaborates with many domestic and international partners to improve the safety of imported products. Through the Prior Notice Center, FDA works cooperatively with U.S. Customs and Border Protection to help identify shipments containing potentially dangerous foods and prevent them from entering the country. By law, certain information must be submitted to FDA about food products before they are allowed to enter the U.S. The Prior Notice Center receives this information 24 hours a day, 365 days a year. FDA requires advanced notification indicating when and where specific food shipments will enter the U.S., what those shipments will contain, the countries and entities where they originate, and the facility where the food was manufactured.

In addition, FDA has a team of more than 2,000 dedicated, scientifically trained specialists who conduct inspections, collect and analyze product samples, perform investigations, oversee recalls, take enforcement actions independently or provide support to partner agencies, and monitor the entry of regulated products at our nation's borders. The Office of Regulatory Affairs (ORA) field force is responsible for overseeing imports of the full range of regulated products including: human food, dietary supplements, cosmetics, animal feed, human drugs, vaccines and other biologics, medical devices, and veterinary drugs.

FDA electronically reviews the prior notice documentation of 100% of imported products before they reach U.S. borders. Based on established criteria and historical information, FDA is alerted to potential concerns. In FY08, ORA reviewed over 16

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million registry entry lines and performed more than 100,000 imported food field exams. FDA collects and analyzes about 24,000 import product samples annually.

In response to greater awareness of the globalization of the marketplace and its domestic impacts, an interagency working group was created to address issues related to increasing imports. The working group was charged with reviewing issues created by a global marketplace and providing recommendations to federal agencies to enhance the protection and safety of American consumers.

On November 6, 2007, the Interagency Working Group<sup>4</sup> on Import Safety presented an Action Plan. The ISAP contains short and long-term recommendations for continuing to improve the safety of imports entering the U.S. marketplace. It also contains 14 broad recommendations and 50 action steps that provide a road map for better protecting American consumers and enhancing the safety of imports. The Action Plan is the product of extensive coordination among federal agencies, months of hands-on information-gathering, feedback, and suggestions from the private sector and the public.

Visit FDA's Action Plans for Import Safety Website at:  
<http://www.fda.gov/oc/initiatives/advance/imports/>.

To see the complete list of FDA accomplishments since issuance of the Action Plan please go to: <http://www.fda.gov/oc/initiatives/advance/imports/activities.html>.

## Beyond Our Borders Initiative

FDA's "Beyond Our Borders Initiative" is a multi-pronged approach to promote and verify compliance of imported food, cosmetics, and medical products or their components with FDA requirements. Goals of the "Beyond Our Borders Initiative" include: increased collaboration and presence in foreign countries, increased number of FDA foreign inspections, greater sharing and use of foreign competent authority inspection reports, use of third party certification, and increased capacity building. FDA has in place more than 70 cooperative arrangements with foreign counterparts to facilitate information sharing and collaborations.

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<sup>4</sup> The Working Group includes the Department of Health and Human Services, The Department of State, the Department of Treasury, the Department of Justice, the Department of Agriculture, the Department of Commerce, the Department of Transportation, the Department of Homeland Security, the Office of Management and Budget, the Office of the United States Trade Representative, the Environmental Protection Agency, and the Consumer Product Safety Commission.

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In the “Beyond our Borders Initiative” FDA:

- Recognizes that working more closely with trusted counterpart agencies provides U.S. leveraging opportunities to more efficiently and more comprehensively perform our oversight responsibilities;
- Recognizes that many of these products come from countries with limited resources for the regulatory oversight needed to assure the safety of the products exported from their country;
- Recognizes there are greater opportunities to evade detection in a global environment for counterfeiters, or for those who see the chance for economic gain by “cutting corners;”
- Recognizes that the 19th and 20th century approach to defending against these dangers using our border as the “front line” of defense is outdated and less effective than working globally in a coordinated way to build regulatory infrastructure that will protect citizens throughout the world; and
- Recognizes that only through development of a much more sophisticated information technology (IT) infrastructure, development of collaborations and communications, and systematized, integrated, in-country presence can FDA address the challenges these 21st century realities present to the public health and national security of the U.S.

