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Life Sciences Industry Group Newsletter

New Good Manufacturing Practices for cosmetic products

On July 5, 2022, the Mexican Official Standard NOM-259-SSA1-2022, Products and services, Good Manufacturing Practices for cosmetic products, was published in the Federal Official Gazette.

The purpose of this NOM is to establish the necessary health controls regarding the manufacturing and related processes for cosmetic products applicable to legal entities and premises operating in this industry, and guarantee that these products do not represent risks to consumer's health, implementation of preventive systems, and control and verification of the products' quality to assure the safety of cosmetic products.

The Good Manufacturing Practices (GMP) are established as guidelines applicable to the manufacturing process of these products, and the NOM is issued to establish the basic requirements that must be followed during the production process, including production conditions, personnel, storage and packaging.

This NOM also establishes the requirements to guarantee the health quality and safety of these products and their use, consumption and effectiveness, through the implementation of these GMPs, which are considered as the basis for health control to assure manufacturing and other processes under health quality conditions, quality improvement, elimination and/or reduction of risks to the consumer's health.

Among the concepts included in this NOM are terms and definitions, symbols, personnel health requirements, training, physical facilities requirements, services, cleaning and maintenance, equipment, accessories and utensils, raw materials and packaging material, production controls, storage, transportation, quality control, complaints, product returns and recalls, documentation requirements, etc.

It is important to mention that this NOM is not only applicable to production and other processes carried out within Mexican territory, but also to those products imported into Mexican territory and, in general, to all the traceability of the processes up to their delivery to the final consumer.

The content and general scope of the NOM presents important challenges for manufacturing companies, but especially for importers of this type of products, since it imposes obligations on importers to have information regarding the manufacturing processes of the products and to be able to have traceability elements of such processes, that, in principle, do not correspond to them, but to the foreign manufacturers.

In this same connection, several obligations are established that go beyond those specifically set forth by the General Health Law and its diverse regulations related to this type of products.

The NOM will enter into force on September 2, 2022. However, the obligations related to documentary controls established therein will enter into force 180 calendar days following the publication, this is, on December

31, 2022. Finally, the obligation to comply with the requirements related to the technical requirements of the facilities will enter into force 240 days after the NOM is published, this is, on March 1, 2023.

Adapting the production and marketing systems of these products to the provisions included in the NOM represents a serious challenge for the industry, and will undoubtedly lead to possible verifications and actions by the health authorities, both at federal and state level.

We will be glad to provide further comments or information upon your request.

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