

# China Health Food Market Access and Regulation Updates

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# Blue Hat Health Food Registration Updates



## 27 Function Claims → 24 claims ?

1. Enhance immunity
2. Improve sleep
3. Protect chemical liver injury
4. Increase anoxia endurance
5. Increase bone density
6. Prevent from radiological hazard
7. Relieve Physical Fatigue ◇

8. Relieve asthenopia ☆
9. Remove acne ☆
10. Remove chloasma ☆
11. Improve skin oiliness (remove) ☆
12. Improve skin moisture ☆

13. Reduce blood fat ★
14. Reduce blood glucose ★
15. Antioxidation ★
16. Improve memory ★
17. Facilitate lead removing ★
18. Throat clearing ★
19. Reduce blood pressure ★
20. Facilitate lactation (remove) ★
21. Lose weight ★ ◇
22. Improve growth and Development (remove) ★ ◇
23. Improve iron deficiency anemia ★
24. Adjust intestinal flora ★
25. Improve digestion ★
26. Relax the bowels ★
27. Protect Gastric Mucosa ★



Blue Hat  
registration

*No Stars - Require Animal Tests, Not Human Clinical Trials*

*☆ Require Human Clinical Trials, Not Animal Tests*

*★ Require both Human clinical trials and Animal Tests*

*◇ Require Stimulant Testing*

## Case study: How is Schiff Move Free Registered in China?



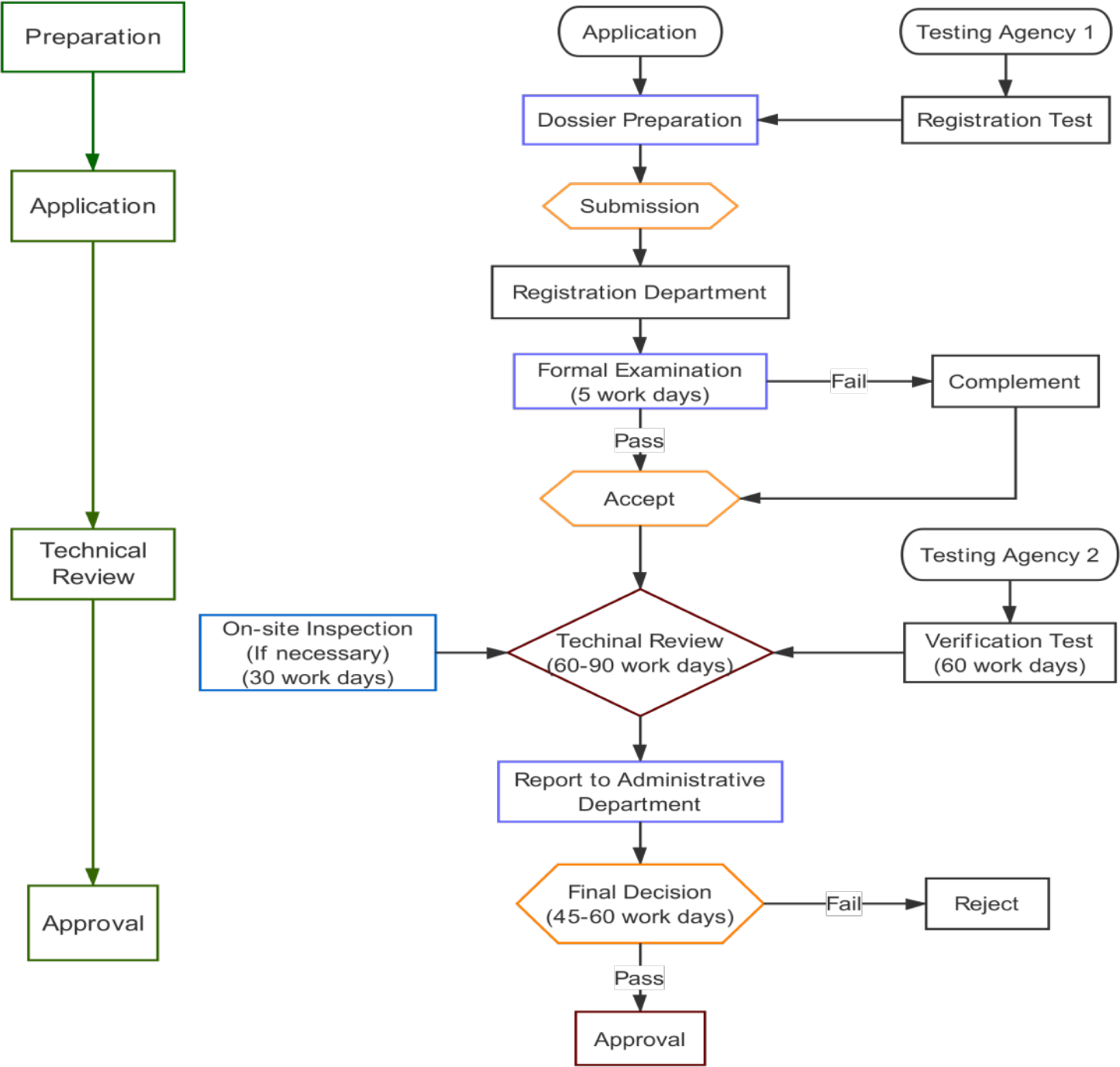
**Increase Bone Density**

# Blue Hat Registration Procedure



**Timeline: 1.5-3+ years**

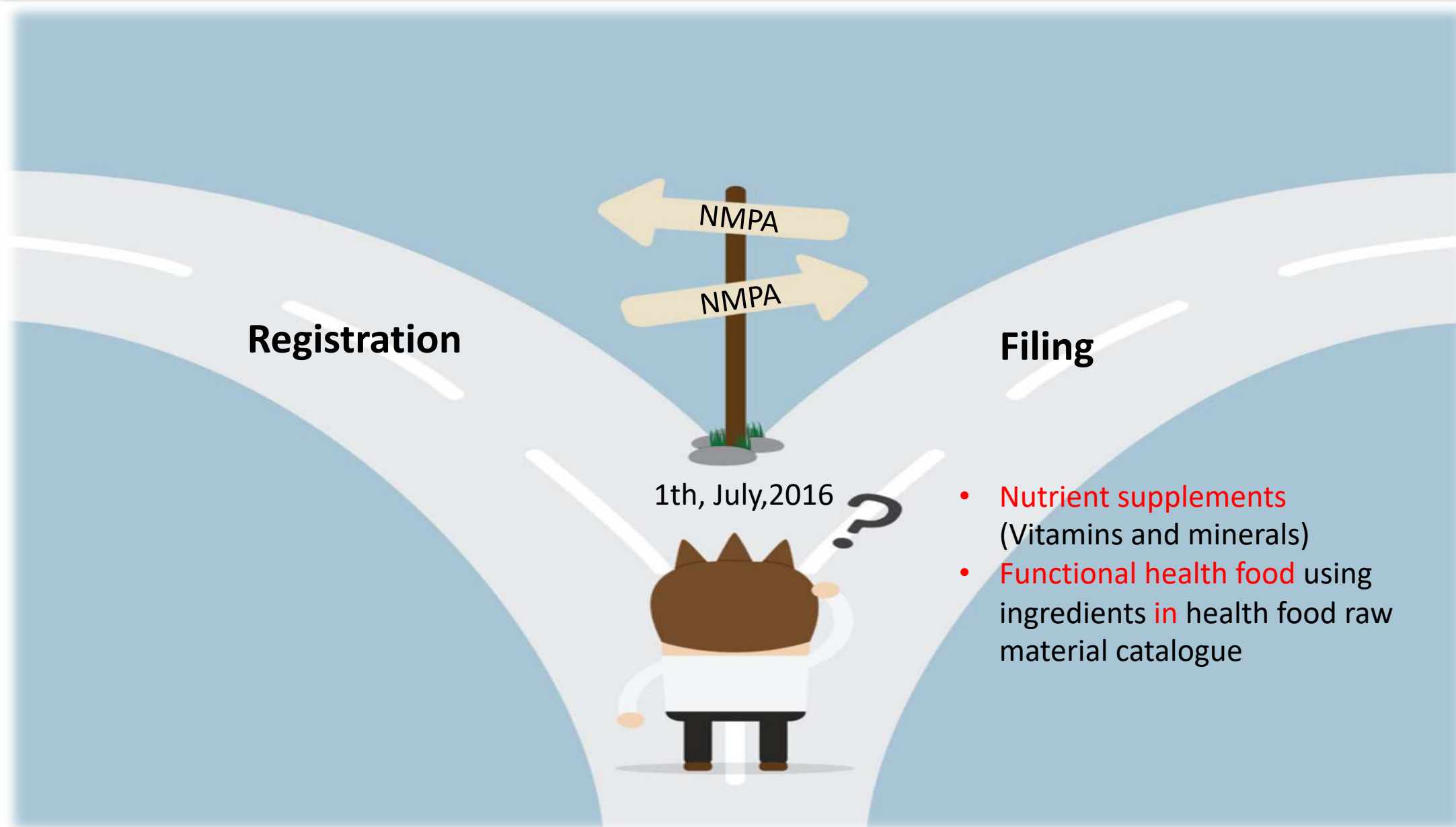
**USD\$50,000- \$150,000**







# Health food registration or filing?



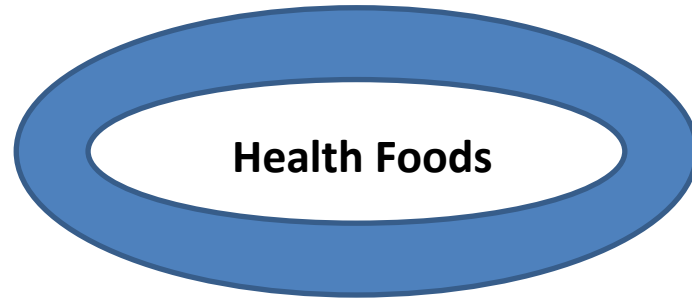


# Health Food Filing Scope Updated

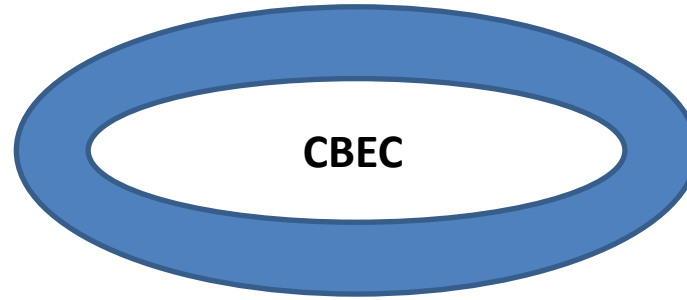
From 22→23 categories of **Vitamins & Minerals** including:

- Vitamin A, Vitamin D, Vitamin C, Vitamin K, Vitamin E, Vitamin B1, Vitamin B6, Pantothenic acid, Folic acid Biotin, Niacin, Calcium, Magnesium, **β-carotene** and others

No.	Ingredient name	Functional Claim	Dosage/day	Dosage form
1	Fish oil	Assist in reducing blood lipid	≤4.0g (EPA+DHA≥1.0g)	Soft capsules
2	CoQ10	Enhance immunity; Antioxidant	30-50mg	Tablets, granules, hard capsules, soft capsules
3	Spirulina	Enhance immunity	3-4g	Tablets, granules, hard capsules
4	Melatonin	Improve sleep	1-3mg	Tablets, granules, hard capsules, soft capsules
5	Shell-broken Ganoderma lucidum spore powder	Enhance immunity	1-4g	Tablets, granules, hard capsules, powder
6	Wait for new approval	...	...	...



