

Imported Healthcare Food “Blue Hat” Registration

- CHENG CHENG PHARMACEUTICAL NZ LTD



Company Information

- Cheng Cheng Pharmaceutical Technology (Taiyuan) Co., Ltd. is a Contract Research Organization (CRO) specializing in research and development, clinical research and submission for external examination and approval for medicine products, health care products, cosmetics, hygiene products. We offer a range of specialized services, including phase I to phase IV clinical studies of medicine products, data management, and statistical analysis, research and development of hygiene products, health care products and cosmetics, as well as imported drug registration, etc.。

Our Service

- **Clinical Research**
- **Data Management**
- **Biostatistics**
- **Third Party Inspection**
- **“Blue Hat” Registration**

“Blue Hat” Registration



The Definition of Healthcare Food

- Healthcare food indicates food declared with specific healthcare functions or with the purpose of supplementing vitamins and mineral substances. It fits for specific population, can adjust body functions, isn't for curing diseases, and doesn't cause acute, subacute, or chronic hazards to human body. (*Food Safety Law of the People's Republic of China*):
- **Two features of health food:** The first is security. It doesn't generate any acute, sub-acute, or chronic toxicity to human body; the second is functionality. It can regulate special groups of population, which cannot cure diseases or replace drugs.

The Characteristic Of Healthcare Food

- Health food is a special kind of food, between other foods and drugs
- Major differences between health food and other foods:
 - (1) Health food emphasizes specific health function, while other foods emphasize offering nutritional ingredients.
 - (2) Health food has specified edible amount, while other foods don' t have demands in edible amount.
 - (3) Health food has specific suitable crowds and unsuitable crowds according to different health functions, while other foods don' t distinguish in this aspect.

The Characteristic Of Healthcare Food

- Major differences between health food and drugs:
- Different intended uses: health food is used for regulating body functions, improving human bodies' abilities in fighting diseases, perfecting sub-health status, reducing disease occurrence risks, and not for regarding preventing or curing diseases as the purpose. Drugs are used for preventing, curing, and diagnosing people's diseases, regulating people's physiological functions and stipulating adaptation diseases, major functions, usages, and dosage.
- Health food shall be taken as per specified edible amount, which doesn't generate any acute, sub-acute, or chronic toxicity to human body. Drugs can have side effects.
- Different application methods: health food can only be taken orally, while drugs can be injected or smeared.
- Different raw materials: toxic and harmful substances cannot be raw materials of health food.

The Classification Of Healthcare Food

- Healthcare food is divided into two categories, one is functional healthcare food (功能性保健品) and the other is nutrient supplements (营养补充剂):
- 27 functions: boost immunity, assist in protecting radiation hazards, improve sleep, increase bone density, relieve physical fatigue, assist in protecting chemical liver injuries, and enhance anoxia endurance; relieve visual fatigue, remove acne, remove chloasma, improve skin moisture, and improve skin oil; assist in reducing blood lipid, blood sugar level, and blood press, assist in protecting gastric mucosa, have effects on anti-oxidation, assist in improving memory, promote lead discharge, clear heat from throat, facilitate milk secretion, lose weight, improve growth and development, cure alimentary anemia, regulate intestinal flora, improve digestion, and facilitate feces excretion.

Functions Applied for Health Food

Notes: [△] only receive animal function tests; * only receive human feeding trials; ** receive animal function tests and human feeding trials; # only receive doping control; the number of health functions of the same product shall not exceed two.

1. Boost immunity [△]	2. Assist in blood lipid reduction **	3. Assist in regulating blood sugar level**
4. Anti-oxidation **	5. Assist in memory improvement **	6. Relieve visual fatigue *
7. Promote lead discharge **	8. Clear heat from throat **	9. Assist in blood press reduction **
10. Improve sleep [△]	11. Facilitate milk secretion **	12. Relieve physical fatigue [△] #
13. Improve anoxia endurance [△]	14. Assist in protecting radiation hazards [△]	15. Lose weight **#
16. Improve growth and development **#	17. Increase bone density [△]	18. Improve alimentary anemia **
19. Assist in protecting chemical liver injury [△]	20. Remove acne *	21. Remove chloasma *
22. Improve skin moisture *	23. Improve skin oil content *	24. Regulate intestinal flora **
25. Improve digestion **	26. Relax the bowels **	27. Assist in protecting gastric mucosal damage **

The Classification Of Healthcare Food

- Nutrient supplements indicate products with the purpose of supplementing vitamin, and material substances rather than offering energy. Its functions are supplementing for food, preventing nutritional deficiency, and reducing risks for causing some chronic degenerative diseases. (Only need filing).

