

Sanitary Requirements

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Requirements for Sanitary Registration of Imported Dietary Supplements in Venezuela

Below is the complete overview of regulatory requirements in Venezuela for the sanitary registration of imported dietary supplements, including prerequisites, dossier documentation, labeling requirements, and estimated approval timelines.

The competent authority is the Ministry of People's Power for Health (MPPS) through the Autonomous Health Comptroller Service (SACS). In Venezuela, supplements are generally classified as food or dietary products, unless they contain pharmacological substances, in which case additional evaluation may be required.

Sanitary Registration of Imported Dietary Supplements

1. Applicant Prerequisites

Before applying for registration:

- Importing company legally established in Venezuela
- Valid sanitary operating license
- Establishment registered with the health authority
- Designated sanitary responsible person
- Authorization from the foreign manufacturer to the importer
- Representation or distribution agreement

2. Administrative Documents

Administrative section of the dossier:

- Official sanitary registration application form
- Importer sanitary license
- Company commercial registration
- Apostilled Power of Attorney from manufacturer to Venezuelan representative
- Free Sale Certificate or Health Certificate from country of origin
- Proof of payment of regulatory fees
- Product holder declaration

3. Technical Requirements of the Dossier

3.1 Product Information

- Supplement trade name
- Type of supplement (vitamin, mineral, herbal, protein, etc.)
- Pharmaceutical form (capsules, tablets, powder, liquid)
- Complete qualitative and quantitative formula of active ingredients and excipients
- Origin of ingredients (plant, synthetic, mineral)
- Nutritional function of each ingredient
- Recommended daily dose
- General manufacturing process description
- Packaging type and materials

3.2 Safety and Quality

- Certificates of analysis of finished product (physicochemical and microbiological)
- Finished product specifications
- Product safety declaration
- Compliance with contaminant limits (heavy metals, microbiology, etc.)
- Bibliographic evidence of ingredient safety (when applicable)

3.3 Samples

- Commercial samples when required by the authority for analysis

4. Labeling Requirements for Dietary Supplements

Labeling must be in Spanish and submitted within the dossier for approval.

Mandatory label information:

- Product name
- Statement "Dietary Supplement"
- Full list of ingredients in descending order
- Amount of active ingredients per serving

- Recommended daily dose
- Consumption warnings (e.g., do not exceed recommended dose)
- Statement: "This product is not a medicine" when applicable
- Net content
- Batch number
- Expiration date
- Storage conditions
- Manufacturer name and address
- Importer name and address in Venezuela
- Country of origin
- Sanitary registration number (once granted)
- Allergen warnings when applicable
- Nutritional information (nutrition table)

Labeling documents within the dossier:

- Final artwork of primary and secondary packaging
- Nutritional table design
- Official Spanish translations when applicable
- Signed declaration of labeling compliance

5. Additional Requirements

- Apostilled or legalized foreign documents
- Official Spanish translations
- Payment of regulatory fees
- Declaration of compliance with Venezuelan food regulations

6. Estimated Approval Timeline

Timelines depend on cosmetic type and technical observations:

Typical timelines:

- Administrative review: 1 – 2 months
- Technical evaluation: 3 – 6 months
- Laboratory analysis (if required): 2 – 4 months

Average total time:

- 6–12 months to obtain sanitary registration.

7. Validity of the Sanitary Registration

- Typical validity: 5 years
- Renewal requires updated sanitary certificates, formula, and labeling