《婴幼儿配方乳粉产品配方注册申请材料项目与要求（试行）》和《婴幼儿配方乳粉产品配方注册现场核查要点及判断原则（试行）》解读

Interpretation of *Items and Requirements of Product Formula Registration Application Documents of Infant Formula Milk Powder (For Trial)* and *Key Points for On-site Inspection and Judgment Principles of Product Formula Registration of Infant Formula Milk Powder (For Trial)*

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为进一步加强婴幼儿配方乳粉产品配方注册工作，根据《中华人民共和国食品安全法》、《婴幼儿配方乳粉产品配方注册管理办法》（国家食品药品监督管理总局令第26 号）等法律法规，国家食品药品监督管理总局制定了《婴幼儿配方乳粉产品配方注册申请材料项目与要求(试行)》（以下简称《申请材料项目与要求》）和《婴幼儿配方乳粉产品配方注册现场核查要点及判断原则（试行）》（以下简称《现场核查要点及判断原则》）。现就两个文件解读如下：

In order to further strengthen the work of product formula registration of infant formula milk powder, China Food and Drug Administration formulated the *Items and Requirements of Product Formula Registration Application Documents of Infant Formula Milk Powder (For Trial)* (hereinafter referred to as *Items and Requirements of Application Documents*) and *Key Points for On-site Inspection and Judgment Principles of Product Formula Registration of Infant Formula Milk Powder (For Trial)* (hereinafter referred to as *Key Points for On-site Inspection and Judgment Principles*) according to the laws and regulations such as the *Food Safety Law of the People's Republic of China* and *Measures for the Management of Product Formula Registration of Infant Formula Milk Powder* (No. 26 order of China Food and Drug Administration). The two documents are explained as below:

一、制定依据是什么？

I. What’s the formulation basis?

《中华人民共和国食品安全法》第八十一条规定：婴幼儿配方乳粉的产品配方应当经国务院食品药品监督管理部门注册。注册时，应当提交配方研发报告和其他表明配方科学性、安全性的材料。

According to Article 81 of the *Food Safety Law of the People's Republic of China*, product formula of the

infant formula milk powder shall be registered in the Food and Drug Administration of the State Council. During registration, it shall submit the formula R&D report and other documents for indicating scientificity and safety of the formula.

食品药品监管总局于2016 年6 月6 日颁布的《婴幼儿配方乳粉产品配方注册管理办法》明确了申请婴幼儿配方乳粉产品配方注册、变更注册、延续注册需要提交的材料以及开展现场核查等工作流程，并要求申请产品配方注册时，应当提交标签、说明书样稿及标签、说明书中声称的说明、证明材料。

The *Measures for the Management of Product Formula Registration of Infant Formula Milk Powder* issued by the Food and Drug Administration on June 6, 2016 defines the documents to be submitted for the application for product formula registration, registration change and registration continuation of infant formula milk powder and the working process of on-site inspection. And if it requires applying for registration of product formula, it shall submit the label, instruction sample manuscript and the instruction and certification documents stated in the label and package insert.

根据《中华人民共和国食品安全法》、《婴幼儿配方乳粉产品配方注册管理办法》等法律法规，食品药品监管总局组织起草了《申请材料项目与要求》和《现场核查要点及判断原则》，于2016 年8月9 日至9 月10 日公开征求社会意见，经反复讨论修改完善后，于10 月29 日发布。

According to the laws and regulations such as *Food Safety Law of the People's Republic of China* and *Measures for the Management of Product Formula Registration of Infant Formula Milk Powder*, China Food and Drug Administration drafted the *Items and Requirements of Application Documents* and the *Key Points for On-site Inspection and Judgment Principles*. After soliciting for social opinions in public from August 9, 2016 to September 10, 2016, and being repeatedly discussed, modified and perfected, the two documents were issued on October 29.

二、《申请材料项目与要求》和《现场核查要点及判断原则》分别规定了哪些主要内容？

II. What are the main contents respectively specified in the *Items and Requirements of Application Documents* and the *Key Points for On-site Inspection and Judgment Principles*.

