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Management Measures for the Administration of the Registration of Infant and Young Children Milk Powder Formula Recipes

Chapter 1 General Provisions

Article 1 To ensure strict administration of the registration of infant and young children milk powder formula recipes, and guarantee quality safety of infant and young children formula milk powder, these Measures are formulated with the *Food Safety Law of the People's Republic of China* (*Food Safety Law*).

Article 2 These Administrative Measures apply to the registration of infant and young children milk powder formula recipes that manufactured and sold within, or imported into, the territory of the People's Republic of China.

Article 3 The registration of infant and young children milk powder formula recipes refers to the process during which the China Food and Drug Administration (hereafter referred to as the "CFDA") reviews the recipes of infant and young children milk powder formula applied for registration according to the process and requirements stipulated in these Measures and decides whether to approve registration or not.

Article 4 The administration of the registration of infant and young children milk powder formula recipe shall follow the principles of scientific-base, transparency, fairness and impartiality.

Article 5 The CFDA is responsible for the administration of the registration of infant and young children milk powder formula recipes.

The Administrative License Acceptance Institution of the CFDA (hereafter referred to as the "Acceptance Institution") is responsible for accepting the applications of the registration of infant and young children milk formula recipes.

The Food Review Institution of the CFDA (hereafter referred to as the "Review Institution") is responsible for the review of the registration of infant and young children milk powder formula recipes.

The Audit Inspection Institution of the CFDA (hereafter referred to as the "Audit Inspection Institution") is responsible for the on-site verification of infant and young children milk powder formula recipes.

The food and drug supervision and administration departments at provincial, autonomous and municipal level are responsible for cooperating with the CFDA conducting the work of on-site verification of the registration of infant and young children formula recipes, and so on.

Article 6 The applicant bears the legal liability and responsibility for the authenticity, integrity and conformity with the laws of the submitted materials.

The applicant shall cooperate with the food and drug supervision and inspection departments to conduct registration-related work of on-site verification, sample inspection and so on.

Chapter II Application and Registration

Article 7 The applicant shall be enterprises manufacturing and selling infant and young children milk powder formula within the territory of the People's Republic of China or manufacturers intended to export infant and young children milk powder formula to China.

The applicant shall be equipped with the relevant R&D, production and testing capacity to manufacture infant and young children milk power formula and execute the good manufacturing practice for powdered infant and young children formula, implement the Hazard Analysis and Critical Control Point System, and inspect the products leaving the factory batch by batch for those items stipulated in the relevant laws and regulations as well as food safety national standards for infant and young children milk powder formula.

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Article 8 The recipe to be applied for the registration of infant and young children milk powder formula shall comply with the requirements of relevant laws and regulations as well as food safety national standards. Research, development and verification reports and sufficient evidences demonstrating the scientificity and safety of the recipe shall be provided.

To apply for the registration of infant and young children milk powder formula recipes, the following materials shall be submitted to the CFDA:

(1) Application form for the registration of infant and young children milk powder formula recipes,
(2) Applicant credential documents,
(3) Quality and safety standards for raw materials and auxiliary ingredients,
(4) R&D report of product recipe,
(5) Description of production process,
(6) Product testing report,
(7) Materials demonstrating R&D, production and testing capacity,
(8) Other materials demonstrating the scientificity and the safety of the recipe.

Article 9 If the same enterprise applies to register more than 2 product recipes for the same age group and product recipes shall be science-based and reasonable. There shall be significant difference among recipes, which shall be confirmed with scientific evidence. Each enterprise in principle shall not have more than 3 recipe series with 9 product recipes. Each recipe series include infant milk powder formula (0-6 months, stage 1), older infant milk powder formula (6-12 months, stage 2) and young children milk powder formula (12-36 months, stage 3).

Article 10 Wholly-owned subsidiaries obtaining the recipe registration of infant and young children milk powder formula as well as production license, can use the registered recipe of infant and young children

milk powder formula from another wholly-owned subsidiary within the same group company. Before production, the group company shall submit written report to the CFDA.

