U.S. – China HPA Health Products Association 美中健康产品协会

Regulatory Insights

Date Released or Passed into Law
September 2, 2015

Government Agency
China Food and Drug Administration

Date Translated
October 8, 2015

Measures for the Registration and Administration of Formulas for Special Medical Purpose (Draft)

《特殊医学用途配方食品注册管理办法》

（试行）（征求意见稿）

Measures for the Registration and Administration of Formulas for Special Medical Purpose (Trial, Draft)

Chapter I General Provisions

Article 1 To strengthen the administration of application of Formulas for Special Medical Purpose, to ensure the quality and safety Formulas for the Special Medical Purpose, the Measures are formulated in accordance with the <Food Safety Law of the People's Republic of China> and its implementing regulations, and the <Administrative Permission Law of the People's Republic of China> and other laws and regulations.

Article 2 The Measures shall apply for the registration and administration of Formulas for Special Medical Purpose to be manufactured in China or imported from abroad

Article 3 The "Formulas for Special Medical Purpose", as mentioned in the Measures, refers to specialized processing preparation of formula to meet the special nutrients or dietary needs of people groups who have eating difficulty, digestion absorbing obstacle, metabolic disorders, or in specific disease state, including the Formulas for Special Medical Purpose for groups over one-year old, and Infant Formulas for Special Medical Purpose for groups between 0-month to 12-month old.

Article 4 The registration of Formulas for Special Medical Purpose, refers to for any application of the Formulas for Special Medical Purpose, China Food and Drug Administration shall review the product formulation, processing technology, label, instructions, and the clinic effect to prove product safety, nutritional adequacy and special medical purposes, and decide whether or not to approve the registration, according to the procedures and requirements of the Measures.

Article 5 China Food and Drug Administration shall be in charge of the registration and administration of the Formulas for Special Medical Purpose.

The administrative permission organization of China Food and Drug Administration shall be in charge of the acceptance of the application of the Formulas for Special Medical Purpose registration.

The food evaluation organization of China Food and Drug Administration shall be in charge of the inspection and appraise of the Formulas for Special Medical Purpose registration.

Article 6 China Food and Drug Administration shall be responsible for building up expert panel for the evaluation of Formulas for Special Medical Purpose. The expert panel is consisted of experts in food nutrition, clinical medicine, food safety, food processing and other fields.

Article 7 The registrant of Formulas for Special Medical Purpose refers to manufacturers applying for the registration of Formulas for Special Medical Purpose, including those companies who shall manufacture and sell the Formulas for Special Medical Purpose in China, and those foreign companies who shall export Formulas for Special Medical Purpose to China.

The manufacturers shall have the relevant abilities in the Research and Development, production, and testing for the Formulas for Special Medical Purpose. Companies shall set up independent R&D department, assigned with appointed staff and equipment, for the Formulas for Special Medical Purpose. Companies shall implement the <Good Manufacturing Practice for the Formulas for Special Medical Purpose>, and <Requirements on Every Unit of the Food Chain in the Food Safety Administration System>. Companies shall have testing capacity for all the items to the standards.

Article 8 After obtaining Manufacturing Permission of Formulas for Special Medical Purpose in accordance with the law, the production companies shall submit the application materials based on facts according the Measures, and be responsible for the truth of the materials.

Article 9 Manufacturers of Formulas for Special Medical Purpose shall manufacture the products according to the technical requirements including product formulas, producing process, which are approved, to ensure the quality and safety of Formulas for Special Medical Purpose.

Article 10 Registration of Formulas for Special Medical Purpose shall follow the principles of Being Scientific, Open, Fairness and Justice.

Article 11 Working staff who are responsible for the registration, and experts who are involved in the evaluation of the Formulas for Special Medical Purpose, shall keep the technical secrets which the applicants submitted confidential

Chapter II Application and Registration

Article 12 To register the Formulas for Special Medical Purpose, an applicant shall be submitted to the general bureau of China Food and Drug Administration with following documents:

(1) Formulas for Special Medical Purpose registration application form;
(2) Products R&D report, Product formulation and formula basis;
(3) Process technology documents;

(4) Product quality standards;
(5) Samples of product labels and package inserts;
(6) Sample testing report;
(7) Other materials to prove the R&D, production, and testing capability;
(8) Other materials to support the products' safety and nutrition sufficiency;
(9) Clinical trial report for the registration of Particular Whole Nutrition Formula.

