

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary Public

Date: 3/25/2016

GAIN Report Number: CH 16025

China - Peoples Republic of

Post: Beijing

Administrative Measures for the Registration of Formula Foods for Special Medical Purposes

Report Categories:

Policy and Program Announcements

Approved By:

Jennifer Clever

Prepared By:

Jennifer Clever and Ma Jie

Report Highlights:

In March 2016, CFDA published the Measures to regulate registration of formula foods for special medical purposes produced and distributed in China, or imported into China. The Measures provide procedures and material requirements for the registration. The Measures are implemented on July 1, 2016.

The following report contains an unofficial translation of the final standard.

General Information:

BEGIN TRANSLATION

Administrative Measures for the Registration of Formula Foods for Special Medical Purposes

China Food and Drug Administration Decree No. 24

March 7, 2016

Chapter I General Provisions

Article 1 These Measures are formulated in accordance with the Food Safety Law and relevant laws, regulations and rules, to regulate the registration of formula foods for special medical purposes (FSMP), reinforce administration of the registration, and ensure the quality and safety of FSMP.

Article 2 Registration of FSMP produced and distributed in China, or imported into China are subject to provisions of these Measures.

Article 3 Registration of FSMP refers to the approval process that China Food and Drug Administration (CFDA) takes to decide whether a FSMP could be registered; after receiving the application for registration, CFDA would, following the procedures and requirements provided in these Measures, review the product formula, production techniques, label, product description, product safety, nutrition sufficiency, and the clinical effect of the special medical use to make the decision.

Article 4 Oversight of the registration of FSMP should be science-based, open, fair and just.

Article 5 CFDA is responsible for the registration of FSMP.

The application acceptance agency of CFDA (the Acceptance Agency) is in charge of accepting applications for registration of FSMP.

The food review agency of CFDA (the Review Agency) is in charge of reviewing the applications for registration of FSMP.

The verification and inspection agency (the Verification Agency) is in charge of on-site verifications in the review for the registration of the FSMP.

Article 6 CFDA establishes the expert bank for review of applications for registration of FSMP. The expert bank is composed of experts specialize in food nutrition, clinical medicine, food safety and food processing, etc.

Article 7 CFDA will strengthen the use of information technology for the registration of FSMP.

Chapter II Registration

Section 1 Application and Acceptance

Article 8 The applicants for the registration of FSMP (the applicant) refer to enterprises intend to produce and sell FSMP in China, and the overseas producing enterprises intend to export FSMP to China.

The applicant should have the R&D and production capacity that match the production of FSMP; the applicant should set up the facilities for R&D of the product, which has full-time researchers, food safety management staffs and food safety-majored technicians; the facility should have the production quality management system following the GMP suitable for the produced foods, and should be capable of testing all required items of every single batch of product as required by the national food safety standards for FSMP.

The R&D facility should have staffs that hold senior professional titles or related competence in food safety related majors.

Article 9 The applicant should submit the following documents to CFDA for registration of FSMP:

1. Application for registration of FSMP;
2. Product R&D report; the product formula design and its basis;
3. Materials of production techniques;
4. Requirements provided in relevant standards concerning product quality;
5. Samples of product label and descriptions;
6. Test report of the samples;
7. Evidencing documents of capacities for R&D, production and testing;
8. Other documents evidencing the product safety, nutrition sufficiency and clinical effect of the FSMP.

To apply for registration of formula foods with special complete nutrition, the applicant should submit the clinical test report as well.

The applicant for registration should be accountable for truthfulness of the application materials.

Article 10 Upon receiving the application for registration, the Acceptance Agency needs to take the following measures accordingly:

1. Timely inform the applicant of items that do not need registration, and decline to accept the application;
2. In case the applied items do not fall in the jurisdiction of CFDA, timely make the decision to decline the application and inform the applicant to submit the application to the appropriate administrative agency;

3. Allow the applicant to correct mistakes in the application materials if the mistakes could be corrected on-site;
4. In case that the application documents are incomplete or do not conform to the required format, inform the applicant immediately or inform the applicant all materials to be supplemented within five working days; without such notification, the applications are deemed to be accepted on the day of the submission;
5. In case the applied item falls in the jurisdiction of CFDA, the applicant has submitted complete application materials which conform to the required form and format, or the applicant has submitted all supplementary materials as requested, the application should be accepted.

The Accepting Agency, accepting or declining the application, should issue a written response with the CFDA's official stamp for accepting administrative licensing application, marked with dates.

Section 2 Review and Decision

Article 11 The Review Agency should review the application documents; when necessary, the review agency could organize on-site verifications to the applicant, conduct sample testing of the samples, conduct on-site verifications for clinical tests, and organize experts to discuss on technical issues.