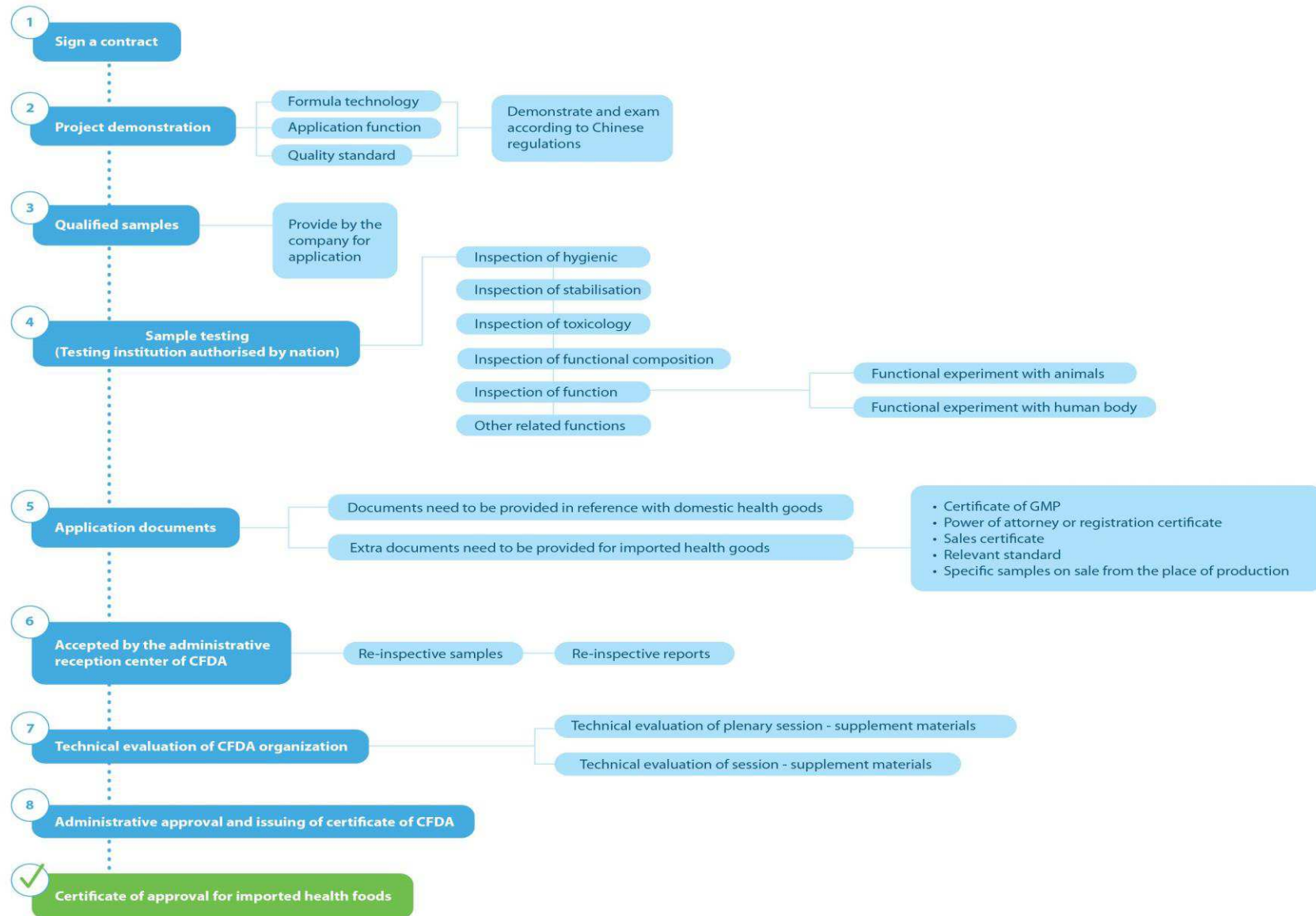
Relevant Regulatory of Chinese Imported Healthcare Food

- “New Food Safety Law ” AND “Administrative *Measures for Registration and Filing of Health food* ”
- Article 70: healthcare food carries out two-way parallel management system of **registration and filing**.
- Article 76: healthcare food using raw materials outside raw material catalogue of healthcare food and firstly imported healthcare food shall be registered in Food and Drug Supervision and Administration Department of the State Council. However, among firstly imported healthcare food, those supplementing such nutrient substances as vitamin and mineral substances shall be filed in Food and Drug Supervision and Administration Department of the State Council. Other healthcare food shall be filed in Food and Drug Supervision and Administration Department of the People’ s Court of the province and municipality.

