Appendix 4-3-5

Registration Conditions and Control Inspection Points of Overseas Manufacturers of Imported Food for Special Dietary Use

Registration number:

Enterprise name:

Address:

Date of filling in:

Notes:

1. According to the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree No.248 of the General Administration of Customs of China), the sanitary conditions of overseas manufacturers of food for special dietary use applying for registration in China shall conform to Chinese laws, regulations, standards and norms. The table is for the overseas competent authorities of imported food for special dietary use to carry out official inspections on manufacturers of food for special dietary use based on the listed main conditions, bases and inspection focuses. At the same time, overseas manufacturers of food for special dietary use fill in and submit supporting materials based on the listed main conditions and bases, and carry out self-examination against the inspection focuses for self-assessment before applying for registration.

2. Overseas competent authorities and overseas manufacturers of food for special dietary use shall make the conformity determination based on the actual inspection situation.

3. The submitted materials shall be truly filled out in Chinese or English. The appendices shall be numbered, and their numbers and contents shall accurately correspond to the item numbers and contents in the column of "Filling in Requirements and Supporting Materials". The list of supporting materials shall be attached.

Item	Conditions and bases	Filling in Requirements and Supporting Materials	Focus of examination	Conformity determination	Remarks
1. Enterprise Overview					
1. Basic information of enterprise	*Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree No. 248 of General Administration of Customs of China)	Fill out Table 1 - Basic Information of Overseas Manufacturers of Imported Food for Special Dietary Use.	1. The registered name, address and registration number are consistent with the relevant registration information in the *Application* submitted by the official competent authority.	□ Conforming □ Non-conforming	
2. Information on products to be	1. *National Food Safety Standard - Infant Formula* (GB 10765-2010); *National Food Safety Standard - Older Infants and Young Children Formula* (GB 10767-2010); *National Food Safety*	1. Product name 2. Packing specification 3. Packaging type 4. HS code/CIQ code 5. If registration has been made	1. Focus on whether the registered product provided by the enterprise conforms to the terms and	□ Conforming □ Non-conforming	

exported to China	*Standard - General Rules for Infant Formula Food for Special Medical Purposes* (GB 25596-2010); *National Food Safety Standard - Complementary Food Supplements* (GB 22570-2014); *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013); *National Food Safety Standard - General Standard for Sports Nutrition Food* (GB 24154-2015); *National Food Safety Standard - Multi-Nutrient Supplementary Food for Pregnant and Lactating Women* (GB 31601-2015); 2. Article 80 of the *Food Safety Law of the People's Republic of China*: Formula food for special medical purposes shall be registered with the food and drug administration under the State Council. Article 82 The registrant or filer of health care food, food for special medical purposes, and infant formula powder shall be liable for the authenticity of materials it submitted. Food and drug administrations of the people's governments at the provincial level or above shall issue the catalogs of registered or filed health care food, food for special medical purposes, and infant formula milk powder and shall	with the food and drug administration in China, relevant registration certificates shall be provided (formula food for special medical purposes includes formula food for special medical purposes and infant formula food for special medical purposes).	definitions set out in the relevant standards. 2. Whether the formula food for special medical purposes has the registration certificate, and whether the product name, packing specification, packaging type of the product are consistent with those contained in the registration certificate.		

	maintain the confidentiality of business secrets made known by registration or filing. The enterprises that produce health care food, food for special medical purposes, and infant formula milk powder shall organize their production according to the technical requirements of their registered or filed product receipts and production processes.				
2. Raw and Auxiliary Materials and Packaging Materials					
2.1 Raw materials of products	1. *National Food Safety Standard - Infant Formula* (GB 10765-2010); *National Food Safety Standard - General Rules for Infant Formula Food for Special Medical Purposes* (GB 25596-2010) (No fructose and unpregelatinized starch shall be used; the raw materials and food additives used shall not contain gluten. No irradiated raw materials and hydrogenated vegetable oil shall be used;) 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (7.2.5 It shall ensure that the urease activity of soybean raw materials is negative.) 3. *National Food Safety Standard - Complementary Food Supplements* (GB 22570-2014) (3.2.1 The food matrix shall	1. Provide the product ingredients in an order of addition, from largest to smallest, with the proportion indicated; 2. If the main raw materials contain raw milk, vegetables (including cultivated edible fungus), meat and meat products, bee products, aquatic products, bird's nest, the country of origin of the ingredients shall be provided; 3. If soybean is used as the main raw material, whether it is genetically modified soybean shall be indicated.	1. Focus on the risk of epidemic diseases in food raw materials of animal and plant origin, and whether subsequent production processes can remove the risk if such materials come from the epidemic area. 2. If soybeans are used as raw materials, please pay attention to whether they are genetically modified, and soybeans and their processed products shall be treated with high temperature and	□ Conforming □ Non-conforming	