Article 12 The Verification Agency, upon receiving notification by the review agency, should complete the on-site verification about the applicant's capacity for R&D, production and testing within 20 working days; the verification agency should issue reports for the conducted verifications.

The Verification Agency should inform the provincial level CFDA where the applicant locates to participate in the on-site verification, and the provincial CFDA should do so.

Article 13 The Review Agency should entrust food testing institutes with legal qualifications to conduct sampling tests.

The testing institute should complete the sampling test within 30 working days upon accepting the entrusted testing task.

Article 14 The Verification Agency should complete the on-site verification on clinical test's truthfulness, completeness, and accuracy, etc. within 40 working days upon receiving notices by the Review Agency, and issue the verification reports.

Article 15 The review agency could select experts from the expert bank for arguments on issues encountered in the review process, form the experts' opinions.

Article 16 Based on the verification report, the inspection report and the experts' opinions, the Review Agency should make the review conclusion within 60 working days upon acceptance of the application.

In case the applicant is requested to submit supplementary materials or make corrections, the Review Agency should inform the applicant all contents that need supplementary information or correction in one time. The applicant should provide such supplementary information and corrections within six

months in one submission. The time needed for such supplementary material and correction is not counted as the review time.

Under special circumstances, the review time could be extended for 30 working days with approval of the person in charge in the Review Agency. The decision for extension should be delivered to the applicant in writing in a timely manner.

Article 17 Deeming the application materials truthful, the product is safe and has sound science basis, the production techniques are reasonable and feasible, the quality is controllable, and the technical requirements and testing methods are science based and reasonable, the Review Agency will propose (to CFDA) to register the product.

Making the recommendation not to register the product, the Review Agency should issue a notice in writing to the applicant; should the applicant opposes the notice, it could file an application for re-examination to the Review Agency within 20 working days upon receiving the notice, and explain reasons for the application. The re-examination will only review items and materials in the original application.

The Review Agency should make the decisions for the re-examinations within 30 working days upon accepting the re-examination application; making different recommendations, the Review Agency should inform the applicant in writing.

Article 18 CFDA will make the decision whether to register the FSMP within 20 working days upon accepting the application.

The time needed for on-site verification, sampling testing, and re-examination are not counted as the review and registration decision time.

Per applications for registration of imported FSMP, (CFDA) will determine the time limits for overseas on-site verification and sampling test based on actual condition of the foreign production enterprise.

Article 19 After CFDA makes the decision to approve the registration application, the Acceptance Agency should issue and deliver the registration certificate within ten working days from the date the decision is made. In case CFDA decides to decline the registration application, the Acceptance Agency should explain reasons for the declination and issue the declination decision to the applicant within ten working days from the date the decision is made; the Acceptance Agency should also inform the applicant of its rights to file an administrative review petition or an administration litigation petition.

The registration certificate for FSMP is valid for five years.

Article 20 The registration certificate for FSMP and its attachment should contain the following items:

1. Product name;
2. Enterprise name, and manufacturing address;
3. Registration number and validity period;

4. Product category;
5. Product formula;
6. Production techniques;
7. Product label and description.

Format of the registration number of FSMP: national food registration symbol “TY” + year (four digits) + sequential number (four digits); TY represents FSMP.

Section 3 Changing (for registration) and Extending Registration

Article 21 In case the applicant needs to change the registration certificate and the items in the attachment of the certificate, he/she should submit the registration changing application to CFDA, along with the following materials:

1. The application for changing registration of FSMP;
2. The proving materials for changing the registration certificate and the items contained in attachment of the certificate.

Article 22 Per applications to change items that may affect the registered product’s safety, nutrition sufficiency and clinical effect (such as product formula or production techniques), CFDA should conduct substantive review, and complete the registration change within time provided in article 18 of these Measures.

Per applications to change items that do not affect the registered product’s safety, nutrition sufficiency or clinical effect (such as the enterprise name or address), CFDA should verify the information, and decides whether such changes in registration could be made within ten working days upon receiving application for the changes.

Article 23 Approving the changes in the registration application, CFDA will reissue a new certificate with the registration number and valid period unchanged; CFDA could decline the application for changing the registration in case (the review makes) the negative decision.

Article 24 When the validity period for the registration certificate is about to end, in case that the applicant needs to continue production or import the registered product, the applicant should submit registration renew application to CFDA six months before the certificate expires. The application should be submitted along with the following documents:

1. Application for registration renew;
2. Quality and safety management for FSMP;
3. Self-inspection reports for the product quality management system;
4. Tracking and assessment of the FSMP.

