Administrative Measures for Product Formula Registration of Infants and Young Children Formula Milk Powder (Order No. 26 of China Food and Drug Administration)

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No. 26

Adopted by CFDA at meeting on March 15, 2016, "Administrative Measures for Product Formula Registration of Infants and Young Children Formula Milk Powder" is now promulgated and shall take effect as of October 1, 2016.

Director General: Bi Jingquan

June 6, 2016

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

Chapter I General Principles

Article 1 In order to carry out strictly administration over the product formula registration of infants and young children formula milk powder and ensure the quality of infants and young children formula milk powder safe, the Measures are hereby formulated in accordance with such laws and regulations as Food Safety Law of the People's Republic of China.

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

Article 3 Product formula registration of infants and young children formula milk powder refers to the approval process that CFDA performs a review on the product formula of the infants and young children formula milk powder applying for registration in accordance with the procedures and provisions of the Measures, and then decides whether to approve the registration.

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

Article 5 CFDA is responsible for the administration over the product formula registration of infants and young children formula milk powder.

The administrative licensing acceptance institutions under CFDA (hereafter referred to as acceptance institution) are responsible for the acceptance of product formula registration of infants and young children formula milk powder.

The food review institutions under CFDA (hereafter referred to as review institution) are responsible for the review of product formula registration of infants and young children formula milk powder.

The examination and verification institutions under CFDA (hereafter referred to as examination and verification institution) are responsible for the on-site verification of product formula registration of infants and young children formula milk powder.

The food and drug administration departments of province, autonomous region and municipality directly under the central government shall take responsibilities to coordinate with CFDA to carry out on-site verification on product formula registration of infants and young children formula milk powder in their respective administrative areas.

Article 6 The applicant shall be responsible for the authenticity, integrity and legitimacy of the materials submitted thereby and bear legal liability.

The applicant shall assist food and drug administration departments to carry out on-site verification and sampling inspection related to registration.

Chapter II Application and Registration

Article 7 The applicant shall be the manufacturing enterprises which plan to product and sell infants and young children formula milk powder within the territory of People’s Republic of China or overseas manufacturing enterprises which plan to import infants and young children formula milk powder to People’s Republic of China.

The applicant shall possess research & development ability, production ability and test ability corresponding with produced infants and young children formula milk powder, conform to the requirements of good manufacturing practices (GMPs) for powdered formula foods for infants and young children, carry out the hazard analysis and critical control point system and perform lot by lot inspection of outgoing products according to relevant laws and regulations and items specified by national food safety standard on infants and young children formula milk powder.

Article 8 The application for product formula registration shall comply with requirements of relevant laws and regulations and national food safety standards, and research & development and demonstration report

as well as sufficient evidence which can prove the scientificity and safety of product formula shall be provided.

In case of application for product formula registration of infants and young children formula milk powder, the following materials shall be submitted to CFDA:

(I) Application for product formula registration of infants and young children formula milk powder;

(II) Qualification certificates of applicant subject;

(III) Quality safety standards for raw and auxiliary materials;

(IV) Development and research report on product formula;

(V) Descriptions on production technology;

(VI) Product test report;

(VII) Evidentiary materials proving the development & research, production and test ability;

(VIII) Other materials proving the scientificity and safety of the product formula.

Article 9 There shall be distinct differences among more than two product formulas designed for the same age group applying for registration by the same enterprise, which shall be confirmed by scientific basis. Each enterprise shall hold no more than 9 product formulas of 3 formula series, each of which includes infant formula (0~6 months, stage 1), older infant formula (6~12 months, stage 2) and young children formula (12~36 months, stage 3).

Article 10 The wholly-owned subsidiary, which has obtained the product formula registration and production license of infants and young children formula milk powder, may use the registered product formula of infants and young children formula milk powder of another wholly-owned subsidiary within the same group company. The group company shall submit written report to CFDA before organizing production.

Article 11 For the application for product formula registration of infants and young children formula milk powder proposed by applicant, the acceptance institution shall handle respectively based on the following circumstances:

(I) Where the applying items is not necessary to register by law, the acceptance institution shall immediately inform the applicant of refusal on application;

(II) Where the applying items are not under the jurisdiction of CFDA by law, the acceptance institution shall immediately make a decision on refusal of application and inform the applicant that it shall file the application to relevant administrations;

(III) Where the mistakes of application materials can be corrected on the spot, it shall be allowed to correct on the spot;

(IV) Where the application materials are incomplete or fail to comply with statutory form, CFDA shall notify the applicant about all the contents necessary to be supplemented at one time on the spot or within 5 workdays; it is deemed to have accepted the application since the date of receiving the application materials if the applicant is not notified within the prescribed time limit;

(V) Where the application materials are complete and in compliance with statutory form, or the applicant submits all the corrected application materials as requested, the registration application shall be accepted.

