

Republic of the Philippines DEPARTMENT OF HEALTH BUREAU OF FOOD AND DRUGS Filinvest Corporate City Alabang, Muntinlupa City

October 23, 1998

BUREAU CIRCULAR No. 07 s. 1998

TO : ALL COSMETIC MANUFACTURERS AND TRADERS, AND

PARTIES CONCERNED

SUBJECT: ADOPTION OF THE GUIDING PRINCIPLES FOR GOOD

MANUFACTURING PRACTICE (GMP) GUIDELINES IN THE

MANUFACTURE OF COSMETIC PRODUCTS

The BFAD hereby adopts the Guiding Principles for GMP Guidelines in the Manufacture of Cosmetic Products adopted and approved by the Joint BFAD-Cosmetic Industry Study Group (JBCISG) in its meeting on September 8, 1998. The same principles would serve as the basic considerations for the guidelines in GMP for the manufacture of cosmetic products which will then be the basic condition for the licensing of cosmetic manufacturers.

The guiding principles and resolution of the JBCISG adopting said guiding principles is hereto attached as Annex "A" and considered as an integral part of this circular.

(Sgd) QUINTIN L. KINTANAR, M.D., Ph.D., CESO I
Director

Date Signed: November 5, 1998

JOINT BFAD-COSMETIC INDUSTRY STUDY GROUP RESOLUTION

WHEREAS, the Joint BFAD-Cosmetic Industry Study Group ("the group"), composed of representatives of the Bureau of Food and Drugs and manufacturers of cosmetic products, recognizes that cosmetic products that are available in the local market need to be safe, of good quality and able to deliver their claimed benefits in order to protect the interest and promote the well-being of consumers.

WHEREAS, to better ensure the attainment of the above objectives, there is a need to formulate specific GMP guidelines for the manufacture, sale and distribution of cosmetic products.

WHEREAS, presently, in the licensing of manufacturers of cosmetic products and their manufacturing, marketing and distribution operations, BFAD uses the GMP guidelines for pharmaceutical products;

WHEREFORE, the above premises considered:

BE IT RESOLVED BY THE JOINT BFAD-COSMETIC INDUSTRY STUDY GROUP, AS IT IS HEREBY RESOLVED, to adopt the following guiding principles in the formulation of Good Manufacturing Practice (GMP) guidelines for cosmetic products.

GUIDING PRINCIPLES FOR COSMETIC GMP

First. <u>Consumers.</u> The best interest of the consumers is the topmost priority of all sectors in the cosmetic industry. Their needs must be met, in terms of product quality, safety and delivery of claimed benefits. They must be assured that the products they use are safe under expected, recommended and customary conditions of use, as well as under reasonably foreseeable conditions of misuse. They must be provided with truthful and adequate information about the products being sold in the market. A product profile must be made available to them.

Second. <u>Cosmetic Manufacturers</u>. Cosmetic manufacturers are ultimately responsible for the overall value of the products they produce and made available to the public. As such, they must have the proper systems and controls to ensure that the products are consistently manufactured according to specified quality, safety, performance and claimed benefits. In addition, product dossiers must be available in the manufacturer's place for easy inspection and verification by regulatory bodies.

Third. <u>Government Agencies</u>. Government agencies associated with, and responsible for, cosmetic products are essential in the assurance of product safety, quality and delivery of claimed benefits of the same. They can effectively serve this mandate by ensuring that the manufacturing facilities of cosmetics meet the established and recognized GMP standards and by actively monitoring the products from the point of manufacture to the marketplace. They have the authority to implement and enforce the rules and regulations concerning cosmetics.

Fourth. <u>Traders/Distributors</u>. Traders and distributors are equally liable for the quality of cosmetic products they market and make available to consumers. They must have the necessary procedures and measures to ensure delivery of safe and quality products to trade. Their systems and controls on product traceability and proper warehousing should be in place. In addition, product dossiers must be available in the marketer's place of business for easy inspection or verification by the regulatory bodies and the consumers.

Fifth. <u>ASEAN/Global Standards</u>. National standards in the Cosmetic Industry must be aligned with the regulations of other ASEAN countries and the global community,

consistent with the recognition of cultural, political and religious diversities. Exchange of information shall be encouraged with a view towards harmonization.

Sixth. <u>Industry-related Professional Organizations</u>. Professional organizations related to the cosmetics industry should serve as resource for scientific, technical and trade knowledge, and should be fora for exchange of information. They should regularly convene and discuss latest trends and issues on cosmetics and cascade learnings to all sectors concerned.

Adopted this 8th day of September, 1998 at BFAD Conference Room, Alabang, Muntinlupa City, MM.

MEMBERS OF JBCISG PRESENT:

Ms. Ofelia M. Alba		-	BFAD
Atty. Lorna Frances E. Filipino	-	BFAD	
Ms. Alice T. Lorenzo		-	BFAD
Ms. Marle B. Koffa		-	BFAD
Ms. Cathy B. Hizo		-	BFAD
Ms. Luzviminda O. Marquez		-	BFAD
Ms. Rizalina A. Opinion		-	BFAD
Mr. A. Vallejos		-	CCIP
Ms. Carole E. Lopena		-	CCIP
Ms. Poly L. Malacad		-	CCIP
Ms. Zeny B. Soriano		-	CPPI, PSCS
Atty. Junie Lutian			- P&GP
Ms. Ampie Carpio			- P&GP
Ms. Tess B. Keil			- PSCS
Ms. Rosalina D. Nolasco		-	Swiss Pharma
Ms. Sothie G. Jordan		_	Swiss Pharma

Ms. Ofelia M. Malagkit J&J

Unilever, PRC CPPI

Ms. Jing G. Garcia
Ms. Ruben S. Javier CPPI Ms. Rosanna A. Robles