

## E-ALERT | Food & Drug

March 25, 2013

### CHINA REORGANIZES THE SFDA AND APPOINTS A NEW COMMISSIONER

China's 12th National People's Congress has recently approved a plan to consolidate most of the country's regulatory authority over food into a ministry-level agency named the China Food and Drug Administration (CFDA), which replaces the State Food and Drug Administration (SFDA). As a result, the agency has started a reorganization under the leadership of a new commissioner. Companies whose food, drug, device, and cosmetic products are regulated by the agency should closely monitor the developments.

On March 22, 2013, in the early morning darkness, and without any opening ceremony or news announcement, SFDA replaced the sign on its headquarters with a new sign that has its new name in Chinese, and also began displaying the new name on the agency's official Chinese and English websites, showing "China Food and Drug Administration" as its English name.

CFDA's Chinese website, on the same day, replaced the name, photo, and short biography of the previous commissioner with that of the new commissioner, Mr. Zhang Yong, without issuing any announcement about the new commissioner. The website did not include the names of any deputy commissioners as of this writing.

The agency has posted a two-paragraph notice on its website announcing that all of the previous functions of SFDA have been merged into the new CFDA, the reorganization is proceeding promptly, and in the interim:

- No change will be made in requirements for the handling of review and approval, examination and testing, inspection and certification, and audit and enforcement;
- All approval documents and certificates will follow the previous format;
- No change will be made to official seals, document formats, and handling procedures; and
- The oversight of safety in food production and distribution will follow the existing channels until the completion of the handover to CFDA.

As a result of this restructuring, CFDA will be a full ministry agency reporting directly to the State Council, which is China's highest administrative body. According to a "[top \[Chinese\] official](#)," this new development seeks "to strengthen regulation and boost people's confidence in the country's food and drug products" by eliminating "blind spots" and overlaps in regulatory authority. The Chinese government [has also indicated](#) that this change will help to promote regulatory oversight and identify responsible parties, especially with respect to the regulation of food, which has been undertaken by SFDA and several other government ministries and agencies.

SFDA's jurisdiction over food primarily started in 2003. The modern day predecessor agency of CFDA was founded in 1998, as State Drug Administration, initially to oversee only drugs and medical devices. In 2003, the agency was given certain jurisdiction over food, and was renamed State Food and Drug Administration, reporting directly to the State Council. The Ministry of Health (MOH)

assumed supervisory authority over SFDA in 2008 after a series of food safety scandals. For example, in 2008, milk and infant formula were found to be [tainted with melamine](#). As a result of this adulteration, six children died, and about 300,000 babies suffered kidney damage. MOH supervision of SFDA was partly intended to consolidate MOH's authorities over food with SFDA's responsibilities over food, and enhance the overall regulation of food. After this change took place in 2008, however, SFDA's regulatory authority over food continued to be shared with multiple government agencies outside MOH, which hold various regulatory authority over different aspects of food growing, manufacturing, processing, distribution, and retail sales.

The Chinese government has been under further pressure in recent years after several highly publicized incidents involving the contamination of food and drugs produced in China. In 2012, for example, the Chinese government investigated allegations that a manufacturer used "gutter oil," or recycled cooking oil, [to make antibiotics](#). Critics argued that the regulatory apparatus overseeing the country's food and drug industry created redundancies in authority across agencies while also opening loopholes for agencies to shirk responsibility.

Accordingly, the State Council proposed, and the National People's Congress approved, consolidating most regulatory authority over food into CFDA. After the consolidation, the regulation of foods will more closely resemble that of the Food and Drug Administration in the United States; the newly elevated and expanded CFDA will integrate the functions of various agencies that regulate food, in addition to keeping its authorities over drugs, devices, and cosmetics. At present, the primary focus has been on the consolidated regulation of food products, so the impact of these structural changes on drugs and devices regulation in China is unclear. The focus on food safety issues has been implemented, partly through the appointment of the new commissioner, who received academy training in economics, rather than in medicine as the previous commissioner, and has been serving as the head of the management office of the State Council's Food Safety Committee since its establishment in February 2010.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

<b>Shaoyu Chen</b>	+86.10.5910.0509	<a href="mailto:schen@cov.com">schen@cov.com</a>
<b>Ellen Flannery</b>	+1.202.662.5484	<a href="mailto:eflannery@cov.com">eflannery@cov.com</a>
<b>Mingham Ji*</b>	+1.202.662.5621	<a href="mailto:mji@cov.com">mji@cov.com</a>

\*Admitted to the New York Bar, but not admitted to the District of Columbia Bar.

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