	be ready-to-use food raw materials, the quality of which shall conform to the appropriate standards and/or relevant regulations. 3.2.2 Soybeans and their processed products shall be subject to high temperature and other processes to eliminate anti-nutritional factors such as trypsin inhibitors. 4. *National Food Safety Standard - Multi-Nutrient Supplementary Food for Pregnant and Lactating Women* (GB 31601-2015) (3.2.1 High-quality protein shall be from one or more of soybeans, soybean products, milk, and dairy products, and its content shall account for 18%-35% of the quality of multi-nutrient supplementary food for pregnant and lactating women. 3.2.2. The raw materials used in multi-nutrient supplementary food for pregnant and lactating women shall conform to the appropriate standards and/or relevant regulations. 3.2.3. Soybeans and their processed products shall be subject to high temperature and other processes to eliminate anti-nutritional factors such as trypsin inhibitors. 3.2.4. No hydrogenated oil and fat shall be		other processes to eliminate anti-nutritional factors; 3. High-quality protein in multi-nutrient supplementary food for pregnant and lactating women shall be from one or more of soybeans, soybean products, milk, and dairy products, and its content shall account for 18%-35% of the quality of multi-nutrient supplementary food for pregnant and lactating women. 4. No hydrogenated oil and fat shall be used in infant food, and no irradiated raw materials shall be used.		

	used. 5. *National Food Safety Standard - Hygienic Specifications of Cannery* (GB 8950-2016) (7.2 Raw materials such as livestock meat, poultry, aquatic products, fruits and vegetables shall be accepted according to relevant standards before being used. 6. *National Food Safety Standard - Specifications for Production Sanitation of Drinks* (GB 12695-2016) (7.4 Strains: For products in which stains are used, the strains must conform to relevant national standards or regulations, and their characteristics must be strictly tested before use, to ensure their activity and prevent contamination by other miscellaneous bacteria. Strains for fermentation shall be stored at an appropriate temperature based on the characteristics of strains to maintain their activity.)				
2.2 Other raw materials (if food additives are used, they shall be	1. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (7.3.8 Qualification confirmation of raw materials shall be carried out for nutritional fortification substances such as vitamins and minerals whose quality is	Provide the name of the additive used according to the types in the *National Food Safety Standard - Standard for the Use of Food Additives* (GB 2760-2014).	Food additives and nutritional fortification substances shall be used reasonably according to the variety, scope and amount specified in the National Food Safety	□ Conforming □ Non-conforming	

marked in accordance with the types in the *National Food Safety Standard - Standard for the Use of Food Additives* (GB 2760-2014))	easy to change during storage, and inspection shall be carried out when necessary to ensure conformity with the requirements of raw materials. 8.5. Food additives and nutritional fortification substances 8.5.1 Food additives and nutritional fortification substances shall be used reasonably according to the variety, scope and amount specified in the National Food Safety Standard. 8.5.2 Accurately weigh food additives and nutritional fortification substances at the time of use and properly keep records.) *2. National Food Safety Standard - Complementary Food Supplements* (GB 22570-2014) (3.9.1 Food additives shall be used according to the *National Food Safety Standard - Standard for the Use of Food Additives* (GB 2760-2014). 3.9.2 Nutritional fortification substances shall be used according to the *National Food Safety Standard - Standard for the Use of Nutritional Fortification Substances in Foods* (GB 14880-2012). The daily addition of NaFeEDTA shall not exceed 2.8 mg (at iron content). 3.9.3 The quality specifications for food additives and nutritional fortification		Standard.		

