Regulations for Application and Evaluation of Health Food Produced by Applying Macro Reticular Resin Abstraction and Purification Technique (interim)

Article 1 With a view to standardizing the reviewing of applying Macro reticular Resin Separation and Purification Technique and ensuring the edible safety of 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 health food of applying Macro reticular Resin Separation and Purification Technique refers to the health food utilizing the processing in the course of manufacturing and raw materials production.

Article 3 Applying for the health food applying Macro reticular Resin Separation and Purification Technique, besides providing the dossiers needed for health food registration application, the following dossiers should also be provided:

(I)The relevant data for Macro reticular Resin

1. The specification criterion of Macro reticular Resin. The criterion should include the name, pattern, configuration, synthesis materials (the name and specification of key raw materials, cross-linking agent, cause-hole agent, dispersant agent, etc), appearance, polarity, diameter range, the quantity of moisture, humidity density, dry density, specific surface area, aperture, porosity, aperture cubage etc. The criterion level of Macro reticular Resin should also be provided.

2. The instruction of macro reticular resin should be provided. The content should include:

(1) Synopsis of performance of macro reticular resin, serviceable range, key raw materials, the kind and name of additives.

(2) Hangover (including non-assembling monomer, cross-linking agent、primary additives) and the measurement method of residue volume, limited quantity criterion and accordance.

(3)The application method and announcements: Including the pretreatment method, retexture method and regarding proceeding of operation, stockpile conditions of new Macro reticular Resin and management method of possible abnormal instance.

3. Product batch number, time and the survey report of product.

4. The documents of relevant certification. The following data should be provided including the name of the enterprise producing macro reticular resin, address, phone number, business license and the copy edition of relevant producing license, etc.

(II) Research data of applying macro reticular resin abstraction and purification for preparation.

1. The purpose and accordance of techniques of applying macro reticular resin abstraction and purification in the preparation technique. It is necessary to illustrate the purpose and necessity of applying macro reticular resin abstraction and purification technique in detail and provide relevant research or literature data.

2. Pretreatment method and eligibility criterion of macro reticular resin abstraction. Pretreatment method includes the technique parameter and operation regulations, such as reviewing the kind of pretreatment solvent、dosage、soaking time、velocity of flow、temperature、pH etc.

3. Research data of processing. The research data include pattern selection of macro reticular resin, contrast preceding pillar quantity, contrast adsorption quantity, contrast eluting quantity, diameter—height ratio of colophony pillar, suitable preceding pillar temperature of extract, pH, velocity of flow, dispelling absorption solvent and the selection of its conditions, determinant method of the end-point of dispelling absorption. All aforementioned data should be part of the product processing.

4. Determining the regeneration method of macro reticular resin. The absorbability of used macro reticular resin will descend, so retexture is needed. According to efficacy component and physical and chemical characters of macro reticular resin, retexture method and eligibility criterion will be figured out. The applicant shall work out relevant criterion and operation regulations and write them into the Standard appendix of the enterprise.

(III) Applying for the health food made of the materials produced by applying macro reticular resin abstraction and purification technique, the applicant should provide the data of raw material manufacturers, preparation techniques of primary materials, detailed quality criterion including the criterion of macro reticular resin residue in the material and detection report. The applicant should also provide detection report of the macro reticular resin residue, which is provided by the inspection institution designated by the State Food and Drug Administration (SFDA).

(IV) The applicant should provide safety appraisal data of macro reticular resin and its purification technique.

Article 4 Applying for the health food produced by utilizing colophony of benzene framework abstraction and purification technique, It should meet the following requirements:

1. It needs pretreatment before macro reticular resin is applied .It should confine organism residue in macro reticular resin to safety range after the pretreatment .As for resin benzene framework, remnant dosage of benzene should be less than 2mg/kg, divinyl-benzene less than 20mg/kg.Limited dosage criterion is according to specific instance as for other macro reticular resin.

2. Generally, when the contrast adsorption quantity of regenerated macro reticular resin descends more than 30%, it should not be used

3. The manufacturers, which apply macro reticular resin separation and purification technique to produce health food material, should inspect or check up residue of macro reticular resin in material. The dosage of divinyl-benzene in preparation of the benzene vinyl framework resin, should be less than 50μg/kg, which should be written into enterprise criterion. If the quality of material can reach aforementioned criterions, the dosage of macro reticular resin residue in the final product of health food should not be detected.

4. Working out the detection method and criterion of resin residue and writing them into enterprise criterion

5. If the health food is produced by applying benzene vinyl framework resin abstraction and purification technique, the dosage of divinyl-benzene in the health food should be less than 50μg/kg.

Article 5 As for the other macro reticular Resins referring to benzene vinyl framework, the relevant residue and residual standard should be formulated combining with the specific breeds.

Article 6 In principle, the mixture of multiple animals and plants can not be used as materials to produce health food by applying macro reticular resin abstraction and purification technique.

Article 7 When necessary, the State Food and Drug Administration (SFDA) can inspect the enterprise producing macro reticular resin and producing the material used in health food by applying macro reticular resin in the spot.

Article 8 The State Food and Drug Administration (SFDA) shall take responsibility to interpret the regulations.

Article 9 The regulations shall go into effect as of July 1st, 2005. The regulations promulgated before, if not in accordance with these regulations, should conform to this one.