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Report Highlights:

On November 28, 2023, the People's Republic of China (PRC) State Administration for Market Regulation (SAMR) released the updated Administrative Measures for Registration of Formula Foods for Special Medical Purposes. The Measures will enter into force on January 1, 2024. This report provides an unofficial translation of the Measures.

Summary:

On November 28, 2023, the People's Republic of China (PRC) State Administration for Market Regulation (SAMR) released updated Administrative Measures for Registration of Formula Foods for Special Medical Purposes (link in Chinese). The Measures aim to clarify registration requirements, prioritize management procedures, strengthen applicant and producer liability, and promote development of the industry. The updated Measures will enter into force on January 1, 2024.

The previous Measures were released on March 7, 2016 and implemented on July 1, 2016 (see FAS GAIN report CH 16025). The major changes to the previous version include:

- Additional conditions for when applicants can apply for privileged review and approval processes to speed up approval processes for urgently needed products.
- Requirement for applicants to have testing capacity in addition to production and research and development capacity, and to bear legal liability for products to increase qualification levels of applicants and producers.
- Includes conditions under which the registration should not be granted.
- Added technical requirements to registration certificates to further ensure product safety.
- Emphasized requirements for product labels and instructions, and clarified language used to deliver clear messages to consumers.
- Stated that electronic registration certificates bear the same legal effect with paper certificates to increase digital management.
- New additional requirements for on-site verifications, for example producers of raw materials and food additives may be inspected according to risk, production samples should be taken, and for clinical trials, traceability.

Other changes include the requirement of a letter of recommendation from the local market regulation management authority for renewal of a valid registration and approval of an ethics committee before clinical trials can be conducted. The Measures also stated that when varieties of ingredients and food additives, orders of ingredient components, and nutrition facts remain unchanged, the usage amount can be adjusted slightly without applicants needing to apply for a change to the current registration. Management principles include nutritional needs and encouragement of innovation to reflect new food safety trends in China.

This report provides an unofficial translation of the Measures.

BEGIN TRANSLATION

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

Released by Order No. 85 of the State Administration for Market Regulation on November 18, 2023, it will enter into force on January 1, 2024.

Chapter I. General Provisions

Article 1. These Measures are formulated in accordance with the Administrative Licensing Law, Food Safety Law, Implementation regulations for the Food Safety Law of the People's Republic of China to Regulate Registration of Formula Foods for Special Medical Purposes (FSMP) and to 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 activity conducted by the State Administration for Market Regulation (SAMR) to review the application of registration for FSMP and decide whether the registration may be granted or not according to procedures and requirements specified in these Measures.

Article 4. Registration management of FSMP should be oriented by clinical nutrition needs, guided by the principles of science-based, open, fair, and just, and motivated by innovation.

Article 5. SAMR is responsible for the registration of FSMP.

Food Review Agency of SAMR (Food Review Center, hereinafter refers to as the Review Agency) is responsible for the acceptance, technical review, on-site verification, certificate preparation, and delivery of registration applications for formula foods for special medical purposes. The Food Review Center may organize experts for verification when needed.

The market supervision and administration departments of provinces, autonomous regions, and municipalities shall cooperate with the on-site registration verification of FSMP.

Article 6. The applicant for registration of formula foods for special medical purposes (hereinafter refers to as applicants) shall be responsible for the authenticity, completeness, legality, and traceability of materials submitted and bear legal liability.

The applicant should cooperate with the market supervision and management departments in carrying out tasks related to registration such as on-site verification and sample testing and provide necessary working conditions.

Chapter II. Application and Registration

Article 7. The applicant should be enterprises intending to produce and sell FSMP in China, or the overseas producing enterprises intending to export FSMP to China.

The applicant must have capacity for research and development and production that meet with requirements for production of FSMP. Applicants should be able to set up organization for foods research and development, establish production quality management system, produce FSMP according to Good Manufacturing Practice, and test batches of products according to requirements of national food safety standards and technical provisions.

Article 8. The applicant should submit the following documents to SAMR for registration of FSMP:

1) Application for registration of the FSMP
2) Applicant’s qualification documents
3) Product research and development report
4) Product formula designs and basis
5) Materials on production processes
6) Product standards and technical requirements
7) Samples of product labels and instructions
8) Product test reports
9) Documents showing capacities for research and development, production, and testing
10) Other documents showing product safety, nutrition adequacy, and clinical effects of special medical purposes

To apply for registration of specific formula foods of complete nutrition, the applicant should also submit the clinical test report.

