

保健食品注册与备案

保健食品分类

- **营养素补充剂**: 仅补充维生素、矿物质而不以提供能量为目的的产品
- **功能性保健食品**: 具有特定保健功能, 含有功效性成分原料的产品。



保健食品监管要求

原料范围	产品类型	责任	实验	职能单位
原料在保健食品原料目录内	进口营养素补充剂	备案	功效成分或者标志性成分、卫生学、稳定性试验及其他必要试验	国家食药监
	国产营养素补充剂			省级食药监
	国产功能性保健食品			
原料在保健食品原料目录外	进口营养素补充剂	注册	功效成分或者标志性成分、卫生学、稳定性试验、毒理试验、功能试验及其他必要试验	国家食药监
	进口功能性保健食品			
	国产营养素补充剂			
	国产功能性保健食品			

注册程序

- 1 样品检测
- 2 卷宗编写准备
- 3 卷宗提交
- 4 技术审评
- 5 现场核查和复核检验 (如有必要)
- 6 批准注册

备案程序

- 1 样品检测
- 2 卷宗编写准备
- 3 卷宗提交
- 4 批准备案

我们的服务

- 保健食品法规培训
- 保健食品法规跟踪
- 保健食品注册
- 保健食品备案
- 单项技术服务
 - > 市场调研
 - > 产品类型分析及配方审核
 - > 中文标签和说明书设计
 - > 卷宗编写准备
 - > 实验委托及跟踪



Health Food Registration and Filing in China

Classification of Health Food

- **Nutrition Supplement:**
Food that replenishes the vitamins and (or) minerals but without providing energy or other active ingredients.
- **Functional Health Food:**
Food that labeled with health function claim has physiological effects on the human body.



Requirements for Health Food

Ingredients Scope	Product Type	Responsibility	Testing	Authorities
In the Scope of Health Food Raw Materials Directory	Imported Nutrition Supplement	Filing	Functional components test, Hygiene health test, Stability test and others if necessary	CFDA
	Domestic Nutrition Supplement			Provincial FDA
	Domestic Functional Health Food			
Out of the Scope of Health Food Raw Materials Directory	Imported Nutrition Supplement	Registration	Functional components test, Hygiene health test, Stability test Safety, toxicology test, Animal and (or) human function test and others if necessary	CFDA
	Imported Functional Health Food			
	Domestic Nutrition Supplement			
	Domestic Functional Health Food			

Registration Procedure

- 1 Sample Test
- 2 Dossier Preparation
- 3 Dossier Submission
- 4 Technical Evaluation
- 5 On-site verification and Re-test if necessary
- 6 Registration Approval

CIRS Services

- Training on Health Food Regulation
- Health Food Regulation Update Monitoring
- Health Food Registration
- Health Food Filing
- Single Technology Services
 - > Pre-market Investigation
 - > Classification Analysis and Formula Review
 - > Chinese Label and Package Insert Design
 - > Dossier Preparation
 - > Test Arrange and Monitoring

Filing Procedure

- 1 Sample Test
- 2 Dossier Preparation
- 3 Dossier Submission
- 4 Filing Approval

