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China

'Business as Usual' for FDA, China Counterpart After Reorganization

BEIJING—China's recent government reshuffle has not affected collaboration between U.S. and Chinese food and drug regulators and does not at this point appear likely to impact U.S. inspections of drugs, medical devices, or food exports, the head of the U.S. Food and Drug Administration's China office told BNA March 29.

As part of a government restructuring announced recently, China officially elevated the State Food and Drug Administration (SFDA) to the ministry level and renamed it the China State Food & Drug Administration (CFDA) March 22. In addition to renaming, the reorganization combines a number of functions previously under other offices and departments under the CFDA.

"We're finding the vast majority of the work is business as usual," Christopher Hickey, the U.S. FDA China country director, told BNA. "At this point, there has not been a dramatic change in terms of day-to-day operations that we have with the Chinese government."

FDA's work with the CFDA is primarily focused on drugs, medical devices, and dietary supplements, Hickey said. Most of FDA's work regarding food has been done with the country's General Administration for Quality and Supervision, Inspection, and Quarantine (AQSIQ).

"What we are hearing from AQSIQ and others is that this reform is focused primarily on China's domestic

food supply and that the system for imports and exports—which AQSIQ oversees—will remain largely intact," Hickey said. "Because our focus at the FDA is on food that is exported from China to the United States, the bulk of our food work will remain with AQSIQ most likely."

Hickey said it was not yet known whether the restructuring would have any impact on clinical trials, international harmonization of standards, drug approvals, or device clearances.

About 22,000 China-based food companies and 600 companies making pharmaceutical ingredients or drug products are registered with FDA as shipping products to the United States, Hickey said. FDA carried out 245 inspections in China in fiscal 2012 across all areas, he added.

In recent years, FDA's China office also has collaborated with its Chinese counterpart to hold trainings for good manufacturing practices, good clinical practices, and to combat internet fraud, Hickey said.

Hickey said more details of the government reorganization might be discussed in an upcoming annual bilateral meeting between the CFDA and U.S. FDA in Washington in April, but added that no specifics have been shared yet in advance of the meeting.

"It is always healthy to take a wait and see attitude" with government restructuring, Hickey said. "Our attitude has been that we have a strong relationship with [China's agency], and will continue to have a strong working relationship with them."

By LESLIE A. PAPPAS