Article 9. The applicant shall mark business secrets, undisclosed information, or confidential information in application materials in accordance with relevant national regulations and indicate the basis.

Article 10. The application for registration should be handled respectively according to below situations:

1) If applied items do not need registration, applicant should be informed in a timely manner that the application will not be processed.
2) If applied items do not fall in the jurisdiction of SAMR, applicant should be informed of decision that the application is not being processed and the appropriate administration agency that handle the application.

3) Allow the applicant to correct mistakes in the application materials if the mistakes could be corrected during submission.
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 SAMR, 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.

Upon approval or disapproval, a certificate sealed with SAMR's executive licensing stamp and marked with the date should be issued.

Article 11. The Review Agency shall review the product formula, manufacturing processes, labels, instructions, product safety, nutritional adequacy, and clinical effects of special medical purposes of the product applying for registration. The review shall be completed within 60 working days from the date of acceptance.

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 notified to the applicant in writing.

Article 12. 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 6 months in one submission. The time needed for such supplementary material and correction is not counted as the review time.

Article 13. The Review Agency may organize experts in nutrition, clinical medicines, food safety, food processing, and other fields to verify the issues encountered during the review process and form expert opinions.

Article 14. The Review Agency conducts production site inspections and sample testing to applicants based on food safety risks and carries out on-site verifications for clinical trials. When necessary, extended inspections can be carried out to manufacturers of food raw materials and food additives.

Article 15. The Review Agency shall notify the applicant of verification matters in writing or electronically. The applicant shall provide feedback on the date of on-site verification within 30 working days. If force majeure or other factors prevent on-site verification within the specified time limit, the applicant shall submit an extension application in writing and explain the reasons.

Article 16. The Review Agency, upon receiving notification by the applicant of date of on-site verification, should complete the inspection on the applicant's capacity for research and development, production, testing, and consistency between application materials and actual situations within 20 working days. The Review Agency should issue reports for the conducted verification.

The Review Agency should inform the provincial level market supervision and management department where the applicant locates to participate in the on-site verification, and the provincial market supervision and management department shall send representatives to participate.

Article 17. The Review Agency takes samples during production for on-site verification and entrusts a legally qualified food testing organization to conduct testing.

The testing institute should complete sample testing within 30 working days of receiving the samples according to national food safety standards and technical requirements and should issue sample testing reports to the Review Agency.

Article 18. For on-site verification of clinical trials when applicant applies for registration of specific formula foods of complete nutrition, the Review Agency shall complete the on-site verification for authenticity, completeness, legality, and traceability of the clinical trials within 30 working days from date confirmed by the applicant and shall issue a clinical trial on-site verification report.

Article 19. The Review Agency should make the review conclusions based on application materials submitted by applicant, on-site verification reports, and sample testing reports.

Article 20. The Review Agency shall make a review conclusion to recommend approval of registration if the applicant's application meets legal conditions and standards, the product is scientific-based and safe, the production process is reasonable and feasible, the product quality is controllable, the technical requirements and testing methods are scientific and reasonable, and the conclusions of the on-site verification report and sample testing reports meet the registration requirements.

Article 21. If any of the following circumstances occurs, the Review Agency shall make a review conclusion that registration is not to be granted:

1) Application materials are fraudulent and untrue
2) Application materials do not support product safety, nutritional adequacy, and clinical effects of special medical requirements
3) The applicant does not have the capability of research and development, production, or testing required for the product applied for registration
4) The applicant fails to submit supplementary and correction materials within the prescribed time limit, or the supplementary and correction materials submitted does not meet the requirements
5) The applicant is unable to confirm the on-site verification date after the due date, refuses or fails to cooperate with the on-site verification and sample testing
6) The conclusions of the on-site verification report or the sample testing reports do not meet registration requirements
7) Other situations when the applicant does not meet registration requirements such as incompliance with laws, regulations, rules, national food safety standards, and technical requirements

If the Review Agency makes a review conclusion of disapproval of registration, it shall issue a proposed disapproval notice to the applicant and explain the reasons for disapproval. If the applicant has any objection to the review conclusion, the applicant shall submit written application to the Review Agency for re-examination within 20 working days from the date of receiving the notification and state the reasons for re-examination. The content of the re-examination is limited to the original application items and materials.

