



Administrative Measures for Product Formula Registration of Infants and Young Children Formula Milk Powder

婴幼儿配方乳粉产品配方注册管理办法

State Administration for Market Regulation

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Translated by ChemLinked

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Administrative Measures for Product Formula Registration of Infants and Young Children Formula Milk Powder

(Promulgated by Decree No. 80 of the State Administration for Market Regulation on June 26, 2023, coming into force on October 1, 2023)

Chapter I General Provisions

Article 1 In order to be stricter in the administration of product formula registration and ensure the quality and safety of infants and young children formula milk powder, the Measures are hereby formulated in accordance with the Administrative Licensing Law of the People's Republic of China, Food Safety Law of the People's Republic of China, Implementation Rules for the Food Safety Law of the People's Republic of China, and other laws and regulations.

Article 2 The Measures shall apply to the administration of product formula registration of infants and young children formula milk powder produced, sold and imported within the territory of the People's Republic of China.

Article 3 The term "product formula registration of infants and young children formula milk powder" refers to the activity organized by the State Administration for Market Regulation, in accordance with the procedures and requirements stipulated in the Measures, to review the product formulas of infants and young children formula milk powder that is applied for registration and decide whether to approve the registration.

Article 4 The administration of product formula registration of infants and young children formula milk powder shall follow the principles of science, strictness, openness, fairness and impartiality.

Article 5 The administration of product formula registration of infants and young children formula milk powder is the responsibility of the State Administration for Market Regulation.

The acceptance, technical review, on-site verification, certificate making and delivery regarding application for product formula registration of infants and young children formula milk powder are the responsibility of the Food Review Institution of the State Administration for Market Regulation (Food Review Center, hereinafter referred to as the "Review Institution"), which also organizes experts for demonstration as needed.

Market regulation departments of provinces, autonomous regions and municipalities directly under the central government shall cooperate with on-site verification and other work related to product formula registration of infants and young children formula milk powder.

Article 6 Applicants of product formula registration of infants and young children formula milk powder (hereinafter referred to as the “applicants”) shall be responsible for the authenticity, completeness and legality of the submitted materials, and shall bear legal liability.

The applicants shall cooperate with market regulation departments to carry out on-site verification, sampling inspection and other work related to registration, and provide necessary working conditions.

Article 7 It is encouraged to research and develop and innovate product formulas of infants and young children formula milk powder, optimize formulas based on breast milk research results, and improve the quality of infants and young children formula milk powder.

Chapter II Application and Registration

Article 8 The applicant shall be a production enterprise that intends to produce and sell infants and young children formula milk powder within the territory of the People’s Republic of China or an overseas production enterprise that intends to export infants and young children formula milk powder to the People’s Republic of China.

Applicants shall have the R&D, production and inspection capabilities that are compatible with the infants and young children formula milk powder they respectively produce, meet the requirements of the good manufacturing practice for powdered formulae for infants and young children, implement the hazard analysis and critical control point system, and carry out batch-by-batch inspection on the ex-factory products in accordance with relevant laws and regulations and the items specified in the national food safety standards for infants and young children formula milk powder. If an enterprise group has an independent R&D institution, the holding subsidiary, as an applicant, can share some of the group’s R&D capabilities.

If an applicant uses a compound ingredient that already meets the nutritional requirements of the national food safety standards for infants and young children



Free



Free trial



Standard



Corporate



Special

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