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**Government Agency**

China FDA

## Check Points of Health Food Label

## 保健食品标签标识检查要点

### 1. Health Food Logo (the blue hat, not brand or trademark) and Registration Approval Number

- 1) The logo and approval number should be arranged in a row or column and be printed on the front of the label in the top left corner.
- 2) The health food registration logo has two parts, a top and bottom row. The registration number should be placed on the top row and the approving agency should be placed underneath the registration number on the bottom row. There are two approval agencies: The Ministry of Health (中华人民共和国卫生部批准) and China Food and Drug Administration (国家食品药品监督管理局).

*Clarification: Prior to 2003 all health food registrations were approved by the Ministry of Health. Beginning in 2003 all health food registrations were/are being approved by China Food and Drug Administration.*

### 2. Health Food Naming

- 1) The name should be consistent with the registration or recording system.
- 2) The name should be placed in an obvious space on the package including smaller packages that are within the main package, ie a box with sachets in it. The writing should be correct, clear, striking and larger than other written content.
- 3) According to <CFDA announcement on issues of health foods naming> (No.43, 2016), beginning on May 1, 2016, functional claims have been forbidden to show up in a products' name including CFDA's 27 approved specific claims such as Increasing immunity and Helping lower blood pressure, etc...

### 3. Health Food Applicants' Name and Address

1) The name and address should be identical on health food registration, business license, production permit (*QS or SC*) and instruction book.

*Clarification: Production permit (QS or SC) is for domestic China health product manufacturers*

2) For applicants who have changed their name or address, they should have a certificate of change from Industrial and Commercial Administration and proof of having submitted “request for change” to CFDA; it should not be regarded as nonconformity in principle.

3) For applicants who have changed their name or address, they should have a certificate of change issued by Industrial and Commercial Administration, but they were unable to submit “request for change” to CFDA with good reason, it should not be regarded as nonconformity in principle.

4) For non-essential changes regarding address, for example wording changes of administrative district, caused by renewing business license should not be regarded as nonconformity in principle. But applicants are required to issue request for change as soon as possible. (*That means if name on the old license was Shanghai XXX Ltd compared to the new name Shanghai Pudong XXX Ltd, its OK*)

### 4. Net Weight (Liquids & Solids)

1) Net weight should be marked in the lower right corner of the front label and be parallel to the bottom edge of the label.

2) Liquid food should be measured by volume, units should be in milliliters (ml) (毫升 in Chinese) or Liters (L) (升 in Chinese). Solid or semi-solid food should be measured by mass, units should be in grams (g) (克 in Chinese) or Kilogram (Kg) (千克 in Chinese).

3) A product having multiple packages inside should list net weight on all smaller packages. Net weight on main package should be marked as number of smaller package “multiplied” by net weight of smaller packages, or Number of health food “multiplied” by the net weight of each health food product.

*Clarification: Number of health food would be five ginseng roots each weighing 100g.*

### 5. Raw Materials, Active Ingredients, Assay, Functions, Suitable Crowd, Edible Methods, Specification, Expiration Date and Storage Method

Should be in accordance with the contents in Health Food Approval Certificate issued by CFDA.

## 6. Unsuitable Crowds

- 1) Should be in accordance with Health Food Approval Certificate or its attachments.
- 2) If not listed in Health Food Approval Certificate or its attachment, omit the text in principle.
- 3) For products containing polygonum multiflorum, people with hypohepatia or have hypohepatia in the family history should be added in unsuitable crowds.
- 4) Type size should be a little larger than suitable crowd.

## 7. Attentions

- 1) Label should be in accordance with Health Food Approval Certificate issued by CFDA
- 2) Label should contain “本品不能代替药物”, (*Means this product can't be used as an alternative of medicine*)
- 3) For products containing polygonum multiflorum, Attentions should include “本品含何首乌，不宜长期超量服用，避免与肝毒性药物同时使用，注意监测肝功能”, (*Means this product contains polygonum multiflorum, long term use is OK without overdosing, remember to supervise liver function while taking*)

## 8. Standard

- 1) Outer package should contain the standard with its code for that individual product. The standard should be placed in the information section (信息版面) of the label, the title should be executive standard, (执行标准).

**Clarification:** the code is given to the company by the Chinese government after they review the company's production standard for that individual product.

- 2) The code has a year attached to it, but the year portion of the code can be omitted on the label.

## 9. Date Marking

- 1) Date should be marked in YYYY-MM-DD, for example, 2017-06-02.
- 2) Production and expiration dating should be marked in the information section (信息版面) of the label, printed after Edible methods (食用方法) and titled as Production Date (生产日期) and Expiration Date (保质期).

## 10. Manufacturer's Name and Address

1) It's the name of factory that produces and packages the product. For imported health foods, importers' and distributors' name must be the same as registered according to law. Imported health foods must indicate their country/area of origin and the name of domestic importer or distributor.

2) OEM products' package and instruction book must contains '委托 XXXX 生产' (Means authorize XXXX to produce) and the address of the factory.