For acceptance or refusal of the registration application, the acceptance institution shall issue dated written certificates with special seal of administrative licensing acceptance stamped by CFDA.

Article 12 The acceptance institution shall deliver the application materials to review institution within 3 workdays after acceptance.

Article 13 The review institution shall review the conformance between the application materials as well as product formula claim and product formula registration content, notify examination and verification institution to carry out on-site verification on the applicant based on actual requirements, organize inspection institution to carry out sampling inspection, organize professors to demonstrate professional matters, and complete the review within 60 workdays from receiving the accepted materials.

In particular cases where the review time shall be prolonged, it can be extended for another 30 workdays with the consent of director of review institution. The decision on extension shall be informed to the applicant in written form.

Article 14 The examination and verification institution shall make on-site verification on research & development ability, production ability and test ability of applicant within 20 workdays from the date of accepting notice of review institution and issue on-site verification report.

The examination and verification institution shall notify the provincial food and drug administration department where the applicant is located to participate in the on-site verification, and the above mentioned department shall dispatch staff in verification.

Article 15 The review institution shall entrust the qualified food inspection institutes to carry out the sampling inspection.

The inspection institution shall complete sampling inspection work within 30 workdays from the acceptance date and issue product inspection report.

Article 16 It shall be determined according to actual conditions for the working time limit of on-site verification and sampling inspection on overseas manufacturing enterprise.

Article 17 The review institution shall carry out review on the basis of application materials, on-site verification report and product inspection report and make a review conclusion.

Article 18 The review institution shall issue a written notice on refusal of registration to the applicant in case of making a decision on refusal of registration. The applicant shall propose a written re-examination application and explain re-examination reason within 20 workdays from acceptance date where he/she is objectionable to the notice. The re-examination content is limited to original application items and materials.

The review institution shall make a decision on the re-examination within 30 workdays from accepting re-examination application and notify the applicant in written form.

Article 19 The review institution shall notify all the contents need to be supplemented and corrected once where it considers necessary to supplement and correct materials. The applicant shall supplement materials once in accordance with the notice on supplementation and correction within 3 months. The time of supplementing and correcting materials is not counted in review time. Failure to supplement and correct in due time, it shall be regarded as not providing materials any more.

Article 20 CFDA shall make a decision on approval or refusal of registration within 20 workdays from the date of acceptance.

The acceptance institution shall issue Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder or notify the applicant of a decision on refusal of registration within 10 workdays from the date of making decision by CFDA.

Article 21 The time necessary for on-site verification, sampling inspection and re-examination is not counted in time limit of technical review and registration decision. The review time is not counted in time limit of registration decision.

Article 22 The applicant may propose administration review application in written form towards CFDA or propose administrative lawsuit towards People's Court where he/she is objectionable to the decision on refusal of registration made by CFDA.

Article 23 The content of Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder and attachments shall include the following items:

(I) Product name;

(II) Enterprise name, legal representative and production address;

(III) Registration number, approval date and validity period;

(IV) Production technology;

(V) Product formula.

The format of registration number for Product Formula of Infants and young children formula milk powder is: GSZZ YP+four-digital year number+4-digital serial number, among which YP stands for product formula of infants and young children formula milk powder.

The validity period of Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder is 5 years.

Article 24 Within the validity period of Product Formula Registration of Infants and Young Children Formula Milk Powder, where the Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder is lost or damaged, the applicant shall propose application in written form towards acceptance institution and explain reasons. He/she shall publish lost declaration on the websites of food and drug administration department of province, autonomous region and municipality directly under the central government in case of applying for reissuance because of losing; and return the original Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder in case of applying for reissuance because of damage.

CFDA shall grant for its reissuance within 20 workdays from the date of acceptance. The reissued Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder shall sign original registration date and indicate the word “Reissued”.

Article 25 Within the validity period of Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder, the applicant shall propose change application for registration towards CFDA and submit the following materials where it is necessary to alternate registration certificate and contents specified on attachments:

(I) Change Application for Product Formula Registration of Infants and Young Children Formula Milk Powder;

(II) Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder and attachments;

(III) Materials relevant to change items.

Article 26 The review institution shall organize and carry out review according to the provisions of Article 13 in the Measures based on actual requirements and make review conclusions where applying for changing product formula by the applicant may influence the scientificity and safety of product formula.

