附件 1

Attachment 1

婴幼儿配方乳粉产品配方

注册申请材料项目与要求（试行）

Items and Requirements of Registration Application Documents for Product Formula of Infant Formula Milk Powder (Trial)

一、申请材料的一般要求

I. General Requirements for Application Documents

（一）申请人通过国家食品药品监督管理总局网站（www.cfda.gov.cn）或国家食品药品监督管理总局食品审评机构 网站（www.bjsp.gov.cn）进入婴幼儿配方乳粉产品配方注册申请 系统，按规定格式和内容填写并打印国产婴幼儿配方乳粉产品配 方注册申请书（附表 1）、进口婴幼儿配方乳粉产品配方注册申 请书（附表 2）、国产婴幼儿配方乳粉产品配方变更注册申请书（附表 3）、进口婴幼儿配方乳粉产品配方变更注册申请书（附 表 4）、国产婴幼儿配方乳粉产品配方延续注册申请书（附表 5）、 进口婴幼儿配方乳粉产品配方延续注册申请书（附表 6）。

The applicant shall access the registration application system of product formula of infant formula milk powder through the websites of China Food and Drug Administration (CFDA) (www.cfda.gov.cn) or Food Review Organization of CFDA (www.bjsp.gov.cn), and fill in and print the attached tables below in accordance with the specified format and contents: Application for Registration of Product Formula of Domestic Infant Formula Milk Powder (Attached Table 1), Application for Registration of Product Formula of Imported Infant Formula Milk Powder (Attached Table 2), Application for Registration of Product Formula Change of Domestic Infant Formula Milk Powder (Attached Table 3), Application for Registration of Product Formula Change of Imported Infant Formula Milk Powder (Attached Table 4), Application for Registration of Product Formula Continuation of Domestic Infant Formula Milk Powder (Attached Table 5) and Application for Registration of Product Formula Continuation of Imported Infant Formula Milk Powder (Attached Table 6)

（二）申请人应当在注册申请书后附上相关申请材料，按照 注册申请书中列明的“所附材料”顺序排列。整套申请材料应有详细材料目录，目录作为申请材料首页。

The applicant shall attach relevant application documents to the Application for Registration, and sequence these materials as per the “attached materials” clearly listed in the Application for Registration. Detailed catalog of materials shall be provided for the whole set of application documents, and the catalog shall be put in the first page of the application documents.

（三）整套申请材料应当装订成册，每项材料应有封页，封页上注明产品名称、申请人名称，右上角注明该项材料名称。各项材料之间应当使用明显的区分标志，并标明各项材料名称或该 项材料所在目录中的序号。

The whole set of application documents shall be bound in a volume, wherein each document shall have a cover page that clearly indicates name of the product, name of the applicant and name of the document at the top right. Obvious mark shall be used to distinguish these documents, and it shall mark clearly the name of each document or the serial number of this document in the catalog.

（四）申请材料使用 A4 规格纸张打印（中文用宋体且不得 小于 4 号字，英文不得小于 12 号字），内容应完整、清楚，不得 涂改。

The application documents shall be printed with A4 paper (the Chinese characters shall be Simsun Font of size 4, and the English words shall not be smaller than size 12), and the contents shall be complete and clear without alternation.

（五）除注册申请书和检验机构出具的检验报告外，申请材 料应逐页或骑缝加盖申请人公章或印章，境外申请人无公章或印 章的，应加盖驻中国代表机构或境内代理机构公章或印章，公章 或印章应加盖在文字处。加盖的公章或印章应符合国家有关用章 规定，并具法律效力。

Except the application for registration and certificate of analysis issued by the analytical facility, official seal or seal of the applicant shall be stamped on every application documents or on the junction page. If an overseas applicant has no official seal or seal, it shall stamp the official seal or seal of representative office in China or domestic agency on the part with characters. The stamped official seal or seal shall comply with relevant national provisions about seal use, and shall have legal force.

（六）申请材料中填写的申请人名称、地址、法定代表人等 内容应当与申请人主体资质证明文件中相关信息一致，申请材料 中同一内容（如申请人名称、地址、产品名称等）的填写应前后 一致。加盖的公章或印章应与申请人名称一致（驻中国代表机构 或境内代理

机构除外）。

The name of applicant, address, legal representative and other contents written in the application documents shall be consistent with relevant information in the subject qualification certifications of the applicant. And the same contents (such as name of applicant, address and product name) written in the application documents shall be consistent. The stamped official seal or seal shall be consistent with name of the applicant (except representative office in China or domestic agency).

