[BFAD BUREAU CIRCULAR NO. 13, S. 2005, June 22, 2004]

SUBMISSION OF SITE INFORMATION FILE (SIF)

In the advent of implementation of the Cosmetics Directive and to facilitate the evaluation and inspection of cosmetic manufacturers' compliance to current Good Manufacturing Practice (cGMP) and other related regulations, you are hereby directed to submit your current site information file (SIF) on or before September 30, 2005.

The purpose of the SIF is to guide regulatory inspectors in assessing manufacturer's compliance with Good Manufacturing Practices and to assure cosmetic products safety. Inspection and licensing of cosmetic manufacturing facilities on the basis of compliance with GMP are crucial elements of cosmetic control.

A Site Information File (SIF) is a document prepared by the manufacturer containing specific and factual information about the production and/or control of cosmetic manufacturing operations carried out at the site and any closely integrated operations at adjacent and nearby buildings. If only part of a cosmetic operation is carried out on the site, the site master file need describe only those operations, e.g. analysis, packaging.

A site information file should be concise and must not exceed 25 pages in A4 size paper excluding annexes. (see attached format)*

Cosmetic manufacturers with changes in their previously submitted SIF must prepare the necessary amendments thereto and submit the same to Regulation Division II on or before the above stated date.

For your information and guidance.

Adopted: 22 June 2004

(SGD.) PROF. LETICIA BARBARA B. GUTIERREZ, M.S.
Director IV

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* Text Available at Office of the National Administrative Register, U.P. Law Complex, Diliman, Quezon City.