

ARGENTINA:

Cannabidiol (CBD) ingredient authorized for cosmetics, products for personal hygiene and perfumes

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The use of Cannabidiol (CBD) for cosmetics, personal hygiene products and perfumes has recently been authorized by the Argentine National Administration of Medicines, Food and Technology (ANMAT) through Regulation No 8504/2021. This regulation was published in the Official Gazette on November 16th 2021, being effective as of November 17th 2021.

The Cannabidiol (CBD) is one of at least 85 active cannabinoids identified in cannabis plant. In the recitals of said regulation, the ANMAT refers that the CBD of natural origin, which generally has traces of delta-9 tetrahydrocannabinol (hereinafter THC), does not produce psychoactive effects and is not associated with a potential for abuse and dependence. Furthermore, there are reported cosmetic functions for the ingredient Cannabidiol (CBD) of natural origin.

In view of this and in order to update the national regulatory framework, the ANMAT authorizes the registration of cosmetic products, personal hygiene products and perfumes containing CBD of natural origin or CBD present in extracts and natural oils of certain parts of the Cannabis sativa L. plant with no more than 0.2% W / W THC.

The regulation establishes some restrictions for the use of the CBD ingredient. It cannot be part of the formulation of products that come into contact with mucous membranes, nor in patches or products where there is a risk of inhalation when handling or using it.

Besides, the CBD products covered by this provision cannot proclaim or refer to analgesic purposes, anti-inflammatory action, actions at the muscle or joint level or any other therapeutic properties.

The activities of preparation, packaging, conditioning, import, export and deposit of cosmetic products, personal hygiene products and perfumes regulated by this

provision, as well as the individuals and legal entities involved in said activities, will be subject to the supervision and control of the Directorate of Evaluation and Monitoring Management of Health Products (which is a Division of the ANMAT).

Requests for the importation of the CBD component as raw material will be controlled by the Foreign Trade Department of the National Institute of Medications (INAME).

The labeling of products containing CBD must not mention the percentage of the CBD ingredient it contains, nor allude to any therapeutic properties of the product.

Additionally, the labelling must include certain warning text, such as: “Do not ingest, only for topical use”, “Cosmetic product, not suitable for medicinal use”, “Exclusive use in adults”, “Its use is not recommended during pregnancy or breastfeeding”, “Do not apply on wounds or where the skin is not intact”.

In order to obtain authorization for these products, Regulation No 8504/2021 establishes the obligation to submit documentation referring to the ingredients allowed with CBD of natural origin with no more than 0.2% W / W of THC, in addition to the information and documents requested for obtaining authorization for regular cosmetic products, products for personal hygiene and perfumes.

This regulation constitutes a step forward to establish a regulatory framework according to the international context in which the sanitary authorities of different countries, such as Canada, Uruguay and the European Union, authorize the commercialization of cosmetic products based on the naturally-derived cannabinoid called Cannabidiol (CBD) containing traces of THC.

The aforementioned regulation can be found in the Argentine Official Gazette:

<https://www.boletinoficial.gob.ar/detalleAviso/primera/252932/20211116>
