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Measures for the Registration and Administration of Formulas for Special Medical Purpose

特殊医学用途配方食品注册管理办法

Regulation's Main Points

Measures for the Registration and Administration of Formulas for Special Medical Purpose

Chapter I General Provisions

Article 1 To strengthen the administration of application of Formulas for Special Purpose, to ensure the quality and safety Formulas for Special Medical Purpose, the Measures are formulated in accordance with the <Food Safety 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 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 4 Registration of Formulas for Special Medical Purpose shall follow the principles of Being Scientific, Open, Fairness and Justice.

Article 5 China Food and Drug Administration (CFDA) is responsible for the Registration of Formulas for Special Medical Purpose.

CFDA accepting institution is responsible for accept the registration application.

CFDA review board is responsible for review the registration application.

CFDA inspection institution is responsible for on-site inspection during the review process.

Article 6 CFDA 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 CFDA should strength informative construction to improve the registration management of Formulas for Special Medical Purpose.

Chapter 2 Registration

Section 1 Application and Acceptance

Article 8 The applicant of Formulas for Special Medical Purpose refers to those companies who manufacture and sell the Formulas for Special Medical Purpose in China, and those foreign companies who export Formulas for Special Medical Purpose to China.

The manufacturers should have relevant abilities in the Research and Development, production, and testing for the Formulas for Special Medical Purpose. Companies should set up independent R&D department, assigned with appointed R&D staff, food safety management staff and food safety technical staff; build up appropriate manufacturing quality management system base on GMP requirements; possess all items testing capacity for each batches base on the national standards.

R&D department should have food related professional staff with senior title or other staff with appropriate abilities.

Article 9 To register the Formulas for Special Medical Purpose, the applicant should submit to CFDA 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;

Clinical trial report should be provided for the registration of Particular Whole Nutrition Formula.
The applicant should be responsible for the reality of the application materials.

Article 10 The accepting institution should handle the registration application base on different conditions as below:

1) If the application items do not need to be registered, the accepting institution should inform the applicant "Not Accept" decision;
2) If CFDA does not responsible for the application items, the accepting institution should inform the applicant "Not Accept" decision and the right administrative officials;
3) If any mistakes exist in the application materials, the accepting institution should allow the applicant make corrections immediately;
4) If the application materials are incomplete or not qualify, the accepting institution should inform the applicant what kind of supplementary materials should be provided immediately or

Within 5 business days. The accepting institution should accept the application materials if past due;

5) If the application items belong to CFDA's responsibility, the application materials are complete, conform to the law, the supplementary materials are quality, the accepting institution should

issue “Accept” decision.

The accepting institution should issue a written paper with special stamp and issue date on it whether the application materials are “accept” or “not accept”.

Section 2 Review and Decision

Article 11 The review board should review the application materials, conduct on-site inspection or sampling test as needed, process clinical trial on-site inspection and organize expert discussion regarding professional issues.

Article 12 The inspection institution should finish the on-site inspection of R&D capability, production ability, test ability etc. and issue the inspection report within 20 business days since receive the notice from the review board.

The inspection institution should inform the provincial FDA of the applicant get involve in the on-site inspection.

Article 13 The review board should assign a food inspection institution with legal qualifications for sampling rest.

The inspection institution should finish the sampling test within 30 business days since receive the assignment.

Article 14 The inspection institution should finish the clinical trials on-site inspection to confirm its reality, integrity, accuracy etc. and issue the inspection report within 40 business days since receive notice from the review board.

Article 15 The review board shall choose experts from the expert panel and discuss any issues related with the review process, and create experts’ comments.

Article 16 The review board should finish review process and make review conclusion within 60

business days since receive the application materials base on the inspection report, test report and experts' comments.

If any supplementary materials need to be provided, the review board should inform the applicant at a time. The applicant should submit the supplementary materials within 6 months. The time limit of prepare supplementary materials does not include in the review time.

The review time can be extended 30 business days after be approved by the review board base on special situations. The review board should notice the applicant the extension decision in a written letter.

Article 17 The review board should issue suggestion of "allow to register" if the product is scientific and safe; manufacturing process is reasonable, practicable and quality controllable; technical requirements and test method are scientific and reasonable.

The review board should issue suggestion of "not allow to register" letter to the applicant. If the applicant disagree with the suggestion, should submit the second review application letter within 20 business days since they receive the suggestion letter. The content of the second review will be only the original application materials.

The review board should make the second review decision within 30 business days since they receive the application. The review board should inform the applicant by a written letter if any changes happen to the final decision.