	substances shall comply with the appropriate standards and relevant regulations.)				
2.3 Quality and safety standards for various raw materials	*National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (7.2.1 The supplier's licenses and product qualification certificates shall be checked for purchased food raw materials; food raw materials for which qualification certificates cannot be provided shall be inspected as per food safety standards.)	Provide the quality and safety standards for raw materials, including indicators, limits, and acceptance requirements.	According to relevant national standards, determine whether the raw materials used meet the requirements of China.	□ Conforming □ Non-conforming	
2.4 Raw material supplier review system	*National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (7.2.2 The enterprise shall establish a supplier management system, stipulating the selection, review and evaluation procedures for suppliers. 7.2.6 The processes and safety measures adopted by suppliers shall be evaluated and, if necessary, on-site review or monitoring of the processes shall be conducted regularly.)	Provide the review system for raw material suppliers, including the selection, review and evaluation procedures for suppliers, a list of qualified suppliers and one copy of assessment records of main raw material suppliers.	Focus on reviewing whether the requirements of quality and safety standards for raw materials are met.	□ Conforming □ Non-conforming	
2.5 Inner packaging materials	1. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (7.4.1 Qualification certificates of products shall	Describe in detail the composition of the inner packaging material of the product and list the quality and safety	Focus on whether the enterprise has provided information on the safety certification of	□ Conforming □ Non-conforming	

of products	be checked at the time of procurement of food packaging materials, containers, detergents, disinfectants and other food-related products, and the supplier's license shall also be checked for food-related products under licensing control. Food-related products such as food packaging materials must be accepted before use.) 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (8.6 Packaging) 8.6.1 It shall comply with the relevant provisions of the *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013). 8.6.2 Packaging materials shall be clean and non-toxic and comply with relevant national regulations. 8.6.3 Packaging materials or gases for packaging shall be non-toxic and shall not affect food safety and product characteristics under specific storage and use conditions. 8.6.4 Reusable packaging materials such as glass bottles and stainless steel containers shall be thoroughly cleaned and disinfected as necessary before use.) 3. *National Food Safety Standard* -	standards of the inner packaging material.	the inner packaging materials, such as the enterprise declaration.		

	Hygienic Specifications of Cannery (GB 8950-2016) (7.5 The material, internal coating, lacquer for striping and sealant of the packaging container used for canned food shall meet the requirements of the relevant safety standards.) 4. *National Food Safety Standard - Specifications for Production Sanitation of Drinks* (GB 12695-2016) (7.3.2 Packaging containers, materials shall comply with relevant standards or regulations and shall not affect food safety and product characteristics under specific storage and use conditions. Additives in food contact packaging containers and materials shall meet the requirements of GB9685 and relevant regulations.)				
3. Production Process Information					
3.1 Provide a detailed production process flow diagram, which shall contain process	1. *National Food Safety Standard - Good Manufacturing Practice for Powdered Formulae for Infants and Young Children* (GB 23790-2010) (9.6 Specific processing steps). 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (8.7.1 General requirements: Each processing process in the production process of formula food for special	Provide a detailed flow diagram, which shall contain process parameters and provide a process description.	1. Focus on whether the enterprise's production process meets the product definition; 2. If the food is the formula for infants and young children and formula food for special medical purposes, please pay	□ Conforming □ Non-conforming	

parameters and provide a process description.	medical purposes shall respectively meet the requirements of the corresponding process-specific processing steps, and shall conform to the provisions of 8.7.2 - 8.7.9).		close attention to whether the processing process belonging to the specific processing steps conform to the relevant standards.		
3.2 Provide cleaning and disinfection procedures that cover the entire production line.	1. *National Food Safety Standard - Good Manufacturing Practice for Powdered Formulae for Infants and Young Children* (GB 23790-2010) (7.3 Cleaning and disinfection). 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (6.3 Cleaning and disinfection). 3. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (8.2.1 Cleaning and disinfection).	Provide the cleaning and disinfection procedures that cover the entire production line.	Focus on cleaning and disinfection effectiveness verification.	□ Conforming □ Non-conforming	
3.3. Provide a list of major equipment and production capacity.	1. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (5.2 Equipment). 2. *National Food Safety Standard - Hygienic Specifications of Cannery* (GB 8950-2016) (5.5 Sterilization equipment). 3. *National Food Safety Standard - Specifications for Production Sanitation of*	1. Provide the name, model, design processing capacity and pictures of key process equipment.	The enterprise shall have processing equipment corresponding to the production process.	□ Conforming □ Non-conforming	