The review institution shall verify and make a conclusion within 10 workdays from the acceptance date where applying for changing enterprise name and production address by the applicant may not influence the scientificity and safety of product formula. Where the name of applicant has been changed, it shall be applied for changing by applicant after changing.

CFDA shall make a decision on approval or disapproval according to the conclusions of the review within 10 workdays from accepting the review conclusion. In case of complying with requirements, CFDA shall handle registration change procedures by law, and the issue date of registration certificate is subject to approval date of change, the original registration number and validity period of certificate remain the same. In case of disapproving the change of registration, CFDA shall make a decision on disapproval of registration change.

Article 27 In case the validity period of Product Formula Registration of Infants and Young Children Formula Milk Powder is expired and needs to be renewed, the applicant shall propose renewal application towards CFDA 6 months before expiration date and submit the following materials:

(I) Renewal Application for Product Formula Registration of Infants and Young Children Formula Milk Powder;

(II) Qualification certificates of applicant subject;

(III) Research & development ability, production ability and test ability of enterprise;

(IV) Self-inspection report of quality management system of enterprise production;

(V) Tracking assessment of nutrition and safety of products;

(VI) Opinions on renewal of registration issued by food and drug administration departments in the province, autonomous region and municipality directly under the central government where the production enterprise is located;

(VII) Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder and attachments.

The review institution shall organize and carry out review on the renewal application for registration on the basis of article 13 in the Measures based on actual requirements and make review conclusions.

CFDA shall make a decision on approval or disapproval according to the conclusions of the review within 20 workdays from the acceptance date. The registration certificate shall be renewed for applicant in case of approving the renewal of registration, and the registration number will remain the same and the period of validity will be recounted as of the day of approval; a decision on disapproval of registration renewal shall be provided to applicant in case of disapproving the renewal of registration. In case the decisions are not made overdue, it shall be deemed approval.

Article 28 In case of any of the following circumstances, the registration renewal shall be refused:

(I) Where the renewal application for registration is not proposed within the prescribed time limit;

(II) Where the enterprise does not organize production in accordance with registered formula within 5 years after registering product formula;

(III) Where the enterprise fails to maintain the research & development ability, production ability and test ability at registration;

(IV) Other circumstances failing to comply with relevant provisions.

Article 29 Where there are no provisions on the procedures for change and renewal of product formula registration of infants and young children formula milk powder, the relevant provisions on product formula registration of infants and young children specified by the Measures shall apply.

Chapter III Label and Specification

Article 30 Where applying for product formula registration of infants and young children formula milk powder, the applicant shall submit sample manuscript of label and specification and explanatory and evidentiary materials declared in the label and specification.

Where the label and specification involves product formula of the infants and young children formula milk powder, it shall be consistent with that in the registered product formula and the registration number shall be marked.

Article 31 Where the product name contains animal origin, the animal origin of dairy raw materials used, such as raw milk, milk powder, and whey (protein) powder, shall be indicated in the List of Ingredients based on product formula. In case the dairy raw materials used have more than two animal origins, the proportion of raw materials with different animal origins shall be indicated.

The specific name of edible vegetable oil shall be indicated in the List of Ingredients according to the descending order of addition amount.

Nutrition Facts shall be indicated in accordance with the nutrients order stipulated by the national food safety standard for infants and young children formula milk powder and according to the categories such as energy, protein, fat, carbohydrates, vitamins, minerals and optional components, *etc*.

Article 32 Where the source of raw materials, such as raw milk or raw material powder, is declared, the specific place of origin or country of origin shall be truthfully indicated, and the fuzzy information such as “imported milk source”, “originate from foreign pasture”, “ecological pasture” and “imported raw materials” shall not be used.

Article 33 The suitable month age of infants and young children formula milk powder shall be indicated in the claims, with simultaneous use of “Stage1, Stage 2, Stage 3”.

Article 34 The label and specification shall not contain the following contents:

(I) The contents concerning function of disease prevention and disease treatment;

(II) The contents explicitly or implicitly declaring the function of health care;

(III) The contents explicitly or implicitly declaring the functions such as “be beneficial to intellectual development”, “increase the resistance or immunity” and “protect the intestinal function”, *etc*.;

(IV) The words such as “no adding”, “no containing” and “additive free”, *etc*. used to emphasize no use or no containing of a certain substance that shall not be used or contained in the product formula according to the food safety standard;

(V) False, exaggerated and absolute contents and those in violation of scientific principle;

(VI) Claims inconsistent with the content of product formula registration.

