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Voluntary Public

Date: 6/17/2016

GAIN Report Number: CH 16037

China - Peoples Republic of

Post: Beijing

CFDA Publishes Measures for the Registration of Infant formula Recipes (CFDA Decree No.26)

Report Categories:

Policy and Program Announcements

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Report Highlights:

On June 6, 2016, China Food and Drug Administration (CFDA) announced the Administrative Measures for the Registration of Recipes for Formula Powder Products for Infants and Young Children (CFDA Decree 26), which will enter into force on October 1, 2016. The measures provide requirements and procedures for registration of infant formula recipes, and elaborate on the requirements for labeling and product descriptions. The measures were notified to the WTO as TBT 1165 in January 2016.

This report contains an unofficial translation of the Administrative Measures.

General Information:

BEGIN TRANSLATION

China Food and Drug Administration Decree No.26

The Administrative Measures for the Registration of Recipes for Formula Powder Products for Infants and Young Children was approved in the Executive Meeting of the China Food and Drug Administration on March 15, 2016, and is hereby announced. The Measures will be implemented on October 1, 2016.

Bi Jingquan

Minister, China Food and Drug Administration

June 6, 2016

Administrative Measures for the Registration of Recipes for Formula Powder Products for Infants and Young Children

Chapter I General Provisions

Article 1 Formulated in accordance with the Food Safety Law and relevant laws, regulations and rules, these Measures will be used to strictly regulate the registration of recipes for formula powder products for infants and young children (infant formula), and to ensure quality and safety of such products.

Article 2 Registration of recipes for infant formula produced and distributed in China, and imported into China are subject to provisions of these Measures.

Article 3 Registration of recipes for infant formula refers to the review process that China Food and Drug Administration (CFDA) takes to decide whether a recipe could be registered; the review is conducted based on the application and following the procedures and requirements set by these Measures.

Article 4 Registration of infant formula recipes should be science-based, strict, open, fair and just.

Article 5 CFDA administers the registration of infant formula recipes.

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

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

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

The provincial food and drug authorities (provincial FDAs, which locate in capitals of provinces/autonomous regions/municipalities) cooperate with CFDA in registration of infant formula recipes in their administrative regions.

Article 6 The applicant bears the legal liability and responsibility for the authenticity, integrity and conformity with the laws of the submitted materials.

The Applicant should assist CFDA in its work, such as on-site verifications and sampling tests, that are related to registration of recipes.

Chapter II Application and Registration

Article 7 The applicant for registration of recipes (the Applicant) refers to an enterprise that intends to produce and sell infant formula products in China, or a foreign producer intends to export such products to China.

The Applicant should have the R&D, production, and testing capacity that match the production of infant formula; the Applicant should follow the good manufacturing practice (GMP) suitable for infant formula production, implement the Hazard Analysis and Critical Control Point (HACCP) system, and should be capable of testing products leaving the factory batch by batch for those items required by the national food safety standards for infant formula.

Article 8 The recipe applied for registration should comply with provisions in relevant laws, regulations, and national food safety standards; the application for registration should present R&D and verification reports proving the recipe's science basis, along with sufficient evidence.

The Applicant should submit the following documents to CFDA for the registration of infant formula recipes:

1. Application form for registration of infant formula recipes;
2. Applicant's credential documents;
3. Quality and safety standards for raw materials and auxiliary materials;
4. Reports about research and development of the recipe;
5. Description of production process;
6. Test report of the product;
7. Evidencing documents of capacities for R&D, production and testing;

8. Other documents evidencing science basis and safety of the recipe.

Article 9 The same business entity, to register more than two (2) product recipes for the same age group, must demonstrate distinct differences between the recipes with science evidence. Each business entity, in principle, could register no more than three (3) formula series with nine (9) product recipes. Each formula series include formula powder for infant (0 to 6 months, Stage 1), formula powder for older infant (6 to 12 months, Stage 2), and formula powder for young children (12 to 36 months, Stage 3).

Article 10 Within the same group company, one wholly-owned subsidiary that has obtained recipe registration and production licensing can use the recipe registered by another wholly-owned subsidiary (for infant formula production). Before production, the group company should submit a written report to CFDA.

Article 11 The Acceptance Agency shall deal with the applications for infant formula recipe registration according to the following conditions:

1. Timely inform the Applicant of items that do not need registration;

2. In case the applied items do not fall in the mandate 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 the application documents are incomplete or do not conform to the required format, (the Acceptance Agency should) 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 its submission;

5. In case the Applicant has submitted complete application materials that 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 to the Applicant, which should have the CFDA's official seal (for administrative permission acceptance) and marked with dates.