Article 13 Within 5 working days from the date of receipt of the application documents, the administrative permission organization of China Food and Drug Administration shall issue a written notice of acceptance of the application to the applicant. If there is no confirmation within the period, it shall take the day of receiving the application documents as acceptance of the application.

For those who lack of documents or failed to meet the legal formats, China Food and Drug Administration shall inform the applicant in one time about all the rest documents need to complete or correct.

No other materials acceptable after the official acceptance of the application.

Article 14 China Food and Drug Administration shall review the application materials, and organize censors to conduct on-site inspection of the manufacturer, sampling inspection of test samples and on-site verification of clinical trials.

Article 15 On-site verification shall be conducted by the food evaluation organization of China Food and Drug Administration, who shall organize a censor team to inspect the Research & Development capability, production capability, testing capability, etc of the applicant, and issue a verification report.

Provincial Food and Drug Administration shall send personnel to participate the on-site inspections to the manufacturing companies which locate in the province.

Article 16 Sampling inspection shall be reviewed by qualified food inspection agencies entrusted by the food evaluation organization of China Food and Drug Administration.

China Food and Drug Administration shall announce the agencies list for the food inspection for the registration of Formulas for Special Medical Purpose.

Article 17 The food evaluation organization of China Food and Drug Administration shall select experts from expert pool for the Formulas for Special Medical Purpose to compose a review experts group, who shall review the application materials, verification reports, testing reports and related clinical trials to issue review conclusions.

Article 18 China Food and Drug Administration shall evaluate the review conclusions to make the approval decision. For approved applicants, the administration permission organization shall issue the <Registration Certificate of the Formulas for Special Medical Purpose > within 10 working days from the decision date. For disapproved applicants, the administration permission organization shall issue the < Disapproval Registration Decision Notice of Formulas for Special Medical Purpose >

within 10 working days from the decision date, and inform the applicants they have the right to apply for administrative reconsideration or bring an administrative lawsuit in accordance with law.

Article 19 Registration Certificate of the Formulas for Special Medical Purpose contains following contents:
(1) Product name;
(2) Company name, legal person, manufacturing address;
(3) Registration number and period of validity;
(4) Product classification;
(5) Product formulation;
(6) Producing process;
(7) Product labels and package inserts.

Article 20 The period of validity of Registration Certificate of the Formulas for Special Medical Purpose Registration lasts for 5 years. Companies who shall continue to manufacture or import the products after the expiration should submit re-register application to China Food and Drug Administration 60 days before the expiration date, and submit the following materials:
(1) Re-register application form of Formulas for Special Medical Purpose;
(2) Registration Certificate of the Formulas for Special Medical Purpose;
(3) Explanation of unqualified cases of production, sales and sample testing in 5 years;
(4) Summary of product usage and adverse effects in 5 years.

Article 21 Disapproval of the re-register when any one of below situations appears:
(1) Failed to obtain manufacturing permission after the registration;
(2) Submission date of re-register doesn't follow the appointed time;
(3) Twice and more unqualified record in the provincial and above inspection within one year after registration;
(4) Companies failed to maintain capability of producing, Research and Development, and testing;
(5) Companies failed to record producing and sales information as required;
(6) Other situations failed to meet the requirements.

Article 22 The food evaluation organization of China Food and Drug Administration shall evaluate and review the re-register application materials, and make review conclusion.

China Food and Drug Administration shall make the approval decision based on the review conclusions. For approved applicants, the administration permission organization shall renew the <Registration Certificate of the Formulas for Special Medical Purpose> with the same registration code and number. For disapproved applicants, the administration permission organization shall issue written notice to the applicants.