Chapter IV Supervision and Management

Article 35 Institutions and personnel that take charge of technical review, on-site verification, sampling inspection, expert argumentation for the product formula registration of infants and young children formula milk powder shall be responsible for the issued review conclusion, on-site verification report, product test report and expert opinion, *etc*.

Institutions and personnel that take charge of technical review, on-site verification, sampling inspection, expert argumentation for the product formula registration of infants and young children formula milk powder shall abide by professional ethics according to the provision of relevant laws, regulations and rules, and carry out the technical review, on-site verification and sampling inspection according to the national food safety standard and technical specification, so as to ensure the scientificity, objectivity and fairness of relevant works.

Article 36 The food and drug administration department shall verify and handle the problem timely after receiving the report from relevant units or individuals about violations of laws and regulations in the works related to product formula registration of infants and young children formula milk powder, such as acceptance, technical review, on-site verification, sampling inspection, expert argumentation and approval, *etc*.

Article 37 CFAD shall publish catalog information of product formula registration of infants and young children formula milk powder within 30 days from the date of approval.

Article 38 Institutions and personnel participating in the application acceptance, technical review, on-site verification, sampling inspection and expert argumentation for the formula registration of the infants and young children formula milk powder shall keep business secrets known during the registration.

The applicant shall mark the business secret in the application materials and indicate the basis according to relevant national provisions.

Article 39 Where the applicant refuses the on-site verification and sampling inspection, CFDA shall disapprove the product formula registration of infants and young children formula milk powder.

Article 40 CFDA shall revoke the product formula registration of infants and young children formula milk powder according to their authority and request from the interested party, in case of any of the following circumstances:

(I) Where the staffs abuse powder and neglect of duty to make the decision on approval of registration;

(II) Where the decision on approval of registration is made by exceeding legitimate authority;

(III) Where the decision on approval of registration is made in violation of legal procedures;

(IV) Where the applicant having no qualification for application or failing to meet the statutory conditions has been approved for registration;

(V) Other circumstances under which the registration may be revoked in accordance with the law.

Article 41 CFDA shall cancel the product formula registration of infants and young children formula milk powder according to law, in case of any of the following circumstances:

(I) Where the enterprise applies for cancellation;

(II) Where the enterprise terminates according to law;

(III) Where the certificate expires and the enterprise has not applied for extension;

(IV) Where the registration is revoked or withdrawn according to law, or the registration certificate is revoked according to law;

(V) Other circumstances that shall be cancelled as stipulated in laws and regulations.

Chapter V Legal Responsibilities

Article 42 Where Food Safety Standard and other relevant laws and regulations stipulate the provisions on the unlawful acts related to product formula registration of infants and young children formula milk powder, the aforesaid provisions shall prevail.

Article 43 Where the applicant conceals relevant information or provides false materials and samples during the application for product formula registration of infants and young children formula milk powder, CFDA shall refuse the acceptance of application or approval of the registration, give the applicant warning and announce to the public. The applicant shall not apply for product formula registration of infants and young children formula milk powder again within a year; for suspected criminal cases, it shall be transferred to the public security organization, and the criminal liability shall be prosecuted.

Where the applicant acquires the Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder by the improper means such as deception and bribery, *etc*., or in the manners such as concealing the true situation and submitting false materials, *etc*., CFDA shall revoke the certificate according to law and impose a fine of not less than 10000 yuan and not more than 30000 yuan. The licensed applicant shall not apply for registration again within three years; for suspected criminal cases, it shall be transferred to the public security organization, and the criminal liability shall be prosecuted.

Article 44 Where the applicant change matters having no effect on the scientificity and safety of product formula but do not apply for change according to law, it shall be instructed to correct and given a warning by the food and drug administration departments above county level; where the applicant refuses to correct, a fine of not less than 10000 yuan and not more than 30000 yuan shall be imposed.

Where the applicant change matters having effect on the scientificity and safety of product formula but do not apply for change according to law, it shall be punished by the food and drug administration departments above county level according to the provisions of Article 124 in Food Safety Law.

Article 45 Where the Product Formula Registration Certificate of Infants and Young Children Formula Milk Powder is forged, altered, sold, leased, lend, transferred, it shall be instructed to correct and given a warning by the food and drug administration departments above county level and a fine of not more than 10000 yuan shall be imposed; for serious violations, a fine of not less than 10000 yuan and not more than 30000 yuan shall be imposed; for suspected criminal cases, it shall be transferred to the public security organization, and the criminal liability shall be prosecuted.

Article 46 Where the producers and distributors of infants and young children formula milk powder violate the provisions of Article 30 ~ 34 in the Measures, it shall be instructed to correct and given a warning by the food and drug administration departments, and a fine of not less than 10000 yuan and not more than 30000 yuan shall be imposed according to the law.