（七）申请人主体资质证明材料、原辅料的质量安全标准、 产品配方、生产工艺、检验报告、标签和说明书样稿及有关证明 文件等申请材料中的外文，均应译为规范的中文；外文参考文献（技术文件）中的摘要、关键词及与配方科学性、安全性有关部 分的内容应译为规范的中文（外国人名、地址除外），外文资料 附后。申请人应当确保译本的真实性、准确性与一致性。

English contents in the subject qualification certifications of the applicant, quality safety standard of raw materials and excipients, product formula, production process, certificate of analysis, label, package insert sample manuscript, relevant supporting documents and other application documents shall be translated into normalized Chinese contents; the abstract and keywords of the English references and the contents relevant to scientificity and safety of the formula shall be translated into normalized Chinese contents (except English names and addresses), attached with the English documents. The applicant shall ensure the authenticity, accuracy and consistency of the translation version.

（八）申请人提交补正材料，应按《婴幼儿配方乳粉产品配 方审评意见通知书》的要求和内容，将有关项目修改后的完整材 料逐项顺序提交，并附《婴幼儿配方乳粉产品配方审评意见通知 书》原件或复印件。

In submitting correction documents, the applicant shall submit all modified complete materials of relevant projects successively in accordance with the requirements and contents of the *Notice on the Review Opinions for Product Formula of Infant Formula Milk Powder*, and attach the original copy or copy of the *Notice on the Review Opinions for Product Formula of Infant Formula Milk Powder*.

（九）申请人应当同时提交申请材料的原件 1 份、复印件 5 份和电子版本；审评过程中需要申请人补正材料的，应提供补正材 料原件 1 份、复印件 4 份和电子版本。复印件和电子版本由原件制 作，其内容应当与原件一致，并保持完整、清晰。申请人对申请材 料的真实性、完整性、合法性负责，并承担相应的法律责任。

The applicant shall synchronously submit the original copy, five copies and one soft copy of the

application documents; in the review process, if the documents shall be supplemented or corrected, the applicant shall provide one original copy of the correction documents, four copies and one soft copy. The copy and soft copy are made by referring to the original copy, so the contents shall be consistent with the original copy, and be complete and clear. The applicant shall be responsible for the authenticity, completeness and legality of the application documents, and undertake corresponding legal liabilities.

各项申请材料应逐页或骑缝加盖公章或印章后，扫描成电子 版上传至婴幼儿配方乳粉产品配方注册申请系统。

After stamping official seal or seal on each page or junction page, each application document shall be scanned as the soft copy and uploaded to the registration application system of product formula of infant formula milk powder.

二、产品配方注册申请材料项目与要求

Items and Requirements of Product Formula Registration Application Documents

（一）产品配方注册申请材料项目

Items of product formula registration application documents

1.婴幼儿配方乳粉产品配方注册申请书；

Application for Registration of Product Formula of Infant Formula Milk Powder;

2.申请人主体资质证明文件；

Subject qualification certifications of the applicant;

3.原辅料的质量安全标准；

Quality safety standard of raw materials and excipients;

4.产品配方；

Product formula;

5.产品配方研发报告；

Product formula R&D report;

6.生产工艺说明；

Instruction for production process;

7.产品检验报告；

Product certificate of analysis;

8.研发能力、生产能力、检验能力的证明材料；

Materials for certifying R&D capability, production capability and test capability;

9.其他表明配方科学性、安全性的材料；

Other materials indicating scientificity and safety of formula;

10.标签和说明书样稿及其声称的说明、证明材料。

Label and package insert sample manuscript and the alleged instruction and certification documents.

（二）产品配方注册申请材料要求

Requirements for product formula registration application documents

1.注册申请书

Application for registration

（1）产品名称由商品名称和通用名称组成，每个产品只能 有一个产品名称，产品名称应使用规范的汉字。申请注册的进口婴幼儿配方乳粉还可标注英文名称，英文名称应与中文名称有对 应关系。

Product name consists of the trade name and generic name. Every product can only be provided with one product name written by normalized Chinese characters. It may mark the English name of imported infant formula milk powder that is applied for registration, and the English name shall correspond to the Chinese name.

（2）商品名称应当符合有关法律法规和食品安全国家标准 的规定，不应包含下列内容：

The name of the product shall meet the provisions of relevant laws and regulations and national standards for food safety, excluding the contents below:

① 虚假、夸大、违反科学原则或者绝对化的词语；

The words that are false, exaggerated, violate scientific principle or absolute;

② 涉及预防、治疗、保健功能的词语；

The words that involve prevention, treatment and healthcare functions;

③ 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；

The statement that explicitly indicates or implies that the product had the functions of reinforcing intelligence, building up resistance or immunity, and protecting intestinal tract;

④ 庸俗或者带有封建迷信色彩的词语；

The words that are vulgar or contain feudalistic superstition color;

⑤ 人体组织器官等词语；

The words that contain tissue and organ of human body;

⑥ 其他误导消费者的词语，如使用谐音字或形似字足以造成 消费者误解的。

Other words that may mislead consumers. For example, the use of homophone or near homograph that is enough to cause misunderstanding of consumers.