	Drinks (GB 12695-2016) (5.3 Equipment).				
3.4 Provide a hazard analysis worksheet and HACCP plan.	1. *National Food Safety Standard - Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant* (GB/T 27341-2009). 2. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (8.1.1 The key links of food safety in the production process shall be identified through hazard analysis methods and control measures for key links of food safety shall be established. In the area where the key link is located, relevant documentation shall be available to implement control measures, such as dosage (feeding) tables and job operating procedures. 8.1.2 Encourage the use of Hazard Analysis and Critical Control Point (HACCP) system to control food safety in the manufacturing process.) 3. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (8.7.7 Control of critical factors for dry mixing in dry process and	1. Production and processing hazard analysis sheets and HACCP plan. 2. Provide monitoring records of CCP points, and provide measures and records related to deviations from critical limits of CCP, if any.	1. Focus on the setting and critical limits of CCP points and the implementation of correction and validation. 2. Whether the HACCP plan includes all products applied for registration.	□ Conforming □ Non-conforming □ N/A	

	wet-dry combined process for powdered food for special medical purposes)				
3.5 In case of any thermal sterilization process, it is necessary to provide proof materials of thermal sterilization effectiveness and specific sterilization temperature and time requirements	1. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (C.6 Heat treatment of products). 2. *National Food Safety Standard - Hygienic Specifications of Cannery* (GB 8950-2016) (5.5.2 The sterilization equipment shall undergo the heat distribution test after installation, to confirm uniform heat distribution before use. Heat distribution test shall be conducted at least once every three years under the premise of ensuring the heat supply and the smooth flow of heat transfer medium. If changes occur in the equipment structure, piping, valves, procedures, etc., the heat distribution test shall be repeated when necessary.) 3. *National Food Safety Standard - Specifications for Production Sanitation of Drinks* (GB 12695-2016) (8.2.7 The sterilization process shall have records or charts of the corresponding sterilization parameters (e.g. temperature, time and pressure) and shall be regularly inspected to ensure conformity with the specified	In case of any thermal sterilization process, it is necessary to provide proof materials of thermal sterilization effectiveness and specific sterilization temperature and time requirements.	1. The sterilization process shall have records or charts of the corresponding sterilization parameters (e.g. temperature, time and pressure) and shall be regularly inspected to ensure conformity with the specified requirements.	□ Conforming □ Non-conforming □ N/A	

	requirements.)				
4. Product Quality and Safety Control System					
4.1 Product online control inspection	1. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (8. Food safety control in the production process); 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB	1. A complete product online inspection plan shall be submitted, which shall specify the inspection content, parameters, frequency and verification frequency by process.	1. Whether the online control measures effectively monitor the hazards analyzed by the enterprise; 2. Focus on the consistency of online	□ Conforming □ Non-conforming	

	29922-2013) (8. Food safety control in the production process); **Uniformity:** 3. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (5.1.3.7 Measuring instruments and key instruments for production shall be calibrated regularly. The equipment for dry mixing shall ensure the uniform mixing of products. 8.7.7.3 Key process parameters related to mixing uniformity (e.g. mixing time) shall be verified; the uniformity of the mix shall be confirmed.) 4. *National Food Safety Standard - Good Manufacturing Practice for Powdered Formulae for Infants and Young Children* (GB 23790-2010) (9.6.5.3 Key process parameters related to mixing uniformity (e.g. mixing time) shall be verified; the uniformity of the mix shall be confirmed.) **Tightness:** 5. *National Food Safety Standard - Hygienic Specifications of Cannery* (GB 8950-2016) (8.4.3 Inspection of sealing performance 8.4.3.1 Before the startup of each shift, the sealing quality of the sealing equipment	2. Relevant information on uniformity verification shall be provided for the powdered formula for infants and young children and formula food for special medical purposes. 3. Relevant information on the tightness of the final product shall be provided for canned food for special dietary use.	checkpoint parameters and frequency with the HACCP plan and process flow. 3. If there are metal detectors, thermometers, etc., pay attention to the calibration and maintenance records. 4. The uniformity of the mix shall be confirmed for products with uniformity requirement (powdered formula for infants and young children, formula food for special medical purposes). 5. The tightness of the final product shall be inspected for canned food for special dietary use;		

