Regulations for Registration of Domestic Capsule and Tablet Vitamin Products (New Application)

According to the official notice released on February 12, 2018 (Wei Shou Shi Zi No. 1061303467)

New application for registration of domestic capsule and tablet vitamin products:

I. The applicant company shall be the manufacturer of the product.

II. For the registration of domestic capsule and tablet vitamin products, the applicant shall pay the application fees and submit completed application forms and all required dossiers to the FDA.

1. An application form.
2. A review sheet.

Explanation:

(1) Product name in foreign language: If the product does not have a foreign name, there is no need to fill the column.

(2) Manufacturer: In the event of OEM products, the column of "name and address of manufacturer" shall specify the name and address of both the principal and the manufacturer.

(3) Manufacturing process: Specify the process flow, including mixing, pelletizing, stuffing, tableting, etc., and the ingredients added in each step.

(4) Recommended daily intake: Recommended daily intake shall be clearly specified. For example, three times a day, on at a time.

(5) The ingredient list:

① The ingredient list shall include the detailed names and contents of all raw materials and food additives, and further indicate the detailed names and contents of raw materials and food additives of the empty capsule in the case of capsular food, and the names and contents of the raw materials of all excipients in the event of tablet food.

② In the column "content of ingredients listed in the table", the content of ingredients shall be expressed according to the product type. For example, "each tablet contains" and "each capsule contains".

③ The ingredient list shall specify the detailed chemical names of additives such as vitamins in the product, if any, for example

Vitamin A, B_1, B_2, B_3, B_5, B_6, B_{12}, D, or E. The content shall specify the exact amount added in the form of weight in mg or μg if indicated in I.U., or the number of I.U.s if indicated in mg or μg.

④ The ingredient list shall specify the animal name if any raw material of the product is made from any livestock tissue or organ (including gland). In the event of cattle and sheep, the original of the relevant official health certificate shall also be produced indicating that such raw materials as their tissues or organs being used are neither directly nor indirectly sourced from a pest area.

⑤ The ingredient list shall be accompanied by relevant information such as the scientific name of the type, part being used as raw material, and method of processing (including name of solvent used in processing, if any), for verification purposes, if the following are used as raw materials in the product: herbs, raw materials made from herbal sources, algae, mushrooms, microorganisms, or raw materials made from sources of microorganisms.

⑥ The ingredient list shall further specify the name of the solvent used in processing, for verification purposes, if the raw materials being used are extracted and processed.

3. Food details in three copies.

Explanation:

(1) The name of the product shall be consistent with that on the ingredient list and undertaking.

(2) Manufacturer: In the event of OEM products, the column of "name and address of manufacturer" shall specify the name and address of both the principal and the manufacturer.

4. An undertaking.

Explanation: The applicant shall guarantee that the applicant fully understand the application, and complies with the Act Governing Food Safety and Sanitation. All the name, trademark, illustration, label, package insert, sign do not involve any act of counterfeiting or insinuation. If any violation is involved, the applicant shall bear any legal responsibilities should they incur and the FDA shall cancel the registration license.

5. A copy of document certifying that the legitimacy of the original manufacturer.

Explanation:

(1) The copy shall include the stamps of the manufacturer and the person in charge.

(2) The original OEM certificate shall also be submitted in the event of OEM products or a certified copy shall be enclosed.

6. A certified copy of business registration certificate with stamps of the manufacturer and the person in charge.

7. An intact sample of the product.

Explanation: One sample of 20 tablets/capsules of product shall be submitted.

III. After the application is submitted and approved according to the Act Governing Food Safety and Sanitation, a license with a validity of five years shall be issued.

IV. If an applicant is requested to submit samples for verification after review of its application, sufficient samples shall be submitted along with an examination fee to the FDA within one month of such notice. Failure to pay the examination fee or submit the samples within the prescribed period will result in the rejection of the application. Results of the examination shall serve as reference for the above authority to rely on in granting approval.