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CFDA Issues Two Key Draft Rules on Infant Formula and Medical Foods

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Food & Drug

On September 2, 2015, CFDA issued two important proposed rules implementing the recently revised Food Safety Law (see our earlier alert on the Food Safety Law here) as it applies to special foods. Special foods is a category that includes infant formula, foods formulated for special medical purposes (FSMPs), and health foods. The first proposed rule, the Draft Administrative Measures on the Registration of Formulas for Infant Formula Products (for Trial Implementation) ("Draft Formula Measures"), implements the pre-market registration process for infant formula product formulations, as applied only to infant formula manufactured in China. Importantly, it also implements a one formula to one brand restriction that could significantly affect suppliers both in China and abroad. The second proposed rule, the Draft Administrative Measures on the Registration of Foods Formulated for Special Medical Purposes (for Trial Implementation) ("Draft FSMP Measures") implements the pre-market registration process for imported and domestic foods formulated for special medical purposes. Comments for both proposals are due on October 1, 2015.

The following alert describes some core features of both proposed rules. Infant formula manufacturers and manufacturers of FSMPs both inside and outside of China should continue to monitor, and consider commenting on, these proposals.

Draft Formula Measures

The Draft Formula Measures set forth the requirements for domestic manufacturers in China to obtain approval from the China Food and Drug Administration ("CFDA") to market a specific formula of an infant formula product. The "formula" of an infant formula milk powder product is defined as all ingredients used in manufacturing and their amounts, and the content of the nutritional ingredients in the product. It is unclear whether CFDA or another agency will release a similar rule related to imported formula products.

General Procedures for Registration of the Formula

In general, the Draft Formula Measures set forth the specific requirements for infant formula registration. The applicant, a company registered in China, would be required to submit to CFDA a report describing the research and development of the product and the manufacturing process, a product testing report, a certification as to its manufacturing, research and development and testing capabilities, sample product label and instructions, and other materials that support the science and safety behind the formula. A provincial-level food and drug regulatory authority will then inspect the manufacturing facility and a government-certified food laboratory would test product samples. Application materials and inspection and testing results will be reviewed by an expert panel organized by CFDA. There are proposed timelines for

review, including five working days to inform the applicant of acceptance of the application, 20 days for the on-site inspection, 30 days for the product inspection report, 60 days for expert review, and 20 days for CFDA to decide whether to approve the application.

The registration would be effective for five years, with re-registration required at least 60 days before expiration of that term. CFDA would be permitted to deny re-registration under certain circumstances, including when the applicant fails product testing from food and drug authorities in its province or from CFDA more than twice in one year, fails to maintain adequate records to permit traceability or fails to meet other regulatory requirements. Manufacturers would be permitted to change their name, the place of manufacturing or label by submitting an application to amend their registration, but other components or processes underlying the registration cannot be modified.

Limitations on Brands

Perhaps the most controversial provisions in the Draft Formula Measures are those that limit domestic companies to one registered formula per brand, meaning that manufacturers cannot use different brand names to market the same formula. The Draft Formula Measures also propose to limit the number of brands per age group by the same company, which is an expansion on what is required by the Food Safety Law. The former restriction finds its basis in the revised Food Safety Law itself, although the Draft Formula Measures apply it more narrowly by potentially limiting it to domestically manufactured formula.

For the latter limitation on brands per age group, the Draft Formula Measures offer two proposals. The first proposal is that the formulas for the same age group must differ from each other by at least six optional ingredients as defined by the food safety national standards. National food safety standards contain the detailed requirements for the content and manufacturing of infant formula. The second option appears to be a hard limitation that companies be limited to “five sets” of 15 different types of product formulations. Under either option, registered formulas must have “clear differences” and be supported by scientific evidence.

Labeling Requirements

The Draft Formula Measures propose certain labeling requirements for domestic infant formula. In general, the label must be truthful and accurate, scientifically legitimate and easy to understand. The Draft Formula Measures impose stylistic labeling requirements, such as font size. The Measures also mandate certain disclosures. The label should indicate any genetically modified ingredients, and if the milk powder raw material is imported, the label should indicate the place of actual manufacturing for the raw material. In addition to required disclosures, the Measures would prohibit certain types of content. Terms like “imported milk source” or “originating from ranches abroad” would be deemed misleading and may not be used. The Measures would also prohibit the inclusion of therapeutic claims, claims that the product is not genetically modified or additive-free claims. The Measures would allow foreign language content on the label, although other than foreign trademarks, the content should also be translated into Chinese.

Draft FSMP Measures

FSMP is a new category of "special food" that was officially created by the revisions to the Food Safety Law. "FSMP" refers to specially processed and formulated foods for meeting food restrictions, digestion and absorption disorders, metabolic disorders or a particular disease state with special nutritional or dietary needs, including FSMPs for individuals of age one and older and FSMPs for infants from zero to twelve months.

General Requirements for Approval of FSMPs

The Draft FSMP Measures set forth the requirements for developing and then seeking approval for marketing of FSMPs. Applicants for approval must be manufacturing enterprises either in China or abroad. The Measures define a "manufacturing enterprise" as those companies that have the capacity to develop, manufacture and test FSMPs.

In order to market their FSMPs, an applicant must submit, among other materials, information about the product's development (including the basis for the formula), the manufacturing process, relevant quality standards, labeling, a report of tests on product samples, and materials confirming the capacity of the applicant to develop, manufacture and test the product. These materials must be submitted to CFDA, which will evaluate them, and conduct a site inspection (if it is manufactured in China) and sample testing. If CFDA approves the application, then it will issue a five-year license.

Clinical Trial Requirements

If the FSMP is considered a special total nutrition formula food, then the applicant must conduct a clinical trial. Special total nutrition formula foods are defined as FSMPs intended to provide a complete nutritional source for populations suffering from a specific disease or medical condition with nutritional requirements. The Draft FSMP Measures list a number of examples of these disorders or medical conditions, including diabetes, respiratory disorders, renal diseases, cancer, liver disease, sarcopenia, increased stress states from trauma, infection or surgery, inflammatory bowel disease, food protein allergies, difficult to cure epilepsy, pancreatitis, and obesity or obesity-reduction surgery. An FSMP clinical trial must be conducted at an institution accredited by CFDA. The FSMP Measures require that CFDA issue good clinical practices for these types of trials, which will presumably add more specific requirements.

The Draft FSMP Measures also contain other requirements, such as those for labeling. These requirements include coverage and font size requirements, as well as certain necessary warnings.

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

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