同一系列不同适用月龄的产品，其商品名称应相同或相似。

The products of the same series but different applicable months shall have the same or similar product name.

（3）根据产品适用月龄，通用名称应为“婴儿配方乳（奶） 粉（0—6 月龄，1 段）”、“较大婴儿配方乳（奶）粉（6—12 月 龄，2 段）”、“幼儿配方乳（奶）粉（12—36 月龄，3 段）”。

According to the applicable months of the product, the generic name shall be “infant formula milk powder (0-6th month, phase 1)”, “older infant formula milk powder (6th -12th month, phase 2)” and “young children formula milk powder (12th -36th month, phase 3)”.

（4）其他需要说明的问题

Other problems that need to explain.

①产品配方曾经不予注册的，应对相关情况及原因进行说 明，并提交原配方不予注册决定书复印件。

It shall explain the relevant situations and causes for the failure of product formula registration, and submit the copy of letter of decision of not registering for the original formula.

②说明产品配方是否为已经上市销售产品的配方，如为已上 市销售产品的配方，应当说明产品名称、上市销售时间、销售国 家或者区域等情况。

State whether the product formula is the one that has been sold in the market. If so, it shall state the situations such as name of product, sales time, sales countries or regions.

③其他需要说明的问题。

Other problems that need to explain.

2.申请人主体资质证明文件

Subject qualification certifications of the applicant

（1）申请人对他人已取得的专利不构成侵权的保证书。

The guarantee for ensuring that the applicant will not infringe the patent obtained by others.

（2）产品名称不构成侵权的保证书。

The guarantee for ensuring that the name of product will not cause infringement.

（3）申请人合法有效的主体登记证明文件复印件。

Copy of the legal and valid subject registration certification document of the applicant.

（4）产品已经上市销售的，提交申请人为该上市产品合法 生产企业的证明材料。

If the product has been sold in the market, it shall submit the materials for certifying that the applicant is the legal manufacturing enterprise of the sold product.

（5）商品名称含注册商标的，应提供国家商标注册管理部 门批准的商标注册证书复印件，商标使用范围应符合要求。商标 注册人与申请人不一致的，应提供申请人可以合法使用该商标的 证明材料。

If name of the product contains registered trademark, it shall provide the copy of certificate of

trademark registration approved by the national trademark registration management department. Range of trademark application shall meet the requirements. If the trademark registrant is inconsistent with the applicant, it shall provide the materials for certifying that the applicant can use the trademark legally.

（6）申请进口婴幼儿配方乳粉产品配方注册的，还应同时提交以下证明材料：

It shall also submit the certification documents below for the application for product formula registration of infant formula milk powder:

①由境外申请人常驻中国代表机构办理注册事务的，提交《外国企业常驻中国代表机构登记证》复印件。

It shall submit the copy of the *Certificate of Registration of Resident Offices of Foreign Enterprises* for the transaction of registration affairs by resident representative office of overseas applicant in China.

②境外申请人委托境内代理机构办理注册事务的，提交经过 公证的授权委托书原件及其中文译本，以及受委托的代理机构营 业执照复印件。

It shall submit the original copy and its Chinese translation of notarized letter of authorization, and the copy of business license of entrusted agency for the transaction of registration affairs by domestic agency entrusted by the overseas applicant.

授权委托书中应载明出具单位名称、被委托单位名称、委托 申请注册的产品名称、委托事项及授权委托书出具日期。授权委 托书的委托方应与申请人名称一致。

In the letter of authorization, it shall write clearly the name of issuing organization, name of entrusted organization, name of the product to be registered under entrusted application, entrusted matters and issuing date of the letter of authorization. Name of the entrusting party of letter of authorization shall be consistent with name of the applicant.

3.原辅料的质量安全标准

Quality safety standard of raw materials and excipients

所用食品原料、食品添加剂的品种、等级和质量要求应当符合相应的食品安全国家标准和（或）相关规定，或者符合相应的食品安全国家标准的安全性指标和（或）相关规定。

The types, grades and quality requirements of all raw-food materials and food additives shall meet

corresponding national standards for food safety and (or) relevant provisions, or meet corresponding safety indexes of national standards for food safety and (or) relevant provisions.

所用食品原料、食品添加剂执行食品安全国家标准和（或）国务院卫生行政部门公告的，提交食品安全国家标准号和（或）国务院卫生行政部门公告名称；无相关食品安全国家标准的，应提交质量要求及使用依据。

It shall submit No. of national standards for food safety and (or) name of the announcement by Health Administrative Department of the State Council for the situation that the used raw-food materials and food additives follow national standards for food safety and (or) announcement of Health Administrative Department of the State Council.

申请人对食品原料、食品添加剂的质量安全负责。

The applicant shall be responsible for the quality safety of raw-food materials and food additives.