The following is a selected list of FDA accomplishments in FY08:

- **Expanded FDA’s International Outreach.** At an April 2008 briefing to foreign embassy personnel on FDA actions under the ISAP and the FPP, FDA discussed import safety with counterparts from Australia, New Zealand, the European Union (EU), India, Vietnam, and several other countries. These discussions support new capacity building, new bilateral agreements, and continued efforts to expand FDA’s foreign presence.
  - **Announcing the hiring of FDA staff for an FDA Office in China.** FDA received approval from U.S. and Chinese governments and has hired staff for a new FDA office in China.
  - **Establishing an FDA Presence in the Middle East.** The FDA Commissioner traveled to Jordan to explore expanding FDA’s presence in the Middle East.
  - **In September 2008, FDA announced office postings in four overseas offices.** The FDA opened Regional Director positions in Europe (Brussels, Belgium), Latin
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America (San Jose, Costa Rica), Middle East (Amman, Jordan), and a Deputy Regional Director for medical products in Europe (London, U.K.).

- **Negotiated a Plan to Leverage Inspectional Resources.** The FDA negotiated a plan for leveraging inspectional resources of the EU in June 2008. The initial effort is to establish a pilot program to coordinate inspection planning.

### Sharing Foreign Inspection Reports

In addition to memoranda of understanding, cooperative agreements, and other international arrangements, FDA now has over 30 confidentiality arrangements with trusted foreign counterparts, many of which allow the exchange of information that can include the sharing of inspection reports, and redacted of proprietary information. FDA intends to increase the use of these arrangements to share useful inspectional information that can help FDA make more informed judgments in the risk-based prioritization of foreign inspection activities.

Through negotiation of specific bilateral confidentially agreements with other foreign counterpart agencies, with whom FDA has established equivalent standards for the protection of the public health, the FDA intends to explore opportunities to acquire useful inspectional information and coordinate work plans. For example, the EU-U.S. Bilateral Technical Working Group on Medicines Quality and Manufacturing is focusing on utilizing and leveraging resources through the exchange of inspectional planning data and inspectional observational data for plants in the U.S., EU and in other countries inspected by either the EU or the U.S.

### Foreign Presence

The FDA agrees that contemporary public health and national security realities render it imperative that the government move quickly to establish an FDA in-country, permanent presence in several countries/regions around the world. FDA is in the midst of operationalizing five overseas offices with senior technical experts and inspector positions. An in-country, permanent presence in several countries/regions around the world is a pivotal component of the FDA's "Beyond Our Borders Initiative." FDA officials in these offices will work to prevent Americans from being harmed by any of the multitude of FDA-regulated products we now import from over 200 countries around the world.

The objective of these in-country offices is to help establish the U.S. border as only one of several integrated checkpoints (not the only checkpoint) to verify that imported products comply, including their manufacture, with U.S. requirements.

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The following efforts address needs in the areas of awareness, capacity building, standards/inspections, and collaboration to help establish FDA's Foreign Presence:

- Gathering better knowledge in-country about the manufacture of products and their transport to U.S. ports;
- Engaging with trusted counterpart agencies abroad to leverage scientific, inspectional, and other resources;
- Engaging with developing counterpart agencies overseas to help build their capacity to better assure the safety of the products produced and exported from their countries;
- Engaging with trusted third parties to provide information about regulated industry compliance with FDA standards;
- Engaging with regulated industry to provide greater information about expectations for the conduct of their global activities;
- Having the capacity to perform more overseas inspections of higher risk facilities, but realizing that we cannot "inspect" our way to safety, inspection is only one part of a more comprehensive security system; and
- Using needed new authorities to meet these new challenges to the security of the U.S. and safety of American consumers.

The following is a selected list of FY08 accomplishments:

