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Key Point of Health Food Re-registration Skill Evaluation (Draft)

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1) Definition of re-registration

According to related procedure, condition and requirement, the CFDA processes the application to extend the validity period of the health food's approval certificate.

2) Principle of skill evaluation

1. Revision on the number and type of ingredients and materials without approval is not allowed.

2. The product techniques need to meet the national standard.

3. If the techniques need to be adjusted, it should be done based on regulations, and supplementary material about the test should be submitted.

4. After re-registration, the product techniques should meet the registration standard of health food.

3) Key evaluation points in ingredient technology

1. Raw material and auxiliary material should be listed as ingredient and put in the required format. The name of the materials should be put based on national standard.

2. The type and number of new and original materials and the composition of the materials should meet the national standard. Those who fail to meet the standard should make adjustments and submit the information, including quality standard and quality test report, of the adjustment to the authority.

3. The applicant should provide the safety evidence of the adjusted material, and conduct test on toxicology, function, stability and hygienics. Those who reduce the material volume are exempted from toxicology test.

4. If the current regulation does not set a specific standard on the ingredient, or there is scientific study to show that this ingredient may pose safety threat, sufficient safety evidence should be presented or adjustment of the ingredient volume should be made.

5. Capsule health food producer should present quality standard, supplier certificate, quality test report as well as producing qualification document.

6. If the ingredient list includes anthraquinone, soy isoflavone and red rice, related information should be submitted.

Regarding nutrient supplements:

If the type of mineral compounds and vitamin does not meet the latest standard, adjustment should be made accordingly. In principle, this ingredient should be replaced by another ingredient that is similar biologically or physically. If the volume of these materials is not up to standard, adjustment should be made and related information should be submitted.

After the adjustment, the product needs to be tested on its function, hygienics and stability. The revision should be noted in the application materials.

If the type is standard, no revision on the targeting group can be made. If the type is not standard, the producer should apply for adjustment and provide related information.

4) Key points in product naming evaluation

1. The producer should re-name the product if its name is not up to standard. The original name can be put in a bracket besides a new name till the next validity period expires.

2. For those which enjoy high social recognition but fail to meet the standard in naming, the producer can apply for the product's original Chinese name. After getting approval from CFDA, the name can be used till the next validity period expires.

5) Key point in label and instruction book evaluation

1. The label and instruction book should meet the standard of latest regulation; otherwise, revision is required.

2. The label and instruction book should indicate the target group and the group which the food is not suitable for. The group should be identified based on the volume, function, research report and safety assessment etc.

3. If the target group includes kids who are younger than 3 years old and pregnant woman, scientific evidence and related research materials should be presented. Otherwise, these groups should be put into the group which the food is not suitable for.

4. Capsule, chewable tablet and big-size tablet should include infant and kids into the group which the food is not suitable for. Wine products should be identified as unsuitable for kids and pregnant woman.

5. Health food that contains phenylalanine and alcohol should identify the group which the food is unsuitable for. Health food which contains pollen, propolis and protein should alert the group who are allergic to these elements.

6. The instruction book should contain information of the initial approval and changes afterwards.

7. If the content of the instruction book or label requires adjustment, the producer should apply for the revision based on regulations.

8. Those products whose instruction book and label include different content with the approved sample will be punished by the provincial FDA.

6) Key point in function test evaluation

1. If the test method, evolution index and judging standard are different from the Health Food Test and Evaluation Skill Regulation (2003 version) or the previous version of "health food function evaluation method" by CFDA, addition function test is not required.

2. If the test method, evolution index and judging standard are different from the latest regulation, additional test is required. If human test is needed in addition to animal test, the test should be conducted based on latest regulation.

3. If the basis of original function test does not meet the latest standard, additional test is required.

4. If an additional test has been made as result of adjustment, related material and test report should be provided.

5. If the ingredient is adjusted, function test should be made based on latest regulation.

6. If stimulant test is required, a test report should be provided.

7) Key point in toxicology evolution

1. If the original toxicology test is not up to the latest standard, additional test should be made.

2. If the ingredient composition and volume are kept unchanged, additional test is not required. If the daily intake of the ingredient increases, additional toxicology test is required.

3. If the new material added into the formula is not tested toxicologically, additional test is required and report should be submitted.

8) Key point in evaluation of functioning element test methodology

If the current test methodology is not up to the latest standard, the producer should apply for adjustment before applying for re-registration.

9) Key point in product technology requirement and quality standard

1. If the requirement, quality standard, and the content in the letter of commitment are unchanged, additional evaluation is not required.

2. If the requirement and quality standard (main content) are not up to the latest regulation, the producer needs to apply for adjustment first before applying for re-registration.

10) Key point in production techniques evaluation

1. If the formula requires no adjustment, the product is exempted from additional test.

2. If the formula does not meet the current standard, adjustment should be made and information should be submitted.

11) Key point in quality test report evaluation

If the product is not produced or sold within the 5-year validity period of approval certificate, on-spot test and evaluation is required. If it does, quality test report should be presented to CFDA for re-registration.

12) Evaluation conclusion and judging basis

The following situation will require additional material submission before granting approval:

1. Product name needs to be changed based on the latest regulation

2. Ingredient name and formula are put in a substandard format

3. Safety evidence is required for ingredient volume

4. Label, instruction book and quality standard are required to adjust

5. Related tests and approbation report are required

6. Test report is substandard or document by test institutions is required

7. Additional evidence on function and safety is required

8. Consumers question the product's safety

9. Other additional materials are required

The following will not be granted approval:

1. The application material does not provide product formula

2. The volume and type of ingredient are inconsistent with the original content in the approval

3. Formula of health food does not meet the latest standard

4. The volume and type of the ingredient of the health food

5. Quality and volume of the ingredient of health good did not adjust according to the latest regulation

6. Number of original and new ingredient of the health food do not meet the standard

7. New ingredient does not pass the toxicology or safety evaluation; or the toxicology test report shows that there is potential safety risk.

8. If the result of the product function test report shows negative, or the scientific document/human use report does not support the claimed health function

9. Function test and toxicology test report shows that there may be potential intake risk.

10. Function and toxicology test reports are not submitted.

11. Product is caught by safety problem after being put into market.

12. The quality index report does not the latest regulation or the quality is substandard.

13. Functioning elements, formula volume and index of producing techniques in the test report are inconsistent with the accounted value of formula and production techniques.

14. Withdraw the approval certificate according to related regulation and laws

15. Other situation that does not meet the national standard

13) CFDA is responsible to explain the key points

Original Chinese Text:
http://www.sda.gov.cn/WS01/CL0780/94071.html