Article 23 Within the validity period of the Registration Certificate of the Formulas for Special Medical Purpose, when there is any change in company name, legal person or manufacturing address, the company should submit the application of information change of the registration to China Food and Drug Administration, and submit Registration Information Change Application Form and related testimonial material.

For other changes for the information stated in the Registration Certificate, company should submit registration application.

Article 24 The food evaluation organization of China Food and Drug Administration shall evaluate and review the registration information change application materials, and make review conclusion.

China Food and Drug Administration shall make the approval decision based on the review conclusions. For approved applicants, the administration permission organization shall change the <Registration Certificate of the Formulas for Special Medical Purpose> with the same registration code and number. For disapproved applicants, the administration permission organization shall issue written notice to the applicants.

Article 25 China Food and Drug Administration shall make the approval decision within 20 working days from the acceptance date of the application for the registration, re-register, and information change of Formulas for Special Medical Purpose.

The time for on-site inspection, sample testing, technology evaluation and review is excluded from the period mentioned above. On-site inspection to domestic companies should be completed within 20 working days. Sample testing to domestic companies should be completed within 30 working days. On-site verification of clinical trials should be completed within 40 days. Technology evaluation and review should be completed within 60 working days.

Time required for the on-site inspection and sample testing for offshore companies shall be confirmed according to actual situations.

Article 26 The general bureau of China Food and Drug Administration shall release in time the information of the product name, company name, legal person, manufacturing address, registration number, validity period, and product classification of the registration approved Formulas for Special Medical Purpose.

Chapter III Clinical Trial

Article 27 Registration for Particular Whole Nutrition Formula has to conduct clinical trial, and other Formulas for Special Medical Purpose not required. When required to conduct clinical trial, the applicant should entrust qualified clinical trial agency to issue clinical trial report.

Clinical trial report should contain complete statistics analysis report and data.

Article 28 Clinical trial shall be conducted following the <Regulation on the Management of Clinical Trial Quality for Formulas for Special Medical Purpose>, which is issued by the general bureau of China Food and Drug Administration.

Article 29 Clinical trial agency should be selected from the appointed agencies by the general bureau of China Food and Drug Administration. The list of clinical trial agencies is appointed and released by China Food and Drug Administration.

Clinical trial can be conducted by several agencies organized by the applicants. The number of clinical trial agencies participated should not exceed five, and leading agency and statistic record agency should be appointed clearly.

Article 30 Registration applicant should be responsible for the quality and safety of the test and control samples for the clinical trial.

Test sample for clinical trial should be manufactured by the applicant, and up to the standards of testing. The manufacturing condition should be in accordance with the <Good Manufacturing Practice of Formulas for Special Medical Purpose>.

Article 31 The food evaluation organization of China Food and Drug Administration shall organize on-site verification for the clinical trials, and conduct sampling on test samples.

On-site verification can be conducted by materials review, return visit on subjects, and other methods.

Chapter IV Labels and Instructions

Article 32 The label for Formulas for Special Medical Purpose should follow the regulations of Article 67 <Food Safety Law of People's Republic of China>, and national standards regulation on labeling for food safety.

Article 33 The relative content on both label and instructions of Formulas for Special Medical Purpose shall be consistent. Content involving information stated in the registration certificate shall be consistent with the registration certificate, and indicate the registration number.

For the labels which cover all the information of instruction, no separate package insert is necessary.

Article 34 Content on the Labels and instructions of Formulas for Special Medical Purpose shall be true, accurate, clear, durable, eye-catching and easy to read. Font color and the background color of the label shall be in contrasting colors, and brightness contrast shall be above 70%.

Article 35 Labels and instructions of Formulas for Special Medical Purpose shall not contain false or fake content, and shall not involve content of function of disease prevention or treatment. Companies shall be responsible for the content of the labels and instructions they provide.

Article 36 The product name of Formulas for Special Medical Purpose shall indicate the real properties of the food. Use the classification names or equivalent names regulated by < General Regulation of Food Safety National Standard for Infant Formula for Special Medical Purpose> and <General Regulation of Food Safety National Standard for Formulas for Special Medical Purpose>. The product name shall be clearly marked on the label and instructions using the largest font.