《申请材料项目与要求》规定了申请材料的一般要求、产品配方注册申请材料项目与要求、产品配方变更注册申请材料项目与要求、产品配方延续注册申请材料项目与要求等4 部分内容，以及产品配方注册申请书、产品配方变更注册申请书、产品配方延续注册申请书。

The *Items and Requirements of Application Documents* specifies four parts including general requirements of application documents, items and requirements of product formula registration application documents,

items and requirements of product formula change registration application documents and items and requirements of product formula continuation registration application documents, as well as application for registration of product formula, application for registration of product formula change and application for registration of product formula continuation.

《现场核查要点及判断原则》规定了产品配方注册现场核查申请人生产能力、检验能力、研发能力、样品试制等4 方面的要求。具体包括生产车间，生产布局，质量管理体系，生产资质，过程控制和工艺文件，关键控制点，采购情况，检验设施、仪器、设备及人员，检验情况，实验室状况，研发机构，研发制度，人员要求，研发情况，样品试制设备，检验状况，食品原料和食品添加剂，试制过程一致性等18 个核查项目。明确了现场核查的核查内容、判断标准、核查结论、判断原则。产品配方注册现场核查与食品生产许可、境外婴幼儿配方乳粉生产企业注册的现场核查侧重点不同，重点核查申请人提交的产品配方注册申请材料的真实性，以及与实际研发情况、原始数据的一致性，并核查能够保障产品配方科学性、安全性的相关生产能力、检验能力。

The *Key Points for On-site Inspection and Judgment Principles* specifies the requirements of four aspects including production capability, test capability, R&D capability and sample trial of on-site inspection applicant for product formula registration. In particular, the 18 items to be verified include workshop, allocation of production, quality management system, production qualification, process control and process document, critical control point, procurement situation, inspection facilities, instrument, equipment and personnel, inspection situation, laboratory condition, R&D organization, R&D system, personnel requirement, R&D situation, trial sample production equipment, inspection status, raw-food material and food additives, and conformance of trial-production process, which define the inspected contents, judgment criteria, inspection conclusion and judgment principle of on-site inspection. Emphasis of on-site inspection of product formula registration is different from that of food production license and registration of overseas infant formula milk powder manufacturer. It shall focus on the verification of authenticity of the product formula registration application documents submitted by the applicant, as well as the consistency with actual R&D situation and original data, and verify relevant production capability and test capability that could guarantee scientificity and safety of the product formula.

三、产品名称有哪些要求？

III. What are the requirements for the product name?

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 product name and common 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.

通用名称按照适用月龄分别为“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 common names 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)”.

商品名称应当符合有关法律法规和食品安全国家标准规定，不应包含虚假夸大宣传、误导消费者等内容。

The product name shall meet the provisions of relevant laws and regulations and national standards for food safety, excluding false and exaggerated propaganda and contents that may mislead the consumers.

四、原辅料质量安全标准有哪些要求？

IV. What are the requirements for quality safety standard of raw and auxiliary materials?

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。申请人对食品原料、食品添加剂的质量安全负责。

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

所用食品原料和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，提交质量要求和使用依据。执行企业标准的，提交食品原料或食品添加剂生产企业备案的企业标准文本及其生产许可证副本复印件。

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. It shall submit quality requirements and use basis, if there is no relevant national standards for food safety. If it follows the enterprise standard, it shall submit the enterprise standard text recorded by raw-food material or food additive manufacturer and the copy of the duplicate of production license.

进口产品使用的食品原料和食品添加剂应当符合我国食品安全国家标准和（或）相关规定。如另有产品标准，需提交符合或者不低于我国食品安全国家标准和（或）相关规定的说明材料。

Raw-food materials and food additives used for imported product shall meet the national standards for food safety and (or) relevant provisions of China. If there is other product standard, it needs to submit the explanatory materials that meet or are not inferior to the national standards for food safety and (or) relevant provisions of China.