- **Provided Technical Assistance to China.** FDA provided training on regulatory requirements and technical training to Chinese regulatory agencies.
  - **Provided Technical Assistance to South Africa.** FDA's Office of Cosmetics and Colors (OCAC) in the Center for Food Safety and Applied Nutrition participated in a USDA/Foreign Agriculture Service workshop for South African regulators and industry representatives. OCAC gave a seminar on regulatory requirements for marketing cosmetics in the U.S., which included specific information on imports and labeling.
  - **Participated in HHS Delegation to Vietnam.** On April 16, 2008, FDA accompanied an HHS delegation to Vietnam. During the visit FDA discussed a cooperative arrangement with the Ministry of Health covering food, feed, and medical products. On June 24, 2008, FDA and Vietnam signed the agreement.
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- **Coordinated Food Safety Exchange of Information.** FDA led the Security and Prosperity Partnership of North America Health Working Group with Canada and Mexico to coordinate and exchange information on food safety investigations and follow-up activities. A summary of the Food Safety Conference was released in November 2008.
- **Modernized FDA's Mission Accomplishment and Regulatory Compliance Services (MARCS).** The MARCS program manages the integration, re-engineering, and enhancement of the legacy systems that support FDA field activities. MARCS was recently upgraded to include the collection of International Mail Courier information and photographs of parcels and their contents.
- **Enabled Single Sign-On for Import Systems.** The FDA enabled a single sign-on capability for several key systems, including imports. By not having to log on to multiple systems, it will be easier for Agency staff to use these systems in accomplishing their work.
- **Improved Interagency Interaction.** Representatives from Customs and Border Protection (CBP), Department of Justice, USDA, Department of Commerce, Consumer Protection Safety Commission, FDA, Environmental Protection Agency, and Department of Transportation held a series of meetings from December 2007 through July 2008 to identify ways to improve upon agency interaction during the cargo clearance process and to maximize the sharing of critical data among agencies.
- **Issued a Compliance Program for Select Imported Biologic Regulated Products (CP 7342.007).** FDA issued a comprehensive compliance program for select biologic imports. The new compliance program gives comprehensive instructions for reviewing import entries of select biologic products. It outlines what regulatory requirements apply and what steps to take if a product does not comply.

### **China Partnerships Initiative**

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Under the leadership of the Secretary, HHS signed a Memoranda of Agreement (MOA), on December 11, 2007, with the Chinese State Food and Drug Administration (SFDA) for drugs and medical devices, and with the Chinese General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) for food and animal feeds to provide a streamlined process for facilitating FDA inspections conducted in China.

The MOA establishes new information sharing capabilities, new registration and certification requirements giving better access to production facilities and enhances reporting of counterfeiters to assure the safety of drugs and medical devices imported into the U.S. from China. These agreements will encourage the greater exchange of

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information, and provide opportunities for FDA to collaborate with regulators and industry in China on the science and standards to ensure product quality and safety aimed at protecting the public health.

The enhanced inspection access aspect of the agreements has already proven effective in giving FDA prompt access to conduct inspections for products contaminated with melamine and heparin. This past year, we conducted approximately 30 inspections of manufacturing and processing sites in China for products that FDA regulates. With the establishment of a permanent overseas office in China, FDA will have greater access for inspections and very importantly, greater interactions between FDA staff and Chinese manufacturers to help assure that products that are shipped to the U.S. meet FDA standards for safety and manufacturing quality.

The first FDA China office opened officially on November 16, 2008.

### **India Partnerships Initiative**

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In addition to China, an FDA delegation visited counterparts in India to begin conversations to establish appropriate counterpart collaborations in that country.

FDA is working with the Indian government on its initiative to rebuild its food, drug, and device regulatory infrastructure. This will provide the FDA with a unique opportunity to aid its Indian counterparts in building a strong regulatory infrastructure and to create enduring organizational relationships. In August 2008, FDA announced international positions opening in New Delhi and Mumbai, India.

In addition, FDA is providing technical assistance to other foreign countries to ensure the safety of imported food. A group from FDA attended the Food Safety Quadrilateral meeting in April 2008, with Canada, New Zealand, and Australia. One proposal under consideration, in support of the ISAP, is the establishment of a rapid alert system to share information from any of the member countries regarding potential significant public health problems found in food or animal feed.<sup>5</sup>

### **Providing for Certification by Third Parties**

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Another component of the “Beyond Our Borders Initiative” leverages private sector resources. As recommended in the ISAP, FDA is pursuing expanded use of third party certification to verify compliance with U.S. safety and manufacturing standards. These third parties can include foreign government agencies and independent entities who

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<sup>5</sup> <http://www.fda.gov/oc/initiatives/advance/food/progressreport.html>

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have been accredited by FDA or by an accreditation organization recognized by FDA. Such third-party certifications can provide FDA with helpful information about a firm's compliance with FDA requirements. This certification would not supplant FDA inspectional or other regulatory activities, but would complement them. This information will aid FDA in prioritizing and targeting its compliance and inspectional resources toward high-risk situations.

The China MOA, for example, includes a provision for a registration program, and will work toward a system that will enable the Chinese government to certify the status of Chinese firms that manufacture components of finished drug products. To support the Chinese registration program, and efforts to work toward a certification program, agencies from the two countries will conduct training programs to cover topics such as inspection methods and clinical trials; and will discuss each country's development of relevant technical guidance documents, regulations, and laws. In addition, the Agency is developing a pilot program that would reduce the delay for firms that take pro-active measures when they import finished drug products and active pharmaceutical ingredients (API). This is particularly relevant given the large volume of imported API used in domestic drug manufacturing.

