

Import Health Foods Registration Procedure

Phase 1 : Pre-registration Analysis

- After having signed a confidentiality agreement, a list of relevant documents and forms will be provided to the client for preparing the basic information needed.
- Documents received from the client will be checked by experts in order to see if the composition is conform to the regulations. The received documents will also be analyzed to select and decide the claimed product functions based on the product's formula. This very important step is performed in close cooperation with the client.
- **Note ! In China health food products are classified into 22 classes according to different health functions. The regulations and registration procedures are different for different classes.**

Phase 2 : Control Tests

All import health food products, before submission of the application to SFDA, need to be controlled in the Control Institute for Food Hygiene Supervision.

To do the control test, the following documents should be provided to the Control Institute for Food Hygiene Supervision:

Documents needed for the control tests

1. Manufacturing technology description with flow chart
2. Formula of the product
3. Specification of the product
4. Testing methods of the functional components/ingredients
5. Samples (the control institute will decide the amount of examination samples according to the smallest package size of the product)

- For different products, the tests take around 3-10 months after receiving the samples and necessary documents. **For some products a clinical trial on the claimed functions is required!** The time and cost of the trial should be negotiated and decided with the Control Institute. At the end of the test, the Control Institute will issue a test report.

Phase 3 : Preparation of the Application File, Official Submission and Administrative Process Follow-up

- Preparation of necessary documents and samples (the list is attached below) according to the regulations of the identified product class.
- Official submission of the application dossier with the test report to the Office for Health Food Product Evaluation of SFDA.
- The Office For Health Food Product Evaluation of SFDA will check the application file and issue an official notice to confirm within one week if the application is accepted or not.
- The Health food Product Evaluation Commission of FSDA will examine and evaluate the dossier.
- This Commission meets 4 times a year (in March, June, September and December) during which all application files will be evaluated.
- SFDA office will summarize the evaluation opinion, and issue the license.

Documents needed for the official application file:

1. Application Form for Import Health Food Hygiene Permission;
2. Composition and mechanism basis of the product;
3. Functional ingredients and their content quantities, as well as the test methods;
4. Production technology and its chart resume;
5. The product specification (Standard of the product of the manufacture);
6. Test report on the product issued by the Institute designed by the Ministry of Health;
7. The package with the labelling of the product;
8. Instruction manual for use of the product;
9. Letter of Entrustment issued by the manufacturer to the applicant agent for the product application;
10. Certificates of the production permission and Free Sales Certificate of the product in the producing country or area;
11. Other documents useful for evaluation and examination of the product can be additionally added;
12. Three product samples of the smallest sales packages size, not opened.

Registration time: roughly 9 -24 months.

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| Phase 1: | about | 1 | months |
| Phase 2: | about | 3 – 18 | months (or even longer in case of clinical trials) |
| Phase 3: | about | 5 | months |

Official fees: to be paid to the authority

Registration fees: 1,000 USD per product/per formulation

Control test fees: *Variable*, depends on product and health function.

Additional expenses:

Translations: 20 – 25 USD/ per 1000 Chinese characters (according to quantity and difficulty)

Copies (13 complete copies needed !!): 250 to 500 USD depending on file

Not included: costs for consulting services.