**Blue Hat Registration VS Filing**



**Cross-border E-commerce**



**GB standards**

**Which fastest route to market?**



## Comparison between Blue Hat Registration, General Food classification, Cross-border Ecommerce (CBEC) and “Daigou” personal postage for importing health supplement

Requirements	1) Health Supplements (Blue Hat)	2) General Food Classification	3) CBEC	4) DaiGou
Comply with China regulations and standards				
Chinese Label				
Tax (Tariff and VAT)				
Product Registration				
Barriers to entry (regulatory)				

- Take the responsibility of product safety and quality.
- Consumer product return policies
- Establish recall and compensation system.
- Establish product quality and safety risk prevention and control system.
- Establish quality traceability system.
  
- Provide risk notification to consumers on the website of CBEC platform. The notification should include:
  - ✓ The product is manufactured in New Zealand under local regulations, but may not be compliant with Chinese regulations;
  - ✓ The product may not have a Chinese label, while the electronic Chinese label should be shown on the website;
  - ✓ The product is only for consumer personal use, reselling is not allowed.

## CBEC Positive list (2019 version)

**1413 HS Codes** of products, including:

- Meat product, aquatic product
- Cereal product, oil product, vegetable and fruit
- Dairy product, infant formula
- Chocolate, biscuit, bread
- Honey, beer, beverage and wine
- Feed and pet food
- **Health food**
  - FSMP
  - Medical apparatus and instruments
  - Cosmetics
  - Consumer product
  - etc.

*References: CBEC Retail import list (2019 version)*

"GB standards"

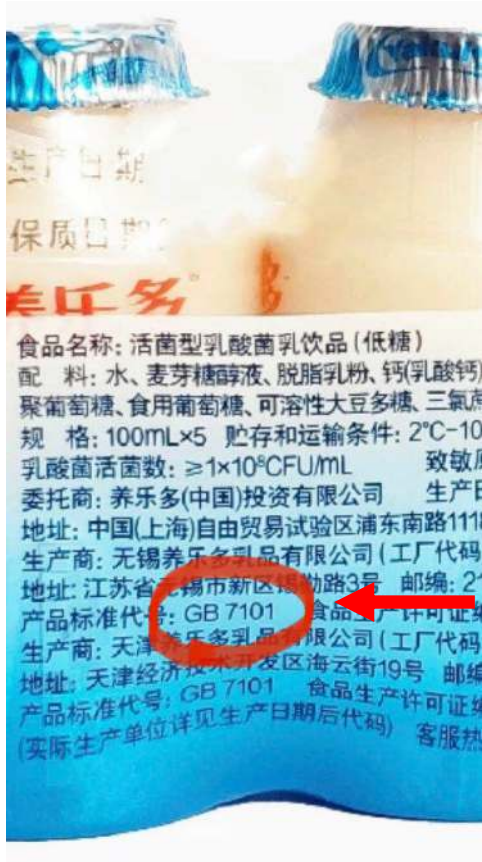
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# General Food Claims: Case study

## Case study: Yakult Probiotics drink



GB Standard  
Beverage



Viable count for Lactobacillus  
 $\geq 1 \times 10^8$  CFU/mL

乳酸菌活菌数:  
 $\geq 1 \times 10^8$  CFU/mL

- **Contains Calcium** (when calcium  $\geq 60$ mg/100mL)
- **Contains Vitamin D** (when vitamin D  $\geq 0.375$ μg/100mL)



Low sugar  
(when sugar  $\leq 5$ g/100mL)

# Health Supplement VS General Food



## Case study: Protein powder

Main ingredients: Soy isolate protein, concentrated whey protein, lecithin

Items	Health supplement	General food
Category	Functional health food	Solid beverage
Formula	Compliant	Compliant
Function claim	Enhance immunity	No function claim
Registration/Regulation	Required	Not required GB/T 29602 solid beverage
Mark	Blue hat mark	No special mark

- Function claim for protein products: Enhance immunity.

# Health Supplement VS General Food

## Case study: Probiotics capsule



Main ingredients: Lactobacillus acidophilus, Bifidobacterium lactis, Lactobacillus paracasei

Health  
Supplement

General  
Food





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