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CFDA Clarifies Regulations on Cosmeceuticals

By Xun Yang

The China Food and Drug Administration (“CFDA”) issued on 10 Jan. 2019 the *Response to Frequent Questions regarding Regulations of Cosmetic Products (Batch I)* (the “*Cosmetics Response*”), which, among other issues, clarified the regulative framework over cosmeceutical products. The issuance of the response suggest strengthened control over the cosmeceutical market.

Background Review

The concept of “cosmeceutical” has been popular in the China market for some years. It represents, via massive public advertisement and promotions, the vision of “more healthy,” “more safety,” and “more scientific.” Some products contain medical ingredients; whilst some products do not. A great number of cosmetic companies entered into the cosmeceutical market because of the relative high profit margin and great potential market.

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However, the term “cosmeceutical” does not exist in the PRC legal regime. Nor is there a regulatory system specifically for cosmeceutical products. Consequently, companies usually apply for manufacture and sales of cosmeceutical products under the names of cosmetic products but nevertheless indicate, either in an express or an implied way, that the products are cosmeceuticals or, even have medical effects.

The Cosmetics Response was issued in response to the lack of clear regulation on the cosmeceutical market and emphasized that the so-called “cosmeceutical product” is not a precise legal concept and no cosmetic product is allowed to claim to be a cosmeceutical.

Regulative Regime

The Cosmetics Response first clarify that the term “Cosmeceutical product” is not a term defined under any PRC law. Actually, the term does not exist in regulations of most countries.

In the PRC legal regime, there is no legislation or statute regulating cosmeceutical products specifically. Most of the cosmeceutical products are considered cosmetic products and subject to regulatory requirements applicable to cosmetic products.

Relevant to cosmeceutical products, CFDA regulates two types of products, pharmaceutical products cosmetic products. The former is defined of substance of which the designed function is to prevent, diagnose, or treat human diseases, or otherwise adjust human functions. The latter is defined as substance designed to clean the surface, to remove unpleasant smell, to protect skins, or to beautify or modify human outward appearances. As such, generally speaking, a cosmeceutical product falls within the scope of cosmetic products because they are not designed to treat specific diseases but to beautify human or improve dermatological health generally.

Besides, the procedures for apply for a drug registration is far more complicated and lengthy, comparing to the procedure for the registration for a cosmetic product. In reality, most so-called “cosmeceutical products” are registered as cosmetic products.

Restrictions on Advertisement

The Cosmetics Response restates the restrictions under the *Supervisory Regulation for Sanitation of Cosmetic Products* (“***Cosmetics Regulation***”) effective in 1989 that labels, packages, and specifications of cosmetic products must not indicate any applicable disease, any medical effect, or otherwise use any medical terminology, and advertisement of cosmetic products must not describe any medical function. The Cosmetics Regulation further clarifies that any product which is registered as a cosmetic product must not indicate itself as a

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“cosmeceutical product” or “medical skincare product.”

This restriction is out of the concern about possible misleading concept of “cosmeceutical products” because cosmeceutical products are in essence cosmetic products registered without mandatory clinical trial but nevertheless the term indicates that it is safer and healthier. As mentioned above, most of the cosmeceutical products are registered as cosmetic products, the restriction may, in reality, denies the viability of “cosmeceutical product.”

Restrictions on Ingredient

According to the Cosmetics Regulation, cosmetic product must only use ingredients which have been included in the *Existing Cosmetic Ingredient Catalogue* (the “**Catalogue**”) or new substance which is approved by CFDA. The inclusion of pharmaceutical ingredients into cosmetic products does not convert such cosmetic products into “pharmaceutical products” but results in these cosmetic products being considered “disqualified” and banned from being distributed.

The Cosmetics Response raised an example that “oligopeptide-1” is included in the Catalogue and, thus, can be used in cosmetic products (including cosmeceutical products). Whilst, “sh-oligopeptide-1” (or EGF), a medical used version of oligopeptide, is a medical substance typically used in empyrosis treatment and not allowed to be included in cosmetic products.

The prohibition on including medical substance in cosmetic products is a response to the public’s misunderstanding that medical substance is more effective. However, the risk is that medical substance typically has notable side-effect and its dosage must be limited whilst the use of cosmetic product is usually not limited. Additionally, the registration for cosmetic products does not go through a clinic trial procedure and, therefore, the safety of the inclusion of medical substance is untested.

Conclusion

The issuance of the Cosmetics Response clarified the grey areas around the regulation over cosmeceutical products and suggests that the government strengthen controls over cosmeceutical administrations. Cosmetic companies are advisable to revisit its market strategy and, in particular, to review the advertisement for their cosmeceutical products to avoid the breach of CFDA regulations.

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