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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Steven M. Solomon, D.V.M., M.P.H., Deputy Director of the Office of Regional Operations, which is part of the Office of Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the important issues relating to the safety of FDA-regulated imported products, including those originating in China.

FDA-regulated products include food and animal feed, human and animal drugs, cosmetics, vaccines and other biological products, and medical devices. FDA is committed to ensuring that the nation's supply of these products continues to be among the safest in the world, but in doing so we face significant challenges. One of those challenges is the rapid increase in the volume of imported products.

Each year, approximately \$2 trillion of imported products enter the United States. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food. Currently, FDA is overseeing over nine million line entries of imported food annually and most of these entries are large volume commercial shipments. It is estimated that approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits, imports account for 50 to 60 percent of the supply.

FDA REGULATION OF IMPORTED PRODUCTS

FDA's primary authority over imported food, cosmetics, drugs, biological products, and medical devices, derives from section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Imported radiation emitting products are regulated under section 534 of the FD&C Act. These authorities provide a broad statutory framework to ensure that the products are safe. Imported products are subject to examination.

When an FDA-regulated product is offered for import into the United States, U.S. Customs and Border Protection (CBP) procedures ensure that FDA is notified. If, based on examination or other information such as the prior history of the product, manufacturer or country, the product appears to be adulterated or misbranded, FDA will give notice advising the owner or consignee of the violation and the right to provide evidence (such as a laboratory analysis by an independent laboratory) to rebut the appearance or, in some circumstances, to request permission to recondition the product. If the product is ultimately refused admission, it must be destroyed within 90 days unless re-exported by the owner or consignee.

Imported Food

To better manage the increasing volume of imported products that we regulate, FDA currently screens electronically-submitted information on all incoming shipments, and then uses a risk-based approach which targets our inspectional resources at products having the greatest potential for causing harm to public health. It is important to note that while FDA is not able to

physically inspect a large percentage of import entries, we electronically screen all import entries through the Operational and Administrative System for Import Support (OASIS) for a variety of risk factors. OASIS is an automated system for processing and helping FDA make admissibility determinations for FDA-regulated products offered for import.

In 2002, Congress gave FDA significant new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism Act). One of the most important provisions is the requirement that FDA be provided prior notice of food (including animal feed) that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target food that may be intentionally contaminated with a biological or chemical agent or which may pose a significant health risk to the American public. Suspect shipments then can be intercepted before they arrive in the U.S. and held for further examination. FDA's electronic screening system currently reviews approximately 33,400 prior notice submissions per business day.

Another significant provision of the Bioterrorism Act provides FDA with the authority to commission CBP employees to conduct examinations and investigations. Under a December 2003 Memorandum of Understanding, FDA has commissioned more than 8,000 CBP officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff. This inter-agency collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade.

FDA has numerous other tools and authorities which enable the Agency to take appropriate action regarding imported products. FDA performs routine surveillance inspections of imported goods to check for compliance with U.S. requirements. Because of the large volume of FDA-regulated foods being exported from a large number of countries, it is not feasible to routinely inspect foreign-produced foods at the point of origin. We do, however, work with foreign governments and food producers to help ensure that imported food is produced, processed and packed in accordance with U.S. requirements.

Another key tool is the Import Alert, which signals FDA inspectors to pay special attention to a particular product, producer, shipper or importer. Typically, they inform FDA field personnel that FDA has sufficient evidence or other information to initiate refusal of admission into the U.S. without physically examining the product. When an Import Alert is issued and FDA initiates refusal, the owner or consignee has an opportunity to introduce evidence to demonstrate that the products are not violative. FDA also performs laboratory analysis on a sampling of products offered for import into the U.S. and performs periodic filer evaluations to ensure that import data being provided to FDA is accurate. In addition, certain violations relating to imported food may lead to civil or criminal charges.

Imported Drugs, Biologics, and Medical Devices

The FD&C Act limits the drugs and biologics, as well as certain medical devices, that may be imported into the U.S. Congress enacted these provisions to create a relatively “closed”

distribution system for such products, which helps ensure that the domestic supply is safe and effective.

To comply with the FD&C Act, any entity that intends to import drugs or biologics requiring pre-market approval into the U.S. must ensure, among other things, that the products comply with the FDA approval in all respects. The importer must ensure that each drug or biologic meets all U.S. labeling requirements, and that prescription drugs are not re-imported after export in violation of the Prescription Drug Marketing Act. FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, and container/closure system. Medical devices requiring pre-market approval are subject to similar requirements.

NEW INITIATIVES

Food Safety Strategy

In May of this year, FDA Commissioner Andrew C. von Eschenbach, M.D., created a new position, the Assistant Commissioner for Food Protection, to provide advice and counsel on strategic and substantive food safety and food defense matters. The Commissioner appointed Dr. David Acheson to this position, and Dr. Acheson is working with FDA's product centers and the Office of Regulatory Affairs, which oversees the Agency's field staff, to coordinate FDA's food safety and defense assignments and commitments.

