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STATEMENT

OF

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INTRODUCTION

Good Morning, Chairman Brown, Co-Chairman Smith, and Members of the Commission. I am Dr. Steven Solomon, Associate Director for Global Operations and Policy in the Office of Global Regulatory Operations and Policy at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's efforts to ensure global product safety and quality and our work related to China.

FDA is responsible for protecting the public health by helping to ensure the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The Agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that emit electronic radiation, and for regulating tobacco products. Imported products must meet the same standards as those produced domestically.

In my testimony today, I will discuss the challenges of an increasingly globalized marketplace, describe FDA's actions to safeguard the global supply chain, and discuss FDA's activities related to China.

CHALLENGES OF GLOBALIZATION

Sweeping economic and technological changes have revolutionized international trade over the last several decades, creating a truly global marketplace for goods and services. Accounting for

20 to 25 percent of all U.S. consumer spending, products regulated by FDA are a substantial component of this global economy. Food and medical products, and their ingredients and components—products that directly and profoundly affect the health and welfare of the U.S. public—are increasingly sourced from abroad. Today, FDA-regulated products originate from more than 200 countries and territories and pass through more than 300 U.S. ports. The number of FDA-regulated shipments has more than tripled from 8 million import entry lines per year a decade ago to 28 million entry lines in Fiscal Year (FY) 2012. In FY 2013, entry lines are anticipated to reach 34 million. By way of background, the Agency tracks import shipments using entry lines. An entry line means each portion of a shipment that is listed as a separate item on an entry document. As trade increases and U.S. consumers continue to demand global products, FDA's ability to ensure the safety and quality of these imported products will depend on its execution of a myriad of global engagement strategies.

Americans benefit greatly from global sourcing of products. For example, U.S. consumers can choose from a wide variety of fruits and vegetables year round, regardless of the domestic growing season. Ten to fifteen percent of all food consumed by U.S. households is imported. Approximately 50 percent of fresh fruits, 20 percent of fresh vegetables, and 80 percent of seafood consumed in the U.S. are imported. Health professionals can also draw on drugs and medical devices developed anywhere in the world, if they have been approved for use in the United States. Approximately 40 percent of finished drugs in the United States come from overseas, as well as more than 50 percent of all medical devices. Approximately 80 percent of the manufacturers of active pharmaceutical ingredients are located outside the United States.

This rapid globalization of commerce poses challenges. For example, some products entering the United States are made or grown in countries that lack the necessary regulatory oversight to ensure their safety. Greater numbers of suppliers, more complex products, and intricate multinational supply chains can introduce risks to product safety and quality. These factors also provide more opportunities for intentional or unintentional adulteration and exposure to contaminated products for consumers. I will discuss below the ways in which FDA is pursuing a comprehensive strategy to enhance the safety of imported products and establish effective global partnerships.

Many of the challenges associated with globalization manifest themselves in China. Historically, FDA has been faced with several public health threats related to imports from China. These include Chinese suppliers of heparin (a critical drug to prevent blood clots), who substituted a lower-cost, adulterated raw ingredient in their shipments to U.S. drug makers, causing deaths and severe allergic reactions. Other examples involved the addition of melamine to pet food made in China, which sickened and killed cats and dogs in the United States, and the presence of animal drug residues in seafood raised through aquaculture from China.

FDA's success in protecting the American public depends increasingly on its ability to reach beyond U.S. borders and engage with its government regulatory counterparts in other nations, as well as with industry and regional and international organizations, to encourage the implementation of science-based standards to ensure the quality and safety of products before they reach our country. FDA is working with its many partners to enhance responsibility and oversight for safety and quality throughout the supply chain.