Article 12 The Acceptance Agency should deliver the application materials to the Review Agency within three working days after the application is accepted.

Article 13 The Review Agency should examine the application documents, and check consistency between the product recipe claims and the content of the recipe registration; when necessary, the Review Agency could request the Verification Agency to conduct on-site verifications to the Applicant, request the testing institutes to conduct sampling test, and organize experts to evaluate on technical issues. The review work should be completed within 60 working days upon receiving the application materials (delivered by the Acceptance Agency).

In special circumstances that require extended review time, the review could be extended for 30 working days with approval of Review Agency's person in charge; the decision of extension should be informed to the Applicant in writing.

Article 14 The Verification Agency should complete the on-site verification on the Applicant's capacity for R&D, production and testing within 20 working days upon receiving request by the Review Agency; a verification report should be issued after the on-site verification.

The Verification Agency should inform the provincial FDA where the Applicant is located to participate in the on-site verification; the provincial FDA shall send officials to the verification.

Article 15 The Review Agency should entrust qualified and eligible food testing institutes with legal qualifications to conduct sampling tests.

The testing institute should complete the sampling test within 30 working days upon receiving the entrusted testing task, and issue product testing reports.

Article 16 Scheduling of on-site verifications and sampling tests to foreign manufacturers will be determined based on the practical situation.

Article 17 The Review Agency would carry out review and make the review conclusion based on the registration application, the on-site verification report, and the product testing report.

Article 18 When making the conclusion not to register the product, the Review Agency should issue a notice in writing to the Applicant. Opposing the notice, the Applicant could file a re-consideration application to the Review Agency within 20 working days upon receiving the notice, and explain reasons for the re-consideration. Contents for re-consideration are only limited to the original application items and materials.

The Review Agency shall make the re-considerations decisions within 30 working days upon accepting the re-consideration application, and inform the decision to the Applicant in writing.

Article 19 In case the Review Agency deems it is necessary to request supplementary materials or corrections, it should inform the Applicant of all contents that need supplementary information or correction all at once. The Applicant should provide such supplementary information and corrections within three months in one submission. The time needed for preparing such supplementary material and correction is not included in the review time. Should the Applicant fail to submit such supplementary materials or make corrections within the given time, the Review Agency will deem the Applicant is not submitting such information.

Article 20 Based on the review conclusions, CFDA will make the decision whether to register or not register the recipe within 20 working days upon receiving the review conclusions.

The Acceptance Agency will issue the registration certificate or the decision not to register the recipe to the Applicant within ten working days after CFDA makes the decision.

Article 21 The time needed for on-site verification, sampling test, and re-consideration are not counted as the technical review and registration decision making time. The review time is not counted as the registration decision making time.

Article 22 Opposing the CFDA’s decision not to register the formula, the Applicant can file an administrative review petition in writing to CFDA, or file an administration litigation petition to the People’s Court.

Article 23 The recipe registration certificate and its attachment should contain the following items:

1. Product name;
2. Enterprise name, legal representative and address of manufacturing;
3. Registration number, date of approving for registration and term of validity;
4. Production process;
5. Product recipe.

The format for the recipe registration number of the approved infant formula should be as follows: national food registration symbol “YP” + year (four digits) + sequential number (four digits); YP stands for infant formula.¹

The recipe registration certificate is valid for five years.

Article 24 Within the valid time of the registration certificate, in case the registration certificate is lost or damaged, the Applicant should file an application in writing to the Acceptance Agency with explanations. In case the certificate is reissued due to loss of the original certificate, a statement of loss should be made in the provincial FDA website; in case the certificate is reissued due to damage of the original certificate, the original certificate should be returned (to the Acceptance Agency).

CFDA will reissue the certificate within 20 working days after accepting the (reissuance) application; the reissued certificate should mark the original approval date, with a note of “Reissue” on it.

Article 25 In case the Applicant needs to change the registration certificate and items in the attachment, he/she should submit the registration changing application to CFDA, along with the following materials:

1. The application form for changing recipe registration;
2. The registration certificate and attachment of the certificate;
3. Proving materials for items to be changed.

Article 26 If the applicant applies for changes of the product recipes and these may affect the product’s science basis or safety, the Review Agency will conduct review pursuant to actual needs and pursuant to provisions in Article 13 of these Measures, and make the review conclusions accordingly.