## **FDA's Government Wide Quality Assurance Program (GWQAP)**

Since 1975 as recommended by the Government Accountability Office (GAO) and directed by the Office of Management and Budget (OMB), FDA maintains information on the CGMP status of firms under the FDA Government-Wide Quality Assurance Program (GWQAP). The program conducts individual reviews and makes Web-based information available, on over 20,000 domestic and foreign pharmaceutical, medical device, and biologics manufacturers, including repackers, relabelers, assemblers, contract sterilizers, and contract testing laboratories. The data is based upon a Current CGMP or Quality System (QS) inspection and the evaluation of a firm's listed product profiles.

Profiles, representing categorical product types, were created as a means of providing Quality Assurance (QA) information on medical supplies being procured by the federal or other government agencies. The information in these profiles is available under confidentiality agreements to foreign government agencies for use in their decision making. This information ensures that foreign entities know if medical supplies are produced in conformance with FDA CGMPs. This program also provides the critical information for the issuance of FDA device and drug Export Certificates.

Currently, a Web-based, redacted version of the database, which is updated daily, is shared with foreign officials who represent a country that holds a signed Memorandum

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of Understanding (MOU) with the FDA. This system is known as "COMSTAT" (Compliance Status Information System) and users of the system are able to view a firm's name and address, FDA Establishment Identifier (FEI) or central file number (CFN), manufacturing compliance profile status, profile status for each active and discontinued profile class(es), as well as the date of last completed QS or CGMP inspection.

Representatives of 11 countries/regulatory authorities have been granted access to this database.

## **ORA Import Field Activities Report FY08**

### **FDA Enforcement Actions**

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- An investigation into an entry of Low Acid Canned Foods (LACF) led to the cancellation of 76 LACF Process Filings (SID). A field examination revealed three different pouched LACF products with abnormal containers, including hard swells of the containers. All three were sampled and indicated spore containing gram positive rods. CFSAN conducted an in-depth review of the filed processes for this foreign manufacturer and cancelled all 76 processes filed by foreign manufacturer.

### **Other FDA Import Activities**

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- An entry of U.S. goods being returned to the U.S. containing an anti-malarial API was detained. A prompt follow up inspection was conducted which revealed lots of the API were adversely affected by an equipment defect resulting in metal fragments and rust in the API. An FDA-483 was issued citing this process failure and other CGMP deficiencies. The manufacturer's corrective actions are being monitored as is the disposition of the quarantined lots.
  - U.S. Customs Brokers Training sessions were conducted in Charleston, SC, Atlanta, GA, and Charlotte, NC. The purpose of the seminars was to provide information to the brokerage community on the FDA entry review process, filer evaluation procedures, electronic filing, the product code builder, and current information regarding imports in ATL-DO. There were approximately 150 brokers in attendance.

### **Import Field Operations Office**

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International Mail Facility (IMF) Referrals:

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- An individual was arrested by OCI agents and the New Hampshire State Police in January 2008. The individual operated under numerous aliases and used multiple addresses to receive contraband drugs. The JFK Mail Review Team (MRT) and OCI agents together tracked locations, collaborators, and created an inventory of the contraband products. Parcels were intercepted by U.S. Customs and referred to the MRT for examination. Analysis by the FDA Forensic Chemistry Center (FCC) laboratory in Cincinnati determined the capsules consisted of fluoxetine (antidepressant commonly known as Prozac), chlordiazepoxide (sedative/hypnotic drug commonly known as Librium), and Fenproporex (an amphetamine derivative used as an appetite depressant).
- FDA intercepted parcels containing various controlled substances at the FedEx international courier hub, which led to a joint investigation between FDA, OCI, CBP, Drug Enforcement Administration (DEA), USDA, and Mexican federal police of an Illinois based firm selling illegal bodybuilding substances on-line. The firm was estimated to gross \$3 million per month in sales. FDA offered testimony that helped lead to the conviction of the defendant.
- FDA and CBP conducted an Operation Safeguard blitz at the St. Thomas IMF. A total of 10,965 packages were screened. Of these packages, 234 mail packages were returned to the sender, 89 packages were referred to CBP, 30 packages were referred to USDA, and 1 package was referred to the Bureau of Alcohol, Tobacco, and Firearms (ATF). CBP made 39 seizures of FDA regulated drugs on FDA's behalf, mostly erectile dysfunction drugs.
- Human Growth Hormone/Testosterone/Steroid packages intercepted through IMF and other actions:
  - FDA identified a Chinese mail parcel containing vials of a powder labeled as ginseng extract. FDA analyses found the product to contain somatropin.
  - Vials of human growth hormone (HGH) destined for California.
  - Vials of testosterone, HGH, and unknown tablets destined for New York.
  - Vials of sustanon testosterone, HGH, nandrolone, andropen testosterone, methenolone, and various other steroids destined for Maine.
  - Vials of HGH destined for Puerto Rico.
  - Vials of HGH destined for New York.