Article 37 Labels and instructions of Formulas for Special Medical Purpose shall indicate the following statements in an obvious place:
(1) Under instruction of doctor or clinical dietitian;

(2) Not suitable for non-targeted people group;
(3) Forbidden for parenteral alimentation and intravenous injection.

Chapter V Legal Liabilities

Article 38 China Food and Drug Administration can revoke the registration certificate base on the appeal of interested party or responsibility, if any of the following situations will be applied:
(1) Administrative staff makes approval decision by misuse of authority and neglect of duty;
(2) Unauthorized registration approval;
(3) Illegal registration approval;
(4) Issue registration to the applicant that disqualify or does not conform to the related rules;
(5) Other situation that can legally revoke the approval certificate of Formulas for Special Medical Purpose.

Any applicant who obtains the registration certificate of Formulas for Special Medical Purpose by fraud, bribery or other improper means shall receive revocation of the registration. The registration revoked applicant can not apply for the registration of Formulas for Special Medical Purpose within five years.

Article 39 Companies producing Formulas for Special Medical Purpose which fail to be registered, or don't follow the product formulation or manufacturing technique as registered, shall receive penalty in accordance with Article 124 of Food Safety Law. For serious cases, revoke the registration certification of Formulas for Special Medical Purpose.

Article 40 For the production operation label and instructions which fail to follow the Measures for Formulas for Special Medical Purpose, it shall be penalized in accordance with Article 125 of Food Safety Law. For serious cases, revoke the registration certification of Formulas for Special Medical Purpose.

Article 41 Companies producing Formulas for Special Medical Purpose which fail to follow the rules to build up production quality management system and operate it effectively, or fail to submit self-check report regularly, shall receive penalty in accordance with Article 126 of Food Safety Law. For serious cases, revoke the registration certification of Formulas for Special Medical Purpose.

Article 42 Companies having food production license revocation can not apply for the registration of Formulas for Special Medical Purpose in five years from the date of the penalty.

Article 43 China Food and Drug Administration shall revoke the registration approval of Formulas for Special Medical Purpose when any one of below situations appears:
(1) Log-off application from the enterprise;
(2) No renew after expiration;
(3) Revoke of production license;
(4) Twice unqualified record of the registered product in sample inspection by Food and Drug Administration at national or provincial level;
(5) Company terminated according to the law;
(6) Cancellation and revocation of registration certificate.

Article 44 Any food test organization or staff who forges testing reports, any certification authority who forges certification results, shall receive penalty in accordance with Article 138 and Article 139 of Food Safety Law separately.

Article 45 Any department or staff of Food and Drug Administration who approves the registration to nonqualified applicants or by overstepping legitimate authority shall receive penalty in accordance with Article 144 of Food Safety Law.

Any department or staff of Food and Drug Administration who abuse of power, neglect of duty, practice favoritism and malpractice during the registration approval procedures, shall receive penalty in accordance with Article 145 of Food Safety Law.

Chapter VI Supplementary Provisions

Article 46 Formulas for Special Medical Purpose for groups over one-year old include Whole Nutritional Formula, Special Whole Nutrition Formula, and Non Whole Nutritional Formula.

Whole Nutritional Formula refers to Formulas for Special Medical Purpose which can be used as single nutrition source to meet the nutritional needs of targeted groups.

Special Whole Nutrition Formula refers to Formulas for Special Medical Purpose which can be used as single nutrition source to meet the nutritional needs of the targeted groups who are in special medical conditions. Common Special Whole Nutrition Formula include: Whole Nutrition Formula for diabetes, Whole Nutrition Formula for respiratory disease, Whole Nutrition Formula for nephropathy, Whole Nutrition Formula for tumor, Whole Nutrition Formula for liver disease, Whole Nutrition Formula for Sarcopenia, Whole Nutrition Formula for trauma, and infection, and surgery and the other state of stress, Whole Nutrition Formula for Whole Nutrition Formula for inflammatory intestinal disease, Whole Nutrition Formula for food protein allergy, Whole Nutrition Formula for intractable epilepsy, Whole Nutrition Formula for gastrointestinal tract mal-absorption and pancreatitis, Whole Nutrition Formula for fatty acid dysbolism, Whole Nutrition Formula for obesity and fat reducing surgery.

