IMPLEMENTATION OF RECENT CHANGES AT NAFDAC: NEW LABELING REQUIREMENT FOR ALCOHOLIC BEVERAGES, TARIFF ADJUSTMENT, AND RISK VERIFICATION OF PRODUCTS

Product Registration Newsletter from Jackson, Etti & Edu.

The National Agency for Food and Drug Administration and Control ('NAFDAC') made some important changes regarding product registration last year. These changes are now being fully implemented, hence the need for manufacturers of regulated products to take necessary steps towards compliance.

The changes include:

1. Additional labeling requirement for alcoholic beverages
2. Tariff adjustment
3. Risk verification

A. Additional Labelling Requirement for Alcoholic Beverages

NAFDAC issued additional labeling requirements for alcoholic products. Hence, all labels of alcoholic beverages must include the following additional information:

a. Mode of Alcohol Declaration – The alcoholic declaration on all labels must be expressed in this format: number/percentage sign/alc/vol (E.g "40%Alc./Vol.")
b. Inscription of the phrase "Drink Responsibly"
c. Age restriction "18+" – should be written in white font shaded in a red circle
d. Pregnant woman warning
e. Recycling symbol

Consequent upon the above, labels of alcoholic products must now include the following information:

1. The general information about the product – product name and description, manufacturer's details (full name and address of the manufacturer,etc)

2. Ingredients - including the net content of the product (weight/volume)
3. Batch Number
4. Production date
5. Expiry date (if any) 6. "NAFDAC REG NO.:"
7. Alcohol Declaration (E.g "40%Alc./Vol.")
8. "Drink Responsiby"
9. Age restriction "18+"
10. Storage condition
11. Direction for use (where applicable)
12. Pregnant woman warning
13. Adequate warnings (where applicable)
14. Recycling symbol 15. The quantity of the product should be written either in cl or ml and not both. (E.g "70cl" or "700ml" and not "70cl/700ml)
16. The information on the label should be written or interpreted in English
17. The label must be informative, clear and accurate.

B. Tariff Adjustment

NAFDAC made certain adjustments to its tariff for the registration of all classes of regulated products. The new NAFDAC tariff for imported product

S/N	CATEGORY	OLD TARIFF (USD)	NEW TARIFF (USD)
1.	Food (Imported Class 1 i.e. products that can be manufactured in Nigeria)	3,443.00	1,350.00
2.	Food (Imported Class 2 i.e products with no existing manufactur)	3,443.00	1,252.00
3.	Cosmetics	3,443.00	1,252.00
4.	Chemical	900.23	972.00
5.	Pharmaceutical (OTC)	4,426.00	967.00
6.	Pharmaceutical (POM1)	1,106.56	1,280.00
7.	Pharmaceutical (POM2)	1,106.56	1,200.00
8.	GMP Inspection	N/A	10,989.01
9.	GMP Inspection (for already inspected Facility or renewal)	N/A	5000.00
9.	Renewal (Imported Food Class 1)	1,467.56	1,080.00
10.	Renewal (Imported Food Class 2)	1,467.56	1,001.60
11.	Pharmaceutical (OTC)	1,956.76	773.60
12.	Pharmaceutical (POM1)	815.31	1024.00
13.	Pharmaceutical (POM2)	815.31	960.00
14.	**Penalty for unregistered product (per product)**	**2,201.35**	**13,888.89**

The old tariff was inclusive of both registration cost and the cost of Good Manufacturing Practice ("GMP") Inspection. Currently, the cost for GMP inspection has been separated in the new tariff. Hence, the cumulative effect of the new tariff is that the registration cost across all categories of imported products has now increased by about 358.38%

C. Risk Verification

Over the years, GMP inspection has led to incessant delays in the registration process, due to the lack of capacity by NAFDAC to attend to numerous applications.

As a stop-gap measure to the capacity challenge, NAFDAC commenced the risk categorization of products to determine the necessity for GMP inspection before registration of products. The applicant is required to submit a risk categorisation form. After risk assessment by NAFDAC, products with low-risk are then considered for registration prior to the conduct of GMP inspection.

In determining the risk verification of the products, NAFDAC will consider the following:

1. The country of manufacture;
2. Whether the Facility has been inspected by NAFDAC Previously?;
3. Whether the Facility has been inspected previously by any relevant Government Regulatory Body (within the country of product origin) in the last two (2) Years?;
4. Whether the Facility has been inspected previously by any relevant/recognised foreign Government Regulatory Body in the last two (2) Years?;
5. Whether the Facility has been certified by any Accredited Certification Body?; and
6. Whether there has been any incident of product recall by the manufacturer in the last (2) two years?

Applicants who can provide evidence of Facility inspection by one or more agencies listed above would be recommended for registration prior to Facility inspection. In order words, applicants who have certificate(s) of Facility inspection from.

NAFDAC, ISO, FDA, HALAL, etc would be considered to NAFDAC registration without NAFDAC officials inspecting the Facility pre-registration. However, the inspection of the Facility will be carried out post-registration.

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