Article 25 CFDA, pursuant to necessity, could conduct substantive review into the registration renewal applications; such review should be completed within the time limit provided in article 18 of these Measures. Failing to make a decision after the time limit is regarded as approval for the registration renewal application.

Article 26 Approving the registration renewal application, CFDA issues the new registration certificate, with the registration number unchanged, and the new valid period starts from the date the renewal application is filed. In case that the application for registration renewal is not approved, CFDA will make the decision that the registration renewal is not approved.

Article 27 Reregistration renewal is not approved in any of the following situations,

1. The registrant fails to submit application for registration renewal within the required time;
2. In 12 consecutive months, the registered product had three batches of disqualification in sampling tests conducted by the provincial food safety authorities;
3. The applicant fails to maintain the production and testing capacity it had when the registration was made;
4. Other situations not complying with related laws, regulations, food safety, nutrition sufficiency and clinical effects of FSMP.

Article 28 Lacking provisions in this section on registration change or registration renewal, relevant provisions in Section 1 and 2 of this Chapter should be applied.

Chapter III Clinical Test

Article 29 Only formula food with special complete nutrition are required to conduct the clinical tests (other FSMP are not required to conduct such tests). In case the clinical test is required, the applicant should entrust a testing institute with certain qualification to issue the clinical test report that contains complete statistical analysis reports and data.

Article 30 The clinical test should be carried out in accordance with the “*Quality Management Code for Clinical Test of Formula Foods for Special Medical Purposes*”.

The “*Quality Management Code for Clinical Test of Formula Foods for Special Medical Purposes*” will be published by CFDA.

Article 31 In case the applicant applies to conduct the multi-center clinical tests, it should identify the leading institution and the statistics analysis institution among the centers.

Article 32 The applicant is responsible for quality and safety of the test samples and the control samples used in clinical tests.

The test samples for clinical test should be produced by the applicant; such samples need to pass the quality inspection; the condition for sample production should comply with the “*Good Manufacturing Practice (GMP) of Formula Foods for Special Medical Purposes*”.

Chapter IV Labeling and Description

Article 33 Labeling of FSMP should comply with provisions in relevant laws, regulations, rules, and national food safety standards.

Article 34 Contents in the label and description of FSMP should be consistent; in case the label and product description involve the registration certificate, such information should be consistent with the content in the registration certificate, and should be marked with the registration number.

In case that the label has covered all contents of the product description, it is not required to attach a separate product description.

Article 35 Label and description of FSMP should be true, accurate, clear and durable, conspicuous and easy to understanding.

Article 36 Label and description of FSMP should not contain fake contents, and should not make statement involving disease prevention or treatment functions. The manufacturer should be accountable for contents in labels and descriptions of its products.

Article 37 Name of FSMP should reflect characteristics of the product, which uses the category name or equivalent name provided in relevant national food safety standards.

Article 38 Label and description of FSMP should comply with relevant provisions in the national food safety standards, and contain the following warning instruction at conspicuous positions (on the package):

1. Please refer to guidance by doctors or clinical dietitians;
2. It is not suitable for the non-target population;
3. This product is prohibited for use for the parenteral nutrition support and intravenous injection.

Chapter V Oversight and Inspections

Article 39 Producers of FSMP should follow the registered product formula and production techniques in their production to guarantee safety of such products.

Before getting approval for its application to change registration, the producer should strictly follow the contents in the approved registration certificate and its attachments in production; it is not allowed to change the production condition or requirements at its own decision.

Once the producer's application for changing registration is approved, it should strictly follow the contents in the changed registration and its attachments in production.

Article 40 Staffs and experts engage in accepting application, technical review, on-site verification, sample tests and clinical tests for registration of FSMP should keep confidentiality of business proprietaries learnt in the registration process.

The applicant should mark the business proprietaries in the applications following relevant regulations and explain reasons.

Article 41 CFDA may revoke the registration certificate upon request by an interested party or in accordance with its jurisdictions in any of the following circumstances:

1. The (CFDA) working staff is found to have abused their power or committed dereliction of duty in approving the registration;
2. Go beyond the statutory purview in approving the registration;
3. Violate the legal procedures in approving the registration;
4. Approve registration filed by an ineligible applicant or an applicant that does not meet the statutory conditions;
5. The producer's production license has been revoked;
6. Other circumstances provided in relevant laws, regulations or rules that the registration certificate may be cancelled.

