HAN KUN LAW OFFICES

Legal Commentary

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Comments on the New Rules for the Registration of Infant Formula Milk Powder Formulas

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Article 81 of the Food Safety Law of the PRC (the "**Food Safety Law**"), revised in 2015, stipulates that the product formulas for infant formula milk powder shall be registered with the food and drug administration under the State Council. As a subsequent supporting regulation, the China Food and Drug Administrative (the "**CFDA**") promulgated the *Administrative Measures for the Registration of Infant Formula Milk Powder Formulas* (the "**Measures**") on June 6, 2016, which shall come into force as of October 1, 2016. We consider the following points to be worthy of attention:

Establishing application thresholds, and equal requirements for domestic and imported products

The Measures apply to the administration of the formula registration of the infant formula milk powder (the "**infant milk powder**") produced, sold and imported to within the territory of the PRC, and applicants must be domestic producers intending to produce and sell the infant milk powder within the territory of the PRC, or offshore producers intending to export the infant milk powder to the PRC. As a consequence, a CFDA-issued formula registration certificate is needed when importing infant milk powder into the PRC.

Meanwhile, the Measures require applicants, which may also be producers, to have the capacity to engage in R&D, produce and test infant milk powder, comply with good production practice requirements for powdered infant formula foods, implement hazard analysis and critical control point systems, and conduct inspections of outgoing infant milk powder batch by batch according to the relevant laws, regulations and national food safety standards for infant milk powder. Without meeting such conditions, producers cannot apply to register infant milk powder formulas.

Limitations on formula quantities to avoid market disorder

The Measures stipulate that each producer shall, in principle, have no more than 9 product formulas under 3 formula series (each series includes 1, 2 and 3 stages), and require different formulas for the same age group to have obvious differences, which must be proven by scientific verification, in order to avoid market disorder caused by an overabundance of formulas.

In addition, the Measures allow wholly-owned subsidiaries within a corporate group, where such subsidiaries already have registered infant milk powder formulas and production licenses, to use the formulas registered by other wholly-owned subsidiaries within the same corporate group. However, according to the Food Safety Law, a producer may not use the same formula to produce different brands of infant milk powder. Thus, where a wholly-owned subsidiary produces infant milk powder products using the formula and brand of another wholly-owned subsidiary within a corporate group, the producer subsidiary may not produce the product by using its own brand and the same formula at the same time, and vice versa. Such regulations reduce waste of administrative resources caused by duplicative applications, and also facilitate internal business arrangements within corporate groups, particularly multinational corporate groups.

Regulating labels and instructions to avoid false and exaggerated promotions

The Measures stipulate that labels and instructions which reference infant milk powder formulations must be consistent with their registered formulas. Our understanding is that not only infant milk powder products, but also other products that may use infant milk power formulas, must comply with this requirement in order to prevent production and sales enterprises from using infant formula foods or other products to evade the higher regulatory requirements for the registration of infant milk powder formulas.

In addition, subject to the related regulatory principles and provisions stated in the new *Advertising Law of the PRC,* which came into force on September 1, 2015, the Measures require truthful and clear expressions as to the place of origin or country of the raw materials, instead of ambiguous expressions such as “imported milk”, “ecological pastures,” and “imported raw materials.” Meanwhile, the labels and instructions shall not contain the following information:

a. the capability to treat or prevent disease;

b. expressly or impliedly indicating health benefits;

c. expressly or impliedly indicating intellectual or immunological enhancement, protection of intestinal function, or descriptions of other capabilities;

d. emphasizing the non-use or being free of materials that must not to be included in formulations pursuant to food safety standards by using words such as “not added”, “does not contain”, “free of…” or other such expressions;

e. content that is false, exaggerated, which violates scientific principles, or is absolute;

f. claims that are inconsistent with the registered content. The last requirement can be seen as a general provision for the CFDA to regulate other forms of promotion that may appear in the further.

Regulating registration applications and strengthening self-regulation

As stipulated in the Measures, where an applicant conceals relevant facts or provides false materials or samples when applying to register infant milk powder formulas, the CFDA will issue a warning to the applicant and make an announcement to the public, and the applicant will not be allowed to file an application for registration of infant milk powder formulas for a period of 1 year. Where an applicant obtains a formula registration certificate for infant milk powder by fraud, bribery or other illegal means, or by concealing facts or providing false materials, the CFDA will revoke the certificate and impose a fine of CNY 10,000 to 30,000, and the applicant will not be allowed to apply for registration of infant milk powder formulas for a period of 3 years. Thus, regardless of whether the application process is complete, applicants that have engaged in illegal conduct during the application process will be imposed with punishment, and the punishment will be more serious if it is later discovered that a certificate has been obtained by illegal means, which is comparable to the treatment of the self-inspection and inspection of pharmaceutical clinical trial data, in order to reinforce applicant self-regulation.

Furthermore, in accordance with the Measures, where an applicant fails to file an application for re-registration, where a formula registration certificate has been forged, altered, resold, leased, lent or transferred, or where a production or sales enterprise breaches the labeling and instruction requirements stipulated in the Measures, the food and drug administration at the county level or above will order the applicant to make remedies, issue a warning and impose fine, or impose punishment in accordance with the Food Safety Law.

Supervision through both formula registrations and production licensing

According to the *Circular of the General Office on Forwarding Opinions of the State Food and Drug Administration and Other Departments on Further Strengthening the Safety Quality of Infant Formula Milk Powder* issued on June 16, 2013, the supervision of infant milk powder shall be strict and refer to the administrative measures for pharmaceuticals. The Measures are issued as another milestone in the area of food supervision, as they introduce a stringent

supervisory system of product registration and production licensing, that has been implemented in the supervision of pharmaceuticals and medical devices.

According to the Measures, formula registration certificates are valid for five years, and applicants shall file an application for renewal within six months of the expiration date. Applications for renewal will be rejected where a producer does not produce products based on a registered formula for 5 years following the registration, or where a producer fails to maintain R&D, production and inspection capability on the registration date. Such provisions show the CFDA's continuous attention to the industrial efficiency of registered formulas and producers' related R&D and production capabilities. In the meantime, the CFDA requires food and drug administrations at the provincial level to further strengthen production license management and daily production supervision, which complement the infant milk powder formula registration regulations to protect the safety of infant milk powder by ensuring the science and safety of formulas, as well as production compliance, dependability of production techniques and controllability of production processes.

As of the issuance of this article, there is no information regarding when producers can apply to register infant milk powder formulas, and no supporting documents have been issued to coordinate with the official implementation of the Measures, such as the required materials for registration applications, regulations for the on-site inspection of manufacturing enterprises and other secondary documents. Hence, questions including how to identify the "obvious differences," how to conduct on-site inspections, especially offshore inspections, need to be further clarified. The CFDA is requiring its departments to accelerate the drafting and publication of related documents and detailed rules to launch the application process as soon as possible. We will continually monitor changes in the relevant laws and regulations.

Important Announcement

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