China to Overhaul Regulation on its Cosmetics Industry

Description

Cosmetics are big businesses.

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With China society getting more and more affluent, cosmetics consumption has been on steady rise over years, and all major brands in the worlds are now in China market. However, China's regulation on cosmetics industry has been lagging far behind reality, indeed a drag on this industrial innovation and progress. Most notorious is that it is extremely difficult in China to apply new raw materials/ingredients in cosmetics products.

On January 3, news had it that China State Council approved the draft regulation on cosmetics businesses entitled "*Regulation on the Supervision and Administration of Cosmetics*" which has been brewed for five years. Though it has not been published, the draft is now worth a good read.

The draft regulation address all major aspects of cosmetics businesses such as raw materials, products, manufacturing, labeling and advertising as well as legal penalties for wrong doings.. We will briefly summarize each section singling out note-worthy points.

I. Cosmetic Products

Cosmetic products are divided into two groups/classes: special cosmetics and general cosmetics.

Special cosmetics include those used for heir-dying, hair-perming, skin-whitening&anti-freckle, sun-screening and those that are alleged to have new functions. All other cosmetics than special ones are regarded as general cosmetics.

Special cosmetics are required to be registered with China National Medical Products Administration (" **NMPA**", used to be called "CFDA"), and only after registration can these special cosmetics be

manufactured and ***imported***.

To apply for registration of special cosmetics, the following documents shall be submitted:

(1) name, address and contact of applicant;

(2) name, address and contact of manufacturer;

(3) name of the product;

(4) formula of the product;

(5) applicable industrial standards;

(6) label and specification of the product;

(7) inspection report of the product;

(8) safety assessment data;

(9) other materials required for ascertaining product safety.

So you can see from the document list that applicant shall conduct some technical assessment and inspection before it applies.

For special cosmetics to be imported into China, on top of those documents listed above, the applicant shall make available documentation to prove its good manufacturing practice or the sale of such products in country of manufacturing or country of origin. For products that are made only for China markets and are not sold elsewhere in the world, applicant shall present research and testing data on Chinese consumers.

Once NMPA entertains the application for registration, it will forward the application materials to its affiliated technical assessment institute for opinions. Within 20 business days of receipt of such opinions, NMPA shall make its decision as to whether or not to issue certificate of registration for the product.

A certificate of registration has a life span of five years.

II. Raw Materials

Reforms on rules about new raw materials for cosmetics have been craved by the industry for long. It is reported that there are only 8783 kinds of raw materials on the Catalogue approved by NMPA and there are more than 22,000 kinds of raw materials used in international markets. In the past 30 years, China has only approved a dozen of new ingredients. It is obvious that the restriction of adopting new ingredients in cosmetics has greatly hindered the advance and progress of China domestic cosmetic companies.

The new regulation sets out in principle that cosmetic raw materials will be classified for purpose of administration.

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In particular, new ingredients shall be either registered or filed while already used ingredients will be administered according to relevant industrial standards. In the meantime, NMPA will publish a negative list of ingredients that are not allowed to be used for producing cosmetics.

New ingredients refer to those natural or synthetic raw materials that are used in China for the first time. New ingredients that are used for antisepsis, sun-screening, coloring, hair-dying and skin-whitening and other new ingredients of relatively high hazards can only be used after registration with NMPA, and all other new ingredients can be used after filing with NMPA. All such new ingredients shall be made public within 10 business days of registration or filing.

Within the first three years of using the new ingredients in cosmetics following their registration or filing, applicants shall biannually submit to NMPA a report about the usage and safety of such new ingredients. If there are no safety problems within the three years, then the new ingredients will be added onto the list of already used ingredients.

As always in the past, application for registration of new ingredient is very complicated and heavily technical, as laid out in details in the *Guidelines on the Application and Examination of New Cosmetic Ingredients* issued by then CFDA in 2011. Various technical data such various toxicological tests and research materials, manufacturing techniques, and quality control requirements and the like shall be submitted for inspection and evaluation as per NMPA rules.

The takeaway here is the positive change of attitude indicated in the new regulation, i.e. new ingredients may be easier to use in formulating new cosmetic products in China, because Article 6 provides that the country encourage and support adoption of advanced technology and management practice. This is probably the reason why most people welcome the new regulation in the news.

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III. Manufacturing of Cosmetics

There are no major reform on legal systems of manufacturing, as relevant framework was installed in the past.

To manufacture cosmetics products in China, the manufacturer shall apply for a special permit from NMPA office at provincial level (immediately below NMPA) by submitting documents and information to prove that it meets the regulatory requirements in terms of manufacturing premises, environment, facilities, staffing, inspection and testing equipment, and management systems. The permit has a 5 year long life.

In the case of OEM manufacturing, the cosmetic product registrants and filers shall only entrust those manufacturers with permits to engage in the manufacturing activities. However it shall be noted that the product registrants and filers are the primarily responsible for the quality safety and efficacy of their cosmetic products.

Cosmetic manufacturers shall conduct production pursuant to quality control standards prescribed by NMPA, and shall set up systems in respect of selecting its suppliers, inspection of raw materials, equipment management, product inspection, recall of defective products, examination and recording of procurement of raw materials and packaging materials, sale of products.

Apparently, these rules are valid and binding on domestic manufacturers, but how about foreign manufacturers who may manufacture products that are sold in China market?