Non Whole Nutritional Formula refers to Formulas for Special Medical Purpose which can meet the nutritional needs of the targeted groups, but not suitable as single nutrition source. Common Non-Whole Nutrition Formula includes nutrient components (protein components, components of fat, carbohydrate components), electrolyte formula, thickening component, liquid formula and amino acid dysbolism formula.

Article 47 Infant Formulas for Special Medical Purpose for groups between 0-month to 12-month old include: Low lactose or Lactose-free formula, partially hydrolyzed Milk protein formula, highly hydrolysis of milk protein formula or amino acids formula, prematurity/low birth weight infant formula, amino acids metabolism disorders formula and breast milk nutritional supplements.

Article 48 The format of approval number of Formulas for Special Medical Purpose is as follows: TS (National Food Registration Charaters) + 4 digitals of the year + 4 digitals as sequence number. TS stands for Formulas for Special Medical Purpose.

Article 49 The China Food and Drug Administration shall be responsible for the interpretation of the Measures.

Article 50 The Measures shall enter into force on XX month XX date, 2015.

Original Chinese Version

特殊医学用途配方食品注册管理办法

（试行）

（征求意见稿）

第一章　总则

第一条　为严格特殊医学用途配方食品注册管理，保证特殊医学用途配方食品质量安全，根据《中华人民共和国食品安全法》及其实施条例、《中华人民共和国行政许可法》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和进口特殊医学用途配方食品的注册管理，适用本办法。

第三条　本办法所称特殊医学用途配方食品，是指为了满足进食受限、消化吸收障碍、代谢紊乱或特定疾病状态人群对营养素或膳食的特殊需要，专门加工配制而成的配方食品，包括适用于 1 岁以上人群的特殊医学用途配方食品和适用于 0 月龄至 12 月龄的特殊医学用途婴儿配方食品。

第四条　特殊医学用途配方食品注册，是指国家食品药品监督管理总局根据申请，依照本办法规定的程序和要求，对特殊医学用途配方食品的产品配方、生产工艺、标签、说明书以及表明产品安全性、营养充足性和特殊医学用途临床效果进行审查，并决定是否准予注册的审批过程。

第五条　国家食品药品监督管理总局负责特殊医学用途配方食品的注册管理工作。

国家食品药品监督管理总局行政许可受理机构负责特殊医学用途配方食品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负责特殊医学用途配方食品注册的审评工作。

第六条　国家食品药品监督管理总局负责组建特殊医学用途配方食品注册审评专家库。专家库由食品营养、临床医学、食品安全、食品加工等领域专家组成。

第七条　特殊医学用途配方食品注册人，是指申请特殊医学用途配方食品注册的生产企业，包括拟在我国境内生产并销售特殊医学用途配方食品的企业和拟向我国境内出口特殊医学用途配方食品的境外企业。

生产企业应当具备与所生产特殊医学用途配方食品相适应的研发、生产和检验能力。企业应当设立独立的特殊医学用途配方食品研发机构，并配备专职人员和设备；执行《特殊医学用途配方食品良好生产规范》与《食品安全管理体系食品链中各类组织的要求》；具有标准规定的全部项目检验能力。