Dr. Acheson is also coordinating the development of a new food safety and defense strategy covering both imported and domestically-produced foods that FDA regulates. The new food strategy will identify the Agency's most critical needs, address the changing nature of the global food production system, and provide a framework to address these challenges. The organizing principles of the new strategic framework will be based on prevention, intervention, and response. The plan will apply enhanced risk-based criteria to the entire life cycle of FDA-regulated imported food. By refining these targeting criteria in a life cycle approach, we will be able to conduct more rigorous and meaningful reviews of potentially high-risk food entries. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the emerging risks posed by the types of foods we regulate.

Interagency Working Group on Import Safety

To promote and enhance the safety of all imported products, the President issued an Executive Order on July 18, 2007, that established the Interagency Working Group on Import Safety. The Working Group, which includes representatives from 12 Federal departments and agencies, is tasked with reviewing the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe. Secretary of Health and Human Services Michael O. Leavitt chairs the Working Group and FDA plays a key role. Secretary Leavitt and FDA Commissioner von Eschenbach traveled extensively throughout the country during the past few months visiting ports of entry and reviewing FDA field operations. The insights they gained are helping to shape the conclusions and recommendations of the Working Group.

On September 10, the Working Group provided the President with an initial report on steps to improve import safety. Their report, “Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety,” outlines an approach that can build upon existing efforts to improve the safety of imported products, while facilitating trade. It recommends that the government work with the importing community in developing methods to address safety risks over the life cycle of imported products and focus actions and resources to minimize the likelihood of unsafe products reaching our borders. A risk-based, prevention-focused model will help ensure that safety is built into products before they reach consumers.

On October 1, the Working Group conducted a meeting in Washington to receive input from stakeholders and the general public. By mid-November, an Action Plan based on the Strategic Framework will be provided to the President. The plan will reflect the public comments and recommend specific steps that the Federal government and stakeholders can take to enhance import safety at all levels.

Federal agencies have already begun to implement high-priority recommendations from the interim report. For instance, by November 12, Federal agencies that rely on Information Technology (IT) systems in their review of imported cargo must develop implementation plans to achieve interoperability of their import data systems with the International Trade Data System managed by CBP. This requirement is consistent with the Security and Accountability for

Every (SAFE) Port Act of 2006 and will ensure a single-window system for reporting on imports electronically.

CHINESE IMPORTS

China is a major producer, exporter, and importer of FDA-regulated products and it presents a diverse range of issues for the Agency. China is presently one of the world's largest producers and consumers of agricultural products, and a major supplier to the U.S. of seafood, canned vegetables, fruit juices, honey, and other processed foods. In the past, FDA has encountered compliance problems with several Chinese food exports, including lead and cadmium in ceramic ware used to store and ship food, and staphylococcal contamination of canned mushrooms.

While improvements have been made in these products, the safety of food and other products from China as well as other trading partners, remains a concern for FDA, Congress, and American consumers. While these concerns are not unique to China, recent incidents have focused greater attention on these issues. Prominent examples of these concerns are discussed below.

Aquacultured Seafood

Aquacultured seafood is a fast-growing sector of the world food economy, accounting for approximately half of all seafood production worldwide. About 80 percent of the seafood consumed in the U.S. is imported from approximately 130 countries, and over 40 percent of that seafood comes from aquaculture operations. By volume, China is the largest exporter of

seafood to the U.S., and the second largest in terms of monetary value. Shrimp and catfish products represent two of the ten most consumed seafood products in the U.S.

As the aquaculture industry continues to grow in developing economies, concern about the use of unapproved drugs and unsafe chemicals in aquaculture operations has increased substantially.

There is clear scientific evidence that the use of antibiotics and other drugs and chemicals such as malachite green, nitrofurans, fluoroquinolones, and gentian violet can result in the presence of residues in the edible portions of aquacultured seafood. Fluoroquinolones have been prohibited from extra-label use in the U.S. and many other parts of the world in aquaculture because of public health concern about the development of antimicrobial resistance. Moreover, prolonged exposure to nitrofurans, malachite green, and gentian violet, or their metabolites, has been shown to induce cancer in humans or animals. From a regulatory perspective, FDA has not approved any of these substances for use as drugs in aquacultured animals. Nor are they generally recognized as safe or approved as food additives under section 409 of the FD&C Act.

