National Agency for Food & Drug Administration & Control (NAFDAC)

Food Registration & Regulatory Affairs (FR & RA) Directorate

GUIDELINES FOR CHANGE IN FORMULATION OF FOOD AND FEED PRODUCTS

1. **General**

1.1. These guidelines are for the interest of the general public and in particular, manufacturers of local and imported food and feed products.

1.2. It is necessary to emphasize that, no regulated food and feed product shall be manufactured, in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

1.3. Change in Formulation (Food Reformulation) is the process of altering the processing or composition of a food or beverage product,

a. to improve its nutritional profile and,

b. to increase, reduce, remove or replace its content of ingredients or nutrients of concern while maintaining taste, flavour and characteristics of the product.

2. **Application**

2.1. A written application for Change in Formulation of Food and Feed product(s) should be made on the company's letter head to the Director-General (NAFDAC), ATTENTION: The Director, Food Registration and Regulatory Affairs (FR & RA) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, Lagos State.

2.2. An online application form for change in food and feed formulation shall be purchased, completed and submitted at https://www.napams.org

2.3. A separate application form shall be submitted for each product.

3. **Labelling Information**

3.1. Labelling should be informative, accurate and in conformance with the Agency's Food Labelling Regulations and the International Code of Marketing of Breastmilk Substitutes Regulations (Control of Marketing of Breastmilk Substitutes) and any other relevant Regulations, as applicable.

Step I

4. **Documentation**

4.1. The application letter stating the purpose and justification for the Change in formulation (Reformulation).

4.2. Evidence of Business Incorporation.

4.3. Current and proposed Batch formulations

4.4. Evidence of product registration.

4.5. Evidence of payment.

4.6. Contract Manufacturing Agreement (where applicable).

4.7. Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be done in the name of the owner of the Trademark/Brand name, as the case may be.

4.8. Current and proposed Product Labels/artworks.

4.9. Comprehensive Certificates of Analysis for current and proposed formulations.

Step II

5. **Product Approval Meeting**

5.1. Upon satisfactory documents review, GMP inspection and laboratory analysis reports, products are presented for Approval Meetings.

5.2. Products not approved at approval meeting are issued compliance directives.

Step III

6. **Issuance of Notification of Approval**

6.1. For products approved at the meeting, a notification of product approval is issued to the applicant.

7. **Tariff**

7.1. Please refer to NAFDAC tariff at www.nafdac.gov.ng

8. **Note**

8.1. Failure to comply with these requirements may result in the disqualification of the application or delay in processing of the application.

8.2. Approval for change in formulation does not automatically confer advertisement permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised.

8.3. Failure to respond to compliance directives within 90 working days will automatically lead to the closure of the Application. Please note that the clock stops once compliance directives are issued.

8.4. The time line for processing applications for change in formulation from submissions to approval is ninety (90) working days.

8.5. Change in formulation approval does not in anyway affect the validity of the product license and elapse when the product license expires.

All correspondences should be addressed to: -

Director-General (NAFDAC),
Attn: The Director
Food Registration and Regulatory Affairs Directorate,
National Agency for Food and Drug Administration and Control (NAFDAC),
Ground Floor, NAFDAC Office Complex
Isolo Industrial Estate
Apapa-Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng
E-mail: food.registration@nafdac.gov.ng
Telephone no.:

All submissions should be made at www.napams.org