China Food and Drug Administration Issues New Guidance Documents on Foods for Special Medical Purposes

On April 18, 2016, the China Food and Drug Administration (CFDA) published a series of guidance documents as the most recent part of its efforts in revamping its regulations on foods for special medical purpose (FSMP) to better promote and protect public health.[1] These guidance documents provide detailed guidelines on how to prepare submissions to CFDA for FSMP registration, and follow the CFDA's publication of its Administrative Measures for Registration of Medical Foods on March 10, 2016.[2] Comments on these guidance documents are due on May 15, 2016.

The term "foods for special medical purpose" or FSMP is defined by CFDA as "foods specially formulated to satisfy the unique nutritional or dietary needs for patients with diet intake restriction, malabsorption, or metabolic disorders."[3] FSMP also includes infant formulas that are designed to meet the unique medical needs of certain infants.[4] The FSMP concept is comparable to the "medical food" in the U.S., which offers specially formulated foods for patients with distinctive nutritional needs that cannot be met by a normal diet alone. However, unlike the medical foods regulated by the U.S. Food and Drug Administration (FDA) in the U.S., marketing of FSMP in China requires pre-market approval from CFDA, which may involve extensive review of manufacturing and clinical trial data, as well as on-site inspection.

Specifically, according to CFDA's Administrative Measures for Registration of Medical Foods, which becomes effective on July 1, 2016, all FSMP manufactured, sold, or imported in China must register with CFDA. The following documents need to be submitted for registration:

1. Petition for the registration of FSMP;
2. Product development plan, formulation, and rationale;
3. Manufacturing process;
4. Specifications;
5. Product labels, example instruction for consumers;
6. Product sample lab testing reports;
7. Supporting materials for research, manufacturing, and testing;
8. Other evidence to support the product safety, nutritional completeness, and efficacy.

For certain categories of FSMP, clinical trial data are also required.

The purpose of the guidance documents just issued by CFDA is to provide more detailed guidelines for FSMP manufacturers when they prepare their submission to CFDA for pre-marketing approvals. In particular, these guidance documents include:

- Administrative guidance for registration of FSMP;
- Guidance on FSMP's label and instructions for consumers;
- Guidance on quality management of clinical trial data for FSMP;
- Guidance on FSMP product stability;
- Guidance on on-site inspection of facilities that manufacture FSMP.

Businesses that manufacture or sell FSMP in China should review these guidance documents and assess how these regulatory requirements would affect their operation.

We will continue to monitor all developments related to China's CFDA. If you have any questions, or if we can be of any assistance, please do not hesitate to contact us.

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1. See "总局办公厅关于公开征求《特殊医学用途配方食品注册管理办法》相关配套文件的意见" available at: http://www.sda.gov.cn/WS01/CL0782/150540.html.
2. See "特殊医学用途配方食品注册管理办法》（国家食品药品监督管理总局令第24号) available at: http://www.sda.gov.cn/WS01/CL0053/146741.html.
3. See "特殊医学用途配方食品注册管理办法》解读" available at: http://www.sda.gov.cn/WS01/CL1297/146743.html.
4. See id.

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