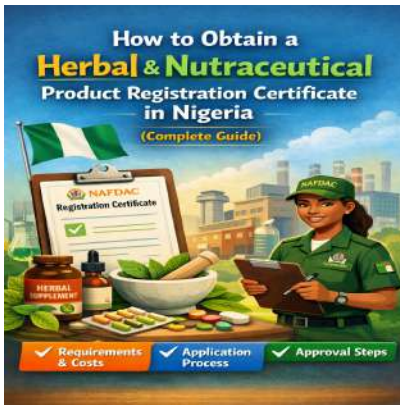




How to Obtain a Herbal & Nutraceutical Product Registration Certificate in Nigeria (Complete Guide)

Description

Herbal medicines and nutraceuticals are among the fastest-growing product categories in Nigeria's health and wellness market. However, before any herbal medicine, dietary supplement, or nutraceutical product can legally be **manufactured, imported, advertised, distributed, or sold in Nigeria**, it must first be registered with the **National Agency for Food and Drug Administration and Control (NAFDAC)**.

This regulatory requirement exists to ensure that products consumed by the public are **safe, effective, properly labeled, and manufactured according to quality standards**.

If you intend to launch a herbal product, nutraceutical supplement, or traditional medicine in Nigeria, understanding the **registration process, costs, documentation, and compliance requirements** is critical to avoid delays, rejection, or regulatory penalties.

This comprehensive guide explains:

- What herbal and nutraceutical registration means in Nigeria
- The legal requirements from NAFDAC guidelines

- Step-by-step procedures for obtaining the certificate
- Required documents and application process
- Government fees and estimated costs
- Timelines and regulatory expectations
- Frequently asked questions from entrepreneurs

This article is based entirely on **official NAFDAC regulatory guidance and tariffs**.

What is a Herbal & Nutraceutical Product Registration Certificate?

A **Herbal & Nutraceutical Product Registration Certificate** is an official approval issued by NAFDAC confirming that a herbal medicine or dietary supplement **meets regulatory standards and is authorised for sale in Nigeria**.

The certificate typically includes:

- Product name
- Manufacturer details
- NAFDAC Registration Number
- Product category
- Registration validity period

Once approved, the product can legally be marketed across Nigeria.

According to NAFDAC regulations:

No herbal medicine or related product may be manufactured, imported, distributed, advertised, or sold in Nigeria without registration.

What Are Herbal Medicines and Nutraceuticals?

NAFDAC classifies these products under the **Drug Evaluation and Research Directorate (DER)**.

Herbal Medicine

Products derived from plants used for **therapeutic or medicinal purposes**.

Examples include:

- Herbal malaria remedies
- Traditional herbal mixtures
- Medicinal teas

Nutraceuticals / Dietary Supplements

Products used to **supplement the diet and promote health**.

Examples include:

- Vitamin supplements

- Herbal capsules
- Mineral tablets
- Dietary herbal extracts

These products must meet **NAFDAC safety and labeling requirements** before market entry.

Why Herbal Products Must Be Registered in Nigeria

The registration system protects public health and ensures product quality.

Key regulatory objectives include:

Purpose	Explanation
Consumer safety	Prevents harmful or contaminated products
Quality control	Ensures standardised manufacturing practices
Proper labeling	Prevents misleading claims
Post-market monitoring	Enables NAFDAC to monitor product safety

Registration also gives businesses legal protection and credibility.

Government Authority Responsible for Herbal Product Registration

In Nigeria, the regulatory authority responsible for herbal medicine and nutraceutical product registration is:

National Agency for Food and Drug Administration and Control

NAFDAC regulates:

- Herbal medicines
- Nutraceuticals / dietary supplements
- Pharmaceuticals
- Food products
- Cosmetics
- Medical devices

Applicants must submit their registration application through the **Drug Registration & Regulatory Affairs Directorate**.

Legal Basis for Herbal Product Registration

The regulation of herbal medicines in Nigeria is governed by:

- **NAFDAC Herbal Medicines and Related Products Registration Regulations**
- **Guidelines for Registration of Herbal Medicines and Dietary Supplements Made in Nigeria**
- **NAFDAC Tariff Regulations**

These regulations apply to all herbal products manufactured or sold in Nigeria.

Requirements for Herbal & Nutraceutical Product Registration

Before applying, the applicant must satisfy several eligibility conditions.

1. Business Registration

The applicant must have a registered business entity such as:

- Limited Liability Company
- Business Name
- Partnership

The business must be registered with the **Corporate Affairs Commission**.

2. Trademark Registration

A registered trademark protects the brand name and helps NAFDAC verify product ownership.

Required documentation may include:

- Trademark certificate
 - Trademark application acknowledgment
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3. Manufacturing Facility Compliance

Manufacturers must meet **Good Manufacturing Practice (GMP)** standards.

NAFDAC may inspect:

- Local manufacturing facilities
- Foreign manufacturing plants

4. Product Formulation Documentation

Applicants must submit detailed product formulation information including:

- Active ingredients
- Botanical names
- Concentrations
- Manufacturing process

5. Product Label and Packaging

Labeling must follow NAFDAC requirements.

Labels must include:

- Product name

- Manufacturer address
- Batch number
- Manufacturing and expiry dates
- Storage instructions
- Dosage instructions

Documents Required for Herbal Product Registration

Applicants must submit a comprehensive documentation package.

Document	Description
Application Letter	Formal request addressed to NAFDAC
Completed Registration Form	Purchased and filled online
Certificate of Incorporation	Proof of company registration
Trademark Certificate	Brand ownership verification
Certificate of Analysis	Laboratory analysis report
Product Label Artwork	Final label design
Product Formulation	Ingredient details
Power of Attorney (for imports)	Authorisation from manufacturer
Manufacturer License	Evidence of manufacturing approval
GMP Certificate	Manufacturing compliance

Supporting documents must be submitted alongside the application.