Article 47 Where the food and drug administration departments and the staffs thereof approve the registration of applicant failing to meet the conditions or approve the registration by exceeding legitimate authority, it shall be published according to the provisions of Article 144 in Food Safety Law.

Where the food and drug administration departments and the staffs thereof abuse powder, neglect duty and play favoritism or fraud in the process of the registration, it shall be published according to provisions of Article 145 in Food Safety Law.

Chapter VI Supplementary Provisions

Article 48 The product formula of infants and young children formula milk powder referred in the Measures refers to the food raw materials and food additives used for production of infants and young children formula milk powder and their usage amount as well as the nutrition content of the product.

Article 49 The Measures shall enter into force from October 1, 2016.

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Business contact person: Chloe Liu (Miss Liu)
Tel: 0535-2126613; QQ: 858875285
E-mail: trans.foodmate@qq.com or trans@foodmate.net
On-line store of Food Translation Center: http://mall.foodmate.net/store-10.html

婴幼儿配方乳粉产品配方注册管理办法

第一章 总 则

第一条 为严格婴幼儿配方乳粉产品配方注册管理，保证婴幼儿配方乳粉质量安全，根据《中华人民共和国食品安全法》等法律法规，制定本办法。

第二条 在中华人民共和国境内生产销售和进口的婴幼儿配方乳粉产品配方注册管理，适用本办法。

第三条 婴幼儿配方乳粉产品配方注册，是指国家食品药品监督管理总局依据本办法规定的程序和要求，对申请注册的婴幼儿配方乳粉产品配方进行审评，并决定是否准予注册的活动。

第四条 婴幼儿配方乳粉产品配方注册管理，应当遵循科学、严格、公开、公平、公正的原则。

第五条 国家食品药品监督管理总局负责婴幼儿配方乳粉产品配方注册管理工作。

国家食品药品监督管理总局行政受理机构（以下简称受理机构）负责婴幼儿配方乳粉产品配方注册申请的受理工作。

国家食品药品监督管理总局食品审评机构（以下简称审评机构）负责婴幼儿配方乳粉产品配方注册申请的审评工作。

国家食品药品监督管理总局审核查验机构（以下简称核查机构）负责婴幼儿配方乳粉产品配方注册的现场核查工作。

省、自治区、直辖市食品药品监督管理部门负责配合国家食品药品监督管理总局开展本行政区域婴幼儿配方乳粉产品配方注册的现场核查等工作。

第六条 申请人应当对提交材料的真实性、完整性、合法性负责，并承担法律责任。

申请人应当协助食品药品监督管理部门开展与注册相关的现场核查、抽样检验等工作。

第二章 申请与注册

第七条 申请人应当为拟在中华人民共和国境内生产并销售婴幼儿配方乳粉的生产企业或者拟向中华人民共和国出口婴幼儿配方乳粉的境外生产企业。

申请人应当具备与所生产婴幼儿配方乳粉相适应的研发能力、生产能力、检验能力，符合粉状婴幼儿配方食品良好生产规范要求，实施危害分析与关键控制点体系，对出厂产品按照有关法律法规和婴幼儿配方乳粉食品安全国家标准规定的项目实施逐批检验。

第八条 申请注册产品配方应当符合有关法律法规和食品安全国家标准的要求，并提供证明产品配方科学性、安全性的研发与论证报告和充足依据。

申请婴幼儿配方乳粉产品配方注册，应当向国家食品药品监督管理总局提交下列材料：

（一）婴幼儿配方乳粉产品配方注册申请书；

（二）申请人主体资质证明文件；

（三）原辅料的质量安全标准；

（四）产品配方研发报告；

（五）生产工艺说明；

（六）产品检验报告；

（七）研发能力、生产能力、检验能力的证明材料；

（八）其他表明配方科学性、安全性的材料。

第九条 同一企业申请注册两个以上同年龄段产品配方时，产品配方之间应当有明显差异，并经科学证实。每个企业原则上不得超过 3 个配方系列 9 种产品配方，每个配方系列包括婴儿配方乳粉（0—6 月龄，1 段）、较大婴儿配方乳粉（6—12 月龄，2 段）、幼儿配方乳粉（12—36 月龄，3 段）。

第十条 同一集团公司已经获得婴幼儿配方乳粉产品配方注册及生产许可的全资子公司可以使用集团公司内另一全资子公司已经注册的婴幼儿配方乳粉产品配方。组织生产前，集团公司应当向国家食品药品监督管理总局提交书面报告。