4.产品配方

Product formula

（1）配方组成

Formula composition

①按照加入量递减顺序列出使用的食品原料和食品添加剂，加入量不超过2%的配料可以不按递减顺序排列。食品原料和食品添加剂的名称应依照现行国家相关标准等予以规范。不得添加国家标准法规规定以外的其他物质。

List the used raw-food materials and food additives as per the descending order of additive amount, but the ingredient with additive amount of less than 2% may not follow the descending order. It shall normalize names of the raw-food materials and food additives in accordance with the current relevant national standards. And it is not allowed to add other substances that are not contained in the provisions of national standard regulations.

②使用复合配料和复配食品添加剂的，在配方组成中标示复合配料和复配食品添加剂的名称，并在其后加括号，按递减顺序一一标示复合配料和复配食品添加剂的各组成成分，加入量不超过2%的配料可以不按递减顺序排列。食用植物油应按照加入量的递减顺序标示具体的品种名称。

It shall mark names of the compound ingredients and compound food additives in the formula

composition for the used compound ingredients and compound food additives, add the bracket afterwards, and mark the compositions of compound ingredients and compound food additives. The ingredient with additive amount of less than 2% may not follow the descending order. It shall mark the specific type name of edible vegetable oil in accordance with descending order of additive amount.

③产品名称中有动物性来源的，应当在配方组成中标明使用的生乳、乳粉、乳清（蛋白）粉等乳制品原料的动物性来源。同一乳制品原料有两种以上动物性来源的，应当标明各种动物性来源原料所占比例。

It shall mark clearly the animal origin of the dairy product materials such as the use of raw milk, milk powder and whey (protein) powder in the formula composition for the product with its name containing animal origins. And it shall mark clearly the proportions of various animal raw materials for the dairy product material with two or more animal origins.

（2）配方用量表

List of formulation dosage

①配方用量表按制成1000kg 婴幼儿配方乳粉所用食品原料和食品添加剂的量计算。应当与试制样品的食品原料和食品添加剂的实际投料量一致，不得以百分比标示。在原料种类不变、符合配料表顺序和营养成分含量要求的条件下，实际生产时食品原料和食品添加剂的使用量允许有一定范围内合理的波动或调整。

Dosages in the list of formulation dosage shall be calculated in accordance with the contents of raw-food materials and food additives used for making 1000kg infant formula milk powder, which shall be consistent with the actual amount of raw-food materials and food additives of the trial sample, and cannot be marked in the form of percentage. Under the conditions that types of the raw materials do not change and meet the sequence in the list of ingredients and the requirements for contents of nutritional ingredients, the amount of raw-food materials and food additives during actual production is allowed to fluctuate or be adjusted within a certain range reasonably.

②配方用量表应当列出使用的全部食品原料和食品添加剂的名称和用量。已有国家标准、行业标准或地方标准，并其加入量小于食品总量25%的复合配料中含有的食品添加剂，符合《食品安全国家标准食品添加剂使用标准》（GB 2760）规定的带入原则且在最终产品中不起工艺作用，或者复配食品添加剂中含有的不在最终产品中发挥功能作用的辅料，如不能提供配方用量，可不在配方用量表中列出，并说明不能提供的理由。但在标签配料表中标示的除外。

The list of formulation dosage shall contain the names and amount of all raw-food materials and food additives. If it fails to provide the formulation dosage of the food additive in the compound ingredient with the additive amount of less than 25% of the total amount of food, which is specified in the national standard, industrial standard or local standard, meets the drag-in principle specified in the *National Food Safety Standards - Use of Food Additives* (GB 2760), and plays no process role in the final product, the food additive is allowed to not be listed in the list of formulation dosage, and it shall explain the reasons. Above situation does not apply to the ones marked in the list of ingredients on the label.

（3）营养成分表

List of nutritional ingredients

①营养成分应当按照在每100kJ 和每100g 中的含量标示，可同时标示每100mL 中的含量。

It shall mark the content of the nutritional ingredients every 100kJ and 100g, and meanwhile mark the contents of every 100mL.

②营养成分应当按照《食品安全国家标准婴儿配方食品》（GB 10765）和《食品安全国家标准较大婴儿和幼儿配方食品》（GB 10767）规定的顺序列出。GB 10765 和GB 10767 规定之外的，按《食品安全国家标准食品营养强化剂使用标准》（GB14880）等规定的顺序列出，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。表1举例婴儿配方乳粉营养成分表格式：

The nutritional ingredients shall be listed as per the sequence specified in the *National Food Safety Standard - Infant Formula* (GB 10765) and *National Food Safety Standard - Older Infants and Young Children Formula* (GB 10767). Except the provisions of GB 10765 and GB 10767, the nutritional ingredients shall be listed as per the sequence specified in the *National Food Safety Standard – Use Standard of Food Nutrition Enhancer* (GB14880). The nutritional ingredients shall be respectively listed as per the types of energy, protein, fat, carbohydrate, vitamin, minerals, optional component, etc. Table 1 is the sample format for the list of nutritional ingredients of infant formula milk powder:

