Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 JUL 2016

FDA CIRCULAR No. 2016-009

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

SUBJECT : **Reiteration on the Classification of Diaper Rash Creams / Lotions / Ointments / Powders and Other Products Containing Zinc Oxide**

I. BACKGROUND

Diaper rash, also known as diaper dermatitis, napkin dermatitis, napkin rash, and nappy rash, is a form of skin irritation or inflammation manifesting as an erythematous rash on an infant's skin covered by diapers. This results from prolonged or extended contact of the skin with urine, feces, moisture or friction. Prevention and treatment include products containing zinc oxide which forms an occlusive barrier between the infant's skin and the likely cause of the diaper rash.

Republic Act No. 9711, otherwise known as "Food and Drug Administration (FDA) Act of 2009" defines drugs as

> *"(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."*

Furthermore, Administrative Order (A.O.) No. 117 s. 1992 entitled "Providing for the Classification of Household Remedies" classifies zinc oxide as one of the household remedies under the jurisdiction of FDA and 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."

On the other hand, the ASEAN Cosmetic Directive (ACD) adopted and implemented by virtue of A.O. No. 2005-0015 and A.O. No. 2005-0025 respectively, in turn defines a cosmetic product as:

"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."

ACD Appendix III – ASEAN Cosmetic Claim Guideline also states that a cosmetic product shall not be presented as treating or preventing disease in human beings.

Considering that zinc oxide in these products functions as a protectant, it is therefore being reiterated that diaper rash creams / lotions / ointments / powders and other such products containing zinc oxide intended to protect, soothe, moisturize, prevent and treat diaper rash are not classified as cosmetic products but as household remedies under the Center for Drug Regulation and Research (CDRR).

II. DETAILS

Companies intending to manufacture, distribute, import, export, sell, offer for sale, transfer, promote and advertise these products are hereby advised to secure authorizations in the form of License to Operate (LTO) as Drug Establishment and Certificate of Product Registration (CPR) from CDRR following its existing rules and regulations.

For products previously notified with Center for Cosmetics Regulation and Research (CCRR) and are already available in the Philippine market, a transition period shall be provided which shall have the following conditions:

1. The transition period shall start upon signing of this circular and shall end on the 31st day of December 2017.

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

3. The transition period shall be used by companies manufacturing, distributing, importing, exporting, selling, offering for sale, transferring, promoting and advertising these products to apply for a LTO as Drug Establishment and CPR from CDRR before the end of the transition period.

4. All products found in the market after the given transition period with no authorizations (LTO and CPR) from CDRR 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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