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On April 21st, 2023, the Public Health Institute ("ISP") issued Exempt Resolution No. 1020, which approves the <u>"Technical Guidelines on recommendations for the labeling of cosmetic products"</u> (the "Guide").

In the Guide, the ISP indicates that, as a result of surveillance activities, they have detected faults in the information that the labeling of cosmetic products should contain, which range from discrepancies with the authorized content to the absence of data regarding regulatory requirements, which affects the correct use of the products, and may lead to eventual adverse reactions. In this context, the Guide provides specific guidelines on the information that should be included in the packaging, package inserts and labels of this class of products, to contribute to the safe use of cosmetics and the development of cosmetovigilance in the country.

The Guide contains a list of the mandatory information that must be included in the labeling of cosmetic products with indelible, easily legible and visible characters, which must correspond exactly to what is declared in the submission for marketing authorization and the content authorized by the ISP. Additionally, the Guide offers a series of considerations and/or recommendations regarding:

- 1 Labeling in general;
- 2 Promotion of cosmetic products;
- 3 Warnings and precautions for use;
- 4 General label legends;
- 5 Specific label legends; and
- 6 Symbology that may be included in the labeling of a cosmetic product.

This Guide includes elements of both the sanitary regulations and other national norms that are linked to the latter and pursue a similar purpose —mainly, the consumer protection law—, as well as recommendations from other agencies, such as those of the European Commission, the Spanish Agency of Medicines and Health Products (AEMPS), and the National Administration of Medicines, Food and Medical Technology of Argentina (ANMAT).

Please note that the publication of the Guide in the Official Gazette is still pending and should be published promptly.

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