表1 营养成分表

Table 1 List of Nutritional ingredients

项目Item	单位Unit	每/100kJ	每/100g
能量 **Energy**	**kJ** **g**		
蛋白质 **Protein**			
乳清蛋白 Whey protein	g		
脂肪 **Fat**	**g**		
亚油酸 Linoleic acid	G mg		
α-亚麻酸 α-linolenic acid			
碳水化合物 **Carbohydrate**	**g**		
乳糖 Lactose	g		
维生素 **Vitamin**			
维生素A Vitamin A ……	μgRE		
矿物质 **Minerals**			
钠Na	mg		

……		
可选择性成分 **Optional component**		
胆碱 Choline	mg	

③营养成分的名称、标示单位应与食品安全国家标准中的标示一致。

The name and marked unit of the nutritional ingredient shall be consistent with those in the national standards for food safety.

5.产品配方研发报告

Product formula R&D report

（1）配方研发

Formula R&D

①阐述产品配方特点、研发目的、市场调查研究情况和相关母乳研究状况。

State features, R&D purpose, market investigation and research situation and relevant breast milk study situation of the product formula.

②证明配方科学性、安全性的充足依据

Sufficient basis for certifying the scientificity and safety of the formula.

依据可为：试验资料、相关国内外法规标准、营养指南或专著、营养数据资料、其他相关研究文献及长期上市食用历史资料等。

The basis could be: Test data, relevant overseas and domestic regulations and standards, nutritional guidelines or monograph, nutrition data, other relevant research literatures and historical materials of long-term sales and consumption, etc.

试验资料为婴幼儿喂养试验资料或针对性动物试验资料；相关国内外法规标准包括与申报配方相关的国内外法规、标准及其研究资料；营养指南或专著为国内外权威医学、营养学机构或学会、协会等发布的营养指南或专著；营养数据资料应具有代表性；研究文献

应权威、充分且有直接相关性，临床研究文献涉及的受试人群应与配方设计的目标人群存在合理关联性，临床试验研究结果支持喂养效果；长期上市食用历史资料应为自上市以来的跟踪评价资料，且未出现过群体性不适反应。

The test materials are infants and young children feeding test materials or targeted animal test materials; relevant domestic and overseas regulations and standards include the declared formula related domestic and overseas regulations, standards and the research data; the nutritional guidelines or monographs are published by domestic and overseas authoritative medical/nutritional organizations, societies or associations; the nutrition data shall be representative; research literature shall be authoritative, sufficient and directly associated, the involved subjects of clinical research literature shall be reasonably associated with the target groups of formula design, and the clinical test research result supports the feeding effect; the historical materials of long-term sales and consumption shall include the tracking evaluation materials since the food is launched on the market, and there shall be no adverse reaction of group.

③论证报告

Argumentation report

论证报告内容包括营养素设计值和（或）标签值的确定依据、原料相关营养数据研究、营养素在生产过程中和货架期衰减研究、营养素设计值和（或）标签值检测偏差范围研究，以及配方组成选择依据和用量设计值、配方验证纠偏过程与结果、所有包装规格产品的稳定性研究及确定情况、产品企业内控标准的确定等。

Contents of the argumentation report include the basis of confirming nutrient design value and (or) label value, research on relevant nutrition data of raw materials, research on nutrient attenuation in the production process and during shelf life, research on detecting deviation range of nutrient design value and (or) label value, formula composition selection basis and amount design value, formula verification and correction process and result, research on stability of products of all packing specifications and confirmation situation, confirmation of internal control standard of product enterprise, etc.

④说明所选用的食品原料和食品添加剂在配方中的作用以及种类、用量与国家相关法律、法规、标准等相符合的情况。

Describe the situation that the functions, types and amount of selected raw-food materials and food additives in the formula shall meet relevant national laws, regulations and standards.

⑤产品上市后，营养、安全方面的跟踪评价方案。跟踪评价方案包括婴幼儿食用情况

和产品稳定性等指标，方案需确定跟踪评价的方式等内容。

Scheme of tracking evaluation on nutrition and safety after the product is sold on the market. The tracking evaluation scheme includes the indexes of infants and young children consumption situation and product stability, and the mode of tracking evaluation that shall be confirmed in the scheme.

（2）配方明显差异性说明

Instruction for obvious difference between formulas

申请人申请注册两个以上同年龄段产品配方时，阐述申请注册配方与申请人同年龄段其他配方相比具有的特点及明显差异。

In applying for the registration of two or more product formulas of the same age group, the applicant shall describe the features and obvious differences of the formula applied to register compared with other formula of the same age group of the applicant.