Article 11 The Acceptance Institution shall deal with the applications of recipe registration of infant and young children milk powder formula according to the following circumstances:

(1) For the matters in an application that are not subject to registration in accordance with the law, it shall immediately inform the applicant of the rejection,

(2) For the matters in an application that are not part of CFDA's responsibilities in accordance with the law, it shall immediately make a decision of rejection and inform the applicant of relevant administrative organ to submit application,

(3) If the errors of the application materials that can be corrected on the spot, it shall be allowed to make correction by the applicant on the spot,

(4) If the application materials are incomplete or fail to comply with the statutory form, the applicant shall be informed on the spot or within 5 working days all at once of all contents to be supplemented and corrected. If it fails to inform so within the timeframe, it will be deemed that the application is accepted upon the day when the application materials are received,

(5) If the application materials are complete and comply with the statutory form or the applicant submit all supplemented and corrected materials as requested, registration application shall be accepted.

The Acceptance Institution shall issue a dated written confirmation stamped with CFDA's special seal for administrative permission acceptance, no matter whether the application is accepted or not by the Acceptance Institution.

Article 12 The Acceptance Institution shall deliver all application materials to the Review Institution within 3 working days upon acceptance.

Article 13 The Review Institution shall examine the application materials and the consistency between the product recipe claim and the content of product recipe registration. The Review Institution shall inform the Audit Inspection Institution to carry out the on-site verification according to the actual condition, arrange inspection institutions to conduct sampling inspection and organise experts to make the argumentation on technical questions. The review process shall be completed within 60 working days upon receiving the acceptance materials.

If time extension is needed for review under special conditions, it can be extended to 30 working days upon the agreement of the people in charge of the Review Institution. The decision of extension shall be informed to the applicant in writing.

Article 14 The Audit Inspection Institution shall complete the on-site verification of R&D capacity, production capacity and testing capacity as well as other status of the applicant within 20 working days upon receiving the notice from the Review Institution and issue the report of the on-site verification.

The Audit Inspection Institution shall notify the provincial food and drug supervision and administration department whereas the applicant is located to participate in the on-site verification. The provincial food and drug supervision and administration department shall send officials to participate in the verification.

Article 15 The Review Institution shall entrust qualified food inspection institutions to conduct sampling inspection.

The inspection institution shall complete sampling inspection within 30 working days upon receiving the delegation and issue the product inspection report.

Article 16 The working days for on-site verification and sampling inspection of overseas manufacturers shall be determined based on the practical situation.

Article 17 The Review Institution shall perform review on the application materials, the on-site verification report and product testing report to draw review conclusions.

Article 18 The Review Institution shall inform the applicant with a written notice of not approval when the Review Institution decides not to approve the application. The applicants shall apply for reconsideration to the Review Institution and state the reason of reconsideration within 20 working days after receiving the written notice whereas the applicant disagrees with the decision. Contents for reconsideration are only limited to the original application items and materials.

The Review Institution shall make the reconsideration decision within 30 working days after accepting the reconsideration application and inform the applicant with written notice.

Article 19 The Review Institution shall inform the applicant of all needed materials of supplement and correction at one time when the Review Institution considers it is necessary. The applicant shall provide all materials required within 3 months at one time. The time for preparing materials of supplement and correction will not be included in the review time. It will be considered as not providing materials of supplement and correction anymore when the applicant fails to submit the materials within the timeframe.

Article 20 The CFDA shall decide whether to approve the registration or not according to the review conclusion within 20 working days upon receiving the review conclusion from the Review Institution.

The Acceptance Institution shall issue the Certificate of Approval for registration of infant and young children milk powder recipes or the decision of not approval within 10 working days upon the day when the CFDA makes the decision.

Article 21 The time for on-site verification, sample inspection and re-examination shall not be counted in the time of technical evaluation and registration decision. Time of evaluation shall not be included in the time of making registration decision.

