13 June 2019

National Medical Products Administration
No. 26 Xuanwumenxi Dajie
Building No. 2
Xicheng District
Beijing, P.R. China
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Dear Sir/Madam

re: Commentary on Regulations for Notification of Non-special Cosmetics (Draft)

The Cosmetic, Toiletry and Fragrance Association (CTFA) represents over 80% of cosmetic companies in South Africa. These range from small to medium enterprise local companies up to and including major multi-national cosmetic manufacturers. Some of the industry members import and export products internationally.

As South Africa is part of a global community, we are in support of China's move towards international convergence of cosmetic regulation in terms of recognition of safety assessments and industry responsibility, which will facilitate the promotion of safe products for local consumers, local cosmetic industry and international trade. We therefore believe that proposed draft regulations should be encompassing of international best practice. As such, the cosmetic industry has developed comments that highlight best practice.

Through our 25 years of interaction with international trade associations and regulators, we have learnt that the regulatory control of manufacturing quality is managed very differently across the world, depending on the respective administrative setup and regulatory model in place. Based on this, we have consolidated the comments below on the draft regulations for Notification of "Non-Special-Purpose Cosmetics Recordation Administration Measures", issued on 27 May by the National Medical Products Administration of China (NMPA) for public comments.

SPECIFIC COMMENTS ON THE PROPOSED DRAFT REGULATION

Article 11

It is not possible for all countries' health authorities to issue quality management certificates, for various reasons. For instance, in South Africa there is a lack of a defined structure for cosmetic regulation enforcement as well as resources to handle cosmetic product regulations. However, it is a requirement that a facility manufacturing cosmetic products in South Africa provide proof of compliance to GMP. In order to ensure compliance to this proposed requirement in the draft

regulation it is important to recognise such national differences and consider alternatives that would be acceptable to the NMPA.
We thus propose, for your consideration, the following workable options as alternatives to the issuing authorities for the required certification:

- Regulatory certificates issued by any level of administration (state, provincial, municipal, etc.)
- Certificates issued by organisations, such as trade associations, that are recognised or authorised by regulators
- Certificates issued by organisations that are recognised by relevant international standards organisations such as International Standards Organisation

Safety-assessment based exemption from toxicology testing

The draft Regulation excludes products for children or infants and products with new ingredients from the possibility of waiving animal testing requirements. Baby care products are regarded as "high-risk" product in most parts of the world due to the vulnerable target market that these products are aimed at. It is on this premise that international practice includes the safety assessment of baby products. New ingredients require safety assessment to understand the potential risk that they may pose to consumers in finished products. In both these cases, the product safety assessment can be adapted to address specific questions and needs for these products. Furthermore, there is no scientific justification to exclude these products from a safety assessment approach.

The draft regulations provide for notification before placing a product on the market, however there is a requirement to justify safety of the products using the new non-animal test methods. The accreditation of laboratories to offer such testing is onerous. For this reason, we propose that a certificate of Good Manufacturing Practice and Certificate of Free Sale be accepted as alternatives. This is not unique as countries like Taiwan have implemented an exemption for toxicology and microbiological testing of products manufactured in facilities that hold a GMP certificate.

As the industry association in South Africa, CTFA has overseen the self-regulatory system for cosmetics for 25 years. Our industry members are committed to the continued development of safe, innovative and efficacious products both for the local market as well as for products destined for export.

Conclusion

We extend our gratitude to the National Medical Products Administration of China for affording the cosmetic industry of South Africa the opportunity to comment on the proposed draft regulation.

We would like to re-iterate that our comments and proposals are based mainly on our experience as an industry that has self-regulated for the past 25 years as well as expert opinion on local and

international cosmetic industry best practice. We anticipate that these comments will receive due consideration in the finalisation of the regulation that will be enacted.

The CTFA remains available to answer further questions and provide detailed interpretation of our comments.

Yours Sincerely,



Adelia Pimentel
CTFA Executive Director



Dershana Valla
CTFA Head: Policy & Regulatory Affairs