产品配方及其差异性的基础应为母乳研究、营养学研究成果。配方明显差异性应遵循下列原则之一：

The basis of product formula and its difference shall be the results of research on breast milk and nutrition. Obvious difference of the formula shall follow one of the principles below:

①产品配方主要原料所提供的宏量营养素，如蛋白质、脂类、碳水化合物组分具有明显差异；

The macronutrients provided by main raw materials of the product formula, such as protein, lipid and carbohydrate component, show a significant difference;

②可选择性成分营养特性的选择具有明显差异。

The selection of nutritive peculiarity of optional components shows a significant difference.

明显差异性的科学证实材料包括与母乳数据的比对或相关营养学研究成果，还可同时提交婴幼儿喂养试验（或针对性动物试验）或其他相关研究文献。

The scientific verification materials that show a significant difference include the comparison with breast milk data or relevant results of the research on nutrition, and it may synchronously submit research literatures of infants and young children feeding test (or targeted animal test) or other relevant research literatures.

将申请注册的产品配方与申请人同年龄段其他配方进行明显差异性比较说明时，文字阐述之外需以对照列表方式将上述存在差异的原辅料的种类和用量等内容列明。

In comparing to explain obvious differences between the product formula that is applied to register and other formula of the same age group of the applicant, it shall not only describe the contents through texts, but also list clearly the types and amount of raw and excipients existing differences.

6.生产工艺说明

Instruction for production process

（1）生产工艺流程提交商业化生产工艺流程，标明主要生产工序、环境条件和关键控制点。

For the production technology process, it shall submit commercial production technology process, and mark clearly the main production processes, environmental condition and critical control point.

（2）具体描述主要生产工序的相关生产设备（名称、型号）、关键控制点控制参数和控制措施。

It specifically describes the relevant production equipment (name and model) of main production processes, and control parameters and control measures of the critical control point.

（3）生产工艺验证

Verification for production process

提交不少于3 批次样品的工艺验证报告，报告内容包括：①批次样品的信息（产品名称、产品批次、原辅料投料量、理论产量、实际产量等）；②工艺验证过程；③样品均匀性分析；④样品的营养成分符合性分析；⑤工艺稳定性分析；⑥工艺验证结论。

Submit the process certification reports of at least 3 batches of samples, and contents of the reports include: ① Information of batch samples (product name, product batch, capacity of raw and excipients, theoretical output, actual output, etc.); ② Process validation process; ③ Sample homogeneity analysis; ④ Analysis on conformance of nutritional ingredients of sample; ⑤ Process stability analysis; ⑥ Process certification conclusion.

7.产品检验报告

Product certificate of analysis

（1）提交不少于3 批次按照申请注册产品配方生产的产品的全项目检验报告，其中不少于1 批次为通过商业化生产线生产的产品的全项目检验报告。产品生产应符合《食品安全国家标准粉状婴幼儿配方食品良好生产规范》（GB 23790）要求。

Submit the certificate of analysis on all items of at least three batches of products produced in accordance with the formula of the product that is applied to register, wherein there must be the certificate of analysis on all items of at least one batch of products produced through commercial production line. Production of the product shall meet the requirements of the *National Food Safety Standard – Good Manufacturing Practice for Powdered Formula for Infants and Young Children* (GB 23790).

若提交不少于3 批次由具有婴幼儿配方乳粉全项目检验法定资质食品检验机构出具按照申请注册产品配方通过商业化生产线生产的产品检验报告的，注册审评过程中审评机构可不再委托检验机构进行抽样检验。

If the food analytical facility with the legal qualification of inspecting all items of the infant formula milk powder issues the product certificate of analysis for at least 3 batches of products produced through the commercial production line in accordance with the product formula that is applied to register, the review organization will not entrust the analytical facility to conduct sampling analysis in the process of registration review.

（2）检验项目应为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全部项目。检验报告应注明样品名称、数量、生产日期、生产批号、执行标准、检验项目、标准指标、检验数据、检测方法、单项判定、检验结论、检验时间、检验报告编号等信息。

The analytical items shall be all items specified in the relevant laws and regulations and provisions of national food safety standard - infant formula milk powder. The certificate of analysis shall indicate clearly the information such as sample name, quantity, date of manufacture, production batch number, executive standard, test items, standard index, test data, test method, item conclusion, analytical conclusion, test time and number of certificate of analysis.

（3）检测方法应符合GB 10765 和GB 10767 及相关国家标准的规定。国家标准未规定的，申请人应自行提交检测方法及方法学研究与验证材料，采用国际和国外标准的，应当提交全文译文。

The analytical methods shall meet the provisions of GB 10765 and GB 10767 and relevant national standards. The applicant shall submit the analytical methods and methodological study and certification materials for the ones not specified by the national standard, and submit the translation of the whole document that adopts international and overseas standards.

（4）检验报告格式应规范，不得涂改；检验数据/结果应真实、客观、准确，使用法定计量单位。

Format of the certificate of analysis shall be normalized without alternation; the test data/result shall be real, objective and accurate, and in legal unit of measurement.