Article 22 The applicant can apply for written application for administrative reconsideration to the CFDA or file an administrative appeal to the people's court whereas the applicant disagrees with the decision made by the CFDA.

Article 23 The Certificate of Approval and attachments shall include the following items:

(1) Product name,
(2) The name of the enterprise, legal representative, the address of manufacture,
(3) Registration number, approval date, and term of validity,
(4) Production process,
(5) Recipes.

The format of the registration number of the approved infant and young children milk powder formula recipes is: Guoshi Zhuzi YP+4 digits of Year +4 digit of sequence number. YP means infant and young children milk powder formula.

The term of validity of the Certificate of Approval is 5 years.

Article 24 The applicant shall submit an application demonstrating the reasons to the Acceptance Institution whereas the Certificate of Approval for registration of infant and young children milk

powder formula recipes is lost or damaged within the term of validity of registration of infant and young children milk powder formula recipes. A declaration of lost statement shall be released on the website of the food and drug administration departments at provincial, municipal and autonomous level whereas the original certificate is lost. The original copy of the Certificate of Approval of registration of infant and young children milk powder formula recipes shall be returned whereas the original certificate is damaged.

The Certificate of Approval shall be reissued within 20 working days after the day of acceptance of application by the CFDA. The original date of approval shall be marked on the reissued Certificate of Approval of the registration of infant and young children milk powder formula recipes, and also the word of "reissue" shall be marked.

Article 25 Within the term of validity of registration of infant and young children milk powder formula recipes, the applicant shall apply for change of registration if changes need to be made in the Certificate of Approval or items listed in the attachment. Following materials shall be submitted to the CFDA:

(1) Application form for change of the registration of the infant and young children milk powder formula recipes,
(2) The Certificate of Approval and the attachment of infant and young children milk powder formula recipes,
(3) Supporting materials related to the changing matters.

Article 26 If the applicant applies for the changes of the product recipes will impact the scientificity or the safety of the product formula recipes, the Review Institution shall conduct reviews according to the Article 13 in these Measures and actual needs, and draw the review conclusions.

If the applicant applies for the changes in the enterprise names, production address name and others which will not impact the scientificty and the safety of the product recipes, the Review Institution shall conduct review and provide review conclusion within 10 working days upon the acceptance. The application for change of applicant names shall be applied by the new applicant when the applicant's name changes.

The CFDA shall decide whether to approve the change of registration or not according to the review conclusion within 10 working days after receiving the conclusion from the Review Institution. Those that meet the requirements, the date of issue of the Certificate of Approval shall be subject to the date of approval of change of registration. The original registration number and the term of validity of the Certificate remains unchanged. The decision of not approval shall be made when the application of change of registration is rejected.

Article 27 The applicant shall submit the application of renewal to the CFDA 6 months before the expiration of the Certificate of Approval, and also submit the following materials:

(1) The application of renewal of infant and young children milk powder formula recipes,
(2) credential documents of the applicant,
(3) The R&D capacity, production capacity and testing capacity of the enterprise,
(4) The Self-inspection report of production quality management system of the enterprise,
(5) The tracking evaluation report of the nutrition and the safety of products,
(6) Opinions on renewal from the local food and drug administration departments at provincial, autonomous and municipal level,
(7) The Certificate of Approval of the registration of infant and young children milk powder formula recipes and its attachments.

The Review Institution shall conduct review on the application of renewal according to the article 13 in these Measures and to provide review conclusions.

The CFDA shall decide whether to approve the renewal or not according to the review conclusion within 20 working days after receiving the review conclusion from the Review Institution. The CFDA shall renew the Certificate of Approval to the applicant if the renewal has been approved. The original registration number will remain unchanged and the term of validity of the certificate shall be recalculated starting from the day of approval of renewal. The CFDA shall decide not to approve the application of renewal if the application is rejected. The application of renewal will be taken as approved if the decision hasn't been made within the timeframe.