第八条　特殊医学用途配方食品生产企业依法取得生产许可后，应当按照本办法的要求如实提交申请材料，并对材料的真实性负责。

第九条　特殊医学用途配方食品生产企业应当按照批准注册的产品配方、生产工艺等技术要求组织生产，保证特殊医学用途配方食品质量安全。

第十条　特殊医学用途配方食品注册，应当遵循科学、公开、公平、公正的原则。

第十一条　负责特殊医学用途配方食品注册的工作人员和参与审评的专家，应当对申请人提交的技术秘密予以保密。

第二章　申请与注册

第十二条　申请特殊医学用途配方食品注册，应当向国家食品药品监督管理总局提出，并提交下列材料：

（一）特殊医学用途配方食品注册申请书；

（二）产品研发报告和产品配方设计及依据；

（三）生产工艺资料；

（四）产品质量的标准要求；

（五）产品标签、说明书设计样稿；

（六）试验样品检验报告；

（七）研发、生产和检验能力证明材料；

（八）其他表明产品安全性、营养充足性的材料。

（九）特定全营养配方食品注册，还应提交临床试验报告。

第十三条　国家食品药品监督管理总局行政许可受理机构应当在5个工作日内书面告知申请人受理情况，逾期不告知的，自收到申请材料之日起即为受理。

申请材料不齐全或者不符合法定形式的，应当一次性告知申请人需要补正的全部内容。

注册申请受理后不再接受申请人提交的其他材料。

第十四条　国家食品药品监督管理总局食品审评机构对申请材料进行审查，并组织审查人员对生产企业进行现场核查、对试验样品进行抽样检验和对临床试验进行现场核查。

第十五条　现场核查由国家食品药品监督管理总局食品审评机构组织核查组对申请人的研发能力、生产能力、检验能力等情况进行核查，并出具核查报告。

生产企业所在地省级食品药品监督管理部门派员参与现场核查。

第十六条　抽样检验由国家食品药品监督管理总局食品审评机构委托有资质的食品检验机构进行。

国家食品药品监督管理总局公布承担特殊医学用途配方食品的食品检验机构名单。

第十七条　国家食品药品监督管理总局食品审评机构从特殊医学用途配方食品审评专家库中选取专家，组成审评专家组，对申请材料、核查报告、检验报告和有关临床试验报告进行技术审评，做出审查结论。

第十八条　国家食品药品监督管理总局根据审查结论做出审批决定，准予注册的，行政许可受理机构自决定之日起 10 个工作日内颁发《特殊医学用途配方食品注册证书》；不予注册的，行政许可受理机构自决定之日起 10 个工作日内发出《特殊医学用途配方食品不予注册决定书》，并告知申请人享有依法申请行政复议或者提起行政诉讼的权利。

第十九条　特殊医学用途配方食品注册证书包括以下内容：

（一）产品名称；

（二）企业名称、法定代表人、生产地址；

（三）注册号及有效期；

（四）产品类别；

（五）产品配方；

（六）生产工艺；

（七）产品标签、说明书。

第二十条　特殊医学用途配方食品注册证书有效期为 5 年。有效期届满，需要继续生产或进口的，应当在有效期届满 60 日前，向国家食品药品监督管理总局提出再注册申请，并提交下列材料：

（一）特殊医学用途配方食品再注册申请书；

（二）特殊医学用途配方食品注册证书；

（三）5 年内产品生产、销售、监督抽检情况，对产品不合格情况应当做出说明；

（四）5 年内产品使用情况及不良反应情况总结。

第二十一条　有下列情形之一的，不予再注册：

（一）注册后未取得生产许可的；

（二）未在规定时间内提出再注册申请的；

（三）注册产品一年内在省级以上监督抽检中出现 2 次及以上不合格的；

（四）企业未能保持生产、研发、检验能力的；

（五）企业未按要求记录生产销售信息的；

（六）其他不符合有关规定的情形。

第二十二条　国家食品药品监督管理总局食品审评机构对再注册申报材料进行审查，做出审查结论。

国家食品药品监督管理总局根据审查结论做出审批决定，准予再注册的，向申请人换发注册证书，注册文号不变；不准予再注册的，向申请发出书面通知。

第二十三条　特殊医学用途配方食品注册证书有效期内，企业名称、法定代表人、生产地址名称发生变化的，应当向国家食品药品监督管理总局提出变更注册申请，并提交变更注册申请书及相应的证明材料。

