Icaza
González-Ruiz
Alemán

REGULATION: MANUFACTURING OF HANDCRAFTED COSMETIC PRODUCTS IN PANAMA

Executive Decree No. 875 of November 18th, 2021

1. **What is considered a handcrafted cosmetic product?**
   Handcrafted cosmetic products are defined as personal care products, such as creams, emulsions, lotions, balms, gels, skin oils, hydro and oil serums, make-up except for eye contour, soaps, bath products, perfumes, eau de toilette, eau de cologne, deodorants, which are included within the categories of cosmetic products prepared following on traditional formulas and techniques not involving technified industrial processes.

2. **Which products are not classified as handcrafted cosmetics?**
   All products intended for the cure of any disease or any product that can be ingested, inhaled or injected into the human body are not considered cosmetic products, since such products should only be applied topically.

3. **What should I do to produce handcrafted products?**
   For the production of handcrafted cosmetic products, interested parties must register with the National Directorate of Pharmacy and Drugs as a Non-Pharmaceutical Establishment.

4. **What are the requirements for registration as a Non-Pharmaceutical Establishment?**
   The requirements for the application for registration as a Non-Pharmaceutical Establishment engaged in the manufacturing of handmade cosmetic products include the Application for Registration of Establishment for the Manufacturing of Handmade Cosmetic Products (EPCA) form, duly signed by the artisan owner, list of products to be produced, certificate and registration card issued by the Ministry of Culture, among others.
   Artisans engaged in the manufacturing of handmade cosmetic products must comply mandatory training three times a year.
   Before authorizing the registration and opening of establishments engaged in the manufacture of handcrafted cosmetic products, the National Directorate of Pharmacy and Drugs shall carry out an inspection of the same, in order to verify that they comply with the infrastructure, equipment, hygiene conditions and environment necessary for the manufacture, storage and handling of these products. This inspection shall not have a service fee.
   The registration of establishments that manufacture handcrafted cosmetic products shall be valid for two years. For renewal, the application must be submitted to the National Directorate of Pharmacy and Drugs, one month before its expiration date.

5. **What are the requirements of the area for the manufacturing of handcrafted cosmetic products and for the personnel working in the premises?**
   For the manufacturing of handcrafted cosmetic products, the premises must be a separate area, enabled and used exclusively for this purpose. Such premises may be located within a residence.

The area for the manufacturing of handcrafted cosmetic products shall comply with the following requirements:

1. To have adequate wall, flooring and ceiling conditions that allow an easy cleaning.
2. To have a stainless steel table.
3. To have implements for the preparation of products, utensils and tools for the exclusive use of this activity.
4. To have metal, plastic or slatted shelves to store the products and materials to be used.
5. To maintain the areas of raw materials, packaging material, labels, weighing, preparation or mixing, filling, drying, packaging, labeling, finished product, clean utensils, properly identified, as applicable.
6. To comply with the established norms of periodic fumigation.

The personnel that shall carry out the manufacturing of handcrafted cosmetics must use protective equipment such as: masks, hair covers, goggles, gloves, aprons, which must be clean and in good condition for their use at all times.

6. Do I need a sanitary registry for my product?

Yes, after completing the procedures required for the establishment, the artisan must comply with the requirements for the sanitary registry of the product, which include the application for the Sanitary Registry Notification, the qualitative composition, among others.

7. What are the requirements of the National Directorate of Pharmacy and Drugs for the products manufactured?

Each non-pharmaceutical establishment dedicated to the manufacture of handcrafted cosmetic products must fill out the form provided by the National Directorate of Pharmacy and Drugs, called Control of the Manufacture of Handcrafted Cosmetic Products; likewise, it must submit to the National Directorate of Pharmacy and Drugs a semi-annual report on the products manufactured.

If there are changes that include serial activities or reproduction by industrial technique or processes, the establishment must apply for a laboratory license and sanitary registry for its products.

8. Is there a list of approved ingredients for handcrafted cosmetics?

The National Directorate of Pharmacy and Drugs recognizes the following references on ingredients that may or may not be incorporated into cosmetics, and their corresponding restrictions or conditions of use:

1. Personal Care Product Council (PCPC).
2. The European Commission Cosmetic Ingredient Database (Cosing).
3. European Union Directives.
4. Central American Technical Regulations for Cosmetics.
5. Guidelines related to the subject matter by the Food and Drugs Administration.

9. What are the requirements for registration and authorization of the quantitative formula?

For the purposes of registration and authorization of the quantitative formula, the following requirements must be met:

1. Submission of the original of the formula, signed by the person responsible for dosage.

2. For cosmetics containing restricted substances, as indicated in the previous article, the name and concentration of such substances must be indicated.
3. The name of each ingredient must be expressed according to the International Nomenclature for Cosmetic Ingredients (INCI) denomination.
4. The name of the product and its variants, if any, must be clearly indicated.
5. If the product is presented in several shades or varieties, the names and International Color Index numbers of the corresponding colorants must be specified.

The use of colorants approved for use by any of the established pharmacopoeias or references shall be accepted.

10. What are the guidelines on labelling of products?

Cosmetic product labels require the following information on both the primary and secondary packaging label, if available:

1. Product name.
2. Content given by weight or by volume.
3. Name of manufacturer or distributor.
4. Country of origin.
5. Batch number.
6. Storage conditions (if required).
7. Registry number of the non-pharmaceutical establishment.
8. Safety information or graphical representation of product use, as applicable.

On the label of the product, on the primary or secondary packaging, or in annexed instructions, the corresponding precautionary legends must be included, which shall be expressed in several languages at the same time, provided that one of them is Spanish. They should be written in a clear and concise manner, so as not to mislead or confuse the consumer.

Any information in addition to the mandatory details of the products, as well as any other information appearing on the labels or inserts of the regulated products, shall be considered as advertising or publicity and, consequently, must strictly conform to the properties derived from their formula. The statement of properties which cannot be verified is prohibited.

For assistance regarding this matter, please contact us at consultas@icazalaw.com.