Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

04 August 2014

FDA Advisory
No. 2014-061

SUBJECT: CERTIFICATES OF GENERAL ACCEPTABILITY OR SAFETY

The Food and Drug Administration as the national health regulatory agency grants authorizations to establishments engaged in manufacturing and distributing of health products. Republic Act number 9711 identifies cosmetics[1] and household hazardous substances[2] to be within the Agency's jurisdiction. Products once registered with the Agency are granted the authority to be advertised, promoted, offered for sale, sold, distributed or used. A certificate of product registration or product notification is issued to the owner (the entity assuming primary responsibility for the quality, safety and efficacy) of the product to prove compliance with national health regulations. The Agency issues no other authorization to the same effect with regards to cosmetics and household/ urban hazardous substances.

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[1] Section 9 of Republic Act no. 9711 amending Section 10 of Republic Act no. 3720 defines 'Cosmetics' to be "any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition."

[2] Section 9 of Republic Act no. 9711 amending Section 10 of Republic Act no. 3720 defines "Household/ Urban Hazardous Substance' to be "(1) Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, or substances intended for use as fuels, coolants, refrigerants and the like; (2) Any substance which the FDA finds to be under the categories enumerated in clause (1) of this paragraph; (3) Any ,by or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard; and (4) This term shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph(1) of this section, by reason of bearing or containing such harmful substances described therein."

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No certificates indicating general acceptability or assurance of safety is issued by the Food and Drug Administration.

Market authorizations are granted to establishments with the understanding that the owners are assuring their products are compliant to current standards, and that they have appropriate systems in place to enable timely and sufficient intervention should adverse events arise from consumption or inadvertent exposure to a product. As an agency with a law enforcement mandate, entities are presumed to be compliant until proven otherwise. Thus the FDA is enhancing post-market approval surveillance activities to afford greater public confidence on top of the pre-approval evaluation.

Product owners (market authorization holders) are reminded of their responsibility to enable complete recalls, to conduct their own vigilance activities to ensure detection of adverse events related to exposure to their products, and to inform the agency of any concern over quality, safety and efficacy.

For more information and inquiries, email us at info@fda.gov.ph

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