



# Regulatory Insights

**Date Released**

March 28, 2019

**Government Agency**

State Administration Market Regulation  
(SAMR)

**Announcement on Soliciting Opinions on Adjusting Health  
Food Functions**

**市场监管总局征求调整保健食品保健功能意见的公告**

In order to further strengthen the management of the health food function claims, plugging the health food function claims to be falsely publicized, improve the consumer's scientific cognition and accurate judgment of the health food function claims, avoid confusion with the disease prevention and treatment. The opinions on adjusting health function claims are released after reviewed by experts in the fields of medicine, pharmacy, food and nutrition etc, on the basis of combing the summarizing the health functions approved in different historical periods.

## **1. The first batch of health functions intended to be adjusted**

The experts believe, in spite of some function claims are in line with the health food supervision and health needs, but the problem of inaccurate expressions still exists and can easily lead to false or exaggerated promotions which may mislead the consumers. In order to make the claims more accurate, some claims are recommended to be adjusted (Appendix 1). After the release of official announcement on the claims adjustment, the owner of health food certificates or related manufactures can directly adjust the relevant functional claims on the package, label and instruction book, no need to apply for a separate registration change. The products on the market can be sold until the expiration date. Products in the process of review and evaluation, the review agency will directly change the claims, the applicant doesn't need to make the corrections.

## 2. The health functions intended to be canceled

The experts believe, some function claims are not in line with the current health food supervision and health needs, especially those aiming at children, pregnant women, wet nurses and other special groups should be conducted a stricter supervision. This part of health claims should be canceled. Meanwhile, the health claims which had been approved in the past but no longer being accepted for review and approval now, should also be canceled (Appendix 2). Since the release of official announcement on above-mentioned claim, the production of relevant health food products should be stopped immediately. The health food which has been produced can be sold until the expiration date as long as it doesn't involve in quality and safety issues. The SAMR will no longer accept and review the above-mentioned health claims.

## 3. The health functions to be further studied

The experts believe, due to the historical supervision, some existing health function claims and evaluation methods can be easily confused with disease treatment. They are recommended to be further studied on the positioning of health claims, expressions and evaluation methods (Appendix 3).

## Appendix 1

### The first batch of health functions intended to be adjusted

No.	Previous Claims	After adjustment	Opinions
1	Immunoregulation/Boost immunity	Supports boosting immunity	
2	Antifatigue/Relieve physical fatigue	Relieve physical fatigue	

3	Antioxidant	Supports antioxidant activity	
4	Improve osteoporosis/ Increasing bone density	Supports bone health	
5	Improve gastrointestinal function(relaxing bowel)	Supports bowel movement	
6	Improve gastrointestinal function regulation of intestinal flora)/Regulation of intestinal flora	Supports intestinal flora regulation	
7	Improve gastrointestinal function (promote digestion) /promote digestion	Supports digestion	
8	Improve gastrointestinal function(help protect gastric mucosa from injury)/help protect gastric mucosa from injury	Supports gastric mucosa protection	

9	Anti-hypoxia / Improve hypoxia tolerance	Anti-hypoxia	
10	Weight loss	Supports body fat regulation	
11	Beauty (Remove chloasma) /Remove chloasma	Supports removal of chloasma	
12	Beauty(Remove acne)/Remove acne	Supports removal of acne	
13	Beauty(Improve skin moisture/oil)/Improve skin moisture	Supports skin moisture	
14	Improve memory/Contribute to improving memory	Supports improved memory	
15	Clear and nourish throat / Clear throat	Clear and nourish the throat	

16	Improve nutritional anemia/Improve iron deficiency anemia	Improves iron deficient anemia	
17	improve eyesight/Relieve visual fatigue	Relieve visual fatigue	
18	Improve sleep	Supports improved sleep	

## Attachment 2

### The health functions intended to be canceled

#### 1.Current health functions intended to be canceled

No.	Previous Functions	Opinions	Reason
1	Beauty (Improve skin oil) / Improve skin oil		
2	Promote body growth and development / Improve body growth and development		
3	Promote lactation		

**2. Health functions intended to be canceled which had been approved in the historical period but no longer being accepted for review and reevaluation (include but not limited to the following functions).**

No.	Previous Functions	Opinions	Reason
1	(Help) inhibit tumor		
2	Antimutation		
3	Improve sexual performance		
4	Regulation of immunity		
5	Regulation of blood fat		
6	Improve microcirculation		
7	Beauty ( breast enlargement )		
8	Prevent alopecia seborrhoeica		
9	Promote intestinal motility		
10	Block the synthesis of n-nitroso compounds		

11	Caries prevention		
12	Promote hair growth		
14	Rise white blood cell		
13	Prevent nearsightedness		
15	Improve skin pH		
16	Reduce sebaceous gland secretion		
17	Reduce wrinkles		
18	Skin Beauty ( reduces uv skin damage )		

**HPA-China commentary:** Number 5 “Regulation of body fat” listed above is similar in meaning to number 10 from Appendix 1, which is, “Supports body fat regulation”. The difference is just in the added word “supports” (有助于).