五、产品配方主要包括哪些材料？

V. What main materials does the product formula include?

产品配方应当提交配方组成、配方用量表和营养成分表，具体要求如下：

For the product formula, it shall submit formula composition, list of formulation dosage and list of nutritional ingredients, and the specific requirements are as below:

（一）配方组成

(1) Formula composition

1.按照加入量递减顺序列出使用的全部食品原料和食品添加剂，包括用于包埋壁材的组成成分等。

1. List all used raw-food materials and food additives as per the descending order of additive amount, including the part for wall imbedding materials, etc.

2.食品原料和食品添加剂的名称应当依照现行国家相关标准等予以规范。既可以作为食品添加剂或食品营养强化剂又可以作为其他配料使用的，应按其在最终产品中发挥的作用规范标示。当作为食品添加剂使用时，应标示其在《食品安全国家标准食品添加剂使用标准》（GB 2760）中规定的名称；当作为食品营养强化剂使用时，应标示其在《食品安全国家标准食品营养强化剂使用标准》（GB 14880）中规定的名称；当作为其他配料发挥作用时，应标示其相应的具体名称。

2. It shall normalize names of the raw-food materials and food additives in accordance with the current

relevant national standards. It shall normalize the indication of the ingredient that could be used as food additive, food nutrition enhancer, or other auxiliary material in accordance with its function in the final product. When it is used as the food additive, it shall mark the name specified in the *National Food Safety Standards - Use of Food Additives* (GB 2760); When it is used as the food nutrition enhancer, it shall mark the name specified in the *National Food Safety Standard – Use Standard of Food Nutrition Enhancer* (GB14880); when it plays the role of other ingredient, it shall mark the corresponding specific name.

3. 说明使用复合配料和复配食品添加剂的情况。

3. It shall state the situation of using compound ingredients and compound food additives.

（二）配方用量表

(II) List of formulation dosage

1.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。

1. The list of formulation dosage shall contain the names and amount of all raw-food materials and food additives.

2.满足以下条件的可不在配方用量表中列出：

2. The ones meeting the conditions below are allowed to not be listed in the formulation dosage:

(1)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的，如不能提供配方用量，可不在配方用量表中列出，同时应说明不能提供的理由。

(1) 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.

(2)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，同时应说明不能提供的理由。

(2) If it fails to provide the formulation dosage of auxiliary material in the compound food additive, which plays no function in the final product, the auxiliary material is allowed to not be listed in the list of

formulation dosage, and it shall explain the reasons.

但在标签配料表中标示的所有食品原料和食品添加剂，都应在配方用量表中列出。

But all raw-food materials and food additives marked in the list of ingredients on the label shall be listed in the list of formulation dosage.

（三）营养成分表

(III) List of nutritional ingredients

1.营养成分表中的维生素指标和矿物质指标应按照《食品安全国家标准婴儿配方食品》（GB10765）和《食品安全国家标准较大婴儿和幼儿配方食品》（GB 10767）的要求标示；可选择性成分既包括上述两个标准中的可选择性成分指标，也包括《食品安全国家标准食品营养强化剂使用标准》（GB 14880）和国家卫生计生委相关公告中可用于婴幼儿配方乳粉的可选择性成分。

1. The vitamin indexes and minerals indexes in the list of nutritional ingredients shall be marked in accordance with the requirements in the *National Food Safety Standard - Infant Formula* (GB 10765) and *National Food Safety Standard - Older Infants and Young Children Formula* (GB 10767); optional ingredients include not only the optional ingredient indexes in the two standards above, but also the optional ingredients that could be used for infant formula milk powder as specified in the *National Food Safety Standard – Use Standard of Food Nutrition Enhancer* (GB14880) and relevant announcement of National Health and Family Planning Commission.

2.应注明即食状态下每100ml 所含婴幼儿配方乳粉的量。

2. It shall mark clearly the amount of infant formula milk powder every 100ml under ready-to-eat status.

六、证明产品配方科学性、安全性的充足依据主要包括哪些？

VI. What are the main sufficient bases for certifying the scientificity and safety of product formula?

依据主要包括试验资料、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、长期上市食用历史资料等。

The basis mainly includes 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.

申请人可提供上述一项或多项依据，并能够充分证明产品配方的科学性、安全性。

The applicant could provide one or more bases above, which are able to fully certify the scientificity and safety of product formula.