Article 42 CFDA may cancel the registration of the formula foods for special medical purposes pursuant to relevant laws and regulations in any of the following circumstances:

1. The producer apply to have the registration cancelled;
2. The registration expires and the producer does not apply to renew the registration;
3. The producer is terminated pursuant to relevant laws;
4. The registration is revoked, recalled, or the registration certificate is revoked pursuant to laws or regulations;
5. Other circumstances provided in laws or regulations that the registration should be cancelled.

Chapter VI Legal Liabilities

Article 43 Finding the applicant hides truths or submits fake materials in registration application, CFDA would reject the application or decline to register the product, and issue a warning; the applicant is not allowed to file the registration application in one years.

Article 44 CFDA will revoke the registration certificate obtained by a licensee by improper means (such as deception or bribery), and impose a fine between 10,000 Yuan to 30,000 Yuan; the applicant is not allowed to file the application for the registration of formula foods for special medical purposes in three years.

Article 45 Finding the registration certificate is faked, altered, sold, leased, lent or transferred, the county and above level FDA will instruct (the producer) to take correction measures, issue warnings and impose a fine of less than 10,000 Yuan; in serious cases, the county and above level FDA could impose a fine between 10,000 Yuan to 30,000 Yuan,

Article 46 Finding the registrant making changes that do not affect product safety, nutrition sufficiency and clinical effect without applying for registration changes, the county and above level FDA should instruct the registrant to take correction measures and issue a warning; in case the registrant refuses to make the corrections, the county and above level FDA will impose a fine between 10,000 Yuan to 30,000 Yuan.

Finding the registrant making changes that affect product safety, nutrition sufficiency and clinical effect (such as changing product formula or production techniques) without applying for registration changes pursuant to relevant regulations, the county and above level FDA should take punitive measures pursuant to provisions in Article 124.1 of the Food Safety Law.

Article 47 CFDA departments/subsidiaries and working staffs are subject to punitive measures provided in the Article 145 of the *Food Safety Law* for approving registration by unqualified applicants or approving the registration beyond their statutory purview.

CFDA departments/subsidiaries and working staffs are subject to punitive measures provided in the Article 145 of the *Food Safety Law* for abusing their power or committing dereliction of duty in registration approving procedure.

Chapter VII Supplementary Provisions

Article 48 Formula foods for special medical purposes in these Measures refer to specifically processed and prepared food for special need of the population with eating restriction, disorder of digestion and absorption, metabolic disorder, or special diseases with respect to nutrients or diets; such foods include formula infant foods for special medical purposes for infant at the age of 0 to 12 months, and formula foods for special medical purposes for people over 1 year old.

Article 49 Infant formula foods for special medical purposes for infants at the age of 0 to 12 months include: lactose-free formula food or low-lactose formula food, formula food with partial hydrolysis of lactoprotein, formula food with deep hydrolysis of lactoprotein or amino acid formula food, formula food for the infants with premature birth/low birth weight, formula food for amino acid metabolic disorder and breast milk nutrition supplement.

Article 50 Formula foods for special medical purposes applicable for people over 1 year old include formula foods with complete nutrition, formula foods with special complete nutrition and formula foods with non-complete nutrition.

Formula foods with complete nutrition refer to formula foods for special medical purposes that could function as the sole source of nutrition for nutrition demand of the target population.

Formula foods with special complete nutrition refer to the formula foods for special medical purposes capable of serving as the sole nutrition source to meet the nutritional demand of the target population with special diseases or under special medical conditions. Common formula foods with special

complete nutrition include formula foods with special complete nutrition for diabetes, formula foods with special complete nutrition for respiratory system diseases, formula foods with special complete nutrition for kidney diseases, formula foods with special complete nutrition for tumors, formula foods with special complete nutrition for liver diseases, formula foods with special complete nutrition for sarcopenia, formula foods with special complete nutrition for trauma, infection, operation and other stress states, formula foods with special complete nutrition for inflammatory bowel disease, formula foods with special complete nutrition for food protein allergy, formula foods with special complete nutrition for intractable epilepsy, formula foods with special complete nutrition for gastrointestinal absorption disorder and pancreatitis, formula foods with special complete nutrition for fatty acid metabolic disorder, and formula foods with special complete nutrition for obesity and fat reduction operation.

Formula foods with non-complete nutrition refer to formula foods for special medical purposes not meeting the part nutrition demand of the target population and not applicable as the single nutrition source. Common formula foods with non-complete nutrition include: nutrient components (protein component, fat component, and carbohydrate component), electrolyte formula, thickening component, liquid formula and amino acid metabolic disorder formula.

Article 51 The nutritious meals for patients prepared by medical institutions are not subject to provisions of these measures.

Article 52 These Measures will be implemented on July 1, 2016.

END OF TRANSLATION