

Regulations for Application and Evaluation of Nucleic Acid Health Food (interim)

Article 1 With a view to standardizing the reviewing of nucleic acid health food and ensuring the safety of nucleic acid health food, the regulations is formulated according to Food Assanation of the People's Republic of China and Provisions for Health Food Registration (interim).

Article 2 The nucleic acid health food refers to the health food which is produced by utilizing nucleic acid (DNA or RNA) as raw materials and appending relevant substances.

Article 3 Applying for the nucleic acid health food, besides providing the dossiers needed for health food application, the following dossiers should also be provided:

- (I) The foundation for the formula of products, which should be provided, should also state clearly the names, sources and contents of the used nucleic acids;
- (II) The scientific documents directly related to the functions in the application should be provided;
- (III) The standard of the enterprise should state clearly the content and purity of all the used nucleic acids and their relevant qualitative and quantitative testing methods, as well as the quality standard;
- (IV) The detailed production techniques of the nucleic acid materials (include the name and amount of the processing aid) should be provided;
- (V) The purity test report of nucleic acid materials issued by an inspection institution designated by the State Food and Drug Administration should be provided.

Article 4 The applicant must not use one single kind of DNA or RNA as the raw material to apply for health food

Article 5 The purity of one single kind of nucleic acid used as raw material in the health food should be higher than 80%.

Article 6 The function range for the application of the nucleic acid health food should be temporarily limited to the function of strengthening people's immunity.

Article 7 The health function assessment test for the nucleic acid health food should be conducted according to the procedures and methods for health food function assessment. The nucleic acid health food should be set three dose groups: high, medium and low, according to the recommendation of intake amount prescribed different multiples. The control group for the ingredients of medium dose (all the other ingredients in the products except nucleic acid) should also be added. If the statistic deviations in the comparisons of the sample group with the blank control group and with the ingredient group appear synchronously, the product can be described with nucleic acid as ingredients.

Article 8 The item of active ingredient in the package insert of nucleic acid health food should clearly states the content of the nucleic acid in the product according to the inspection results in the inspection report issued by an inspection agency designated by the State Food and Drug Administration.

Article 9 The daily recommendation dosage of nucleic acid in the nucleic acid health food is 0.6g-1.2g.

Article 10 No health food should be named after “nucleic acid”.

Article 11 The package insert and label of the nucleic acid health food should state clearly “gouty patients” as well as the relevant exegesis items on “unsuitable users” according to the relevant regulations on health food.

Article 12 These regulations shall be interpreted by the State Food and Drug Administration.

Article 13 These regulations shall go into effect as of July 1, 2005. The regulations promulgated before, if not in accordance with these regulations, should conform to this one.