第十一条 受理机构对申请人提出的婴幼儿配方乳粉产品配方注册申请，应当根据下列情况分别作出处理：

（一）申请事项依法不需要进行注册的，应当即时告知申请人不受理；

（二）申请事项依法不属于国家食品药品监督管理总局职权范围的，应当即时作出不予受理的决定，并告知申请人向有关行政机关申请；

（三）申请材料存在可以当场更正的错误的，应当允许申请人当场更正；

（四）申请材料不齐全或者不符合法定形式的，应当当场或者在5个工作日内一次告知申请人需要补正的全部内容；逾期不告知的，自收到申请材料之日起即为受理；

（五）申请材料齐全、符合法定形式，或者申请人按照要求提交全部补正申请材料的，应当受理注册申请。

受理机构受理或者不予受理注册申请，应当出具加盖国家食品药品监督管理总局行政许可受理专用章和注明日期的书面凭证。

第十二条 受理机构应当在受理后3个工作日内将申请材料送交审评机构。

第十三条 审评机构应当对申请材料以及产品配方声称与产品配方注册内容的一致性进行审查，并根据实际需要通知核查机构对申请人开展现场核查，组织检验机构开展抽样检验，组织专家对专业问题进行论证，自收到受理材料之日起60个工作日内完成审评工作。

特殊情况下需要延长审评时间的，经审评机构负责人同意，可以延长30个工作日，延长决定应当书面告知申请人。

第十四条 核查机构应当自接到审评机构通知之日起20个工作日内完成对申请人研发能力、生产能力、检验能力等情况的现场核查，出具现场核查报告。

核查机构应当通知申请人所在地省级食品药品监督管理部门参与现场核查，省级食品药品监督管理部门应当派员参与。

第十五条 审评机构应当委托具有法定资质的食品检验机构开展抽样检验。

检验机构应当自接受委托之日起30个工作日内完成抽样检验工作，出具产品检验报告。

第十六条 对境外生产企业现场核查、抽样检验的工作时限，根据实际情况确定。

第十七条 审评机构应当根据申请人申请材料、现场核查报告、产品检验报告开展审评，并作出审评结论。

第十八条 审评机构作出不予注册审评结论的，应当向申请人发出拟不予注册的书面通知。申请人对通知有异议的，应当自收到通知之日起 20 个工作日内向审评机构提出书面复审申请并说明复审理由。复审的内容仅限于原申请事项及申请材料。

审评机构应当自受理复审申请之日起 30 个工作日内作出复审决定，并书面通知申请人。

第十九条 审评机构认为需要申请人补正材料的，应当一次性告知需要补正的全部内容。申请人应当在 3 个月内按照补正通知的要求一次补正材料。补正材料的时间不计算在审评时间内。逾期未补正的，按申请人不再提供补正材料处理。

第二十条 国家食品药品监督管理总局自受理申请之日起20个工作日内根据审评结论作出准予注册或者不予注册的决定。

受理机构应当自国家食品药品监督管理总局作出决定之日起 10 个工作日内向申请人发出婴幼儿配方乳粉产品配方注册证书或者不予注册决定。

第二十一条 现场核查、抽样检验、复审所需时间不计算在技术审评和注册决定的期限内。审评时间不计算在注册决定的期限内。

第二十二条 申请人对国家食品药品监督管理总局作出不予注册决定有异议的，可以向国家食品药品监督管理总局提出书面行政复议申请或者向人民法院提起行政诉讼。

第二十三条 婴幼儿配方乳粉产品配方注册证书及附件应当载明下列事项：

（一）产品名称；

（二）企业名称、法定代表人、生产地址；

（三）注册号、批准日期及有效期；

（四）生产工艺；

（五）产品配方。

婴幼儿配方乳粉产品配方注册号格式为：国食注字 YP＋4 位年代号＋4 位顺序号，其中 YP 代表婴幼儿配方乳粉产品配方。

婴幼儿配方乳粉产品配方注册证书有效期为 5 年。

第二十四条 婴幼儿配方乳粉产品配方注册有效期内，婴幼儿配方乳粉产品配方注册证书遗失或者损毁的，申请人应当向受理机构提出书面申请并说明理由。因遗失申请补发的，应当在省、自治区、直辖市食品药品监督管理部门网站上发布遗失声明；因损坏申请补发的，应当交回婴幼儿配方乳粉产品配方注册证书原件。