The Review Agency shall make decision within 30 working days from the date of accepting the re-examination application and notify the applicant.

Article 22. The time required for on-site verification, sample testing, and re-examination is not included in the review time limit.

The working time frame for overseas on-site verification and sample testing shall be determined based on the actual situations.

Article 23. SAMR makes the decision to approve or disapprove the registration application after the review process. An FSMP registration certificate should be issued if registration is granted. In the case that SAMR decides to decline the registration application, a decision letter should be issued and reasons for disapproval should be stated. The applicant should also be informed of its rights to file an administrative re-examination petition or an administration litigation petition.

Article 24. SAMR shall make decisions within 20 working days after acceptance of the applications.

The Review Agency shall deliver registration certificate of FSMP or decision letter of disapproval to the application within 10 working days after SAMR make decisions.

Article 25. The registration certificate of FSMP and its attachment should contain the following items:

1) Product name
2) Enterprise name and manufacturing address
3) Registration number, approval date, and period of validity
4) Product category
5) Product formula
6) Production processes
7) Samples of product labels and instructions
8) Other technical requirements for the product

Format of the FSMP registration number is national food registration symbol "TY" + year (four digits) + sequential number (four digits). TY represents FSMP.

Article 26. In case the applicant needs to change the registration certificate and the items in the attachment of the certificate within its period of validity, he or she should submit the application for revision to SAMR, along with the following materials:

1) The application for revision of registration of FSMP
2) Verification reports for product changes
3) Other materials relevant for changing the registration certificate

Article 27. For applications to change items that may affect the registered product's safety, nutrition adequacy, and clinical effects such as product formula or production processes, SAMR should conduct review and make review conclusion according to Article 11 of these Measures.

For applications to change items that do not affect the safety, nutrition adequacy, or clinical effects of the registered product, such as changes of enterprise name, manufacturing address, and product name, the Review Agency should make review conclusion within 10 working days upon acceptance of application for the changes. If the enterprise name of the applicant has changed, the applicant should use the new name for filing the application.

Article 28. SAMR will issue a decision for approval or disapproval of the change of the registration within 10 working days after making the review conclusion. If the registration change is approved, a registration certificate will be issued to the applicant, marking the change date and changes. The registration certificate issuance date shall be based on the change approval date. The original registration number will remain unchanged, and the period of validity of the certificate will stay the same. If the registration change is not approved, a decision letter will be issued, reasons for disapproval will be stated, and the applicant will be informed of the rights to apply for administrative re-examination or initiation of administrative litigation in accordance with the law.

Article 29. If the types of food raw materials and food additives of the product, the order of the ingredient components list, and the nutrition facts remain unchanged, there is no need to apply for changes of registration when the usage amount fluctuates or adjusts reasonably within a certain range.

Article 30. When the period of validity for the registration certificate is about to end, if the applicant needs to continue production or import of the registered product, the applicant should submit registration renewal application to SAMR 6 months before the certificate expires. The application should be submitted along with the following documents:

1) Application for registration renewal of FSMP
2) Qualification documents of applicants
3) Capacity of research and development, production, and testing of the enterprise
4) Self-inspection reports for the product quality management system
5) Tracking and evaluation of product safety, nutrition adequacy, and clinical effects of special medical purposes

6) Renewal registration recommendation letter provided by market supervision and management departments of the province, autonomous region, or municipality where the enterprise is located
7) Other materials related to registration renewal

Article 31. The Review Agency should conduct review of the registration renewal application and make review decision according to Article 11 of these Measures.

Article 32. SAMR will decide on approval or disapproval of registration renewal within 20 working days after the acceptance of the renewal application. If the renewal of registration is approved, a renewed registration certificate will be issued to the applicant. The original registration number will remain unchanged, and the period of validity of the certificate will be re-calculated from the date of approval. If the renewal of registration is not granted, a letter of decision will be issued, explaining the reasons. The applicant will be informed of their right to apply for administrative re-examination or initiation of administrative litigation in accordance with the law. If no decision is made within the time limit, the extension is deemed to be approved.