In case the changes do not affect the recipe’s science basis and safety, such as enterprise name or address of manufacturing, the Review Agency should verify the information, and decide whether such

¹ Editor’s Note: “YP” is the abbreviation for infant formula in Chinese (Ying Pei).

changes could be made within ten working days upon receiving the application. The application for changing the Applicant's name should be made by the Applicant with the changed name.

CFDA shall decide to change or not change the registration within ten working days upon receiving the review conclusions. For applications that comply with relevant provisions, CFDA will make the changes; the issuance date of the registration certificate is the date the change of registration is made, while the original registration number and the term of validity remain unchanged. For applications CFDA does not approve, the decision of not changing registration will be made.

Article 27 When the valid time for the registration certificate is about to end, and the Applicant needs to renew the registration, the Applicant should submit a registration renew application to CFDA no later than six months before the certificate expires. The application should be submitted along with the following documents:

1. Application form for recipe registration renew;
2. Applicant's credential documents;
3. Evidencing documents of capacities for R&D, production and testing;
4. Reports of self-inspection of the production quality management system;
5. Tracking and assessment of the product's nutrition and safety;
6. Opinions by the provincial FDA where the producing enterprise locates concerning registration renew;
7. The registration certificate and its attachments.

The Review Agency will conduct review pursuant to Article 13 of these Measures and the actual condition, and make the review conclusions accordingly.

CFDA shall decide to renew or not renew the registration within 20 working days after receiving Review Agency's review conclusions. Approving the registration renew application, CFDA will issue the new registration certificate, with the registration number unchanged, and the new validity period starts from the date the renew application is approved; CFDA shall decide to decline the application for registration renewal if the application is rejected.

In case CFDA fails to make a decision within the time limit, the application of renewal will be regarded as approved.

Article 28 Reregistration renewal will not be approved in any of the following situations:

1. The Applicant fails to submit application for registration renew within the required time;
2. The Applicant fails to produce products following the registered formula in five years after the registration;
3. The Applicant fails to maintain the capacity of R&D, production and testing it had when the registration was made;
4. Other circumstances that do not comply with relevant provisions.

Article 29 For other conditions which are not covered under the procedures for changing registration or renewing recipe, CFDA shall refer to relevant provisions for formula registration in these Measures.

Chapter III Labeling and Description

Article 30 Applying for recipe registration, the Applicant should submit samples of the product's label and description, and present explanations and evidence materials for claims in the product's label and description.

In case the label and product description contains recipe of the infant formula, such content should be consistent with the registered recipe, and include the registration number.

Article 31 In the case the product name indicates materials derived from animal sources, the ingredient table should accurately list the dairy materials (such as raw milk, milk powder, whey permeate/protein powder) derived from animal sources according to the product recipe. When containing more than two kinds of dairy materials derived from animal sources, the label should indicate percentages of each material derived from animal sources.

The ingredient table should list the varieties of edible vegetable oils in descending order based on quantity used.

The nutrition fact table should list nutrients in the sequence order requested by the national food safety standards for infant formula powder; the nutrients should be listed by the categories of energy, protein, fats, carbohydrates, vitamins, minerals and optional ingredients.

Article 32 The labels with claims of origin of materials (such as raw milk or milk powder) should accurately indicate the origin (region or country); it is not allowed to use vague information, such as "produced from imported milk", "origin of foreign ranch", or "imported materials".

Article 33 The claims should specify the applicable age for use; and could label the product with "Stage 1, Stage 2, Stage 3" at the same time.

Article 34 The product label and description should not contain the following content:

1. Involving disease prevention and treatment;
2. Expressing or implying health functions;
3. Expressing or implying functional benefits, such as good for intelligence development, build up immunity/resistance to disease, or protect the intestinal tract, etc.;
4. Using the expressions "not adding", "not containing", or "zero adding" to emphasize the unused or non-existing substances that are prohibited in food recipes or to be used in foods by food safety standards;
5. Content that is false, exaggerated, or against science principles, or gives absolute (statement);
6. Claims that are inconsistent with the registered recipe.

Chapter IV Supervision and Inspection

Article 35 The organizations or personnel undertaking technical review, on-site verification, sampling tests and expert evaluation for recipe registration are accountable for the review opinions, the on-site verification report, the product testing reports, and the experts' opinions.

The organizations or personnel undertaking technical review, on-site verification, sampling tests and expert evaluation for recipe registration should follow relevant laws, regulations and rules; they are required to obey ethnic rules, and follow relevant national food safety standards/technical standards to ensure science-based, objective and fair conclusions in their work.