SAFEGUARDING THE GLOBAL SUPPLY CHAIN

To address the challenges described above and strengthen protections for American consumers, FDA is utilizing a variety of engagement strategies, in collaboration with our many partners. Our efforts are in line with the 2012 U.S. *National Strategy for Global Supply Chain Security*, which emphasizes a layered, risk-based approach to achieving global supply chain systems that are secure, efficient, and resilient. In 2011, FDA released its report, *Pathway to Global Product Safety and Quality*, which outlines the Agency's strategy to transform itself from a predominantly domestically-focused Agency to one that is fully prepared for a complex, globalized regulatory environment. I would like to discuss just a few of the activities we are pursuing as part of this strategy.

International Offices and Foreign Posts. FDA's international offices and posts help to build strong partnerships with our foreign counterparts by providing enhanced opportunities for cooperation and capacity building. They also expand our knowledge base and provide a platform for inspection of foreign facilities. We now have a permanent FDA presence overseas in 12 foreign posts in nine countries. Our overseas employees are located in China, India, Latin America, Europe, the Middle East, and South Africa.

Risk-based Monitoring of Imported Products. While FDA does not have sufficient resources to physically inspect all imported shipments, even if we had such resources, physically inspecting all imports would be neither practical nor strategic. However, the Agency electronically screens all imports using an automated risk-based system to determine if shipments meet identified criteria for physical examination or other review. To enhance our

ability to target high-risk products, FDA developed the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting application, or PREDICT. This is a sophisticated screening system that uses intelligence from many sources—such as intrinsic product risks, past inspection results, intelligence data, and even information about such threats as extreme weather that could spoil a shipment—to provide the entry reviewer with risk scores on every import line. PREDICT utilizes information sources that include FDA and U.S. Customs and Border Protection (CBP) data, as well as data collected from our foreign offices, foreign regulatory counterparts, other federal agencies, and our state counterparts. It also utilizes risk analyses we receive through agreements with academic institutions and international organizations. As we continue to increase data sharing with state, federal, and foreign government partners, as well as private partners, we will continue to incorporate more information into PREDICT. This system allows FDA to focus its resources on those imports that are most likely to pose a danger, while at the same time facilitating entry of low-risk products. FDA, the United States Department of Agriculture (USDA), and the Department of Homeland Security have also developed improved systems for monitoring for the potential of economically-motivated adulteration, which uses CBP and trade data.

Technical Cooperation and Capacity Building. FDA recognizes the need to engage in effective regulatory cooperation with our global partners. The capacities of governments to manage, assess, and regulate products within increasingly complex supply chains are a fundamental factor affecting product safety and efficacy. FDA is working strategically with a range of countries to provide information, tools, training, and exchange programs that contribute to building or strengthening regulatory capacity of our trading partners. I will describe later in my testimony some of our collaborations with Chinese government officials.

Implementing Major New Laws. In addition to these activities, FDA is implementing significant new authorities provided by Congress that will help ensure the safety of imported products.

- **The FDA Food Safety Modernization Act (FSMA).** FSMA, the most sweeping reform of our food safety laws in more than 70 years, creates a modern food safety system. The new authorities increase FDA's ability to focus on preventing, rather than reacting to, food safety threats, share information with public health and regulatory counterparts, and make informed, risk-based decisions.

  Earlier this year, FDA published for comment two proposed rules that would establish science-based standards for the prevention of foodborne illnesses—one on safe growing and handling practices for produce and another on prevention practices in facilities that process, handle, and store human food. These standards, when finalized, will apply to both domestic and foreign firms.

  FSMA also provides other new tools to hold imported food to the same standards as domestic foods. For the first time, once the regulations are in place, importers will have explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. The law also provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program through which imported food shipments may receive expedited review for importers that have taken certain measures to ensure the safety of the food they import. In addition, FSMA

directs FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. requirements for food safety.

- **The Food and Drug Administration Safety and Innovation Act (FDASIA).** With the passage of FDASIA last year, Congress granted FDA important new authorities, reauthorized human drug and device user fees, and authorized new user fees for generic human drugs and biosimilar biologics. These authorities and fees are intended to maintain a predictable and efficient review process for medical products, provide incentives for developing new antibacterial and antifungal drugs, combat drug shortages, and enhance the Agency's efforts to ensure that American consumers have more timely access to safe, high-quality, and affordable medicines.