证书载明的其他事项需要变更的，提出注册申请。

第二十四条　国家食品药品监督管理总局食品审评机构对变更注册申报材料进行审查，做出审查结论。

国家食品药品监督管理总局根据审查结论做出审批决定，准予变更注册的，向申请人换发注册证书，注册文号不变；不准予变更注册的，向申请发出书面通知。

第二十五条　国家食品药品监督管理总局应当自受理申请之日起 20 个工作日内对特殊医学用途配方食品注册、再注册与变更注册申请做出审批决定。

现场核查、抽检检验、技术审评所需时间不计算在前款规定的期限内，其中对境内生产企业的现场核查应当在 20 个工作日内完成，对境内试验样品的抽样检验工作应当在 30 个工作

日内完成，对临床试验的现场核查工作应当在 40 个工作日内完成，技术审评工作应当在 60 个工作日内完成。

对境外生产企业现场核查和对境外试验样品的抽样检验工作所需时间根据境外生产企业实际情况确定。

第二十六条　国家食品药品监督管理总局应当及时公布批准注册的特殊医学用途配方食品名称、企业名称、法定代表人、生产地址、注册号及有效期、产品类别信息。

第三章　临床试验

第二十七条　特定全营养配方食品需进行临床试验，其他特殊医学用途配方食品不需要进行临床试验。需要进行临床试验的，由注册人委托有资质的临床试验机构出具临床试验报告。

临床试验报告应当包括完整的统计分析报告和数据。

第二十八条　临床试验应当按照《特殊医学用途配方食品临床试验质量管理规范》开展。

《特殊医学用途配方食品临床试验质量管理规范》由国家食品药品监督管理总局发布。

第二十九条　临床试验机构应当在国家食品药品监督管理总局认定的临床试验机构中选择。临床试验机构名单由国家食品药品管理总局认定、公布。

临床试验可由申请人组织多中心临床试验，参加临床试验机构不得多于五个，应当明确组长单位和统计单位。

第三十条　注册申请人应当对用于临床试验的试验样品和对照样品的质量安全负责。

用于临床试验的试验样品应当由申请人生产并经检验合格，生产条件应符合《特殊医学用途配方食品良好生产规范》。

第三十一条　国家食品药品监督管理总局食品审评机构组织对临床试验资料进行现场核查，对试验样品进行抽样检验。

现场核查可以采用查阅资料、回访受试者等方式进行。

第四章　标签和说明书

第三十二条　特殊医学用途配方食品的标签，应当按照《中华人民共和国食品安全法》第六十七条和食品安全国家标准的规定进行标注。

第三十三条 特殊医学用途配方食品的标签和说明书对应的内容应当一致，涉及特殊医学用途配方食品注册证书内容的，应当与注册证书内容一致，并标明注册号。

标签已涵盖说明书全部内容的，可不另附说明书。

第三十四条 特殊医学用途配方食品标签、说明书的内容应当真实准确、清晰持久、醒目易读。

标签上的字体颜色和底色应当采用对比色，并且亮度对比应当在 70%以上。

第三十五条　特殊医学用途配方食品标签、说明书的内容不得含有虚假内容，不得涉及疾病预防、治疗功能。生产企业对其提供的标签、说明书的内容负责。

第三十六条　特殊医学用途配方食品的产品名称应反映食品的真实属性，使用《食品安全国家标准特殊医学用途婴儿配方食品通则》、《食品安全国家标准特殊医学用途配方食品通则》中规定的分类名称或等效名称，并在食品标签、说明书的主要位置用最大的字体清晰标示。

第三十七条　特殊医学用途配方食品标签、说明书应在醒目位置标示以下警示说明：

（一）请在医生或临床营养师指导下使用；

（二）不适用于非目标人群使用；

（三）本品禁止用于肠外营养支持和静脉注射。

第五章　法律责任

第三十八条　有下列情形之一的，国家食品药品监督管理总局根据利害关系人的请求或者依据职权，可以撤销特殊医学用途配方食品注册证书：

（一）工作人员滥用职权、玩忽职守做出准予注册决定的；

（二）超越法定职权做出准予注册决定的；

（三）违反法定程序做出准予注册决定的；

（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决定的；

（五）依法可以撤销注册证书的其他情形。

申请人以欺骗、贿赂等不正当手段取得注册证书的，应当予以撤销，申请人五年内不得提出特殊医学用途配方食品注册申请。

第三十九条　生产经营未按规定注册的特殊医学用途配方食品，或者未按注册的产品配方、生产工艺等技术要求组织生产的，按照《食品安全法》第一百二十四条的规定给予处罚，情节严重的吊销特殊医学用途配方食品注册证书。

