NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)
DRUG EVALUATION & RESEARCH DIRECTORATE

GUIDELINES FOR INSPECTION OF MICRO SCALE COSMETICS, HERBAL AND HOUSEHOLD PRODUCTS FACILITIES IN NIGERIA

NAFDAC/DER/MSFI/17/00

1. GENERAL

1.1 These guidelines are for the interest of the general public and in particular individuals intending to engage in manufacturing of cosmetics and household products on a micro scale in Nigeria.

1.2 Organizations that qualify to operate this scheme should be engaged in the manufacture of **not more than five (5) products from only one of the product classes approved for this scheme**.

1.3 These guidelines prescribe the minimum Good Manufacturing practice (GMP) requirements for the facilities and controls to be used in the manufacture of products approved for this scheme to ensure quality and safety of the products.

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 and a Certificate of Recognition as a manufacturer is issued by NAFDAC.

1.6 Only products in the below-listed product classes can be manufactured under this scheme:

1.6.1 **Cosmetics**

1.6.1.1 Petroleum jelly

1.6.1.2 Shea butter

1.6.1.3 Hair cream (Oil based)

1.6.1.4 Oils (e.g. Coconut oil)

1.6.1.5 Soaps (Laundry, Toilet, Multipurpose, Liquid)

1.6.2 Household Products

1.6.2.1 Liquid air freshener

1.6.2.2 Laundry starch

1.6.2.3 Disinfectants for use on inanimate surfaces (e.g. Chlorhexidine Solution, Chloroxylenol Solution, Phenolic Disinfectants etc.)

1.6.3 Herbal Medicines

2. APPLICATION FOR INSPECTION

2.1 An application for inspection should be made to the Director, (Drug Evaluation & Research). The applicant should provide their exact location address (NOT P.O. Box), functional e-mail address and telephone number(s) with the following supporting documents.

2.1.1 Evidence of business registration or company incorporation
2.1.2 Evidence of acceptance of product trademark by Trademarks Registry
2.1.3 Artwork of product label(s).

2.2 **Note:** Payment Advice is issued to the applicant upon submission of a satisfactory application. The applicant is expected to make payment and submit a photocopy of receipt of payment for inspection and laboratory analysis before being scheduled for inspection.

GOOD MANUFACTURING PRACTICE REQUIREMENTS

3. PERSONNEL

3.1 There should be a personnel strength of not more than five (5) staff.
3.2 Persons in charge of production in a micro-scale enterprise for the manufacture of cosmetics/herbal medicines/household products should have a minimum of Ordinary National Diploma in a relevant science discipline or provide evidence of registration with the Traditional Medicine Board (for herbal medicines) and requisite experience.
3.3 Personnel should wear protective apparel/gears, such as head, face, hand and arm coverings to protect the products from contamination.
3.4 Personnel should practice good sanitation and hygiene practices.
3.5 Personnel should undergo medical examination at least once a year.
3.6 Personnel who have direct contact with the product and are known to be suffering from communicable diseases or with wounds should be excluded from duty until they are certified medically fit.

4. BUILDING/FACILITIES

4.1 The building should provide for segregated production areas, storage areas and cloak rooms.
4.2 The production facility should have adequate space to ensure free flow of the production process without external interference, proper storage of raw and packaging materials as well as finished products.
4.3 The rooms should be adequate for the orderly placement of equipment and materials to prevent mix-ups between different categories of materials.
4.4 Windows and entrance doors should be screened with insect-proof netting and the doors should be self-closing to prevent contamination.
4.5 Adequate ventilation and lighting should be provided.
4.6 The facility should be kept clean at all times.
4.7 Raw materials and, packaging materials and finished products should be stored on pallets or shelves.
4.8 Access into the facility should be controlled.

5. EQUIPMENT

5.1 The equipment must be cleanable, nonreactive, non-leaching, non-absorptive and non-adsorptive.

5.2 The water treatment plant for water-based products must be adequate to consistently produce de-ionized water (for cosmetics and germicides) and potable water (for herbal medicines) of the required physical, chemical and microbiological quality.

5.3 Equipment should be washed and dried before and after use.

6. RAW/PACKAGING MATERIALS AND SOURCES

6.1 Raw and packaging materials should be purchased form traceable sources.

6.2 They should be of good quality and standards.

6.3 All materials should be stored under appropriate storage conditions.

7. ENVIRONMENTAL SANITATION

7.1 Waste should be disposed in an appropriate and sanitary manner.

7.2 Fumigation of the facility should be carried out quarterly.

7.3 Water system toilets and hand washing facilities should be appropriately located away from the production area and kept clean.

7.4 Eating, drinking and smoking should not permitted in the production area.

8. DOCUMENTATION

The following documents should be made available during the inspection:

8.1.1 Standard Operating Procedure (SOP) for Production

8.1.2 SOP for Quality Control

8.1.3 SOP for Cleaning of Equipment and Premises

8.1.4 SOP for water treatment (where applicable)

8.1.5 SOP for Product Distribution and Recall

8.1.6 Certificate of analysis of treated water and finished products

8.1.7 Batch Formulation

8.1.8 Batch Manufacturing Records

8.1.9 Toxicological Report of Finished Product (for herbal medicines)

8.1.10 Medical certificate of fitness for production staff

8.1.11 List of raw materials and their sources

8.1.12 List of production equipment

8.1.13 Certificate of fumigation of the facility

8.1.14 Personnel File (Education certificates, training and experience records)

8.1.15 Product label/artwork

9. DISTRIBUTION SYSTEM

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

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

10. TRANSPORTATION AND HANDLING

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.

11. LABEL

11.1 A micro scale operator has to comply with the applicable labelling regulations of the Agency.

11.2 Products should be labelled adequately in English language and should contain the following:

11.2.1 Name of product

11.2.2 Net weight/volume

11.2.3 Batch Number

11.2.4 Manufacturing Date

11.2.5 Expiry date

11.2.6 Provision for NAFDAC REG. NO

11.2.7 List of ingredients (Quantitative list of all ingredients by their botanical or common names for herbal medicines)

11.2.8 Exact factory location address (Not P.O. Box)

11.2.9 Directions for use

11.2.10 Storage conditions

11.2.11 Cautions (where necessary)

11.2.12 For herbal medicines, the following additional requirements apply to the product labels:

11.2.12.1 Disclaimer stating that the product claims have not been evaluated by NAFDAC

11.2.12.2 Herbal medicines and nutraceuticals may be accompanied by a product information leaflet which should have relevant information on the description of the product, indications, contraindications, usage, dosage and administration, adverse reactions, precautions, toxicology and storage conditions.

All correspondence should be addressed to:

The Director,
Drug Evaluation & Research Directorate
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