  Title VII of FDASIA focuses on improving the safety and integrity of drugs imported into, and sold in, the United States. The new authority increases FDA's ability to collect and analyze data to enable risk-informed decision-making, advance risk-based approaches to facility evaluation, partner with foreign regulatory authorities to leverage resources through information-sharing and recognition of foreign inspection, and drive safety and quality throughout the supply chain through the use of strengthened tools. For example, the law requires foreign and domestic companies to provide complete information on threats to the security of the drug supply chain and improves current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic manufacturers.

The new authorities provided by FSMA and FDASIA align with the strategies outlined in the *Pathway* report. Both FSMA and FDASIA promote collaboration with global regulatory partners, utilizing data systems to facilitate information-sharing and risk analytics and leveraging the efforts of our regulatory and public health partners. We are working hard to implement both of these important laws.

FDA ACTIVITIES RELATED TO CHINA

Nowhere is the shift toward a global marketplace more evident than in U.S. trade with China. China is the source of a large and growing volume of imported foods, drugs, and ingredients. During FY 2007-2012, the total number of shipments of FDA-regulated products from China increased from approximately 1.3 million entry lines to 4.5 million lines. Of the 4.5 million lines arriving from China in FY 2012, 67 percent were drugs and devices, and 6 percent were human food products. Three percent of our imported food, 8 percent of animal food, and 5 percent of drugs and biologics come from China.

As the number of products imported from China has increased, so have the challenges. There are currently 74 active FDA Import Alerts that include firms located in China. Forty of the Import Alerts concern food products. These alerts signal FDA investigators at the U.S. border to pay special attention to a particular product, or a range of products from a particular country, producer, shipper, or importer. Under these Import Alerts, products may be detained at the border and may be refused admission into U.S. commerce unless the importer is able to demonstrate that the products are in compliance with all laws and regulations. There are

currently nine country-wide Import Alerts for China. For example, in September 2008, FDA became aware of thousands of infant illnesses in China associated with the consumption of infant formula reported to contain melamine. To keep these products out of the country and protect American consumers, the Agency issued an Import Alert for milk and milk products from China because of the presence of melamine. In addition, FDA continues to find residues of several animal drugs in shipments of aquacultured seafood products from China. As a result, FDA has imposed a country-wide Import Alert on all farm-raised catfish, basa, shrimp, dace, and eel from China.

FDA is taking several actions in response to these challenges. FDA has 13 officers posted in three locations in China: Beijing, Shanghai, and Guangzhou. This includes eight U.S. civil servants and five Chinese staff. The mission of FDA's China Office is to strengthen the safety, quality, and effectiveness of FDA-regulated products produced in China for export to the United States. FDA's China Office works to fulfill this mission through:

- Collaborating, capacity-building, and confidence-building with Chinese regulatory counterparts at the central, provincial, and municipal level;
- Reaching out to regulated Chinese firms that wish to export their products to the United States to enhance understanding of and compliance with FDA standards;
- Monitoring and reporting on conditions, trends, and events that could affect the safety and effectiveness of FDA-regulated products exported to the United States;
- Conducting inspections at facilities that manufacture FDA-regulated goods;

- Increasing the knowledge base and understanding of key stakeholders about FDA regulations and science-based approaches to strengthen product safety, quality, and effectiveness; and
- Working closely with other relevant offices within the U.S. Embassy and Consulates in China, such as the Foreign Commercial Service of the Department of Commerce, the Foreign Agricultural Service of USDA, and the Centers for Disease Control and Prevention of HHS.