Step-by-Step Process to Obtain Herbal & Nutraceutical Product Registration in Nigeria

Below is the standard process based on NAFDAC regulatory procedures.

Step 1: Purchase and Complete the Online Application Form

Applicants must first **purchase the product registration form online** through the NAFDAC portal.

The form must be properly completed with:

- Company information
- Product details
- Manufacturing information

NAFDAC guidelines require applicants to purchase and complete the form before submission.

Step 2: Submit Application and Required Documents

After completing the form, applicants submit:

- Application letter
- Completed registration form
- Supporting documentation

NAFDAC will review the documentation for completeness.

Step 3: Payment of Applicable Fees

Applicants must pay the required **product registration and processing fees**.

The fees depend on:

- Product type
 - Local or imported product
 - Scale of manufacturing
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Step 4: Product Vetting and Sample Submission

Applicants may be requested to submit **product samples** for vetting.

Typical requirements include:

- Labeled product samples
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- Certificate of analysis
 - Import permit (for foreign products)

NAFDAC will issue an acknowledgment upon receipt of samples.

Step 5: Laboratory Analysis

Product samples are subjected to **laboratory testing** to confirm:

- Safety
- Quality
- Ingredient composition

NAFDAC laboratories conduct the analysis independently.

Step 6: Facility Inspection

NAFDAC may inspect the manufacturing facility to verify:

- Good Manufacturing Practices (GMP)
 - Hygiene standards
 - Production procedures
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Step 7: Approval and Issuance of Registration Certificate

Once all requirements are satisfied:

- The product is approved
- A **NAFDAC registration number** is issued
- The product is entered into the national registry

The registration certificate is typically **valid for five years**.

Cost of Herbal & Nutraceutical Product Registration in Nigeria

The cost varies depending on product origin and scale.

NAFDAC Official Tariff

Category	Cost
Full registration (per product)	approx. \$1,252
Listing	approx. \$612

These fees are derived from NAFDAC tariff schedules.

Estimated Additional Costs

Service	Estimated Fee
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Laboratory analysis ₦54,000 – ₦135,000

Facility inspection ₦15,000 – ₦40,000

GMP certificate approx. ₦20,000

These costs depend on product scale and inspection requirements.

Estimated Timeline for Herbal Product Registration

The total timeline depends on documentation accuracy and compliance.

Stage	Timeline
Document review	10 – 20 days
Facility inspection	10 – 30 days
Laboratory testing	20 – 40 days
Final approval	30 – 60 days

Total estimated duration: **up to 120 working days.**

Key Compliance Requirements After Registration

Obtaining the certificate is not the end of regulatory compliance.

Companies must:

- Maintain GMP standards
- Ensure proper labeling

- Report adverse reactions
- Renew the certificate when due

Common Reasons Herbal Product Registration Applications Fail

Many applications are delayed or rejected because of:

1. Incomplete Documentation

Missing documents can delay approval.

2. Non-Compliant Labels

Incorrect label information violates NAFDAC rules.

3. Poor Manufacturing Standards

Facilities that fail GMP inspections may face rejection.

4. Failed Laboratory Tests

Products failing safety tests must be reformulated.

Common Misconceptions About NAFDAC Herbal Registration

Misconception 1: Herbal Products Do Not Require Approval

Many entrepreneurs believe herbal products are not regulated.

In reality, **all herbal medicines must be registered before sale.**

Misconception 2: NAFDAC Registration Is Only for Imported Products

Both **locally manufactured and imported herbal products require registration.**

Misconception 3: One Application Covers Multiple Products

NAFDAC requires **separate registration for each product.**

Benefits of Obtaining Herbal Product Registration

Businesses that register their products gain several advantages.

Legal Market Access

Products can be sold in supermarkets, pharmacies, and online platforms.

Consumer Trust

Customers trust products bearing a NAFDAC number.

Export Opportunities

Registration facilitates regional and international trade.

Frequently Asked Questions (FAQs)

How long does NAFDAC herbal product registration take?

The process typically takes **up to 120 working days**, depending on documentation accuracy and compliance with regulatory requirements.

Can I sell herbal products without NAFDAC approval?

No. Herbal medicines cannot be manufactured, imported, distributed, or sold without NAFDAC registration.

Can a foreign company register herbal products in Nigeria?

Foreign manufacturers must appoint a **Nigerian company as their local agent** to register the product with NAFDAC.

Is product testing conducted abroad acceptable?

NAFDAC conducts its own laboratory analysis during the registration process.

How long is the NAFDAC certificate valid?

The certificate of registration is **valid for five years and renewable**.

Can the registration certificate be transferred?

No. The certificate belongs to the registered product owner and cannot be transferred without NAFDAC approval.

Expert Tips to Speed Up Herbal Product Registration

Businesses can reduce delays by:

- Preparing complete documentation before submission
- Ensuring product labels meet regulatory standards
- Conducting pre-submission laboratory testing
- Ensuring GMP compliance

Final Thoughts

Registering herbal and nutraceutical products in Nigeria is a **mandatory regulatory requirement designed to protect public health and ensure product quality**.

Although the process involves several stages; documentation review, laboratory testing, facility inspection, and regulatory approval, businesses that understand the requirements and follow NAFDAC guidelines can successfully obtain certification.

With the increasing demand for herbal medicine and nutraceutical products in Nigeria, obtaining a **NAFDAC Herbal & Nutraceutical Product Registration Certificate** is not just a legal requirement, it is also a strategic step toward building a credible and sustainable health product brand.

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