



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, City of Muntinlupa
PHILIPPINES



22 June 2004

BUREAU CIRCULAR

No. 13 s. 2005

TO : ALL COSMETIC MANUFACTURERS
SUBJECT : 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.


PROF. LETICIA BARBARA B. GUTIERREZ, M.S.
Director IV

SITE INFORMATION FILE (COSMETIC LABORATORY)

1 GENERAL INFORMATION:

- 1.1 Brief information on the firm (include, Name and Address, telephone numbers, fax number, e-mail address, if applicable);
- 1.2 Describe your quality policy/credo, if any
- 1.3 License
- 1.4 Other licenses
- 1.5 Types of Cosmetic products manufactured in the site, and information about specifically toxic or hazardous substances handled, monitoring the way they are manufactured (e.g., in dedicated facilities or on a campaign basis)
- 1.6 Any other, (than Cosmetic products), manufacturing activities carried out on the site, e.g. pharmaceutical, veterinary, household hazardous substances

Indicate the type of actual products manufactured.

- 1.7 Indicate the names and addresses of clients, if applicable and services offered
- 1.8 Short description of the site.

In not more than one page, include:

- The location and immediate environment (e.g. residential, commercial, industrial, identify nearby industries)
 - The size of the site (in sq. m.)
 - Types of buildings
- 1.9 Number of employees in the following:
 - Production
 - Quality assurance or quality control
 - Storage and distribution
 - Technical and engineering support services
 - 1.10 Use of outside services or technical assistance
 - Name and address of the company

- Telephone number
- Fax number

2. SPECIFIC INFORMATION:

The following are the major topics to be included:

2 PERSONNEL

- 2.1 Organization chart, showing the arrangements for quality assurance, including production and quality control
 - Organogram for quality assurance including productions and quality control record, senior managers and supervisor
- 2.2 Qualifications, experience and responsibilities of key personnel
 - Brief details of academe qualifications and work related qualifications and years relevant experience since qualifying.
- 2.3 Outline of arrangements for basic and in-service training and how records are maintained
 - Describe how training needs are identified and by whom
 - Give details of training relative to GMP requirements.
 - State the form of training, e.g. in-house, external and how practical experience is gained and which staff are involved.
 - Explain how the effectiveness of the training is assessed e.g. by questionnaires.
 - Give brief details of records kept.
- 2.4 Personnel hygiene requirements, including clothing
 - Are there suitable washing, changing and rest areas?
 - Is the clothing suitable for the activity undertaken? Briefly describe the clothing.
 - Are there clear instructions on how protective clothing should be used and when it should be changed?
 - Is in-house or external laundry used?

3. PREMISES AND EQUIPMENT:

Premises:

- 3.1 Simple plan or description of manufacturing areas with dimensions.
 - Provide floor plan identifying each area with corresponding dimensions; include support systems, if any.
- 3.2 Nature of construction and finishes; include all processing and critical storage areas.
- 3.3 Equipment. Brief description of major productions and control laboratory equipment (List of equipment)
 - Maintenance - a description of planned preventative maintenance programmes and recording system.
 - Who is responsible for maintenance and servicing?
 - Are there written procedures and contractual details for outside work?
 - Are records kept for the type and frequency of service check, details of service repairs and modifications?
 - Are reports made known to the users?
- 3.4 Qualification and calibration, including the recording system.
 - Briefly describe the company's general policy and records kept.
- 3.5 Cleaning and sanitation procedures for manufacturing areas and equipment.
- 3.6 Pest Control Measures

4. DOCUMENTATION

Noted: This section refers to all documentation used in manufacture. Manufacture involves all activities relating to the production and control of cosmetic products.

- 4.1 Arrangements for the preparation, revision, and distribution of necessary documentation for manufacture, e.g. batch records, SOP's.
 - Is there a description of the documentation system?
 - Who is responsible for the preparation, revision and distribution of documents?
 - Where are the master documents stored?

- Is there a standard format and instructions of how documents are to be prepared?

Are there documents for:

- Product Process specifications
- Raw Material specifications
- Packaging component specification
- Standard process instructions including packaging
- Batch records including packaging
- Analytical methods
- QA release procedures

- How is the documentation controlled?
- For how long are documents kept after the release of the batch?

4.2 Any other documentation related to product quality, that is not mentioned elsewhere, e.g. microbiological controls on air and water.

- Equipment specification
- Standard operating procedures
- Quality Control Procedures
- Training procedures
- Computer program specifications (if applicable)
- Documentation control of process deviations.
- Calibration and test documents
- Validation documents
- Reconciliation of batches of raw materials, major packaging components i.e. product-contact and printed materials.
- List and briefly explain the use of any additional standard documentation used routinely.

4.3 Batch numbering system

5. PRODUCTION:

5.1 Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters.

5.2 Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage.

- Identification of supplier's lot number with the company's lot number
- Sampling plan
- Labeling e.g. by using labels or by computer
- Issue of materials to manufacture and package
- In-process checks

- How are materials being used for manufacture identified and release?

5.3 Packing

- Release of bulk, semi-finished products, packaging materials
- Confirmation of identity and line clearance checks
- In-process checks

5.4 Quarantine and release of finished products

5.5 Arrangements for the handling of rejected materials & products

- Are reject materials & products clearly labeled?
- Are they stored separately in restricted areas?
- Describe arrangements for sentencing the materials and their disposal. Is destruction recorded?

6. QUALITY CONTROL:

6.1 Description of the quality control system and the activities of the quality control department,

- Briefly describe the activities of analytical testing, packaging component testing, biological & microbiological testing.
- If the review of batch documentation and release of final documentation takes place in the department: give details.
- Outline the involvement in the arrangements for the preparation, revision and distribution of documents in particular those for specification test methods and release criteria if not mentioned elsewhere

7. CONTRACT MANUFACTURING AND/OR ANALYSIS

7.1 Description of the way in which the GMP compliance of the contract manufacturer is assessed.

7.2 Are there written agreements with all contract acceptors, specifying GMP responsibilities.

8. DISTRIBUTION / COMPLAINTS & PRODUCT RECALL

8.1 Arrangements and recording system for distribution.

- Is the warehouse secure?
- Is it environmentally controlled?

- Is there refrigerated storage? (cool room)
- How are the materials stored e.g. pallet racking?
- How is the status of products controlled e.g. by computer, by label?
- What are the methods of distribution to customers?
- Does the dispatch order ensure first in first out and identify the lot number?

8.2 Arrangements for handling complaints and products recalls

8.2.1 Complaints

- Is there a written complaint procedure?
- Who is responsible for:
 - Logging
 - Classifying
 - Investigating complaints
- Are written reports prepared?
- Who reviews those reports?
- For how long are complaints' records kept?

8.2.2 Product Recalls

- Is there a written procedure which describes the sequence of actions to be followed including?
 - Retrieval of distribution data:
 - Notification of customers:
 - Receipt segregation inspection of returned products:
 - Investigation/reporting of cause;
 - Reporting corrective action
- Who is responsible for coordinating product recalls?
- Who notifies BFAD of the complaints
- Is BFAD involved in complaints & decision to recall?

9. SELF INSPECTION :

9.1 Short description of the self inspection system

- Describe how the self-inspection system verifies that those activities that have a bearing on quality comply with the planned arrangements.
- Are there documented procedure for the self inspection system and for the follow up actions?
- Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found.