



FDA Facts: Implementing Arrangements With China

The U.S. Food and Drug Administration (FDA) signed two Implementing Arrangements (IAs) with its Chinese counterparts to create a framework for expanded FDA staffing in China. The documents, signed with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and China's Food and Drug Administration (CFDA), outline commitments from FDA and AQSIQ regarding inspections of food facilities, and commitments from FDA and CFDA regarding inspections of drug facilities.

The IAs spell out commitments in the following areas:

- **Scope of inspections:** the IAs make clear FDA's intent to conduct inspections in Chinese facilities that manufacture or process food or drugs for export to the United States;
- **Planning:** FDA commits, in most cases, to provide advance notice to Chinese authorities regarding its inspections;
- **Intent:** these documents make clear that FDA's intent in its inspections is to determine whether Chinese firms comply with FDA's requirements;
- **Information sharing:** the IAs create mechanisms for information sharing, including sharing of inspectional reports, to the extent permitted by law;
- **Joint efforts in inspectional work:** the IAs outline a framework through which Chinese inspectors will be able to observe FDA inspectors during inspections in China;
- **Public health hazards:** FDA and its Chinese counterparts commit to notify one another regarding inspectional findings that might constitute potential hazards to health; and
- **Technical collaboration, leveraging information:** FDA, AQSIQ and CFDA commit in these documents to continue to strengthen their collaboration on technical issues, and to look for opportunities to leverage information from one another's regulatory systems.

The IAs follow a bilateral agreement made between the United States and China during Vice President Biden's December 2013

visit to Beijing, in which China pledged to promote bilateral communication and cooperation with respect to medical products, food and feed, as well as to issue visas for increased numbers of FDA staff in China.

Through the China Safety Initiative, FDA received \$10 million in increased funding for staffing in China. This funding supports the addition of 10 drug inspectors and seven food inspectors to FDA's in-country presence in China, and will move FDA's overall staffing in China to 26 U.S. direct hires.

Background:

In 2007, HHS entered into two agreements with the Chinese government.

1. The first is between HHS and AQSIQ of the People's Republic of China. It established a means of cooperation between FDA and AQSIQ on food and feed safety.
2. The second is between HHS and CFDA (formerly, the State Food and Drug Administration, or SFDA). Like the first agreement, this established a mechanism for regulatory cooperation, but for the safety of drugs and medical devices.

Since these agreements were signed, FDA's international work and foreign presence has grown, and has become increasingly important in light of globalization.

Under the terms of the agreement reached during Vice President Biden's visit to Beijing in December 2013, FDA agreed to work with AQSIQ and CFDA to frame the expansion of its staffing in China.

FDA is working to significantly increase the number of overseas inspections it conducts annually, including in China.

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