## 11. Requirements on Marks

Health product registration logos are not allowed to be separated from the package. Instruction book should be included inside the outer package. The logo and words, icons, symbols on instruction book should be clear, visual and easy to recognize. Characters should be normal Chinese Characters, at the same time, Pinyin, minority characters, foreign characters are allowed only if they have direct correspondence with relevant Chinese words and be written correctly. Pinyin and foreign language content is not allowed to be larger than the relevant Chinese words.

Units of measurement must be national legal measurement units.

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Original Chinese Document Below

### 保健食品标签标识检查要点

#### 一、保健食品标志与保健食品批准文号

1、保健食品标志与保健食品批准文号应并排或上下排列标于保健食品主要展示版面的左上方。

2、保健食品批准文号分为上下两行，上行为保健食品批准文号，下行为“中华人民共和国卫生部批准”或“国家食品药品监督管理局（总）局批准”，原则上以该保健食品最新有效批件的批准机构为准。

#### 二、保健食品名称

1、保健食品名称应当与注册或备案的内容一致。

2、保健食品名称应标于最小销售包装的“主要展示版面”的明显位置，应端正、清晰、醒目，并大于其它内容的文字。

3、根据《总局关于保健食品命名有关事项的公告》（2016年第43号）有关要求，自2016年5月1日起，保健食品名称中不得含有表述产品功能的相关文字，包括不得含有已经批准的如增强免疫力、辅助降血脂等27种特定保健功能的文字。

### 三、保健食品申请人名称和地址

1、保健食品申请人名称和地址，原则上应做到保健食品批准证书、营业执照、保健食品生产许可、产品标签说明书四者的相应内容一致。

2、对于保健食品申请人名称或地址改变，企业能够提供工商部门变更证明，并能提供已向国家食品药品监督管理总局提出变更申请的证明的，原则上不认定为不一致。

3、对于保健食品申请人名称或地址改变，企业能够提供工商部门变更证明，并能提供因客观原因导致无法办理变更申请的证明的，原则上不认定为不一致。

4、对于保健食品申请人地址，因企业换发新版营业执照，仅增加“XX省”、“XX市”、“XX县（区）”等行政区域信息或“XX县”改为“XX区”的而未发生实质改变的，原则上不认定为不一致，但应要求保健食品申请人尽快按要求办理变更。

### 四、净含量及固形物含量

1、净含量应标于“主要展示版面”的右下方，应与“主要展示版面”的底线相平行。

2、液态食品：用体积。单位为：毫升、升，或 ml、L；固态与半固态食品：用质量。单位为：克、千克，或 g、Kg。

3、同一销售包装中的保健食品分装于各容器或以相互独立的形态包装时，应在最小容器的包装上标示该容器中保健食品的净含量。同时，销售包装的保健食品净含量应标示为最小容器的数量乘以（×）最小容器中的保健食品净含量，或独立形态的保健食品数量乘以（×）单一形态的保健食品净含量。

### 五、主要原料、功效成分或者标志性成分及其含量、保健功能、适宜人群、食用方法及食用量、规格、保质期、贮藏方法

应当与卫生部或国家食品药品监督管理（总）局颁发的《保健食品批准证书》所载明的内容相一致。

### 六、不适宜人群

1、《保健食品批准证书》及其附件中载明不适宜人群的，应当与载明的内容相一致。

- 2、《保健食品批准证书》及其附件中未载明不适宜人群的，原则上不标注不适宜人群。
- 3、含何首乌（生何首乌、制何首乌）的保健食品，标签标识中不适宜人群应增加“肝功能不全者、肝病家族史者”。
- 4、“不适宜人群”字体应略大于“适宜人群”的内容。

## 七、注意事项

- 1、应当与卫生部或国家食品药品监督管理（总）局颁发的《保健食品批准证书》所载明的内容相一致。
- 2、应当注明“本品不能代替药物”。
- 3、含何首乌（生何首乌、制何首乌）的保健食品，标签标识中注意事项应增加“本品含何首乌，不宜长期超量服用，避免与肝毒性药物同时使用，注意监测肝功能”。

## 八、执行标准

- 1、外包装要标示所执行的标准代号和编号。执行标准应标于“信息版面”，标题为“执行标准”。
- 2、可以不标示年代号。

## 九、日期标示

- 1、日期的标示为年一月一日，如 2017-06-02。
- 2、生产日期和保质期应标于“信息版面”，位于“食用方法”之后，标题为“生产日期”和“保质期”。

## 十、保健食品生产企业名称与地址

- 1、保健食品制造、分装、包装的企业名称和地址，进口保健食品的国内进口商或经销代理商的名称和地址必须与依法登记注册的相一致。进口保健食品必须标示原产国、地区（港、澳、台）名称及国内进口商或经销代理商的名称。
- 2、委托生产的保健食品在产品包装标识及说明书上必须注明“委托 XXXX 生产”，并注明受委托生产企业的地址。

## 十一、标示方式的要求

保健食品标识不得与包装容器分开，所附的产品说明书应置于产品外包装内。保健食品标识和产品的说明书的文字、图形、符号清晰、醒目、直观，易于辨认和识读。以规范的汉字为主要文字，可以同时使用汉语拼音、少数民族文字或外文，但必须与汉字内容有直接的对应关系，并书写正确。所使用的汉语拼音或外国文字不得大于相应的汉字。

计量单位必须采用国家法定的计量单位。