Article 28 The application of renewal will not be approved under any one of the following circumstances:

(1) Fails to apply for the renewal within the stipulated timeframe,
(2) The applicant fails to conduct manufacturing products following the registration of the product recipes within 5 years,
(3) The enterprise fails to maintain the R&D capacity, manufacture capacity and testing capacity when registering.
(4) Any other circumstances fail to comply with relevant provisions.

Article 29 Other conditions which are not covered by the procedures of change of registration or renewal of the infant and young children milk powder formula recipes shall follow the relevant provisions about the registration of the infant and young children milk powder formula recipes in these measures.

Chapter III Labels and Instructions

Article 30 The applicant shall submit samples of both label and instruction as well as explanation and demonstration materials of the claims in label and instruction. If label and instruction contain information about the infant and young children milk powder formula recipes, such information shall be consistent with the content of the product recipe registered and registration number shall be labelled on the label.

Article 31 Whereas the product name claims on animal origin, the animal origin of dairy ingredients in use such as raw milk, milk powder, whey (protein) powder shall be labelled accurately in the ingredients list according to the product recipe. Whereas the dairy ingredients in use have more than two animal origins, the proportion of each animal source should be labelled respectively.

For edible vegetable oil in the ingredient list of infant and young children milk powder formula, the names of individual types of edible vegetable oil shall be specified in a decreasing order according to the dosage.

Nutritional facts of infant and young children milk powder formula shall be listed according to the sequence of ingredients in the food safety national standard for infant and young children milk powder formula, and classified into the categories of energy, protein, fats, carbohydrates, vitamins, minerals, optional ingredients and so on.

Article 32 The infant and young children milk powder formula that claims on the ingredient source of raw milk, milk powder ingredients and other dairy ingredients shall specify the country of origin or place of origin. It is forbidden to label "imported milk sources", "origin from overseas dairy farm", "ecologic dairy farm" as well as other vague wording.

Article 33 The applicable age group of infant and young children milk powder formula shall be specified in the claim and it is allowed to specify by "Stage1, Stage 2 or Stage 3" at the same time.

Article 34 The claims of infant and young children milk powder formula shall not contain any of the following items:

(1) Being related to disease-preventing and therapeutic function,

(2) Expressing or implying that the product has any healthcare functions,

(3) Expressing or implying that the product has the functions of benefiting intelligence, strengthening the immune system and protecting intestinal tract,

(4) For substance that shall not be used or will not be contained in the product recipe according to the food safety standards, it is forbidden to use words such as "no addition" "no contain" and "zero addition" to emphasise the substance is not used / contained,

(5) False, exaggerated or extreme content,

(6) Contents or claims that is not consistent with the content of the registered product recipe.

Chapter IV Supervision and Inspection

Article 35 The institutions and personnel who undertake the work of technical review, on-site verification, sampling inspection and expert argumentation during the registration of infant and young children milk powder formula recipe shall be responsible for the review conclusions, on-site verification reports, the product test reports and the expert advice issued.

The institutions and personnel who undertake the work of technical review, on-site verification, sampling inspection and expert argumentation during the registration of infant and young children milk powder formula recipe shall follow the provisions of the relevant laws, regulations and standards, as well as abide by professional ethics. They shall conduct the review, on-site verification and sampling

inspection of the recipe for infant and young children milk powder formula according to the food safety national standards and technical regulations, enduring that the relevant work is scientific, objective and justified.

Article 36 The food and drug supervision and administration departments that receive reports on the illegal behaviours of application acceptance, technical review, on-site verification, sampling inspection, expert argumentation or registration approval during the recipe registration of infant and young children milk powder formula, shall verify and process the case on a timely basis.

Article 37 The CFDA shall release the catalogue information of the registered infant and young children milk powder formula recipes within 20 working days upon approval.

Article 38 The institutions and personnel who undertake the work of technical review, on-site verification, sampling inspection and expert argumentation during the registration of infant and young children milk powder formula recipe shall maintain the confidentiality of the trade secret informed.