- Vials of stanazolic, testosterone/nandrolone, HGH, and unknown tablets destined for North Carolina.
- Vials of gonadotropin, nandrolone, testosterone, and unknown tablets destined for New Jersey.
- Vials of bulk chorionic gonadotropin.
- Parcels containing various commercial quantities of anabolic steroids going to individuals throughout the U.S. The value of these parcels was estimated to be over to be \$300,000.
- Bulk shipment of Chinese herbal sexual enhancement products containing seven different kinds of products. FCC testing on four of the products indicated they contained sildenafil.
- Packages containing tablets of ephedrine from Pakistan.

### **Referrals for Additional Investigation or Action**

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All of the below cases were referred for additional investigation or action:

- A shipment to a port in New York was declared as frozen whelk meat, but the product label declared queen conch. FDA referred the entry to the U.S. Fish & Wildlife Service (FWS), who collected a sample and identified the product as queen conch.
- A tip received by a local officer on the CBP National Complaint Network concerning the possible importation of illegal chemotherapy drugs led to an OCI referral. A joint OCI and CBP Immigration and Customs Enforcement (ICE) action was taken.

Collaboration between FDA Import Field Operations and other government agencies:

- FDA referred a case to the DEA based on a violative sample of a purported dietary supplement found to contain sibutramine, a scheduled drug. DEA seized the product.
  - FDA detained bulk shipments of fish meal found to be infested with insects by FDA analysis. The shipment was held at the Mississippi manufacturing plant and reconditioned under FDA supervision. The FDA worked with the Department of Commerce/National Marine Fisheries Services located in Mississippi to inspect the reprocessed material.
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- FDA referred multiple entries of a dietary supplement imported from Canada to USDA at a UPS in Kentucky. The shipments were subsequently seized by USDA for the inclusion of gelatin from a non-permitted source, then exported or destroyed. FDA identified a prescription drug, sibutramine, in a sample.
- FDA examined multiple entries of a dietary supplement imported from Canada at a UPS in Kentucky. Investigations determined the product is listed with DEA as a street drug alternative. All entries were subsequently refused, and either exported or destroyed in collaboration with CBP.

### **CBP Actions Taken as a Result of FDA Activities/Collaboration with CBP**

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- CBP seized a shipment of previously refused raisins, requesting entry through a port in New York. A private lab analysis, as part of petitioner's claim, revealed the raisins were adulterated with two different pesticide residues. CBP collected fines/penalties.
- CBP seized a shipment of previously refused toothpaste and over-the-counter (OTC) products which entered through New York. The articles originally entered in Texas, where they were refused by FDA. The importer failed to redeliver the products. The FDA exam at the entry revealed the same articles, unmanifested on the entry, which had not been brought into compliance.
- CBP seized teeth bleaching medical devices. This was the second seizure of shipments from the same importer of record (IOR) in two months. Entry documents declared one x-ray machine but failed to declare the teeth bleaching medical devices.
- CBP collected payment for a liquidated damages case from an importer for failure to redeliver articles refused admission by FDA. The importer failed to redeliver sacks of pumpkin seeds detained without physical examination, and ultimately refused admission for the presence of salmonella. FDA sent the IOR an informational letter for failure to hold an FDA regulated commodity.
- Based on information obtained from a TV advertisement, FDA initiated an investigation into a Chinese dietary supplement sold in gas stations and small supermarkets. Samples were analyzed, and results reported that the dietary supplement contained sildenafil, tadalafil, and vardenafil, which are active ingredients indicated for erectile dysfunction. As a result of this finding, mail shipments were seized by CBP upon FDA's request. In addition, products held at the importers facility were seized with the assistance of U.S. Marshals.