国家食品药品监督管理总局自受理之日起 20 个工作日内予以补发。补发的婴幼儿配方乳粉产品配方注册证书应当标注原批准日期，并注明“补发”字样。

第二十五条 婴幼儿配方乳粉产品配方注册证书有效期内，需要变更注册证书及其附件载明事项的，申请人应当向国家食品药品监督管理总局提出变更注册申请，并提交下列材料：

（一）婴幼儿配方乳粉产品配方变更注册申请书；

（二）婴幼儿配方乳粉产品配方注册证书及附件；

（三）与变更事项有关的证明材料。

第二十六条 申请人申请产品配方变更等可能影响产品配方科学性、安全性的，审评机构应当根据实际需要按照本办法第十三条的规定组织开展审评，并作出审评结论。

申请人申请企业名称变更、生产地址名称变更等不影响产品配方科学性、安全性的，审评机构应当进行核实，并自受理机构受理之日起 10 个工作日内作出结论。申请人名称变更的，应当由变更后的申请人申请变更。

国家食品药品监督管理总局自接到审评结论之日起 10 个工作日内根据审评结论作出准予变更或者不予变更的决定。对符合条件的，依法办理变更手续，注册证书发证日期以变更批准日期为准，原注册号不变，证书有效期保持不变；不予变更注册的，作出不予变更注册决定。

第二十七条 婴幼儿配方乳粉产品配方注册证书有效期届满需要延续的，申请人应当在注册证书有效期届满 6 个月前向国家食品药品监督管理总局提出延续注册申请，并提交下列材料：

（一）婴幼儿配方乳粉产品配方延续注册申请书；

（二）申请人主体资质证明文件；

（三）企业研发能力、生产能力、检验能力情况；

（四）企业生产质量管理体系自查报告；

（五）产品营养、安全方面的跟踪评价情况；

（六）生产企业所在地省、自治区、直辖市食品药品监督管理部门延续注册意见书；

（七）婴幼儿配方乳粉产品配方注册证书及附件。

审评机构应当根据实际需要对延续注册申请按照本办法第十三条组织开展审评，并作出审评结论。

国家食品药品监督管理总局自受理申请之日起20个工作日内作出准予延续注册或者不予延续注册的决定。准予延续注册的，向申请人换发注册证书，原注册号不变，证书有效期自批准之日起重新计算；不予延续注册的，应当作出不予延续注册决定。逾期未作决定的，视为准予延续。

第二十八条 有下列情形之一的，不予延续注册：

（一）未在规定时限内提出延续注册申请的；

（二）申请人在产品配方注册后5年内未按照注册配方组织生产的；

（三）企业未能保持注册时研发能力、生产能力、检验能力的；

（四）其他不符合有关规定的情形。

第二十九条 婴幼儿配方乳粉产品配方变更注册与延续注册的程序未作规定的，适用本办法有关婴幼儿乳粉产品配方注册的相关规定。

第三章 标签与说明书

第三十条 申请人申请婴幼儿配方乳粉产品配方注册的，应当提交标签和说明书样稿及标签、说明书中声称的说明、证明材料。

标签和说明书涉及婴幼儿配方乳粉产品配方的，应当与获得注册的产品配方的内容一致，并标注注册号。

第三十一条 产品名称中有动物性来源的，应当根据产品配方在配料表中如实标明使用的生乳、乳粉、乳清（蛋白）粉等乳制品原料的动物性来源。使用的乳制品原料有两种以上动物性来源时，应当标明各种动物性来源原料所占比例。