The applicant shall mark the trade secret in the application materials according to the relevant provisions and cite the reference.

Article 39 If the applicant denies the required on-site verification or sampling inspection, the CFDA shall not approve its application for product recipe registration.

Article 40 The CFDA can revoke the Certificate of Approval according to its responsibilities or the request of interested parties under any of the following circumstances:

(1) The approval is granted due to the misuse of authority or dereliction of duty by the personnel,
(2) The approval is granted by overstepping the legal authority,
(3) The approval is granted while violating the legal process,

(4) The approval is granted to the applicant that is not qualified for application or does not comply with the legal qualifications,

(5) Other legal conditions for revocation of the Certificate of Approval.

Article 41 The CFDA shall cancel the registration of the Certificate of Approval under any of the following circumstances:

(1) The enterprise applies for cancellation,

(2) The enterprise is terminated in accordance with the laws,

(3) The Certificate of Approval expires and is not renewed,

(4) The registration is revoked, withdrawn or the Certificate of Approval is revoked according to the law,

(5) Other legal conditions for cancellation of the registration.

Chapter V Legal Liability

Article 42 Whereas there are provisions in the *Food Safety Law* and other laws regulations on the violations of the registration of infant and young children milk powder formula recipe, those provisions shall prevail.

Article 43 Whereas the applicant conceals relevant conditions or provides false materials or samples to apply for the registration of infant and young children milk powder formula recipe, the CFDA shall not accept the application nor approve the application, give a warning to the applicant, and announce to the public. The applicant shall not re-apply for the registration of infant and young children milk powder formula recipe within 1 year. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Whereas the applicant obtains the Certificate of Approval by fraud, bribery or other improper means, or concealing relevant real conditions or providing false materials, the Certificate of Approval shall be revoked in accordance with the law. A penalty of 10000 to 30000 RMB will be imposed to the applicant. Applications for registration submitted by the applicant will not be accepted within 3 years. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Article 44 Whereas the applicant fails to apply for modification according to these Measures, which does not impact the scientificity or the product safety, the food and drug supervision and administration departments at or above the county level shall request the applicant to correct and give a warning to the applicant. If the applicant still refuses to correct, a penalty of 10000 to 30000 RMB will be imposed to the applicant.

Whereas the applicant fails to apply for modification according to these Measures, which impacts the scientificity or the product safety, the food and drug supervision and administration departments at or above the county level shall impose penalty according to the provisions in the Article 124 of the *Food Safety Law*.

Article 45 Whereas the applicant forges, alters, resells, rents or transfers the Certificate of Approval for the registration of infant and young children milk powder formula recipe, the food and drug supervision and administration departments at or above the county level shall order the applicant to correct, give a warning and impose a penalty below 10000 RMB. For serious cases, a penalty of 10000 to 30000 RMB shall be imposed to the applicant. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Article 46 Whereas the manufacturer or the seller of infant and young children milk powder violates the provisions of Article 30 to Article 34 of these Measures, the food and drug supervision and

administration departments shall order the applicant to correct and impose a penalty of 10000 to 30000 RMB according to these Measures.

Article 47 Whereas the food and drug supervision and administration departments and their personnel approve the registration of the applicant who is not qualified or approve the registration overstepping the legal authority, actions shall be taken according to the provisions in the Article 144 of the *Food Safety Law.*

Whereas the food and drug supervision and administration departments and their personnel misuse authority, neglect their duties and practice favoritism during the review process, actions shall be taken according to the provisions in the Article 145 of the *Food Safety Law.*

Chapter VI Supplementary Provisions

Article 49 The recipe of infant and young children milk powder formula mentioned in these Measures means all food ingredients, food additives and their dosage used in manufacturing infant and young children formula milk powder, as well as the contents of nutrients in the product.

Article 50 These Measures shall enter into force on Oct 1, 2016.