
CFDA's 2014 Plans for Health Product (Dietary Supplement) Regulations

September 30, 2013

1. Any product can't have a health claim on the label and the instructions.
2. Any product which has a limited dosage per day in the form of tablet, soft gel, liquid in bottle, powder, or pill **can't be imported as general food, must have a blue hat.** It will come into effect on January 1, 2014. Any product imported before that date can be sold in China till the product expiration date.
3. The raw material used for health products can't be used in general food.
4. For the manufacturers who have blue hats, they should follow the documents strictly. Can't produce, operate or import OEM health products.
5. FDA in all levels should administrate the Internet sales of health products effectively. The Internet sales should also follow the same regulations.
6. Any customer who finds any health product, which is breaking the law should report to local FDA.

Managing Regulation of Instruction Book and Label of Health Food (Dietary Supplements)

September 30, 2013

1. To strengthen health food supervision and protect the rights of consumers, this regulation is drafted based on Food Safety Law of China and Health Food Registration Managing Regulation.
2. All health food that are produced in China need to meet the requirement of this regulation regarding label and instruction book.
3. The instruction book of health food that this regulation refers to are text materials in the product package regarding product registration, production and application. The health food label refers to text, image and signs and all the other instructions in the package of the health food.
4. The package of the health food needs to be printed or with labels according to regulations and laws. Instruction book should be included into a package for independent sales. If the label includes an instruction, a separate instruction book is not required.
5. Health food package cannot contain promotion materials, except label and instruction book.
6. The production company needs to be responsible for content in the instruction book and label of the health food. The China-based agent or institution of a imported health food is held responsible for the instruction and label of the health food.
7. The production company should keep abreast of the safety and function situation of the health food after it is put into market. The company needs to apply for necessary revision on the instruction in time. Based on scientific progress, the CFDA can request revision on the instruction book. The company must revise the instruction in time after getting approval for doing that.

8. The order of content in the instruction book needs to be as follows:

- 1) name of the product
- 2) introduction
- 3) main ingredient
- 4) functioning element or major element and volume
- 5) function
- 6) applied group
- 7) not-applied group
- 8) usage and volume
- 9) standard
- 10) quality guarantee period
- 11) storage method
- 12) notice for attention
- 13) the name of the production company
- 14) production permit number (imported food excluded)
- 15) address, phone number and post code of the production company

9. The label must include the 15 items above. The label of imported food must point out the country/area of origin, and the contact of its agent in China.

10. The independent package with a surface area less than 10 cm² needs to be written with the product logo, name, approval number, standard, quality guarantee period, notice for attention, storage requirement, production company, product permit number, production date and batch number. Dependent package needs to be at least with the product name, standard, production date and batch number.

11. The label and instruction book of health food should not include the following content:

- 1) referring to function of treating or preventing disease
- 2) exaggerating or misleading word or image
- 3) descriptive or fraudulent promotion that misleads consumers
- 4) the companies mentioned should not include those which are not production company nor operating companies of the product.
- 5) Name of unapproved health food

- 6) Anti-science, pornographic or superstitious content
 - 7) Content that is forbidden by laws and regulations
12. Label and instruction of health food needs to meet the following requirement:

1) the display should be clear-cut, lasting, accurate, scientific and legal, and easy-to-understand-and -identify. The text and background should be presented in contrasting colors.

2) if the label and instruction involve content in the approval certificate, the content should be in accordance with that in the certificate.

3) Chinese character should be used as the main language, with Chinese pinyin, language of the minority groups and foreign language, but they need to be with corresponding Chinese and are written accurately. The font of other language should not be bigger than corresponding Chinese. Imported Chinese should go with Chinese instruction book and label.

4) Measurement unit should be the national statutory measurement unit.

5) It is forbidden to mislead consumer by text, image or signs, or confuse the consumer and lead them to connect this product with others, or mislead consumer by color and font of the package.

6) The production company or the agent for imported food in China, whose name and address are illustrated in the label and instruction book of the health food, should be legally registered. The health food that is commissioned to be produced, should bear the name, address and production permit number of the company that is commissioned.

7) Notice for attention needs to indicate“This product cannot replace medicines, nor used for disease prevention or treatment”.

8) Label cannot be separated from package (container). The content including production date and quality guarantee period in the instruction book or label cannot be revised or added by paste, copy or alter.

13. The label of health food needs to meet the following standard:

1) The logo, name and approval number of the health food need to be written in the cover of the package clearly.

2) The logo of health food needs to be put on the upper left side of the cover in blue color. If the cover size is bigger than 100cm², the width of the logo cannot be less than 2 cm.

3) The name of health food should be written completely and clearly; the font, size and color of the text should be consistent. The name should be bigger than other content in the cover. It is forbidden to add other logo or production name at will. The name should be put in the upper side of a horizontal version or right side of a vertical version.

4) Notice for attention, unapplied group as well as storage method should be illustrated in a noticeable place. The word size should be not smaller than that of “target group”.

5) The net volume and standard should be illustrated in the main display of the package or container, and should be parallel with the base line of the main display.

When a package contains more than one independent package, the package should illustrate net volume as well as standard.

6) Production date, production number and quality guarantee period should be indicated clearly and accurately. Production date and quality guarantee period need to be indicated in the order of year, month and day or year and month; if the production permit number and date are the same, these two can be combined in the label. The quality guarantee period can be indicated as “xx months (days/years)”.

7) The contact needs to include the address, post code and telephone number.

8) When the package surface area surpasses 35 cm, the height of word, image and number indicated should be no less than 1.8 mm.

14. The nutrient supplement should put the words “nutrient supplements” in the same cover with product name. It should be put in the function section

of the instruction book and label with "supply xx nutrient", and it should not claim to have health function.

15. When the health food label contains other trademark besides the product name, it should be put in the upper right side of the health food label. The size of the font per word should not surpass half of the font of the product name.
16. The label of health food with the same approval number should bear the same trademark.
17. Health food that are processed by ionizing radiation need to put words like "irradiated food" or "this product is irradiated" in the package. Raw material that was proceeded by ionizing radiation need to bear words like "irradiated".
18. Health food that are free-of -charge for consumers are under the same regulation regarding the instruction book and label with products for sales.
19. The logo of health food should be put based on the regulation of CFDA. The registered number of the health food need to be under the health food logo and connected with it in a clear-and-easy-to-recognize fashion.
20. Net volume, cover size and the surface area of package need to be calculated based on the Principle of National Standard on Food Package and Label (GB7718-2011).
21. CFDA is responsible for explaining this regulation.
22. This regulation will be put into effect from xx,xx, 2013. Products that are made or imported after xx, xx, 2014 must meet the requirement of this regulation regarding instruction book and label. Products that were made or imported before this date can continue to be sold within quality guarantee period.

The U.S. – China Health Products Association is working towards the development of China’s natural health product industry by advocating for a more open and transparent regulatory environment. The association is committed to increasing the trade and availability of its member’s products, which will benefit the health and wellbeing of both industry and consumers alike.



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