Article 33. Renewal of registration will not be granted in any of the following situations:

1) The registrant fails to submit application for registration renewal within the required time frame
2) Registered product had three batches disqualified in sample testing conducted by the provincial food safety authorities within 12 consecutive months
3) The applicant fails to maintain the capacity of research and development, production, and testing it had when the registration was granted
4) Other situations not complying with relevant provisions

Article 34. Applicants may apply for priority review and approval process if the FSMP meets one of the following criteria:

1) FSMP related to rare diseases
2) New types of FSMP that are urgently needed for clinical use and have not yet been approved
3) Other priority review and approval situations specified by SAMR

Article 35. The applicant should communicate with the Review Agency before submitting the registration application. After confirmation with the Review Agency, the applicant may submit a priority review and approval application together with the registration application. After review, if the circumstances stipulated in Article 34 of these Measures are met and no objections are raised after public announcement, the Review Agency will include the application in the priority review and approval process.

Article 36. Review time for FSMP included in the priority review and approval process is 30 working days. After communication and confirmation, the applicant may submit supplementary technical materials. If on-site verification and sample testing are required, priority will be given to the applicant.

Article 37. During the review process, if a registration application for FSMP included in the priority review and approval process is found not meeting the conditions for priority review and approval applications, the Review Agency shall terminate the priority review and approval process for the product, continue the review according to general review procedure, and inform the applicant.

Article 38. If there are no provisions specified on change and renewal of registration, and priority review and approval processes of FSMP, the relevant regulations on the registration of FSMP shall apply.

Chapter III. Clinical Trials

Article 39. The ethics committee must review and approve clinical trials for registration of specific formula foods of complete nutrition.

Article 40. The clinical test should be carried out in accordance with the Quality Management Rules for Clinical Tests of Formula Foods for Special Medical Purposes.

The “Quality Management Rules for Clinical Tests of Formula Foods for Special Medical Purposes” is published by SAMR.

Article 41. The applicant should entrust a testing institute with certain qualifications to conduct clinical trials. The entrusted clinical testing institute should issue the clinical test report that contains complete statistical analysis reports and data.

Article 42. If the applicant applies to conduct multi-center clinical tests, the leading institution and the statistics analysis institution should be identified among the centers.

Article 43. The applicant is responsible for the quality and safety of the test samples and control samples used in clinical tests.

The test samples for clinical trials should be produced by the applicant according to the ingredients and production processes of the product applied for registration, the production conditions should comply with the Good Manufacturing Practice for FSMP, and the product should comply with relevant national food safety standards and technical requirements.

Chapter IV. Labels and Instructions

Article 44. Labels and instructions of FSMP should comply with provisions in relevant laws, regulations, rules, and national food safety standards, and should be marked according to SAMR regulations.

Article 45. The name of the FSMP should reflect the true attributes of the product and use the classification name or equivalent name specified in the national food safety standards.

Article 46. Product name, registration number, applicable groups, and language of “please use under the guidance of a doctor or clinical nutritionist” should be marked on the main display page of the labels of FSMP.

Article 47. The labels and instructions for FSMP should describe the characteristics of the formula or nutrition the product and label them in accordance with the provisions of national food safety standards using the languages “Not suitable for non-target groups” and “This product is prohibited for use for parenteral nutrition support and intravenous injection.”

Article 48. Applicant is responsible for the content of labels and instructions provided for the FSMP. Labels and instructions must be true, accurate, clear, and conspicuous. They must not contain false content, must not involve disease prevention or treatment functions, must not make functional claims about nutrients and other ingredients in the product, and must not mislead consumers.

Article 49. The content of labels and instructions for FSMP should be consistent. If it involves the content of the registration certificate, it should be consistent with the content of the registration certificate.

If the label already covers all the contents of the instruction manual, no instruction manual is required.

Chapter V. Oversight and Management

Article 50. Institutions and personnel responsible for technical review, on-site verification, and sample testing shall be responsible for the review conclusions, on-site verification reports, sample testing reports, etc. Experts participating in discussion and verification shall abide by professional ethics when providing expert opinions.

Technical reviews, on-site verifications, sample testing, and expert discussion should be carried out in accordance with laws, regulations, rules, national food safety standards, and technical specifications to ensure that the relevant work is scientific, objective, and fair.

Article 51. The market supervision and management department shall in a timely manner verify and deal with any illegal activities reported by relevant units or individuals in the registration of FSMP.

Article 52. Without the consent of the applicant, institutions and personnel involved in the registration of FSMP shall not disclose trade secrets, undisclosed information, or confidential business information submitted by the applicant, unless otherwise stipulated by law or involving national security or significant social and public interests.