七、产品配方明显差异性如何进行说明？

VII. How should the obvious differences between product formulas be explained?

申请人申请注册两个以上同年龄段产品配方时，应当说明申请注册的产品配方与申请人其他同年龄段产品配方相比具有的特点及明显差异性。

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。配方明显差异性可根据实际情况选择从以下一个或两个方面进行说明，并将存在差异的原辅料种类和用量等以对照列表方式列明：

The basis of product formulas and their differences shall be the results of research on breast milk and nutrition. One or more aspects below could be selected to explain obvious differences between product formulas as per the practical situation, and the differences in the types and amount of the raw and auxiliary materials shall be clearly listed in the form of contrast list:

（一）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；

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

（二）可选择性成分营养特性的选择具有明显差异。

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

明显差异性说明应提供相应科学证实材料。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。

It shall provide corresponding scientific verification materials for the instruction of significant difference. Scientific verification materials 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.

八、申请注册的同一产品配方如果生产不同包装规格产品，是否可以仅提供一种包装规格的产品检验报告？

VIII. For the application for registration of one product formula, if there are products of different packing specifications, whether it is allowed to provide the product inspection report of only one packing specification?

申请注册的同一产品配方如果生产不同包装规格产品，提供的产品检验报告可以是同一种包装规格产品的检验报告，也可是不同包装规格产品的检验报告。

For the application for registration of one product formula, if there are products of different packing specifications, it may provide the product inspection report of one packing specification, or product inspection reports of different packing specifications.

九、产品检验报告中“单项判定”应当进行哪些判定？

IX. What are the contents of the “item conclusion” in the product inspection report?

产品检验报告中“单项判定”应当对每个检验项目进行是否符合食品安全国家标准以及标签明示值的符合性判定。

According to the “item conclusion” in the product inspection report, it shall confirm whether every inspection item meets the national standards for food safety and ostensive values on the label.

十、标签和说明书样稿及其声称的说明、证明材料有哪些要求？

X. What are the requirements of the label and package insert sample manuscript, as well as stated instruction and certification documents?

申请人应当提交申请注册产品配方的所有包装规格产品的标签和说明书样稿及其声称的说明、证明材料，并符合以下要求：

The applicant shall submit the labels and package insert sample manuscripts of the products of all packing specifications that apply for the registration of product formula, as well as the stated instruction and certification documents. And the requirements below shall be met:

（一）符合有关法律法规和食品安全国家标准规定，标签与说明书中对应的内容一致，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。

(I) It shall meet the provisions of relevant laws and regulations and national standards for food safety, and

the 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.

（二）标签和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。

(II) 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.

（三）不得含有涉及疾病预防、治疗功能，明示或者暗示具有保健作用，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，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不含有，虚假、夸大、违反科学原则或者绝对化的内容，与产品配方注册内容不一致的声称等内容。

(III) The statement shall not involve disease prevention and treatment functions, shall not explicitly indicate or imply that the product has health care effect, shall not explicitly indicate or imply that the product has the functions of reinforcing intelligence, building up resistance or immunity, and protecting intestinal tract, shall 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, shall not contain the contents that are false, exaggerated, violate scientific principle or absolute, and shall not contain the content that is inconsistent with the registered contents of the product formula.

十一、产品配方变更注册需要提交哪些材料？

XI. Which documents are required for the product formula change registration?

产品配方变更注册需要提交的材料主要包括：

The materials that are required for product formula change registration mainly include:

（一）婴幼儿配方乳粉产品配方变更注册申请书；

(I) Application for Registration of Product Formula Change of Infant Formula Milk Powder;

（二）婴幼儿配方乳粉产品配方注册证书及附件复印件；

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

（三）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；

(III) 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;

（四）申请人合法有效的主体资质证明文件复印件；

(IV) Copy of the legal and valid subject registration certification document of the applicant;

（五）变更事项的具体名称、理由及依据。

(V) Specific name, reasons and basis of the change item.

十二、申请注册已上市销售婴幼儿配方乳粉的产品配方，是否需要重新开展研发论证工作？

XII. Whether it needs to carry out R&D and discussion work again for the application for registration of the product formula of infant formula milk powder sold on the market?