Registration application and approval processes of imported health food

- Stage 1: project demonstration of imported health food
- Stage 2: test (corresponding: affirmed inspection body)
- Stage 3: application
- Stage 4: examination and approval
- Stage 5: import declaration

Registration and Application Procedures of Imported Health Goods



Government agencies involved in applying for healthcare food

- Testing Organization: be responsible for conducting technical inspection on products and issuing test report. It shall be Centre for Disease Control (or Sanitation and Anti-epidemic Station) of each province or city, Nutrition and Food Security Institute of Chinese Centre for Disease Control and Prevention, Chinese Academy of Preventive Medicine, or some medical colleges.
- Filing Office: be responsible for preliminarily auditing enterprises' application materials. As for materials meeting requirements, it is responsible for arranging products to participate in Review Meeting, informing enterprises review comments, reporting products to be approved to China Food and Drug Administration, and issuing certificates. It shall be Health Food Approval Institution of each province or city or Health Food Filing Office of National Traditional Chinese Medicine Protection and Review Committee of China Food and Drug Administration.

Government agencies involved in applying for healthcare food

- Review Committee: be responsible for conducting technical review on applied products. It shall be First Trial Committee of each province or city or Review Committee of China Food and Drug Administration.
- Hygiene Administrative Department: audit products passing technical review of Review Committee further, and report or approve those meeting provisions of relevant regulations. China Food and Drug Administration has final approval authority. It shall give approval number of health food to approved products.

Government agencies involved in applying for healthcare food

- Approval authority of health food: China Food and Drug Administration (CFDA) is responsible for registration and management of national health food and approving imported health food.

Budget on Application Fees of Health Food

Time: 2-3years

Cost: Around RMB 1M per sku

NOTE: Nutrient supplements ONLY need to be filing. time: 6month. cost: RMB 500k.

Items		Expense budget (RMB 10 thousand)	Remarks
① Tests on toxicology, hygiene, stability, and functional component		10-12	All products shall accept such tests (nutrient supplements cannot accept toxicology text).
② Function verification test	Boost immunity, improve sleep, relieve physical fatigue, enhance anoxia endurance, anti-radiation, and protect liver.	4-8	Actual accrual shall prevail.
	Relieve visual fatigue, remove acne, remove chloasma, improve skin moisture, and improve skin oil content.	10-12	Actual accrual shall prevail.
	Reduce lipid, reduce blood glucose, reduce press, anti-oxidation, improve memory, promote lead discharge, clear heat from throat, promote lactation, lose weight, improve growth and development, increase bone density, improve anemia, relax the bowels, protect gastric mucosa from damage, regulate intestinal flora, and improve digestion.	15-25	Actual accrual shall prevail.
③	Conduct doping control (relieve physical fatigue, lose weight, and improve growth and development)	1	
④	Re-inspection fees	0.5-1	All products shall accept.
⑤	Other agency fees, translation fees, and notary fees		It all depends.
As for all-in costs of each product, actual accrual shall prevail.			

Why choosing us

- Our company's CEO has been working in the medicine field for 30 years (as a medicine professor in China, he has been undertaken the role of CEO for 12 years). He has gained sound knowledge of biostatistics and research and development of medicine and health products, and is familiar with the external examination and drug approval procedures.
- Our company has built a stable customer base comprising of a number of large domestic pharmaceutical companies (Beijing Tongrentang Co., Ltd., China Sinopharm Group Company Limited, Yangtze River Pharmaceutical Group, Xiuzheng Pharmaceutical Group Company Limited), and has developed a good and stable cooperative relationship with these well-known pharmaceutical companies in China.
- The company has carried out a number of independent research and development projects, and have developed 12 new products including nitroglycerin micro emulsion spray and functional health products containing melanin, etc., among which some have already obtained patents issued by the State Intellectual Property Office.
- Our company has established cooperative relations with more than 60 domestic drug clinical trial institutions certified by China Food and Drug Administration. These institutions are located in various Chinese cities. We have established the university–enterprise cooperation with Shanxi University of Chinese Medicine.
- Our company's employees are talented professionals, and we have an excellent Technical Consulting team.



The Our business philosophy

utmost integrity and win-win cooperation

Our Partner





Question?