China Creates a New Regulatory Regime for Foods for Special Medical Purposes

On September 2, 2015, the China Food and Drug Administration (CFDA) published a draft Registration Rules for Food for Special Medical Purpose (FSMP), soliciting public comments by October 1, 2015 (the Draft Rules). FSMP is a regulatory concept China developed based upon a similar category in the European Union. It refers to “a category of food specially processed or formulated to satisfy the special nutrition or dietary needs of a group of population with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs, or population with specific diseases.”

In 2013, China’s National Health and Family Planning Commission (NHFPC) developed three national standards for FSMP products: General Principles for FSMP, General Principles for FSMP for Infants, and Good Manufacturing Practice (GMP) for FSMP (collectively, the FSMP National Standards). The recently amended Food Safety Law of China embodies this concept and authorizes the CFDA to develop a pre-market approval system for FSMP products imported, manufactured and/or marketed in China:

- CFDA follows the FSMP National Standards, and classifies FSMP Products into four categories: (i) Nutritionally Complete FSMP; (ii) Specific Nutritionally Complete FSMP; (iii) Nutritionally Incomplete FSMP; and (iv) FSMP for Infants.

- All categories of FSMP products must go through a product registration process with the CFDA, which is similar to the one currently applicable to drugs and medical devices. Registration of certain FSMP products, e.g., Specific Nutritionally Complete FSMP, would require clinical studies in China, and the CFDA would develop separate Good Clinical Practices (GCPs) to guide such studies.

- Manufacturers would be the owner of FSMP product registrations in China. To obtain and maintain product registrations, local manufacturers need to have an FSMP manufacturing license issued by the CFDA and comply with GMP requirements, while foreign manufacturers would be subject to the CFDA’s audit of their manufacturing sites outside China.

- To market FSMP products, manufacturers cannot make any claim relating to disease prevention or treatment on FSMP labels, and must instruct customers to use the products under the supervision of physicians or clinical nutritionists.
• Each FSMP product registration would be valid for five years, and the statutory timeline for the CFDA to review and approve each product registration is from 135 to 175 working days.

Prior to creation of the FSMP concept, certain FSMP products were manufactured and marketed in China as drugs. It remains to be seen how those existing products will be treated under the new FSMP pre-market approval system.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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