Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 MAY 2018

FDA CIRCULAR No. 2018-007

TO : **ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

SUBJECT : **Reiteration on the Classification of Cuticle Tints Containing Benzalkonium Chloride With Antiseptic, Antibacterial or Disinfectant Claim as Household Remedy**

Cuticle tints are cosmetic products intended to give the nails a healthy appearance. It is usually applied as part of the manicure process after manually cleaning the nails with cuticle remover and nail pusher. Post-market surveillance (PMS) conducted on cuticle tints showed that these products are notified with the Center for Cosmetics Regulation and Research (CCRR) as cosmetic and are marketed with an antiseptic / antibacterial / disinfectant claims printed on the product labels, claims which are permitted as a secondary minor function of cosmetic under the ASEAN Cosmetic Directive (ACD) Appendix III – ASEAN Cosmetic Claim Guidelines. However, when the manner of application is taken into consideration, uncertainty in the correct product classification of these products becomes evident. On the one hand, cuticle tints are cosmetic even with the secondary minor antibacterial / antiseptic / disinfectant claims. On the other, the manual process of cleaning the nails has a high probability of causing trauma to the intact skin, thus, the application of the product is no longer on an intact skin but a broken one.

Under the current drug regulation, benzalkonium chloride is allowed as an active ingredient in antiseptic/disinfectant products as well as a microbial preservative in pharmaceutical preparations to kill or inhibit the growth of microorganisms to prolong the product's shelf life or maintain the product's sterility. Pursuant to Republic Act (RA) No. 9711 or the "Food and Drug Administration Act of 2009," drug products are "*(1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories.*" Moreover, Administrative Order (AO) No. 117 s. 1992 "Providing for the Classification of Household Remedies" defines household remedy as "*any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments which may be*

dispensed without a medical prescription in original packages, bottles or containers, the nomenclature of which has been duly approved by BFAD in the process of registration."

According to RA 9711 and ACD, cosmetic product, on the other hand, refers to "*any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or, protecting them or keeping them in good condition.*" Furthermore, ACD Appendix III, while stating that a cosmetic product may have a secondary minor function, also provides that cosmetic products must not be presented as having properties for treating and/or preventing a disease. Hence, in one of the previous ASEAN Cosmetic Committee (ACC) Meeting and its related events, the ASEAN Member States (AMS) agreed that though antimicrobial leave-on products may be considered as a cosmetic, its application to broken skin (i.e. wound cleansing) is not permitted.

Considering all pertinent drug and cosmetic regulations, it is, therefore, determined and reiterated that cuticle tints containing benzalkonium chloride with antiseptic / antibacterial / disinfectant claims are classified as HOUSEHOLD REMEDY regardless of whether the antiseptic / antibacterial / disinfectant claim is a primary or a secondary one. However, this does not preclude companies from manufacturing, distributing, importing, exporting, selling, offering for sale, transferring, promoting and advertising cuticle tints as a cosmetic product provided that (1) the product is compliant with the ACD, its ingredient annexes and appendices, and (2) in case the product contains benzalkonium chloride, its sole function is as a microbial preservative and no claims of antiseptic / antibacterial / disinfectant is made.

In view of the foregoing, establishments intending to manufacture, distribute, import, export, sell, offer for sale, transfer, promote and advertise cuticle tints containing benzalkonium chloride with antiseptic / antibacterial / disinfectant claims are instructed to secure the appropriate authorizations from the Center for Drug Regulation and Research (CDRR) following its existing rules and regulations.

For cuticle tints containing benzalkonium chloride with antiseptic / antibacterial / disinfectant claims which are previously notified with CCRR and are already available in the Philippine market, a transition period is provided with the following conditions:

1. The transition period shall start upon the signing of this circular and shall end on 30 June 2021 after which all valid notifications for these products shall be automatically cancelled.

2. Products that are notified with CCRR shall be allowed to be marketed as cosmetic products until the end of the transition period.

3. Product labels reflecting (a) antiseptic / antibacterial / disinfectant claims, or (b) a product name which includes the words "benzalkonium chloride" thereby implying

the presence of an active ingredient shall be allowed to be used until its exhaustion or until the end of the transition period, whichever comes first.

4. The transition period shall be used by establishments manufacturing, distributing, importing, exporting, selling, offering for sale, transferring, promoting and advertising these products to apply for a License to Operate (LTO) as Drug Establishment and a Certificate of Product Registration (CPR) from CDRR before the end of the transition period.

5. All products found in the market after the given transition period with no authorizations (LTO and CPR) from CDRR shall be considered as without the appropriate market authorization and shall be subjected to seizure, in accordance with existing laws, rules and regulations.

Dissemination of the information to all concerned is requested.

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