申请注册已上市销售婴幼儿配方乳粉的产品配方，申请人可使用已完成的相关研究数据资料，但应符合《申请材料项目与要求》要求，并提交已上市销售婴幼儿配方乳粉的产品配方与申请注册产品配方为同一配方的证明材料，以及产品上市后的生产、销售、管理、人群食用及跟踪评价情况的分析报告，型式检验报告和监管部门抽检情况等材料。

For application for registration of the formula of the product that has been sold on the market, the applicant could use the completed relevant research data that meets the requirements of *Items and Requirements of Application Documents*, and submit the documents for certifying that the product formula of infant formula milk powder sold on the market is the same as the one to be applied for registration, as well as the report for analysis on post-marketing production, sales, management, consumption and tracking evaluation situations, and type inspection report and spot check situation of supervision department.

十三、现场核查判断原则是什么？

XIII. What's the judgment principle of on-site inspection?

现场核查的判断原则为：

Judgment principle of on-site inspection:

现场核查满足符合项下全部条款判断标准的，核查结论为符合，核查单位作出通过现场核查的决定。

If all judgment standards of the conformance items are met through on-site inspection, it gets the conclusion that the verification has been passed, and the unit for verification will make the decision that the on-site inspection has been passed.

存在基本符合项下任何一条所描述情形的，核查结论为基本符合；当任何1 个至4 个项目核查结论为基本符合的，申请人应对基本符合项进行整改，整改应在10 日内完成，申请人认为整改到位的，由当地省级食品药品监督管理部门予以核查确认并签字，核查单位作出通过现场核查的决定。

The conclusion of the verification is basically conforming if there is any one of the described situations of the basic conformance items; if inspection conclusions of 1-4 items are basically conforming, the applicant shall rectify the basic conformance items within 10 days. If the applicant thinks that the rectification is proper, local provincial level Food and Drug Administration shall verify the situation and sign for confirmation, and the unit for verification shall make the decision that the on-site inspection has been passed.

存在不符合项下任何一条所描述情形的，核查结论为不符合；当任何1 个项目的核查结论为不符合或者5 个及以上项目为基本符合、或逾期未完成整改或整改不到位的，核查单位作出不予通过现场核查的决定。

The conclusion of the verification is non-conforming if there is any one of the described situations of the non-conformance items; the unit for verification will make the decision that the on-site inspection is not passed, if there is the non-conforming conclusion of one item, there are 5 and more basically conforming items, the rectification is not completed within specified time, or the rectification is improper.

十四、婴幼儿配方乳粉产品配方注册现场核查与生产许可现场核查内容主要有哪些不一样？

XIV. What are the differences between on-site inspection for product formula registration of infant formula milk powder and on-site inspection for production permit?

婴幼儿配方乳粉产品配方注册现场核查与生产许可现场核查的侧重点不同，内容也有所差异。产品配方注册现场核查主要核查申请人提交产品配方注册申请材料的真实性，以及与实际研发情况、原始数据的一致性，并核查能够保障配方科学性、安全性的相关生产能力、检验能力等。包括生产能力、检验能力、研发能力和样品试制等4 方面18 个核查项目。生产许可现场核查主要核查生产企业生产条件中保障食品安全的实质内容，主要包括生产场所、设备设施、设备布局和工艺流程、人员管理、管理制度及试制产品检验合格报告等6 方面34 个核查项目。

Emphasis of on-site inspection of product formula registration of infant formula milk powder is different

from that of production permit, and the contents are also different. On-site inspection of product formula registration focuses on the verification of authenticity of the product formula registration application documents submitted by the applicant, as well as the consistency with actual R&D situation and original data, and the verification of relevant production capability and test capability that could guarantee scientificity and safety of the product formula. The 18 items to be verified include four aspects of production capability, test capability, R&D capability and trial sample production. On-site inspection of production permit focuses on the essence contents in the production conditions of the manufacturer for guaranteeing food safety, mainly including 34 verification items in 6 aspects of production site, equipment and facilities, equipment layout and technological process, personnel management, management system and trial-product qualification test report.