INTELLECTUAL PROPERTY	OVERVIEW OF PRODUCT REGISTRATION AND OTHER INCIDENTAL MATTERS AT THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

FREQUENTLY ASKED QUESTIONS

What is NAFDAC?

NAFDAC refers to the National Agency for Food and Drug Administration and Control which is the government regulatory agency charged with the mandate of regulating and controlling the manufacture, importation, exportation, distribution, advertisement, sale and use of certain products referred to as "**Regulated Products**".

What products need to be registered with NAFDAC?

"**Regulated Products**" include foods, drugs, cosmetics, medical devices, packaged water, chemicals, detergents.

Therefore, before any of the "Regulated Products" can be bought, manufactured, sold and distributed into the Nigerian market, it must have been registered with NAFDAC.

Can a foreign manufacturer of any of the Regulated Products apply directly to NAFDAC?

No, it cannot. Foreign Manufacturers ("**FMs**") are required to register their products through Nigerian entities /persons, in whose name the product registration will be issued. FMs usually achieve this through the following methods:

a. Incorporation of local subsidiaries in Nigeria for the purpose of registering their products with the NAFDAC;

b. Appointment of an already existing Nigerian company (such as their local distributor) as their local agents in Nigeria; or

c. The use of B&I's Shelf Entity, which is duly registered with the Corporate Affairs Commission and other applicable agencies in Nigeria. Its business is to provide custodial services to FMs who do not

want to appoint their local distributors as their local representative and also do not want to go through the inconvenience of incorporating a company in Nigeria solely for the purpose of holding their product registration. **The Shelf Entity which bears its own corporate costs, holds the NAFDAC registrations and will apply for Notice of No Objections to enable distributors import your products into the Nigerian market.** However, please note that Terms & Conditions apply.

How long is the NAFDAC product registration process?

According to the official NAFDAC website, the registration process can be completed within 90 working days from the date of acceptance of the application for food products, and 120 working days for drug products.
However, please note that this may take longer in practice, taking into consideration the bureaucratic delays/ objections that often arise.

What documents are required for registration?

The following documents are required to register a product with NAFDAC:

1. Power of attorney ("**PoA**") granted to a Nigerian representative **or** an agreement between the manufacturer and the Nigerian agent empowering the Nigerian agent to register the product(s) in Nigeria;

2. Certificate of Manufacture and Free Sale;

3. Comprehensive Certificate of Analysis;

4. Certificate of Incorporation of the Nigerian agent/ representative with the Corporate Affairs Commission;

5. Certificate of Registration (or Notice of Acceptance) or Renewal Certificate (where applicable) of the brand name/trade mark with the Trade Marks Registry;

6. Invitation letter written by the manufacturer addressed to NAFDAC, requesting for the inspection of the manufacturer's factory;

7. Application letter for Import Permit by the Nigerian agent/ representative (where applicable);

8. Adequate number of samples of the product;

9. Samples of the labels of each product which contain relevant information such as the list of ingredients, batch number of the products issued by NAFDAC, date marking instructions etc.;

10. Evidence to support any special labeling claims regarding the character, quality and safety of the product; and

11. A declaration to be made before a notary public by the Nigerian agent/ representative in Nigeria confirming that the information and documents submitted to NAFDAC are authentic.

***Documents listed are based on the current regulatory requirements which may change without prior notice, based on NAFDAC Regulations and may be product specific.**

What is the procedure for product registration?

The procedure can be broken down into the following stages:

- Submission of Application;
- Document Verification;
- Facility Inspection/ Sampling;
- Laboratory Analysis;
- Final Vetting;
- Approval Meeting; and
- Issuance of NAFDAC Registration Number/ Certificate of Registration.

Can you give the estimated costs for product registration?

The estimated costs for product registration would be dependent on the type of products to be registered and are typically indicated on the NAFDAC website (For example, Food, Drinks Drugs, Medical devices etc.)

How long is a NAFDAC product registration certificate valid for?

5 (Five) years. This may be renewed for subsequent periods of 5 (Five) years each.

How do I transfer ownership of product registration?

An application will need to be made to NAFDAC, which is usually a Letter of Notification from the manufacturer to NAFDAC informing it of the transfer of the product, revocation of former PoA (if applicable) and introduction of the new owner of the product. This will be supported by additional documents such as:

- PoA issued from the new owner to its representative;
- Copy of Product Registration Certificate; and
- Evidence of assignment of the trademark.

Please note that further documents will be required where there is a change in manufacturing facility.

How do I terminate a relationship with a local representative?

The appointment of a Nigerian representative can be terminated by:

1. Revocation of the PoA issued to the local representative (if applicable); and
2. According to the terms agreed by the parties in their initial agreement.

After registration, can I change the product label?

Yes, you can. However, any change in the product label of a NAFDAC regulated product will require a notification to NAFDAC, which may require the submission of the revised labelling information to NAFDAC to ensure compliance with its labelling requirements.

What is the difference between pack size, variance and primary packaging material of a product?

Pack size is the standard full-case quantity of units for each product. Furthermore, pack size extension is the introduction of new net contents into already registered products through the original packages or in new primary packages.

Variation, however, is any administrative or substantive change to the details of a registered product, which is subject to acceptance by NAFDAC prior to implementation.

Primary packaging material ("**PPM**") is any packaging material that comes in direct contact with the registered product. Therefore, additional packaging material includes: (i) **secondary packaging material** (the material in which the PPM is enclosed); and (ii) **tertiary packaging material** (the outer carton where multiples of saleable units of the registered product are packed for distribution).

Please note that any change in the primary package of a registered product requiring a pack size extension will have to undergo a laboratory evaluation by NAFDAC to ensure the product quality is not compromised.

Can I register products myself without going through an agent?

Only FMs are required to apply through a Nigerian agent. A Nigerian person/entity is not required to use an agent to register with NAFDAC.

Is there an expedited process?

No, there is not. NAFDAC's product registration process includes a cumbersome vetting process that takes about 90 working days from the date of acceptance of the application for food products, and 120 working days for drug products (barring all bureaucratic delays or objections raised by NAFDAC) to ensure that all approved products meet the minimum health and safety standard for public use.

What is Good Manufacturing Practice?

Good Manufacturing Practice ("**GMP**") is a quality assurance practice that ensures the Regulated Products are consistently manufactured and controlled to the quality appropriate for its intended use. Therefore, NAFDAC has stipulated the minimum standards of GMP that manufacturers are required to comply with to ensure the quality of the Regulated Products.

Will NAFDAC inspect the factory where my products are manufactured before registering my products?

Yes, it will. Part of NAFDAC's mandate is to undertake appropriate investigations into production premises and establish the relevant quality assurance systems to certify such premises. Therefore, an application is usually made by the manufacturer to the Director-General, NAFDAC during the registration process, requesting for a facility inspection.

Does NAFDAC have any new reform agenda regarding NAFDAC regulated products?

Yes, it does. NAFDAC has recently integrated its e-Permit for NAFDAC regulated products with e-Form 'M' on the Nigeria Trade Portal for products with non-overlapping HS Codes with the Standards Organization of Nigeria (SON). HS Codes are a set of numerical symbols, adopted by the World Customs Organization, for the classification of all goods in international trade. What this means is that only digital forms of NAFDAC Permits shall be used for the processing of import transactions in respect of regulated products. Accordingly, the integrated e-Permits and e-Form 'M' shall thenceforth be required for import processing on the Nigeria Trade Portal. This exercise commenced on September 9, 2019.

For further information on the registration of your products with NAFDAC, kindly contact our **Intellectual Property and Technology Practice Group** at ipgroup@banwo-ighodalo.com

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