第四十条　生产经营标签、说明书不符合本办法规定的特殊医学用途配方食品的，按照《食品安全法》第一百二十五条的规定给予处罚，情节严重的吊销特殊医学用途配方食品注册证书。

第四十一条　特殊医学用途配方食品生产企业未按规定建立生产质量管理体系并有效运行，或者未定期提交自查报告的，按照《食品安全法》第一百二十六条的规定给予处罚，情节严重的吊销特殊医学用途配方食品注册证书。

第四十二条　被吊销食品生产许可证的企业，自处罚决定作出之日起五年内不得提出特殊医学用途配方食品注册申请。

第四十三条　有下列情形之一的，由国家食品药品监督管理总局注销特殊医学用途配方食品注册证书：

（一）企业申请注销的；

（二）有效期届满未延续的；

（三）生产许可证被吊销的；

（四）注册产品两次被国家、省级食品药品监督管理部门监督抽检不合格的；

（五）企业依法终止的；

（六）注册证书被撤销、吊销的。

第四十四条　食品检验机构、食品检验人员出具虚假检验报告，认证机构出具虚假认证结论的，分别按照《食品安全法》第一百三十八条、第一百三十九条的规定给予处罚。

第四十五条　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，按照《食品安全法》第一百四十四条的规定给予处罚。

食品药品监督管理部门及其工作人员在注册审批过程中滥用职权、玩忽职守、徇私舞弊的，按照《食品安全法》第一百四十五条的规定给予处罚。

第六章　附则

第四十六条　适用于 1 岁以上人群的特殊医学用途配方食品，包括全营养配方食品、特定全营养配方食品、非全营养配方食品。

全营养配方食品，是指可作为单一营养来源满足目标人群营养需求的特殊医学用途配方食品。

特定全营养配方食品，是指可作为单一营养来源满足目标人群在特定疾病或医学状况下营养需求的特殊医学用途配方食品。常见特定全营养配方食品有：糖尿病全营养配方食品，呼吸系统疾病全营养配方食品，肾病全营养配方食品，肿瘤全营养配方食品，肝病全营养配方食品，肌肉衰减综合征全营养配方食品，创伤、感染、手术及其他应激状态全营养配方食品，炎性肠病全营养配方食品，食物蛋白过敏全营养配方食品，难治性癫痫全营养配方食品，胃肠道吸收障碍、胰腺炎全营养配方食品，脂肪酸代谢异常全营养配方食品，肥胖、减脂手术全营养配方食品。

非全营养配方食品，是指可满足目标人群部分营养需求的特殊医学用途配方食品，不适用于作为单一营养来源。常见非全营养配方食品有：营养素组件（蛋白质组件、脂肪组件、碳水化合物组件），电解质配方，增稠组件，流质配方和氨基酸代谢障碍配方。

第四十七条　适用于 0 月龄至 12 月龄的特殊医学用途婴儿配方食品有：无乳糖配方食品或低乳糖配方食品，乳蛋白部分水解配方食品，乳蛋白深度水解配方食品或氨基酸配方食品，早产/低出生体重婴儿配方食品，氨基酸代谢障碍配方食品和母乳营养补充剂。

第四十八条　特殊医学用途配方食品批准文号的格式为：国食注字 TS+4 位年号+4 位顺序号，其中 TS 代表特殊医学用途配方食品。

第四十九条　本办法由国家食品药品监督管理总局负责解释。

第五十条　本办法自 2015 年 XX 月 XX 日起施行。