Article 18 CFDA should make a decision of the registration application within 20 business days since accept the application.

On-site inspection, sampling test and the second review will not be calculated into the time limit of the review process and registration final decision process.

Article 19 The accepting institution should issue and deliver the registration certificate of Formulas for Special Medical Purpose within 10 business days since CFDA make the "allow to register" decision.; The accepting institution should issue "Not allow to register" decision within 10 business days and inform the applicant about their litigation rights since CFDA make the "Not allow to register" decision.

The validity of the registration certificate of Formulas for Special Medical Purpose is 5 years.

Article 20 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.

Format of registration number of Formulas for Special Medical Purpose is ‘国食注字 TY+Year (XXXX)+sequence number (XXXX): TY represents Formulas for Special Medical Purpose.

Section 3 Alternation and Renewal

Article 21 The applicant should submit alteration application materials as below if they want to make changes on the registration certificate and its attachments:

1) Alteration application form;
2) Support documents of the original registration certificate and its attachments.

Article 22 CFDA should conduct inspection if the applicant makes changes on the product formula, manufacturing process etc. which may affect product safety, nutrition sufficiency and clinical response. And CFDA should finish the alteration review within the time limit (See Article 18).

CFDA should confirm those changes if the applicant makes changes on the company name, manufacturing address etc. which will not affect product safety, nutrition sufficiency and clinical response. And CFDA should issue the final decision within 10 business days since they accept the application.

Article 23 CFDA should issue a new registration certificate with the same registration number and validity date if they approve the alteration application; Or issue "Not allow to alternate the registration" if they disapprove the alteration application.

Article 24 The period of validity of Registration Certificate of Formulas for Special Medical Purpose is 5 years. Companies who shall continue to manufacture or import their products after the expiration date should submit registration renewal application to CFDA 6 months before it gets expired, and submit the following materials:

1) Registration renewal application form;
2) Quality safety management condition;
3) Self-test report of the Quality management system;
4) Follow-up evaluation report.

Article 25 CFDA should conduct inspection if the applicant applies for registration renewal and finish the registration renewal process within the time limit (See Article 18). It will be recognized as approve renewal if CFDA didn't make decisions after due day.

Article 26 CFDA should issue a new registration certificate with the same registration number if they approve the renewal application and the validity date will be recalculated since it gets approve; Or issue "Not allow to renew the registration" if they disapprove the renewal application.

Article 27 Disapprove of the registration renewal when any one of the below situation appears:

1) Submission date of the registration renewal doesn't follow the appointed time;
2) Three or more unqualified batches are found during the provincial and above level inspection within one year after registration;

3) Companies failed to maintain capability of R&D and testing;
4) Any situations not conform to the law and regulations related with product safety, nutrition sufficiency and clinical response.

Article 28 Any other situations of the registration alteration and renewal which are not mentioned in this section will be regulated by the section 1 and section 2 of this chapter.

Chapter 3 Clinical Trials

Article 29 Registration for Particular Whole Nutrition Formula has to conduct clinical trials. The applicant should assign qualified clinical trial center to issue clinical trial report. Clinical trial report should contain complete statistics analysis report and data.

Article 30 Clinical trial should be conducted following the Registration on the Management of Clinical Trial Quality for Formulas for Special Medical Purpose, which is issued by CFDA.

Article 31 The applicant should conduct multi-center clinical trials and clarify the leading agency and statistic agency.

Article 32 The applicant should be responsible for the quality and safety of the test and samples for clinical trials.
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.

Chapter 4 Label and Instruction Book

Article 33 The label for Formulas for Special Medical Purpose should follow the law, regulation, guidance and food safety national standard.

Article 34 The relative content on both label and instruction book of Formulas for Special Medical Purpose shhould be consistent. Content involving information stated in the registration certificate shall be consistent with the registration certificate, and indicate the registration number.
For labels which cover all the information of instruction, no separate package insert is necessary.

Article 35 Content on the labels and instruction book of Formulas for Special Medical Purpose should be true, accurate, cleat, durable, easy to catch and read.

Article 36 Labels and instruction book of Formulas for Special Medical Purpose should not contain false or fake content, and should not involve content of function of disease prevention or treatment. Companies shall be responsible for the content of the labels and instruction book they provide.

Article 37 The product name of Formulas for Special Medical Purpose should indicate the real properties of the food. Use the classification names or equivalent names regulated by food safety national standard.

Article 38 Labels and instruction book of Formulas for Special Medical Purpose should indicate the following statements in an obvious place:

1) Under instruction of your doctor or clinical dietitian;
2) Not suitable for non-targeted people group;
3) Forbidden for parenteral alimentation and intravenous injection.