## Appendix 3

### The health functions to be further studied

No.	Previous Claims	Suggestions (reserve OR cancel)	Reason	If suggest to reserve, suggestions on function name and evaluation method
1	Supports lowering blood lipids			
2	Supports lowering blood glucose			
3	Supports lowering blood pressure			
4	Protects liver from chemical injury			
5	Supports the protection function against radiation poisoning			



6	Promote lead removal			
---	----------------------	--	--	--

**Original Chinese Document listed Below**

**市场监管总局征求调整保健食品保健功能意见的公告**

为进一步加强保健食品保健功能声称管理，堵塞保健食品功能声称被虚假宣传的漏洞，提升消费者对保健食品功能声称的科学认知和准确判定，避免与药品疾病预防和治疗作用混淆，在对不同历史时期批准的保健功能进行梳理汇总的基础上，组织医学、药学、食品、营养等领域专家进行多次论证，研究提出了调整保健功能的意见。现就有关事项公告如下：

**一、首批拟调整功能声称表述的保健功能。**专家论证认为，现有部分保健功能声称虽符合保健食品监管定位和健康需求，但存在表述不准确问题，容易被虚假或夸大宣传利用，误导消费。为使功能声称更准确，建议调整部分保健功能声称表述（详见附件1）。功能声称表述调整发布后，保健食品产品注册证书持有人或授权生产企业可直接调整其产品的包装、标签、说明书中的相关功能表述，无需单独申请变更注册，已上市产品可销售至保质期结束；处于受理审评审批过程的，审评机构将直接调整功能声称，申请人无需补正。

**二、拟取消的保健功能。**专家论证认为，部分现有保健功能声称与现行的保健食品监管定位和健康需求不契合，特别是针对少年儿童、孕妇、乳母等特殊人群的保健功能应当实行更为严格的监督管理，该部分保健功能应予以取消。同时，应当取消过往历史时期曾批准过但现已不再受理审评审批的保健功能（详见附件2）。自发布取消上述保健功能之日起，相关产品应当立即停止生产，已生产的保健食品，不涉及质量安全的，可销售至保质期结束；国家市场监督管理总局不再受理、审评审批上述保健功能。

**三、有待进一步研究论证的保健功能。**专家论证认为，因监管历史沿革，现有部分保健功能声称和评价方法容易与药物疾病治疗混淆，建议对现有部分功能声称的定位、表述以及相关功能评价方法进一步研究论证、广泛征求意见（详见附件3）。

## 附件 1

### 首批拟调整功能声称表述的保健功能

序号	原功能名称	调整后功能名称	意见建议和理由
1	免疫调节/ 增强免疫力	有助于增强免疫力	
2	抗疲劳/ 缓解体力疲劳	缓解体力疲劳	
3	抗氧化	有助于抗氧化	

4	改善骨质疏松/ 增加骨密度	有助于促进骨健康	
5	改善胃肠功能 (润肠通便) / 通便	有助于润肠通便	
6	改善胃肠功能 (调节肠道菌群) / 调节肠道菌群	有助于调节肠道菌 群	
7	改善胃肠功能 (促进消化) / 促进消化	有助于消化	
8	改善胃肠功能(对 胃黏膜损伤有辅助 保护作用) / 对胃黏膜损伤有辅 助保护功能	辅助保护胃粘膜	
9	耐缺氧/ 提高缺氧耐受力	耐缺氧	
10	减肥	有助于调节体脂	
11	美容(祛黄褐斑) /祛黄褐斑	有助于改善黄褐斑	

12	美容 ( 祛痤疮 ) / 祛痤疮	有助于改善痤疮	
13	美容 ( 改善皮肤水分/油分) / 改善皮肤水分	有助于改善皮肤水分状况	
14	改善记忆 / 辅助改善记忆	辅助改善记忆	
15	清咽润喉 / 清咽	清咽润喉	
16	改善营养性贫血 / 改善缺铁性贫血	改善缺铁性贫血	
17	改善视力 / 缓解视疲劳	缓解视觉疲劳	
18	改善睡眠	有助于改善睡眠	

## 附件 2

### 拟取消的保健功能

#### 一、拟取消的现有审评审批范围内的保健功能

序号	原功能名称	意见建议	理由
1	美容 ( 改善皮肤油分 ) / 改善皮肤油分		

2	促进生长发育/ 改善生长发育		
3	促进泌乳		

## 二、拟取消的过往历史时期曾批准过但现已不再受理审评审批的保健功能（包括但不限于以下功能）

序号	原功能名称	意见建议	理由
1	(辅助)抑制肿瘤		
2	抗突变		
3	改善性功能		
4	单项调节免疫		
5	单项调节血脂		
6	改善微循环		
7	美容(丰乳)		
8	预防脂溢性脱发		
9	促进肠蠕动		
10	阻断 N-亚硝基化合物的合成		
11	防龋护齿		
12	促进头发生长		
14	升高白细胞		
13	预防青少年近视		
15	改善皮肤酸碱度		
16	减少皮脂腺分泌		
17	减少皱纹		
18	皮肤美容(减轻紫外线皮肤的损伤)		

## 附件 3

### 有待进一步研究论证的保健功能

序号	原功能名称	调整建议 (保留或取消)	理 由	如建议保留，对功 能名称及功能评价 方法的调整建议
1	辅助降血脂			
2	辅助降血糖			
3	辅助降血压			
4	对化学性肝损伤有辅助保护功能			
5	对辐射危害有辅助保护功能			
6	促进排铅			

备注：调整建议可作为附件一同上传。