

FDA Opens Offices in China More Inspections Likely

The Food and Drug Administration recently opened three new offices in China, the FDA's first outside the United States.

It appears likely that FDA officials will be performing more regular inspections of Chinese-based facilities producing pharmaceuticals, medical devices, and food for export to the United States.

Function of FDA Offices in China

The new FDA offices are located in Beijing, Guangzhou, and Shanghai.

- The Beijing office, which opened on November 19, 2008, will serve as a liaison between FDA and Chinese regulatory agencies.
- The Guangzhou and Shanghai offices, which opened on November 20 and 21, respectively, will conduct inspections and train Chinese inspectors.
- FDA officials from the United States will staff the offices with translation and interpretation support from additional Chinese staff.
- Chris Hickey, currently Director of HHS's Office of Asia and the Pacific, will serve as the FDA Country Director.

We understand that the principle responsibilities of the new FDA offices in China will be (1) performing inspections, (2) advising on U.S. quality standards, and (3) training local experts to conduct inspections on behalf of FDA.

- The FDA offices will perform joint inspections with Chinese regulatory authorities, including the General Administration of Quality, Supervision, Inspection and Quarantine ("[AQSIQ](#)"), which has general responsibility for product quality and safety, and the State Food and Drug Administration ("SFDA"), which has specific authority over human pharmaceuticals.
 - AQSIQ has been harshly criticized for several food safety issues in China and the United States over the last two years, including melamine in milk products, tainted heparin, and melamine in pet food.
 - FDA hopes to develop a strong relationship with AQSIQ and SFDA and share insights on inspection quality and strategy to increase AQSIQ's and SFDA's inspection capacity and capabilities.
 - It is unclear whether FDA employees will conduct inspections of Chinese manufacturing locations in the absence of AQSIQ officials.
- FDA's new offices also will advise Chinese government agencies, Chinese companies, and other interested parties on U.S. quality standards.
- Over the long term, FDA will seek to train credible, independent, third-party institutions to inspect factories that produce pharmaceuticals, medical devices, and food for export to the United States.

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U.S. Pressure for Additional Inspections in China

The new offices in China come as FDA has received increased pressure in the United States to perform more inspections of overseas suppliers of pharmaceutical and food products.

- FDA estimates that 714 drug manufacturing establishments located in China directly or indirectly supply API or finished products to the United States.
 - This is the highest number of establishments in a single country outside the United States, and FDA predicts this number will rise significantly in the coming years.
 - From 2002 to 2007, FDA inspected only 80 of these Chinese establishments.
- Congressional oversight committees and government inspectors have chastised FDA's relative lack of inspections of pharmaceutical, medical device, and food manufacturers in China, as evidenced in four reports by the Government Accountability Office in 2008 (available [here](#), [here](#), [here](#), and [here](#)).
- In July 2008, Senator Kennedy and Representative Dingell proposed separate pieces of legislation that would require FDA to inspect registered foreign drug establishments as frequently as domestic establishments -- at least once every two years -- with certain exceptions.
- Publicity from the [New York Times](#) and other sources has highlighted that FDA has inspected only a small percentage of foreign food and drug manufacturing plants, particularly in China.
- In reaction to this publicity and criticism, China is prominently featured in FDA's recently released "[One-Year Summary of Progress Under the Food Protection Plan](#)" (though not featured at all in FDA's original [Food Protection Plan](#), issued in November 2007).

Chinese Cooperation

The FDA offices in China are an outgrowth of two [Memoranda of Understanding](#) signed in December 2007 between the U.S. and Chinese governments on the safety of food, feed, pharmaceuticals, and medical devices.

It remains to be seen how U.S.-Chinese cooperation on inspections and training will play out. Although China has cooperated with some U.S. efforts to perform inspections of Chinese companies and factories in the past, other efforts have been less successful.

Covington's Resources in China

Covington & Burling LLP, with offices in Beijing, Brussels, London, New York, San Diego, San Francisco, Silicon Valley, and Washington, D.C., is well positioned to assist pharmaceutical, medical device, and food companies in dealings with FDA officials in China, including preparing factories for inspection, clinical trials, and other regulatory issues.

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