Effective Date: 2ND July 2018
Review Date: 1ST July 2020

National Agency for Food & Drug Administration & Control (NAFDAC)
Drug Evaluation & Research (DER) Directorate

GUIDELINES FOR PRODUCTION INSPECTION OF LARGE AND MEDIUM SCALE COSMETICS MANUFACTURING FACILITIES

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1. GENERAL

1.1 These requirements are for the interest of individuals intending to engage in manufacturing of cosmetics and related products in Nigeria.

1.2 This prescribes the minimum Good Manufacturing practice (GMP) requirements for the facilities and controls to be used in the manufacture of these products to ensure quality and safety.

1.3 It also prescribes the requirements for conducting a Production Inspection of the cosmetics manufacturing facility

1.4 It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

1.5 A regulated product should not be manufactured in Nigeria unless the facility has been inspected.

1.6 Cosmetics and related products may include Hair products, makeup products, disposable wipes, Fragrance, Laundry products, Household products, Soaps, Creams, Lotions, jellies, Nail products etc.

1.7 All required documents as stated below must be available for review while photocopies of documents listed in 6.1-8 will be required for submission.

2. APPLICATION FOR INSPECTION

2.1. An application for Production Inspection should be made on the company's letter-headed paper and addressed to:

The Director-General, National Agency for Food and Drug Administration and Control (NAFDAC),

ATTENTION: Director, Drug Evaluation & Research Directorate, NAFDAC Office Complex, Apapa-Oshodi Expressway. Isolo, Lagos. The exact location address (NOT P.O. Box) of the factory, functional e-mail address, telephone number(s) and product(s) intended for registration (including the pack sizes) should be stated.

2.2. The application letter should be submitted to The Director, Drug Evaluation & Research Directorate; 1st Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos) with the following supporting documents:

2.2.1. Evidence of company incorporation with CAC

2.2.2. Evidence of acceptance of product trademark by Trademarks Registry.

2.2.3. Artwork of product labels.

2.3. The applicant should follow the below-listed steps to make payment for the inspection:

2.3.1. Collect a payment advice for the inspection from the Drug Evaluation & Research (DER) Directorate; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Express Way Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

2.3.2. Visit **www.remita.net** to generate a Remita invoice and print out a copy of the invoice.

2.3.3. Visit the nearest commercial bank to make the payment.

2.4. The applicant should collect an official receipt of payment from the Finance & Accounts Section; 3rd Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

3. SCHEDULING OF FACILITY FOR INSPECTION

3.1 Upon submission of evidence of payment to DER Directorate, the facility is scheduled for inspection at the earliest convenient date.

4. GOOD MANUFACTURING PRACTICE REQUIREMENTS

4.1 Please refer to the NAFDAC Good Manufacturing Practice for Cosmetics Products Guidelines 2018 for full guidance. The guidelines are available at www.nafdac.gov.ng

5. DOCUMENTATION

The following documents should be made available during the inspection

5.1 Product labels should be in English language and should contain the following:

5.1.1 Name of product
5.1.2 Net weight/volume
5.1.3 Batch Number
5.1.4 Manufacturing Date
5.1.5 Expiry Date
5.1.6 Provision for NAFDAC REG. NO
5.1.7 List of ingredients
5.1.8 Exact factory location address (Not P.O. Box)
5.1.9 Directions for use
5.1.10 Storage conditions
5.1.11 Cautions (where necessary)

5.2 Company Organogram
5.3 Certificate of analysis of all raw materials and finished product(s)
5.4 Certificate of analysis of raw and treated water.
5.5 Personnel File Records (Letter of Appointment and Acceptance of offer, certificates, job description, training records)
5.6 Standard Operating Procedure (SOP) for Production
5.7 Batch Formulation of the Product
5.8 SOP for Quality Control Checks
5.9 SOP for Cleaning of Equipment and Factory Premises
5.10 SOP for water treatment (where applicable)
5.11 SOP for Product Distribution and Recall
5.12 SOP Line clearance for facility producing multiple products
5.13 List of Production Facilities/Quality Control with their sources of purchase
5.14 Medical certificate of fitness for production staff
5.15 List of raw materials and their sources
5.16 List of production equipment and sources

5.17 Certificate of fumigation of the facility

6. DISTRIBUTION SYSTEM

6.1 Records of product distribution network must be properly kept for easy recall of defective products.

6.2 Distributors names, addresses, telephone numbers, email addresses, quantity of products issued, batch numbers, dates of manufacture and expiry should be maintained.

7. TRANSPORTATION AND HANDLING

7.1 Products should be handled and transported under conditions which prevent deterioration, contamination, spoilage and breakage to ensure that the product quality is maintained up to the time of delivery to the consumer.

8. TARIFF

8.1 Please to refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng

8.2 All fees attract 5% VAT.

9. CORRESPONDENCE

All correspondence should be addressed to:

The Director-General (NAFDAC)

Attn: The Director,

Drug Evaluation & Research Directorate

1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway Isolo, Lagos State.

NAFDAC website: www.nafdac.gov.ng

E-mail address: der.headquarters@nafdac.gov.ng

Telephone Number: