U.S. – China HPA Health Products Association 美中健康产品协会

Regulatory Insights

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Government Agency
National People's Congress

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China Food Safety Law

中华人民共和国食品安全法

Regulation's Main Points

Article 75 Functional claims of health food should be based on scientific researches. Health food should not cause any acute, sub-acute or chronic hazards to human.

The catalog of health food ingredients and catalog of permitted health functional claims are promulgated and amended by the CFDA along with health departments of national congress and state administration of traditional Chinese Medicine.

The names, allowed potencies and corresponding functional claims of the ingredients should be included into the health food ingredients catalog. Ingredients listed in health food ingredients can be used only in health food.

Article 76 Health food using ingredients not listed in the health food ingredients catalog and health food imported for the first time should be registered with CFDA. However, health food imported for the first time belongs to vitamins and minerals should be filed with CFDA. Other health food should be filed with provincial CFDA.

Imported Health food products should be approved for sale by authorities of the exporting country or region.

Article 77 Research report, product formulation, process of manufacturing, safety and health function evaluation, label, instruction, samples along with relevant proving dossiers should be submitted for registration of health food products. CFDA is responsible for health food products evaluation. Products meeting the safety standards and functional claim requirements can be registered. CFDA should state the reasons for rejecting the registration in written documents. Food ingredients registered as health food products with CFDA, which is not listed in health food ingredients catalog, should be included into health food ingredients catalog without delay.

In the case of health food products that need to be filed, food formulation, process of manufacturing, label, instruction and dossiers of safety and functional claims should be submitted.

Article 78 Labels and instructions of health food product should not contain description of disease prevention or treatment. They should be real and consistent with registered or filed information which include applicable groups, unsuitable groups, functional ingredients or key ingredient and their contents, with the statement “This product is not a substitute of medicine.” The functions and contents of health food products must be consistent with the label and instruction.

Article 79 Advertisements of health food should contain a statement of “This product is not a substitute of medicine.” Besides, it must comply with article 78.Provincal CFDA is in responsible for the approval of the content of health food advertisements. The list of approved health food advertisement and the contents should be updated and published without delay by provincial CFDA.

Article 37 Safety evaluation materials should be submitted to Health Administration Departments of State Congress when health food products use new food ingredients, new food additives or new ingredient related to food. Health Administration Departments should review the materials in 60 days. Products meeting the safety would be approved and published. CFDA should state the reasons for rejecting the registration in written documents.

Article 62 E-Commerce companies or merchants should undergo real name registration with online third party food trading platform, and the responsibility in management of food safety should be clarified. The platform should also examine the license of related companies and merchants.

Article 83 Companies manufacturing health food, medical food, infant formula food and food for special groups should build up production quality management system according to its products by good manufacture procedure. Companies should do routine self-check of the system and report it to county CFDA.

Article 93 Foreign exporters, manufactures or its entrusted Chinese importers could submit the finish product’s foreign or global standards to Heath Administration Department of State Congress for imported food without any national standard. The departments are responsible for evaluating the standards. The standards that meet the Chinese safety standards can be applied temporarily and then enact national standard in time.

Chinese Version

第七十五条　保健食品声称保健功能，应当具有科学依据，不得对人体产生急性、亚急性或者慢性危害。

保健食品原料目录和允许保健食品声称的保健功能目录，由国务院食品药品监督管理部门会同国务院卫生行政部门、国家中医药管理部门制定、调整并公布。

保健食品原料目录应当包括原料名称、用量及其对应的功效；列入保健食品原料目录的原料只能用于保健食品生产，不得用于其他食品生产。

第七十六条　使用保健食品原料目录以外原料的保健食品和首次进口的保健食品应当经国务院食品药品监督管理部门注册。但是，首次进口的保健食品中属于补充维生素、矿物质等营养物质的，应当报国务院食品药品监督管理部门备案。其他保健食品应当报省、自治区、直辖市人民政府食品药品监督管理部门备 案。

进口的保健食品应当是出口国（地区）主管部门准许上市销售的产品。

第七十七条　依法应当注册的保健食品，注册时应当提交保健食品的研发报告、产品配方、生产工艺、安全性和保健功能评价、标签、说明书等材料及样品，并提供相关证明文件。国务院食品药品监督管理部门经组织技术审评，对符合安全和功能声称要求的，准予注册；对不符合要求的，不予注册并书面说明理由。对使用保健食品原料目录以外原料的保健食品作出准予注册决定的，应当及时将该原料纳入保健食品原料目录。

依法应当备案的保健食品，备案时应当提交产品配方、生产工艺、标签、说明书以及表明产品安全性和保健功能的材料。

第七十八条　保健食品的标签、说明书不得涉及疾病预防、治疗功能，内容应当真实，与注册或者备案的内容相一致，载明适宜人群、不适宜人群、功效成分或者标志性成分及其含量等，并声明“本品不能代替药物”。保健食品的功能和成分应当与标签、说明书相一致。

第七十九条 保健食品广告除应当符合本法第七十三条第一款的规定外，还应当声明“本品不能代替药物”；其内容应当经生产企业所在地省、自治 区、直辖市人民政府食品药品监督管理部门审查批准，取得保健食品广告批准文件。省、自治区、直辖市人民政府食品药品监督管理部门应当公布并及时更新已经批 准的保健食品广告目录以及批准的广告内容。

第三十七条　利用新的食品原料生产食品，或者生产食品添加剂新品种、食品相关产品新品种，应当向国务院卫生行政部门提交相关产品的安全性评估材料。国务院卫生行政部门应当自收到申请之日起六十日内组织审查；对符合食品安全要求的，准予许可并公布；对不符合食品安全要求的，不予许可并书面说明理由。

第六十二条　网络食品交易第三方平台提供者应当对入网食品经营者进行实名登记，明确其食品安全管理责任；依法应当取得许可证的，还应当审查其许可证。

第八十三条　生产保健食品，特殊医学用途配方食品、婴幼儿配方食品和其他专供特定人群的主辅食品的企业，应当按照良好生产规范的要求建立与所生产食品相适应的生产质量管理体系，定期对该体系的运行情况进行自查，保证其有效运行，并向所在地县级人民政府食品药品监督管理部门提交自查报告。

第九十三条　进口尚无食品安全国家标准的食品，由境外出口商、境外生产企业或者其委托的进口商向国务院卫生行政部门提交所执行的相关国家 （地区）标准或者国际标准。国务院卫生行政部门对相关标准进行审查，认为符合食品安全要求的，决定暂予适用，并及时制定相应的食品安全国家标准。