

Regulations for Application and Evaluation of Life Beneficial Bacterium Health Food (interim)

Article 1 With a view to standardizing the life beneficial bacterium health food application and ensuring the edible security of life beneficial bacterium health food, the regulations is formulated according to the Food Assanation of the People's Republic of China and Provisions for Health Food Registration (interim).

Article 2 Life beneficial bacterium health food is the micro zoological products this is useful for health and can promote the balance of intestinal bacterium cluster.

Article 3 Bacterium breeds of life beneficial bacterium must be the members of normal bacterium clusters in vivo. The live bacterium, died bacterium and outcome of metabolism can be used. Life beneficial bacterium health food must be safe and credible, that is edible safely, having no unfavorable reaction; Bacterium breeds used in production should have definite and stabile property of biology, genetics and efficacy.

Article 4 List of breeds of life beneficial bacterium that can be used in health food should be promulgated by the State Food and Drug Administration (SFDA).

Article 5 Appraisal units of life beneficial bacterium breeds used in health food should be determined by the State Food and Drug Administration (SFDA). Appraisal of life beneficial bacterium health food's bacterium breeds should be carried out in appraisal units determined by the State Food and Drug Administration (SFDA).

Article 6 Applying to register life beneficial bacterium health food, besides the application documents required by the correlative regulations for health food registration, the following documents should be provided:

1. Formula and formula foundation shall have affirmatory category name of bacterium breeds ,specific name and bacterium clone number. The category name of bacterium breeds, specific name should have the corresponding Latin formal name.
2. Cultivation conditions of bacterium breeds (nutritive medium, cultivation temperature etc)
3. Origin of bacterium breeds as well as domestic and oversea edible security data
4. Bacterium breeds appraisal report brought forth by appraisal units determined by the State Food and Drug Administration (SFDA)
5. Safety evaluation data of bacterium breeds (including toxicology test)
6. Conserve methods of bacterium breeds
7. For the bacterium breeds under domestication and induced mutation, the data including methods and reagent of domestication and induced mutation should be provided.
8. For the health food used died bacterium and / or the outcome of metabolism as main functional factors, functional factors or the name and examine methods of characteristic ingredients should be provided.
9. Technical specification and technical guarantee for production.
10. Evincive documents of production conditions in accordance with Good Manufacturing Practice of Health Food.

11. Utilizing the bacterium breeds out of List of life beneficial bacterium breeds Utilized in Health Food, the documents must be provided, which include research papers and pertinent literature possessing efficacy, the production of the strain and its metabolism having asepsis and harmless.

Article 7 Applicants shall buy live bacterium freeze –dry powder and product health food directly, the producing and processing should be only the course of mixing and perfusion. The data in sixth Article of the regulations can be also manifolds offered by the providers of live bacterium freeze –dry powder materials (cachet of raw materials provider should be stamped on), provide vouchers of purchase and sale at the same time.

Article 8 Applying to register bacterium breeds used to produce life beneficial bacterium health food, the breeds should conform to the following qualifications:

1. Bacterium breeds used to product health food should adopt germ block system ,the original germ block 's records, history, origin and biological properties should be checked clearly. Main germ block is passed down form the original germ block and preserved after amplifying. Work germ block is passed down form the main germ block and preserved after amplifying; the biological properties of work germ block should be consistent with original germ block. Every block of main germ and work germ should be stored, checked and used as the requirements of regulations. In the appropriate nutritive medium, main germ can not be passed down over ten generations; work germ can not be passed down over five generations.
2. Trial- manufacture units should have special departments and personnel to manage and product bacterium breeds, establish archives data of bacterium breeds which include the complete records of the origin, history, filtration, examination, preserve methods, quantity, starting to use act.
3. The bacterium breeds and their outcome of metabolism must be innocent, toxicant and injurant as well as substance lead to anaphylaxis can not be added to the cultural medium used to product.
4. Live bacterium consisted with the breeds identified and applied to ratify can be separated from life beneficial bacterium health food of live bacterium kinds.

Article 9 The trial- manufacture location for samples of life beneficial bacterium health food should possess the following qualifications:

- 1.It shall meet the requirements of Good Manufacturing Practice of Health Food(GMP), and establish quality guarantee system of hazard analysis critical control points .
2. It shall possess the capacity of middle pattern, that is 500L every day at least, and apply as middle pattern products at same time.
3. It must have special workshops or plants, appropriative equipments and establishments; The laboratory of life beneficial bacterium must be equipped, bacterium breeds must be managed by special person, and taken charge by the technician of bacterium professional who have the title of a technical post above middle level. Relevant particular technical regulations and guarantee should be constituted.

Article 10 The bacterium breeds used for production and the producing techniques cannot be changed.

Article 11 It is not recommended to produce live bacterium products of life beneficial bacterium health food in the form of liquid state.

Article 12 The number of live bacterium in life beneficial bacterium health food cannot be under 10⁶cfu/mL (g) during its preservation period.

Article 13 If the life beneficial bacterium health food needs to preserve under specific conditions, it should be indicated in the label and explanatory memorandum.

Article 14 Any functional propagation ingredient can be added to the used breeds of life beneficial bacterium during the process of ferment except culture medium.

Article 15 The bacterium breeds that are under genetic modification cannot be used for health food.

Article 16 The State Food and Drug Administration (SFDA) shall take responsible for interpreting the regulations.

Article 17 The regulations shall go into effect as of 1st July 2005. The regulations promulgated before, if not in accordance with these regulations, shall conform to this one.

List of life beneficial bacterium breeds can be used in health food

Bifidobacterium bifidum
Bifidobacterium infantis
Bifidobacterium longum
Bifidobacterium breve
Bifidobacterium adolescentis
Lactobacillus delbrueckii subsp. bulgaricus
Lactobacillus acidophilus
Lactobacillus casei subsp. Casei
Streptococcus thermophilus
Lactobacillus reuteri