Article 36 The food and drug authority should process in a timely basis the reports submitted by relevant entities or individual persons about violations in recipe registration application acceptance, technical review, on-site verification, sampling tests, expert evaluation and approval work.

Article 37 CFDA will announce the catalogue of registered infant formula recipes within 20 working days after approving (the registrations).

Article 38 The agencies or personnel handling application acceptance, technical review, on-site verification, sampling tests and expert evaluation shall keep the confidentiality of business proprietary information obtained in the registration process.

The Applicant shall indicate the business proprietary information in the application materials pursuant to relevant provisions, and indicate reasons for such request.

Article 39 CFDA will not approve the recipe registration application if the Applicant refuses to accept the on-site inspection or sampling testing.

Article 40 CFDA will revoke the registration certificate upon request by an interested party or in accordance with its mandates in any of the following circumstances:

1. A (CFDA) working staff is found to have abused his/her power or committed dereliction of duty in approving the registration;
2. (CFDA staffs) went beyond the statutory purview in approving the registration;
3. (CFDA staffs) violated the legal procedures in approving the registration;
4. (CFDA staffs) approved registration filed by applicant not qualified to apply, or an applicant that does not comply with the legal conditions;
5. Other circumstances provided in relevant laws, regulations or rules that the registration certificate may be revoked.

Article 41 CFDA will cancel the registration of the recipes pursuant to relevant laws and regulations in any of the following circumstances:

1. The Applicant applies to have the registration cancelled;
2. The producer is terminated in accordance with relevant laws;

3. The registration certificate expires and the Applicant does not apply to renew the registration;
4. The registration is revoked, withdrawn, 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 V Legal Liabilities

Article 42 Whereas the Food Safety Law and other regulations already have provisions that address violations in registration of infant formula recipes, those provisions prevail.

Article 43 Whereas the Applicant is found to conceal relevant conditions or submit fake materials/sample products in registration application, CFDA will not accept the application nor will CFDA register the recipe; a warning will be issued to the Applicant, which will be announced to the public. The Applicant is not allowed to re-apply for recipe registration in one year; suspected of violating criminal laws, the Applicant will be transferred to the public security authorities for criminal investigation.

Whereas the Applicant is found to have obtained the registration certificate by improper means (such as fraud or bribery), or concealing relevant conditions/submitting false materials, CFDA will revoke the registration certificate and impose a fine between 10,000 RMB to 30,000 RMB; the Applicant is not allowed to re-apply for recipe registration in three years; suspected of violating criminal laws, the Applicant will be transferred to the public security authorities for criminal investigation.

Article 44 Whereas the Applicant fails to apply for change in registration for changes that do not affect recipe's science basis and safety, the county and above level FDA will issue a warning and instruct the Applicant to take correction measures; in case the Applicant refuses to make the corrections, the county and above level FDA will impose a fine between 10,000 RMB to 30,000 RMB.

Upon finding the Applicant making changes that affect the recipe's science basis and safety without applying for registration changes, the county and above level FDA should take punitive measures pursuant to provisions in Article 124 of the Food Safety Law.

Article 45 Whereas the registration certificate is found to be falsified, altered, sold, leased, lent or transferred, the county and above level FDA will issue a warning and instruct (the producer) to take corrective measures, as well as impose a fine between 10,000 to 30,000 RMB; suspected of violating criminal laws, the Applicant will be transferred to the public security authorities for criminal investigation.

Article 46 Finding the infant formula producers or traders violating provisions in Article 30 to Article 34 of these Measures, the food and drug authorities will instruct the producer/trader to take corrective measures, and impose a fine between 10,000 to 30,000 RMB pursuant to relevant provisions.

Article 47 CFDA departments/subsidiaries and working personnel are subject to punitive measures provided in Article 144 of *the Food Safety Law* for approving registration by unqualified applicants or approving the registration beyond their statutory purview.

CFDA departments/subsidiaries and working personnel 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 VI Supplementary Provisions

Article 48 “Recipe for formula powder products for infants and young children” in these Measures refers to food materials and food additives and their dosage used in producing formula powder for infants and young children, and contents of nutrients in the product.

Article 49 These Measures will enter into force on October 1, 2016.

END OF TRANSLATION

Full text of the Decree No.26 could be found at: <http://www.cfda.gov.cn/WS01/CL0053/155260.html>