Article 52 of this draft regulation confers upon NMPA the power to conduct site inspection on overseas manufacturers to ensure their manufacturing is in compliance with relevant quality control standards. It is interesting to see how NMPA will exercise this power against foreign manufacturers.

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IV. Traders and Trading Activities

Cosmetic traders shall establish systems of examining and recording of products they buy in, and of verifying relevant registration and filing certificates from suppliers/sellers, and shall store and transport cosmetics as per requirements indicated on the labeling of such products.

Such traders are prohibited from formulating and sub-packaging cosmetics.

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For operators of cosmetics trading centers, organizers of exhibitions/fairs and lessor of counters, they shall examine the business qualification of participating traders, manage and periodically inspect them, and immediately stop and report their activities not in compliance with this regulation.

Operators of online cosmetic transaction platforms are obligated to register the real names of participating cosmetic traders, and examine their permits. Overall, online platforms operators shall manage such online participating traders, monitor their activities and report wrongdoings and in serious

circumstances, shall suspend their online services.

The regulation also makes it clear that barber shops, beauty saloons and hotels that provide cosmetics to their customers are considered cosmetics traders under the draft regulation.

V. Labeling & Advertising

The regulation requires that the label shall be attached on the minimum sale unit of cosmetic products. Labeling shall conform to the industrial standards, regulations and laws, and shall contain true, complete and accurate information.

Imported cosmetic products may directly use labels in Chinese or add Chinese labels on original foreign labels provided that the Chinese version shall be in consistence with the foreign language version.

A label on cosmetic product shall contain information such as name, address of product registrant or filer, name and address of manufacturer and their manufacturing permit, code of certificate of registration for special cosmetics, code of industrial standard, all ingredients, expiration date, net content, instructions and warnings and other information as required by law.

With regard to advertising, there is only one clause to the effect that advertisements shall be true and legal, and shall in no means allege or hint any medical effect and shall not contain false and misrepresentation information to cheat and mislead consumers.

VI. Supervision and Administration

The NMPA and its local counterparts/offices are empowered to take various actions and measures against unlawful activities such as issuing prompt letter, warning letter, ordering rectification within prescribed time limit, call for admonition talk, publishing safety warning message, ordering recall of products, ordering suspension of production, importing and trading.

When they conduct actual inspections, they have the power to do the following: entering business premises for on-site inspection, sampling inspection, checking and copying contracts, invoices and accounting books and other materials, sealing up and impound raw materials and products that may be hazardous to human health, or equipment and facilities that is *prima facie* used for illegal manufacturing and trading or shut down the business premises on which illegal activities are engaged.

According to this draft regulation, China will establish a system to monitor cosmetic adverse reaction, and a monitoring agency will be set up for collecting, analyzing and evaluating adverse reaction data, and propose actions to deal with the same.

The new regulation also requires that product registrants or filers, and cosmetic traders shall actively monitor their own products that are sold on market. In the meantime, medical institutions are obligated to report possible adverse reaction associated with cosmetics.

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On top of adverse reaction monitoring, China will set up an overall cosmetic safety risk monitoring and assessment system, monitoring and assessing factors affecting cosmetic qualify and safety, providing scientific basis for sampling inspection, formulating risk-control measures and relevant laws,regulations and policies in relation to cosmetic qualify safety.

VII. Penalties and Liabilities

Compared to penalties and liabilities under old regulations, the new regulation dramatically increases penalties and liabilities, raising the cost of law breakings.

Through my prior work for a cosmetic raw materials supplier, i have learned that international cosmetic ingredient suppliers are spearheading Chinese market and because of the old stringent rules, some of them are walking a tightrope disguising their unlisted ingredient in the name of one that is on the list of already used ingredients.

Article 55 of the draft regulation provides that in one of the following circumstances, NMPA and its local counterparts may sequester illegal gains, raw materials, packaging materials, equipment and facilities that are used for illegal manufacturing and trading of cosmetics, and in the meantime impose a fine of RMB 50,000 – 100,000 if the value of goods in question is not up to RMB 10,000, or a fine of 10 to 20 times the value of goods in question if such value is more than RMB 10,000 (inclusive); in a serious case, may revoke relevant permits, halt importing and trading of products of such perpetrators, and won't entertain application for cosmetic permits from such perpetrators for the ensuing 10 years; in the case of illegal activities by corporate entities, the person in direct charge shall receive a fine of RMB 20,000 to 100,000, and such entities shall not engage in cosmetic manufacturing and trading for the ensuing 10 years following the NMPA decision:

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(1) manufacturing cosmetics without permit;

(2) manufacturing or importing special cosmetics that have not been properly registered;

(3) using prohibited raw materials, failing to comply with compulsory standards of raw materials, use novel ingredient that should have been registered, or adding substances that could cause harm to human health.

There are a number of other specific clauses addressing other illegal activities with penalties and liabilities of various degrees.

We believe the new regulation will clean up the messes in the industry and will prompt and spur the whole industry to a higher level of development, something good for serious international and domestic market players.

Apparently, these harsh penalties will have a great impact on the industry with many small manufacturers and traders feeling pinched or doomed. A new wave of mergers and acquisitions in China cosmetic industry is on the horizon, the inevitable way of upgrading the whole industry.

Date Created
February 2020
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