



Requirements for Registering Cosmetic Products EL SALVADOR 2014

Cosmetic products need to be registered with the Imports, Exports, and Donations Unit of the National Medicine Directorate (DNM). The registration requirements for cosmetic products are described in the Regulations of the Medicines Law of April 2012.

As a first step, the US company must identify a local legal representative or importer, and a pharmaceutical chemical representative (a power of attorney must be in Spanish or translated into Spanish if necessary and notarized or apostille).

The documents required by the DNM for the sanitary registration of cosmetic products are:

- a) Sanitary Registration Form (which requests information on the product name, manufacturer, importer, legal representative, etc.)
- b) Good Manufacturing Practices Certificate issued by regulator or authorized authority of the country where the manufacturer is located.
- c) Power of attorney on behalf of the Legal Representative.
- d) Qualitative complete formula, specifying the quantity of restricted substances issued by the manufacturer and signed and approved by the local pharmaceutical chemical representative.
- e) Specifications of the finished product issued by the manufacturer
- f) Original packaging. A copy is not accepted. Labeling must be in Spanish.
- g) Receipts of payment of registration process, which will include the fees for the respective analysis.

Once all the documents are submitted, the DNM will issue a sanitary certificate within 10 business days. All documents should be authenticated or Apostille. The registration is valid for 5 years. Registration fee is US\$75 per product and renewal fee is US\$25.

In addition, all cosmetic registration process should comply with the Annex 2 of the Central American Technical Regulation (RTCA) for Cosmetic Registration and the Annex 3 of the Central American Technical Regulation (RTCA) for Cosmetic Products Labeling:

- a) Anexo 2 de la Resolución No 231- 2008 (COMIECO-L) RTCA 71.01.35:06 Productos Cosméticos. Registro e Inscripción Sanitaria de Productos Cosméticos.
- b) Anexo 3 de la Resolución No. 231-2008 (COMIECO-L) RTCA 71.03.36:07 Productos Cosméticos. Etiquetado de Productos Cosméticos.

The above RTCA's are available in Spanish at:

http://www.medicamentos.gob.sv/index.php?option=com_content&view=article&id=129&Itemid=190

Regulatory Institution Contact Information:

National Medicine Directorate (Dirección Nacional de Medicamentos - DNM)

Address: Edificio DNM Nivel 4 y 5 Ciudad Merliot, Santa Tecla, La Libertad

Tel: (503) 2247-6000

E-mail: info@medicamentos.gob.sv

Website: www.medicamentos.gob.sv

For More Information

Global Markets in San Salvador, El Salvador can be contacted via e-mail at:

office.sansalvador@trade.gov ; Phone: (503) 2501-3211; or visit our website:

www.export.gov/elsalvador.

Global Markets – Open For Business

Global Markets has a federal government presence both across the United States and in countries that represent 91percent of worldwide GDP with authoritative, impartial, accessible professionals who have specific trade and investment expertise. As trusted intermediaries with extensive public and private sector contacts, credibility and influence in foreign markets, GM effectively assists U.S. businesses and partners in entering and expanding international markets, addressing barriers to accessing foreign markets, winning foreign government procurements and attracting inward investment. To locate the nearest office visit www.export.gov.

Disclaimer: The information provided in this report is intended to be of assistance to U.S. exporters. While we make every effort to ensure its accuracy, neither the United States government nor any of its employees make any representation as to the accuracy or completeness of information in this or any other United States government document. Readers are advised to independently verify any information prior to reliance thereon. The information provided in this report does not constitute legal advice.

International copyright, U.S. Department of Commerce, 2014. All rights reserved outside of the United States.