China New Regulation on Cosmetics (I): Rules on New Raw Materials

Description

On June 29, 2020, China officially published its long-awaited regulation on cosmetic industry, titled as "*Regulation on Supervision and Administration of Cosmetics*" (hereinafter "**New Regulation**").

It is kind of a surprise to see how many changes have been made in contrast to the draft that was said to be passed at the meeting of China State Council early this year.

This post focuses on those rules in the New Regulation in regard of the administration and use of new cosmetic materials in end products.

If you are familiar with China cosmetic industry, you must have known how hard it is in the past to apply for approval of new cosmetic materials before they can be used in cosmetic products in China.

1. **Encouraging Innovation in Cosmetic Industry**

Article 9 of the New Regulation provides:

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> *Chinese Version of Article 9 of the China Regulation on Supervision and Administration of Cosmetics*

Basically, it says that China encourages and supports research and innovation on cosmetics to meet the demand of the consumers, to boost cosmetic branding; the country protects legitimate interests of entities and individuals engaged in such research and innovation; the country encourages and supports the adoption of advanced technology and management practices in the manufacturing and trading of cosmetics; encourages and supports research on China's featured plants and resources in cosmetics.

This proclaiming provision sets the tone for industrial attitude for new technologies and innovations.

2. **Classification and Administration of New Raw Materials**

Under the New Regulation, raw materials/ingredients are classified into two classes: new raw materials and used raw materials. Used materials are put on a list maintained by China National Medical Products Administration ("**NMPA**", formerly known as "**CFDA**").

For new raw materials, the New Regulation further classifies new raw materials into (1) high-risk new raw materials, and (2) other new raw materials.

High-risk new ingredients/raw materials refer to those that have ***antisepsis, sun-screening, coloring, hair-dying and skin-whitening functions***. In the meantime, the New Regulation also provides that NMPA may amend the list of the high-risk or high-hazard new raw materials to cover more ingredients.

Accordingly, high-risk new raw materials shall be subject to administration of registration system which is very much an equivalent of approval system, and without obtaining the approval, the new raw materials cannot be used; other new raw materials will be subject to administration of a filing system whereby applicants simply file certain information and data with NMPA, then without approval, such raw materials can be used.

The New Regulation sets a three-year observation period for all new raw materials. If any safety issue is found during the three years, then the registration and filing will be cancelled, and if there is no any safety issue, the new raw materials will be put on the list of Used Raw Materials.

3. **Registration System on High-Risk New Raw Materials**

For international cosmetic raw materials research and distribution companies, China cosmetic market is the high lands that they must conquer. They cannot afford to miss it.

So how to apply for registration of high-risk new ingredients with NMPA?

Article 12 of the New Regulation provides for the following data and information required for registration and filing of new raw materials:

(i) name, address and contact information of the registrants or filers;

(2) a report on the research and manufacture of the new raw materials;

(3) other data concerning manufacturing techniques, stability and quality control standards; and

(4) safety evaluation data of the new ingredients.

How long will an approval be issued after submitting all data?

Many international industrial players have been thwarted under original approval system prior to the New Regulation. It is said that in the past 30 years, China CFDA had only approved about a dozen new cosmetic ingredients.

The major breakthrough in the New Regulation that is widely welcomed is the imposition of a time limit for NMPA to register a high-hazard new ingredient. Article 13 reads:

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> Article 13 NMPA shall forward the application for registration of new ingredient to the Technical Evaluation Institution within 3 business days of accepting the said application. Technical Evaluation Institution shall complete the evaluation within 90 business days of receipt of the application data and submit its opinions to NMPA. Then, NMPA shall make its decision within 20 business days of receipt of the said opinions. If the application data meets the requirements, a registration certificate shall be issued for the new ingredients, and if the application data fails to meet the requirements, registration shall be rejected with written explanations.
> *Article 13 of the New Regulation regarding Time Limit on Registration of New Ingredients.*

Recently before the publishing of the New Regulation, we have helped a client in inquiring about the possible time framework under the old regulations, we have been told that it may require some 2-3 years, too long to wait.

In the meantime, it shall be cautioned that possible delay could be anticipated if the Technical Evaluation Institution or NMPA requires the applicants to supplement technical data during the process.

Overall, the New Regulation gives great hope to international cosmetic ingredient researching and distribution companies that have been eyeing China market for long.

It is time to prepare for the industry’s upcoming spring in China.

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