（5）检验报告应当由生产企业质量负责人或质量受权人签名并盖公章。检验报告由具有法定资质的食品检验机构出具的，应当有检验机构负责人签名并盖公章。

Quality principal or quality authorized person of the manufacturer shall sign and stamp official seals on the certificate of analysis. The principal of the analytical facility shall sign and stamp official seal on the certificate of analysis issued by food analytical facility with statutory qualification.

8.研发能力、生产能力和检验能力的证明材料

Materials for certifying R&D capability, production capability and analytical capability;

（1）提交研发人员、生产人员、检验人员的数量、专业、学历、职称、从业经历等基本情况的说明，并提交开展的研发工作情况和发表的有关论文、专著、获得的专利等情况。

Submit the instruction for the basic situations including numbers, major, education background, title and working experience of R&D personnel, production personnel and analytical personnel, as well as the situations of the implemented R&D work and relevant published papers, monographs and obtained patents.

（2）提交研发、生产和检验的主要设备、设施清单和场所平面图。

Submit the list of main equipment and facilities and plan of the site for R&D, production and analysis.

（3）提交能证明符合粉状婴幼儿配方食品良好生产规范要求和实施危害分析与关键控制点体系的材料。

Submit the materials for certifying that the requirements for good manufacturing practice of powdered infant formula foods are met, and for implementing hazard analysis and critical control point system.

（4）境外申请人应提交实施逐批检验的检验机构名称及其法定资质证明材料等。

The overseas applicant shall submit the name of the analytical facility for implementing lot by lot analysis and the materials for certifying the statutory qualification.

9.其他表明配方科学性、安全性的材料

Other materials indicating scientificity and safety of formula

（1）提交食品原料、食品添加剂合法来源证明文件，如供应商的主体登记证明文件、销售发票、出厂及进厂检验报告复印件等。采用进口原辅料的，还应提交出入境检验检疫部门出具的相关材料。

Submit documents for certifying legal sources of raw-food materials and food additives, such as copies of subject registration certification documents, invoice for sales, in and out factory certificate of analysis of the supplier. It shall also submit the relevant materials issued by entry-exit inspection and quarantine department for the use of imported raw and excipients.

（2）已上市销售的产品配方，应当提交产品的生产、销售、管理、人群食用及跟踪评价情况的分析报告，以及监管部门抽检情况和上市以来的型式检验报告。

For the formula of the product that has been sold on the market, it shall submit the report for analysis on product production, sales, management, consumption and tracking evaluation situations, as well as spot check situation of supervision department and type certificate of analysis since the product is sold on the market.

（3）申请注册进口婴幼儿配方乳粉产品配方的，如不适用上述第2 款要求，应当提交申请人已上市的同类产品或相似产品的生产、销售、监管部门抽检和企业检验、人群食用及跟踪评价情况的分析报告，及在中国注册需特别说明的情况。

If the application for the registration of product formula of imported infant formula milk powder does not apply to the requirements in clause 2 above, it shall submit the reports of the applicant for the analysis on the situations of production and sales of the same or similar products on the market, spot check of supervision department and analysis of enterprise, consumption and tracking evaluation, as well as the situation that shall be specially explained for registration in China.

（4）食品原料、食品添加剂中可能含有的危害成分的研究和控制情况，并应当在原辅料质量安全要求中增加限量指标；与产品直接接触的包装材料中可能含有的危害物质的研究和控制说明。

It shall submit the situations of researching and controlling possible hazardous ingredients in the raw-food materials and food additives, and add limited amount indexes in the requirements for

quality safety of raw and excipients; as well as the instruction for researching and controlling possible hazardous substances in the packaging materials that directly contact the product.

10.标签和说明书样稿及其声称的说明、证明材料

Label and package insert sample manuscript and the alleged instruction and certification documents

（1）提交申请注册产品配方的所有包装规格产品的标签、说明书样稿。产品标签、说明书符合有关法律法规和食品安全国家标准的规定，产品标签和说明书中对应的内容应当一致。进口婴幼儿配方乳粉应当有中文标签和说明书。有标签但无说明书的，应注明。

Submit the labels and package insert sample manuscripts of the products of all packing specifications that apply for the registration of product formula. The product label and package insert shall meet the provisions of relevant laws and regulations and national standards for food safety, and the product label shall be consistent with corresponding contents in the instruction. Imported infant formula milk powder shall be provided with Chinese label and package insert. It shall mark clearly the product with label but without package insert.

（2）标签、说明书中涉及的声称应当提交与产品配方注册的内容一致性的说明及有效可靠证实材料。

For the statement in the label and package insert, it shall submit the instruction and effective and reliable certification documents that are consistent with the contents of product formula registration.