Since November 2001, FDA has tested shipments of aquacultured seafood products from China and other countries, and when warranted, has placed individual firms on Import Alert. In 2006, FDA broadened these restrictions significantly by issuing an Import Alert providing for the detention without physical examination of eel from anywhere in China due to findings of malachite green. Through increased sampling of imported Chinese aquacultured seafood from October 1, 2006, through May 31, 2007, FDA continued to find residues of unapproved drugs and unsafe chemicals in species including catfish, basa, shrimp, and dace. Because we saw

problems from many different companies located in various parts of China, on June 28 of this year, FDA imposed a countrywide Import Alert on all farm-raised catfish, basa, shrimp, dace and eel from China. Under the Import Alert, FDA can refuse admission of a shipment, even without physically examining it, unless it is shown to be free of the residues that led to the Import Alert.

Pet Food and Farm Feed

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. Analysis by the Agency's Forensic Chemistry Center revealed melamine and melamine analogues in the pet foods and in the wheat gluten used as ingredients. After FDA traced the suspect wheat gluten to a single supplier in China, we issued an Import Alert focused on this firm and began sampling 100 percent of all wheat gluten from China. In April, FDA launched an investigation into imported rice protein concentrate that also was used as an ingredient in some pet foods and was found to contain melamine and its analogues. The Agency traced the suspect product to another Chinese supplier. We issued an Import Alert focused on this supplier and began sampling 100 percent of all rice protein concentrate from China.

Ultimately, Import Alert #99-29 was issued on April 27, 2007, to expand on the previous alerts to cover all vegetable protein products from China. Under the Import Alert, FDA can refuse admission of these products unless third party analysis or other evidence demonstrates they are not contaminated with melamine or its analogues. FDA believes that all of the contaminated wheat gluten and rice protein from China used in the manufacture of pet food has been removed from commerce.

During the investigations that traced the distribution of contaminated pet food, it was discovered that byproducts (or scraps) from the manufacture of this pet food were distributed to farms in a limited number of states and added to the feed consumed by swine and poultry. A panel of scientists from five Federal agencies determined that there was unlikely to be a significant risk to human health from consuming food from animals that ate tainted feed, due to the small amounts present and the small amounts that would be consumed.

Drugs

Chemical counterfeiting in many foreign locations are on-going concerns for the U.S. and other nations. Ten years ago, Chinese counterfeit glycerin contaminated with diethylene glycol (DEG) killed nearly 100 children in Haiti. Last year in Panama, Chinese glycerin contaminated with DEG again caused scores of deaths. Recently, toothpaste imported from China to the U.S. was also found to contain DEG.

The recent DEG episode has reinvigorated attention on China's regulation of its finished drug products, active pharmaceutical ingredients (APIs) and excipients. While some Chinese firms are state-of-the-art in technology and manufacturing expertise, many are at the opposite end of the spectrum. Further, in the past four years, the number of FDA-registered drug manufacturers in China has at least doubled. China is in the process of re-writing its existing current Good Manufacturing Practices (cGMPs) for drugs. In the meantime, however, drug manufacturers in China, and some other developing countries, comply with cGMPs inconsistently and to varying

degrees. Provincial authorities who conduct inspections of drug manufacturing sites are not always equipped with the expertise needed for this complex undertaking.

MEMORANDA OF AGREEMENT

While these concerns are not unique to China, recent incidents have focused greater attention on these issues. FDA and others within the Department of Health and Human Services (DHHS) are actively engaged with our Chinese counterparts in negotiating comprehensive Memoranda of Agreement that will include commitments in many areas of food and feed production to increase our confidence in the safety of these Chinese products that are exported to the U.S.

Last May, in conjunction with the 2nd Strategic Economic Dialogue, DHHS initiated discussions regarding the need for legally binding agreements with relevant regulatory agencies in China. The agreements are intended to help assure the safety, quality and effectiveness of FDA-regulated products exported from China to the U.S.

The most recent step in this ongoing process occurred last week when a delegation of senior DHHS and FDA officials held a series of initial negotiations with senior officials in Beijing. Represented agencies included the Chinese State Food and Drug Administration; the General Administration of Quality Supervision, Inspection and Quarantine; the Ministries of Health and Agriculture; and the Certification and Accreditation Administration. These sessions initiated formal negotiations on two Agreements, one on the safety of food and feed, and another on the

safety of drugs and medical devices. Negotiations will continue next month. FDA believes these talks have yielded significant progress towards achieving two, strong, action-oriented documents.

CONCLUSION

Ensuring the safety of the food supply continues to be a top priority for FDA and we are working hard to ensure the safety of all human food and animal feed, in collaboration with our Federal, state, local, and international food safety partners. FDA is working diligently to efficiently and effectively use the resources and authorities provided by Congress to protect the public health of the U.S. and to help ensure that imported products are safe for American consumers. Despite the challenges which face us, the American food supply continues to be among the safest in the world. Thank you for the opportunity to testify. I look forward to responding to any questions you may have.