

ANNEX II
REPUBLIC OF PANAMA
MINISTRY OF HEALTH
DEPARTMENT OF FOOD PROTECTION
SECTION OF HEALTH REGISTRATION, HYGIENE AND FOOD CONTROL
PHONE NUMBER: 512 9180 Ext. 1157

DOCUMENTATION MUST BE PRESENTED COMPLETE, WITHIN A FOLDER WITH A HOOK

REQUIREMENTS FOR SANITARY REGISTRATION AND SANITARY INSCRIPTION OF HYGIENE PRODUCTS FOR THE FIRST TIME

The interested person must submit to the Department of Food Protection of the Ministry of Health in a timely and complete manner the following data:

1. REQUEST:

Application filed by a lawyer for registration or inscription of hygienic products signed by the appropriate professional responsible, which must include the following information:

- Product Data:
 - a) Name
 - b) Type (Annex B)
 - c) Use

Note: Up to ten variants can be grouped in a single application, depending on the characteristics of aroma and color, provided they are manufactured in the same country and in the same plant and that maintain the same physical form, use and main components.

Data of the legal representative of the company registering the product:

- a. Name
- b. Identification Number
- c. Address
- d. Phone Number
- e. Fax
- f. Email

Manufacturer information:

- a. Name
- b. Reason or social denomination
- c. Address
- d. Phone Number
- e. Fax
- f. Email

Data of the appropriate professional technician:

- a. Name
- b. Identification Number
- c. Address
- d. Phone Number
- e. Fax
- f. Email
- g. Registration number of professional suitability
- h. Signature and seal of the responsible professional

Data of the company registering the product:

- a. Name
- b. Identification Number
- c. Address
- d. Phone Number
- e. Fax
- f. Email
- g. Health license number or current operating permit, when applicable

Data of the holder:

- a. Name, reason or social denomination
- b. Address
- c. Phone Number
- d. Fax
- e. Email

- 2. Original document or legalized copy of the legal entity of the registrant company.

3. Power in favor of the legal representative. If the document is granted abroad, it must be legalized.
4. Certificate of free sale, good manufacturing practices or certification of the manufacturer laboratory (foreign products). The same must be in Spanish and authenticated.
5. Safety sheet (Material Safety Data Sheet, MSDS). In case of imported products, whose security sheet is in a different language, the information must be presented in Spanish language according to the form in Annex C. It must be no more than three (3) years from its date of issue.
6. Qualitative and quantitative formula signed by the responsible professional.
7. Specifications of the finished product in original and copy of the physical-chemical and microbiological specifications of the finished product, attaching also the material safety data sheet of the product (toxicological information).
8. Two copies of the physical-chemical analysis method used by the manufacturer to analyze the product should be attached to the application. If the manufacturer follows the analytical method of a pharmacopoeia, it suffices to indicate the reference, edition and year of the same.
9. Analytical controls.
10. Original tag or its readable project.
11. Copy of the Sanitary Permit of Operation of the company that protects the product that is wanted to register or copy of the Certification of Plant (national products).
12. Four Intact Product Samples:
The samples must be presented as the product will be distributed and duly identified with its label. These must be from the same lot. Each sample must weigh at least 100 g, in case they have a lower weight, they must present samples up to 400 g.
13. Proof of payment for the right to process registration or inscription and health surveillance:
 - a. Receipt of original payment of registration and control (DGS / Ministry of Health Treasury).
 - b. Receipt of original payment of the Income to the National Treasury (Ministry of Economy and Finance, National Products: B / .10.00, Foreign Products: B / .25.00).

Note: Payment receipts must be presented on the same day of payment to be given the corresponding course.

Withdrawal of Certificate of Sanitary Registration:

Once the requirements have been met, copies of the payment vouchers detailed in item 10 must be submitted; Together with B / . 8.00 in tax stamps.

Note: Any modification in relation to the half-life of the packaging, the process of preparation, formulation and / or labeling of the product during the period of validity of the sanitary registration shall be notified by request of updating the respective dossier.

Note: When changes occur that warrant the printing of a new certificate of sanitary registration, it must be requested in writing and will cost b. / 5.00.

REQUIREMENTS FOR THE RENEWAL OF THE REGISTRATION OR SANITARY INSCRIPTION OF HYGIENIC PRODUCTS:

The renewal of the registration or sanitary inscription for hygienic products must be made in advance of the expiration of the products.

The requirements to carry out the renewal process are as follows:

1. Request for renewal signed by the appropriate responsible professional technician.
2. Proof of payment by right to process registration or inscription and health surveillance:
 - a. Payment to the Ministry of Economy and Finances.
 - b. Payment by authorized laboratory analysis tests.

5.1.1 Affidavit certified by a notary or document in the nature of a public faith of the legal representative and the appropriate professional responsible, stating that the original conditions or approved modifications to the registration or inscription of the product are maintained.

5.1.2 Original product labels.

LEGAL BASIS:

Law No. 66 of November 10, 1947.

Decree No. 256 of June 13, 1962.

Decree No. 331 of July 22, 2008.

Decree No. 855 of August 4, 2015.

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