Chapter 5 Supervision

Article 39 Manufacturer should follow the product formula, production process and other technical requirements on the registration certificate to conduct the manufacturing which ensure the food safety.

Manufacturer should follow its original registration certificate to produce their products without making any changes to the production conditions or requirements before the alternation registration application been approved.

Manufacturer should follow the alternated registration certificate to product their products after the alternation registration application been approved.

Article 40 Any staffs or experts who get involve in the registration acceptance, technical review process, on-site inspection, sampling test, clinical trials should keep trade secret confidential.

The applicant should indicate the trade secret in the application materials.

Article 41 CFDA should revoke food approval certificate when any one of below situations appears:

1) Approve the registration by any administrative officers who abuse their power;
2) Approve registration beyond legal responsibility;
3) Approve registration violate legal process;
4) Approve registration which submitted by some applicants who are not qualified;
5) Food production permit has been revoked;
6) Other situations.

Article 42 CFDA should cancel registration when one of below situations appears:

1) Company apply for cancelation;
2) Didn't submit renewal after the certificate been expired;
3) Legally terminated;
4) Certificate has been legally revoked, recalled or cancelled;
5) Other situations.

Chapter 6 Legal Liability

Article 43 CFDA shall not accept or allow to register and issue a warning letter if the applicant conceal the fact or provide any false application material; the applicant cannot submit any

registration application in the following one year.

Article 44 CFDA shall revoke the registration certificate and request a penalty of 10000-30000 RMB if the applicant achieve the registration certificate by cheating, bribing or any other improper means; the applicant cannot submit any application in the follow three years.

Article 45 Town or above level FDA should charge corrections and issue a warning letter if counterfeit, obliterate, resell, rent, borrow or transfer the health food registration certificate, and impose a penalty below 10 thousand RMB; if the case is serious, a penalty of 10000-30000 RMB will be applied.

Article 46 Regarding any alternations do not affect the product safety, nutrition sufficiency and clinical response without filing the application, town or above level FDA should charge corrections and issue a warning letter; if the company refuse to make corrections, a penalty of 10000-30000 RMB will be applied.

Regarding any alternations may affect the product safety, nutrition sufficiency and clinical response without filing the application, town or above level FDA should conduct punishment base one Food Safety Law Article 124 Clause 1.

Article 47 Food Safety Law Article 144 will be applied if any departments or officers of FDA approve registration which submitted by some applicants who are not qualified.

Food safety law Article 145 will be applied if any departments or officers of FDA abuse authority, neglect duty.

Chapter 7 Appendix

Article 48 Formulas for Special Medical Purpose is a kind of formula food which can support patients with feeding inhibition, digest and absorb problems, metabolic disorder or require other special diets; Infant formulas for Special Medical Purpose for group between 0-month to 12-month old and

Formulas for Special Medical Purpose for groups over one-year old are all belong to Formulas for Special Medical Purpose.

Article 49 Infant formulas for Special Medical Purpose for group 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 50 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 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, infection, surgery and other state of stress, 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 Nutrition Formula refers to Formulas for Special Medical Purpose which can meet the nutritional need of the targeted groups, but not suitable as single nutrition source. Common Non-Whole Nutrition Formula included nutrient components (protein components, components of fat, carbohydrate components), electrolyte formula, thickening component, liquid formula and amino acid dysbolism formula.

Article 51 Diet provided by the hospital cannot be regulated by this measures.

Article 52 The measure will be effective in July 1st 2016.

Original Chinese Version

特殊医学用途配方食品注册管理办法

第一章 总 则

第一条 为规范特殊医学用途配方食品注册行为，加强注册管理，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》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特殊医学用途配方食品的注册管理，适用本办法。

第三条 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过程。

第四条 特殊医学用途配方食品注册管理，应当遵循科学、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受理机构（以下简称受理机构）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（以下简称审评机构）负责特殊医学用途配方食品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）负责特殊医学用途配方食品注册审评过程中的现场核查工作。

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

第七条 国家食品药品监督管理总局应当加强信息化建设，提高特殊医学用途配方食品注册管理信息化水平。

第二章 注 册

第一节 申请与受理

第八条 特殊医学用途配方食品注册申请人（以下简称申请人）应当为拟在我国境内生产并销售特殊医学用途配方食品的生产企业和拟向我国境内出口特殊医学用途配方食品的境外生产企业。

