

DOCUMENT TITLE: REGULATORY DIRECTIVE ON REVISED REGISTRATION TIMELINES FOR DRUG PRODUCTS, FOOD PRODUCTS, VACCINES, BIOLOGICS, AND MEDICAL DEVICES		
DOC. REF. NO.: NAFDAC-RDRT-038-00	EFFECTIVE DATE: 01/05/2025	REVIEW DUE DATE: 30/04/2030



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

REGULATORY DIRECTIVE ON REVISED REGISTRATION TIMELINES FOR DRUG PRODUCTS, FOOD PRODUCTS, VACCINES, BIOLOGICS, AND MEDICAL DEVICES

1.0 Purpose:

This regulatory directive establishes revised registration timelines for Drug Products, Food Products, Vaccines, Biologics, and Medical Devices within NAFDAC. The purpose of this directive is to align registration timelines with operational realities, improve efficiency, and ensure timely processing of applications while maintaining regulatory standards. The revised timelines are based on a comprehensive review of historical data, operational challenges, and stakeholder feedback.

2.0 Scope:

This directive applies to all new, renewal, and variation applications for the following categories of products regulated by NAFDAC:

1. Drug Products
2. Food Products
3. Vaccines
4. Biologics
5. Medical Devices

3.0 Directive Details:

1. Drug Products, Vaccines, Biologics, and Medical Devices:

- **Current Timeline:** 120 working days
- **Revised Timeline:** 240 working days

2. Food Products:

- **Current Timeline:** 90 working days
- **Revised Timeline:**
- Micro, Small, and Medium Enterprises (MSMEs): 120 working days
- Other Food Categories: 180 working days

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4.0 Implementation:

This Directive takes effect immediately. All new, renewal, and variation applications submitted after the effective date will be processed according to the revised timelines. Marketing Authorization Holders (MAHs) and applicants are expected to comply with the new timelines.

Approved By:
Director-General (NAFDAC)
Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature: 

Date: 1/5/2025