（3）标签和说明书不得含有下列内容：

The label and package insert shall not contain the contents below:、

①涉及疾病预防、治疗功能；

The contents that involve disease prevention and treatment functions;

②明示或者暗示具有保健作用；

The statement that explicitly indicates or implies that the product has health care effect;

① 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；

The statement that explicitly indicates or implies that the product has the functions of reinforcing

intelligence, building up resistance or immunity, and protecting intestinal tract;

④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；

Use the words of “no additive”, “does not contain” and “zero additive” to emphasize that it does not use or contain the substances not contained or used in the product formula in accordance with the food safety standard.

⑤虚假、夸大、违反科学原则或者绝对化的内容；

The contents that are false, exaggerated, violate scientific principle or absolute;

⑥与产品配方注册内容不一致的声称。

The statement that is inconsistent with the registered contents of the product formula.

三、产品配方变更注册申请材料项目与要求

Items and Requirements of Product Formula Change Registration Application Documents

（一）产品配方变更注册申请材料项目

Items of product formula change registration application documents

1.婴幼儿配方乳粉产品配方变更注册申请书；

Application for Registration of Product Formula Change of Infant Formula Milk Powder;

2.婴幼儿配方乳粉产品配方注册证书及附件复印件；

Registered certificate and attachment copies of product formula of infant formula milk powder;

3.与变更事项有关的证明材料。

Certification documents relevant to change items

（二）产品配方变更注册申请材料要求

Requirements of product formula change registration application documents

1.变更注册申请书

Change registration application

（1）变更事项应为产品配方注册证书及附件载明的事项。

The change items shall be the ones written clearly in the registered certificate and attachment of the product formula.

（2）变更注册的申请人应当是婴幼儿配方乳粉产品配方注册证书的持有者；企业名称变更的，应当由变更后的申请人提出申请。

The applicant for changing the registration shall be the person holding the product formula registration certificate of infant formula milk powder; upon change, the applicant shall put forward the application for changing the enterprise name.

2.与变更事项有关的证明材料

Certification documents relevant to change items

（1）境外申请人委托办理变更事项的，参照产品配方注册提交委托相关证明材料。

For the transaction of change item entrusted by overseas applicant, it shall submit relevant certification documents of entrustment by referring to the product formula registration.

（2）申请人合法有效的主体资质证明文件复印件（如营业执照、组织机构代码和境外申请人注册资质等）。

Copy of the legal and valid subject registration certification document of the applicant (such as business license, code of organization and registration qualification of overseas applicant)

（3）变更事项的具体名称、理由及依据

Specific name, reasons and basis of the change item

①申请商品名称变更的，拟变更的商品名应符合相关命名规定。

For the application for change of the product name, the product name to be changed shall meet relevant naming rules.

②申请企业名称、生产地址名称和法定代表人变更的，应当提交当地政府主管部门出具的相关变更证明材料。

For the application for the change of enterprise name, production address name and legal

representative, it shall submit relevant change certification documents issued by the competent department of local government.

③申请产品配方变更的，列表标注拟变更和变更后内容。提交变更的必要性、安全性、科学性论证报告。对于影响产品配方科学性、安全性的变更，应当根据实际需要按照首次申请注册要求提交变更注册申请材料。

It shall mark the contents to be changed and that have been changed in the list of the application for product formula change. Submit the report for discussing the necessity, safety and scientificity of the change. For the change that influences the scientificity and safety of product formula, it shall submit the materials of application for change registration in accordance with the actual requirements and the registration requirements of the first application.

四、产品配方延续注册申请材料项目与要求

Items and Requirements of Product Formula Continuation Registration Application Documents

（一）婴幼儿配方乳粉产品配方延续注册申请书；

Application for Registration of Product Formula Continuation of Infant Formula Milk Powder;

（二）申请人主体资质证明文件复印件；

Copy of subject qualification certifications of the applicant;

（三）企业研发能力、生产能力、检验能力情况；

Situation of R&D capability, production capability and test capability of enterprise;

（四）生产企业质量管理体系自查报告；

Report of self-examination on quality management system of manufacturing enterprise;

（五）产品营养、安全方面的跟踪评价情况，包括五年内产品生产（或进口）、销售、监管部门抽检和企业检验情况总结，对产品不合格情况的说明，以及五年内产品不适反应情况总结等；

Tracking evaluation on product nutrition and safety, including the summary of situations of product manufacturing (or import), sales, spot check of supervision department and analysis

of enterprise within five years, instruction for non-conformity of products and summary of the adverse reaction of the product within 5 years;

（六）申请人所在地省、自治区、直辖市食品药品监督管理部门延续注册意见书；

Opinions for continued registration in the local food and drug administration of province, autonomous region and municipality of the applicant;

（七）婴幼儿配方乳粉产品配方注册证书及附件复印件。

Copies of registered certificate and attachment of product formula of infant formula milk powder.