申请人应当具备与所生产特殊医学用途配方食品相适应的研发、生产能力，设立特殊医学用途配方食品研发机构，配备专职的产品研发人员、食品安全管理人员和食品安全专业技术人员，按照良好生产规范要求建立与所生产食品相适应的生产质量管理体系，具备按照特殊医学用途配方食品国家标准规定的全部项目逐批检验的能力。

研发机构中应当有食品相关专业高级职称或者相应专业能力的人员。

第九条 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其依据；

（三）生产工艺资料；

（四）产品标准要求；

（五）产品标签、说明书样稿；

（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、营养充足性以及特殊医学用途临床效果的材料。

申请特定全营养配方食品注册，还应当提交临床试验报告。

申请人应当对其申请材料的真实性负责。

第十条 受理机构对申请人提出的特殊医学用途配方食品注册申请，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）申请事项属于国家食品药品监督管理总局职权范围，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。

第二节 审查与决定

第十一条 审评机构应当对申请材料进行审查，并根据实际需要组织对申请人进行现场核查、对试验样品进行抽样检验、对临床试验进行现场核查和对专业问题进行专家论证。

第十二条 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的研发能力、生产能力、检验能力等情况的现场核查，并出具核查报告。

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现场核查。

第十三条 审评机构应当委托具有法定资质的食品检验机构进行抽样检验。

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。

第十四条 核查机构应当自接到审评机构通知之日起 40 个工作日内完成对临床试验的真实性、完整性、准确性等情况的现场核查，并出具核查报告。

第十五条 审评机构可以从特殊医学用途配方食品注册审评专家库中选取专家，对审评过程中遇到的问题进行论证，并形成专家意见。

第十六条 审评机构应当自收到受理材料之日起 60 个工作日内根据核查报告、检验报告以及专家意见完成技术审评工作，并作出审查结论。

审评过程中需要申请人补正材料的，审评机构应当一次告知需要补正的全部内容。申请人应当在 6 个月内一次补正材料。补正材料的时间不计算在审评时间内。

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，延长决定应当及时书面告知申请人。

第十七条 审评机构认为申请材料真实，产品科学、安全，生产工艺合理、可行和质量可控，技术要求和检验方法科学、合理的，应当提出予以注册的建议。

审评机构提出不予注册建议的，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。改变不予注册建议的，应当书面通知注册申请人。

第十八条 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申请作出是否准予注册的决定。

现场核查、抽样检验、复审所需要的时间不计算在审评和注册决定的期限内。

对于申请进口特殊医学用途配方食品注册的，应当根据境外生产企业的实际情况，确定境外现场核查和抽样检验时限。

第十九条 国家食品药品监督管理总局作出准予注册决定的，受理机构自决定之日起 10 个工作日内颁发、送达特殊医学用途配方食品注册证书；作出不予注册决定的，应当说明理由，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，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。

特殊医学用途配方食品注册证书有效期限为 5 年。

第二十条 特殊医学用途配方食品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、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。

特殊医学用途配方食品注册号的格式为：国食注字 TY+4 位年号+4 位顺序号，其中 TY 代表特殊医学用途配方食品。

第三节 变更与延续注册

第二十一条 申请人需要变更特殊医学用途配方食品注册证书及其附件载明事项的，应当向国家食品药品监督管理总局提出变更注册申请，并提交下列材料：

（一）特殊医学用途配方食品变更注册申请书；

（二）变更注册证书及其附件载明事项的证明材料。

第二十二条 申请人变更产品配方、生产工艺等可能影响产品安全性、营养充足性以及特殊医学用途临床效果的事项，国家食品药品监督管理总局应当进行实质性审查，并在本办法第十八条规定的期限内完成变更注册工作。

申请人变更企业名称、生产地址名称等不影响产品安全性、营养充足性以及特殊医学用途临床效果的事项，国家食品药品监督管理总局应当进行核实，并自受理之日起 10 个工作日内作出是否准予变更注册的决定。

第二十三条 国家食品药品监督管理总局准予变更注册申请的，向申请人换发注册证书，原注册号不变，证书有效期不变；不予批准变更注册申请的，应当作出不予变更注册决定。

第二十四条 特殊医学用途配方食品注册证书有效期届满，需要继续生产或者进口的，应当在有效期届满 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）特殊医学用途配方食品延续注册申请书；

（二）特殊医学用途配方食品质量安全管理情况；

（三）特殊医学用途配方食品质量管理体系自查报告；

（四）特殊医学用途配方食品跟踪评价情况。

第二十五条 国家食品药品监督管理总局根据需要对延续注册申请进行实质性审查，并在本办法第十八条规定的期限内完成延续注册工作。逾期未作决定的，视为准予延续。

第二十六条 国家食品药品监督管理总局准予延续注册的，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；不批准延续注册申请的，应当作出不予延续注册决定。