	shall be inspected, and such equipment can be put into production after the inspection is passed. 8.4.3.2 The appearance quality and sealing performance shall be controlled and tested properly in the production process based on the requirements of the sealing operation procedures, and records shall be made. 8.4.4 The sealed semi-finished product shall be sterilized within 2h.)				
4.2 Testing and release of final products	1. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (9. Inspection). 2. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (10.1 Relevant provisions of the *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) shall be complied with.) 3. Representative finished product samples shall be taken batch by batch and shall be tested and retained according to relevant national regulations and standards. 4. Laboratory quality management shall be strengthened to ensure the accuracy and authenticity of test results.	Provide test plans, test standards and release requirements for final product release.	The inspection report for the final product shall cover the limit requirements set out in the national food safety standards in China.	□ Conforming □ Non-conforming	

	5. *National Food Safety Standard - Specifications for Production Sanitation of Drinks* (GB 12695-2016) (9.2 After filling and capping (sealing), the appearance, filling volume, container condition, tightness of capping (sealing) and visible objects of the product shall be inspected.)				
4.3 Control measures for mold, yeast, and foreign body	1. *National Food Safety Standard - Good Manufacturing Practice for Powdered Formulae for Infants and Young Children* (GB 23790-2010) (Appendix A (Normative Appendix) Guidance on Environmental Monitoring of Salmonella spp., Cronobacter sakazakii and Other Enterobacteriaceae in Cleaning Work Areas for Powdered Formula for Infants and Young Children; 2. Effective control measures for foreign bodies, such as the installation of screens, strong magnets, and metal detectors, shall be adopted by manufacturers to prevent and check foreign bodies. These measures shall be monitored for the implementation process or validated for effectiveness.) 3. *National Food Safety Standard - General Principles for the Formula Foods for Special Medical Purpose* (GB 29922-2013) (Appendix B Guidance on Environmental Monitoring of Salmonella spp., Cronobacter sakazakii and Other	Provide control measures for mold, yeast, and foreign body.	1. The focus of monitoring shall cover areas where microorganisms are easy to hide and breed; 2. Whether the integrity of relevant facilities for preventing foreign bodies is regularly inspected.	□ Conforming □ Non-conforming	

	Enterobacteriaceae in Cleaning Work Areas for Powdered Formula Food for Special Medical Purposes; 4. Effective control measures for foreign bodies, such as the installation of screens, strong magnets, and metal detectors, shall be adopted by manufacturers to prevent and check foreign bodies. These measures shall be monitored for the implementation process or validated for effectiveness.) 5. *National Food Safety Standard - General Hygienic Regulation for Food Production* (GB14881-2013) (Appendix A Guidance on Monitoring Procedures for Microorganisms in Food Processing; 6. A management system shall be established to prevent contamination caused by foreign bodies, possible sources and routes of contamination shall be analyzed, and corresponding control plans and procedures shall be developed.				
5. Declaration					
5.1 Declaration by enterprise	1. Articles 8 and 9 of the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree No. 248 of General Administration of Customs of China).		1. It shall be signed by the legal person and stamped with official seal of the enterprise.	□ Conforming □ Non-conforming	

5.2 Confirmation by competent authority	1. Articles 8 and 9 of the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree No. 248 of General Administration of Customs of China).		1. It shall be signed by an officer of the competent authority and stamped with the seal of the competent authority.	□ Conforming □ Non-conforming	