Food and animal feed exported from China are regulated by the General Administration of Quality, Supervision, Inspection, and Quarantine (AQSIQ). This food-export system is separated from China's system for regulating its domestic food supply. On the domestic side, the Ministry of Agriculture has responsibility for primary food production, and the China Food and Drug Administration (CFDA) has responsibility for food processing, food in retail circulation, and restaurants. Until March 2013, these responsibilities had been held by three different ministries within the Chinese Government. FDA, through efforts led by its China Office, has established active working relationships with the food safety agencies in Beijing and will continue to work with key stakeholders in China to strengthen the safety of food exported to the United States by encouraging the implementation of science-based standards. On the human drug side, domestic drugs and certain exported drugs are regulated by the CFDA. Domestically, AQSIQ and the Ministry of Agriculture share responsibility for the regulation of animal drugs, animal feed, and feed ingredients.

I would now like to provide some examples of our collaborations with Chinese government officials.

In mid-April, FDA met with CFDA in Washington to discuss the substantive collaboration between FDA and CFDA across more than a dozen topic areas. While much of the strengthening of our relationship with CFDA has come through day-to-day collaboration between FDA's China Office and CFDA officials in Beijing, there are other significant ties in multiple areas across our agencies, such as:

- A working group on economically-motivated adulteration (the fraudulent substitution of a substance in a product to increase value or reduce production costs for the purposes of economic gain) meets on a regular basis by video, linking Washington-based experts with CFDA's key decision-makers.
- Experts from FDA's Center for Devices and Radiological Health now meet regularly with their counterparts from CFDA under the auspices of the International Medical Devices Regulatory Forum, as China has recently joined the Forum.
- FDA and CFDA collaborate closely under the auspices of the World Health Organization's Working Group for Member States on Substandard, Spurious, Falsely-Labeled, Falsified and Counterfeit Medicines. FDA and CFDA inspectors regularly observe one another's inspections.
- On May 21, 2013, FDA and CFDA co-hosted a workshop to enhance our collaboration in the fight against Internet-based, illegal distribution of adulterated drugs.

Other examples include:

- Between 2010 and 2012, FDA held a series of workshops on good clinical practices for Chinese inspectors who inspect sites that conduct trials to support the development of pharmaceuticals. Prior to the workshops, CFDA had few well-trained inspectors able to conduct inspections of clinical research sites. FDA's training in this area helped CFDA to establish its national clinical research inspectorate. FDA regularly invites these CFDA inspectors to observe Agency clinical research inspections in China to continue to enhance CFDA's understanding of FDA requirements.
- At the request of CFDA, FDA's China Office and Office of Criminal Investigations worked with U.S. Internet-hosting companies to shut down 16 Chinese-language websites that illegally sold unapproved medical products through servers located in the United States.
- In 2012, CFDA provided to FDA's China Office a list of Chinese pharmaceutical firms against which CFDA had taken regulatory action because of their failure to comply with relevant standards for good manufacturing practices. From the list, FDA identified 61 firms that had shipped products to the United States and targeted these firms as priorities for inspection.
- FDA's country-wide Import Alert on five species of aquaculture fish has been in place since 2007, yet FDA continues to find positive samples of illegal drugs and additives from Chinese aquaculture products shipped to the United States. In November 2012 and May 2013, FDA and AQSIQ held workshops for members of Chinese industry to address concerns regarding aquaculture practices for fish farms. These workshops have significantly enhanced FDA's understanding of China's oversight system for aquaculture products, and have provided Chinese industry with a clearer understanding of FDA's requirements and practices.

CONCLUSION

Thank you for the opportunity to describe some of FDA's actions to address the challenges of an increasingly globalized marketplace and to discuss our work in China. FDA is pursuing a comprehensive strategy to enhance the safety of imported products and establish an effective global safety net.

Firms always have the primary responsibility to produce safe products, but it is important that governments provide meaningful and robust regulation. FDA is working with China to help them improve their regulatory system and to educate them on the new standards being implemented in our regulatory system.

I am happy to answer any questions you may have.