Article 53. After the application for an FSMP is accepted, if the applicant proposes to withdraw the application for registration, the applicant shall submit a written withdrawal application and explain the reasons. If withdrawal of the application is granted, SAMR will terminate its registration process.

If behaviors found that violated laws such as suspected concealment of truth or provision of false information during the technical review, on-site verification, and sample testing, the illegal acts shall be dealt with in accordance with the law, and the applicant shall not withdraw the registration application.

Article 54. SAMR may revoke the registration upon request by an interested party or in accordance with its jurisdictions in any of the following circumstances:

1) The working staff is found to have abused their power or committed dereliction of duty in approving the registration
2) Registration decision was made beyond the scope of legal authority
3) Registration decision was made by violating the legal procedures
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 55. SAMR may cancel the registration of FSMP pursuant to relevant laws and regulations in any of the following circumstances:

1) The enterprise applies to cancel the registration
2) The enterprise is terminated pursuant to relevant laws
3) The registration expires and the applicant does not apply to renew the registration
4) The registration is revoked, recalled, or the registration certificate is canceled pursuant to laws or regulations
5) Other circumstances provided in laws or regulations that the registration should be cancelled

Chapter VI. Legal Liabilities

Article 56. If the "Food Safety Law" and other laws and regulations have provisions on illegal registration of FSMP, those provisions shall prevail.

Article 57. If an applicant conceals relevant information or provides false materials to apply for registration, SAMR shall not accept the application or shall deny registration and will give the applicant a warning. The applicant may not apply for registration of FSMP again within one year. Those suspected of committing crimes will be transferred to the public security in accordance with the law and investigated for criminal liability.

Article 58. If an applicant obtains a registration certificate of FSMP through improper means such as deception or bribery, SAMR shall revoke it in accordance with the law, and the licensee shall not apply for registration of FSMP again within three years. A fine of not less than 10,000 yuan but not more than 30,000 yuan shall be imposed. If harmful consequences are caused, a fine of not less than 30,000 yuan but not more than 200,000 yuan shall be imposed. If a crime is suspected, the person shall be transferred to the public security in accordance with the law and investigated for criminal liability.

Article 59. Anyone who forges, alters, resells, rents, lends, or transfers the registration certificate of FSMP shall be fined not less than 30,000 yuan but not more than 100,000 yuan by the market supervision and management department at or above the county level. If harmful consequences are caused, a fine of not less than 100,000 yuan but not more than 200,000 yuan shall be imposed. If a crime is suspected, the person shall be transferred to the public security in accordance with the law and investigated for criminal liability.

Article 60. If the applicant changes matter that do not affect product safety, nutritional adequacy, or clinical effects of special medical purposes, and fails to apply for changes in accordance with the law, the market supervision and management department at or above the county level shall order the applicant to make corrections within a time limit. If the applicant fails to make changes within the time limit, he or she shall be punished with a fine of not less than 1,000 yuan but not more than 10,000 yuan.

If the applicant made changes to product formulas and production processes that may affect product safety, nutrition adequacy, and clinical effects of special medical purposes, and have not applied for changes in accordance with the law, the market supervision and management department at or above the county level will impose penalties in accordance with the provisions of Article 124 of the Food Safety Law.

Article 61. If the market supervision and administration department and its staff approve the registration of an applicant who does not meet the conditions, or exceeds its legal authority to approve the registration, they shall be handled in accordance with the provisions of Article 144 of the Food Safety Law.

If the market supervision and management department and its staff have behavior of abuse of positions, violation of power, dereliction of duty, or malpractice for personal gain during the registration and approval process, they shall be dealt with in accordance with the provisions of Article 145 of the Food Safety Law.

Chapter VII. Supplementary Provisions

Article 62. Formula foods for special medical purposes in these Measures refer to specifically processed and prepared foods for special need of the population with dietary restrictions, disorders of digestion and absorption, metabolic disorders, or special diseases conditions with respect to nutrients or diets, such foods include formula infant foods for special medical purposes for infants at the age of 0 to 12 months and formula foods for special medical purposes for people over 1 year old.

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.

Article 63. Nutritious meals for patients prepared by medical institutions are not subject to the provisions of these Measures.

Article 64. These Measures will enter into effect on January 1, 2024. The “Administrative Measures for Formula Foods for Special Medical Purposes” released by Order No. 24 of the former State Food and Drug Administration of People’s Republic of China on March 7, 2016, was abolished at the same time.

END OF TRANSLATION

Attachments:

No Attachments.