第二十七条 有下列情形之一的，不予延续注册：

（一）注册人未在规定时间内提出延续注册申请的；

（二）注册产品连续 12 个月内在省级以上监督抽检中出现 3 批次以上不合格的；

（三）企业未能保持注册时生产、检验能力的；

（四）其他不符合法律法规以及产品安全性、营养充足性和特殊医学用途临床效果要求的情形。

第二十八条 特殊医学用途配方食品变更注册与延续注册程序，本节未作规定的，适用本章第一节、第二节的相关规定。

第三章 临床试验

第二十九条 特定全营养配方食品需要进行临床试验的，由申请人委托符合要求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。

第三十条 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。

第三十一条 申请人组织开展多中心临床试验的，应当明确组长单位和统计单位。

第三十二条 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，生产条件应当符合特殊医学用途配方食品良好生产规范。

第四章 标签和说明书

第三十三条 特殊医学用途配方食品的标签，应当依照法律、法规、规章和食品安全国家标准的规定进行标注。

第三十四条 特殊医学用途配方食品的标签和说明书的内容应当一致，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。

标签已经涵盖说明书全部内容的，可以不另附说明书。

第三十五条 特殊医学用途配方食品标签、说明书应当真实准确、清晰持久、醒目易读。

第三十六条 特殊医学用途配方食品标签、说明书不得含有虚假内容，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。

第三十七条 特殊医学用途配方食品的名称应当反映食品的真实属性，使用食品安全国家标准规定的分类名称或者等效名称。

第三十八条 特殊医学用途配方食品标签、说明书应当按照食品安全国家标准的规定在醒目位置标示下列内容：

（一）请在医生或者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 监督检查

第三十九条 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安全。

特殊医学用途配方食品生产企业提出的变更注册申请未经批准前，应当严格按照已经批准的注册证书及其附件载明的内容组织生产，不得擅自改变生产条件和要求。

特殊医学用途配方食品生产企业提出的变更注册申请经批准后，应当严格按照变更后的特殊医学用途配方食品注册证书及其附件载明的内容组织生产。

第四十条 参与特殊医学用途配方食品注册申请受理、技术审评、现场核查、抽样检验、临床试验等工作的人员和专家，应当保守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。

第四十一条 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：

（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）食品生产许可证被吊销的；

（六）依法可以撤销注册的其他情形。

第四十二条 有下列情形之一的，国家食品药品监督管理总局应当依法办理特殊医学用途配方食品注册注销手续：

（一）企业申请注销的；

（二）有效期届满未延续的；

（三）企业依法终止的；

（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注册的其他情形。

第六章 法律责任

第四十三条 申请人隐瞒真实情况或者提供虚假材料申请注册的，国家食品药品监督管理总局不予受理或者不予注册，并给予警告；申请人在 1 年内不得再次申请注册。

第四十四条 被许可人以欺骗、贿赂等不正当手段取得注册证书的，由国家食品药品监督管理总局撤销注册证书，并处 1 万元以上 3 万元以下罚款；申请人在 3 年内不得再次申请注册。

第四十五条 伪造、涂改、倒卖、出租、出借、转让特殊医学用途配方食品注册证书的，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。

第四十六条 注册人变更不影响产品安全性、营养充足性以及特殊医学用途临床效果的事项，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。

注册人变更产品配方、生产工艺等影响产品安全性、营养充足性以及特殊医学用途临床效果的事项，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第一款的规定进行处罚。

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给予处理。

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，依照食品安全法第一百四十五条的规定给予处理。

第七章 附 则

第四十八条 特殊医学用途配方食品，是指为满足进食受限、消化吸收障碍、代谢紊乱或者特定疾病状态人群对营养素或者膳食的特殊需要，专门加工配制而成的配方食品，包括适用于 0 月龄至 12 月龄的特殊医学用途婴儿配方食品和适用于 1 岁以上人群的特殊医学用途配方食品。

第四十九条 适用于 0 月龄至 12 月龄的特殊医学用途婴儿配方食品包括无乳糖配方食品或者低乳糖配方食品、乳蛋白部分水解配方食品、乳蛋白深度水解配方食品或者氨基酸配方食品、早产或者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等。

第五十条 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，是指可以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，是指可以作为单一营养来源满足目标人群在特定疾病或者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，是指可以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。

第五十一条 医疗机构配制供病人食用的营养餐不适用本办法。

第五十二条 本办法自 2016 年 7 月 1 日起施行。