配料表应当将食用植物油具体的品种名称按照加入量的递减顺序标注。

营养成分表应当按照婴幼儿配方乳粉食品安全国家标准规定的营养素顺序列出，并按照能量、蛋白质、脂肪、碳水化合物、维生素、矿物质、可选择性成分等类别分类列出。

第三十二条 声称生乳、原料乳粉等原料来源的，应当如实标明具体来源地或者来源国，不得使用“进口奶源”“源自国外牧场”“生态牧场”“进口原料”等模糊信息。

第三十三条 声称应当注明婴幼儿配方乳粉适用月龄，可以同时使用“1 段、2 段、3 段”的方式标注。

第三十四条 标签和说明书不得含有下列内容：

（一）涉及疾病预防、治疗功能；

（二）明示或者暗示具有保健作用；

（三）明示或者暗示具有益智、增加抵抗力或者免疫力、保护肠道等功能性表述；

（四）对于按照食品安全标准不应当在产品配方中含有或者使用的物质，以“不添加”“不含有”“零添加”等字样强调未使用或者不含有；

（五）虚假、夸大、违反科学原则或者绝对化的内容；

（六）与产品配方注册的内容不一致的声称。

第四章 监督管理

第三十五条 承担婴幼儿配方乳粉产品配方注册技术审评、现场核查、抽样检验、专家论证的机构和人员应当对出具的审评结论、现场核查报告、产品检验报告、专家意见等负责。

婴幼儿配方乳粉产品配方注册技术审评、现场核查、抽样检验、专家论证的机构和人员应当依照有关法律、法规、规章的规定，恪守职业道德，按照食品安全国家标准、

技术规范等对婴幼儿配方乳粉产品配方进行技术审评、现场核查和抽样检验，保证相关工作科学、客观和公正。

第三十六条 食品药品监督管理部门接到有关单位或者个人举报的婴幼儿配方乳粉产品配方注册受理、技术审评、现场核查、抽样检验、专家论证、审批等工作中的违法违规行为，应当及时核实处理。

第三十七条 国家食品药品监督管理总局自批准之日起20个工作日内公布婴幼儿配方乳粉产品配方注册目录信息。

第三十八条 参与婴幼儿配方乳粉注册申请受理、技术审评、现场核查、抽样检验、专家论证等工作的机构和人员，应当保守在注册中知悉的商业秘密。

申请人应当按照国家有关规定对申请材料中的商业秘密进行标注并注明依据。

第三十九条 申请人拒绝现场核查或者抽样检验的，国家食品药品监督管理总局不批准其产品配方注册申请。

第四十条 有下列情形之一的，国家食品药品监督管理总局依据职权或者根据利害关系人的请求，可以撤销婴幼儿配方乳粉产品配方注册：

（一）工作人员滥用职权、玩忽职守作出准予注册决定的；

（二）超越法定职权作出准予注册决定的；

（三）违反法定程序作出准予注册决定的；

（四）对不具备申请资格或者不符合法定条件的申请人准予注册的；

（五）依法可以撤销注册的其他情形。

第四十一条 有下列情形之一的，由国家食品药品监督管理总局注销婴幼儿配方乳粉产品配方注册：

（一）企业申请注销的；

（二）企业依法终止的；

（三）注册证书有效期届满未延续的；

（四）注册依法被撤销、撤回，或者注册证书依法被吊销的；

（五）法律法规规定应当注销的其他情形。

第五章 法律责任

第四十二条 食品安全法等法律法规对婴幼儿配方乳粉产品配方注册违法行为已有规定的，从其规定。

第四十三条 申请人隐瞒有关情况或者提供虚假材料、样品申请婴幼儿配方乳粉产品配方注册的，国家食品药品监督管理总局不予受理或者不予注册，对申请人给予警告，并向社会公告。申请人在1年内不得再次申请婴幼儿配方乳粉产品配方注册；涉嫌犯罪的，依法移送公安机关，追究刑事责任。

申请人以欺骗、贿赂等不正当手段，或者隐瞒真实情况、提交虚假材料等方式取得婴幼儿配方乳粉产品配方注册证书的，国家食品药品监督管理总局依法予以撤销，处1万元以上3万元以下罚款。被许可人在3年内不得再次申请注册；涉嫌犯罪的，依法移送公安机关，追究刑事责任。

第四十四条 申请人变更不影响产品配方科学性、安全性的事项，未依法申请变更的，由县级以上食品药品监督管理部门责令改正，给予警告；拒不改正的，处1万元以上3万元以下罚款。

申请人变更可能影响产品配方科学性、安全性的事项，未依法申请变更的，由县级以上食品药品监督管理部门依照食品安全法第一百二十四条的规定处罚。

第四十五条 伪造、涂改、倒卖、出租、出借、转让婴幼儿配方乳粉产品配方注册证书的，由县级以上食品药品监督管理部门责令改正，给予警告，并处1万元以下罚款；情节严重的，处1万元以上3万元以下罚款；涉嫌犯罪的，依法移送公安机关，追究刑事责任。

第四十六条 婴幼儿配方乳粉生产销售者违反本办法第三十条至第三十四条规定的，由食品药品监督管理部门责令改正，并依法处以1万元以上3万元以下罚款。

第四十七条 食品药品监督管理部门及其工作人员对不符合条件的申请人准予注册，或者超越法定职权准予注册的，依照食品安全法第一百四十四条的规定处理。

食品药品监督管理部门及其工作人员在注册审评过程中滥用职权、玩忽职守、徇私舞弊的，依照食品安全法第一百四十五条的规定处理。

第六章 附 则

第四十八条 本办法所称婴幼儿配方乳粉产品配方，是指生产婴幼儿配方乳粉使用的食品原料、食品添加剂及其使用量，以及产品中营养成分的含量。

第四十九条 本办法自2016年10月1日起施行。