



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

DRUG REGISTRATION & REGULATORY AFFAIRS (DR&R) DIRECTORATE

GUIDANCE TO APPLICANTS FOR REGISTRATION OF HERBAL MEDICINES MADE IN NIGERIA

This guidance outlines NAFDAC's requirement for registration of herbal medicines made in Nigeria.

1) REGISTRATION GUIDANCE

- a) Product
- b) Documentation

2) LABEL GUIDANCE

3) NAPAMS

1) REGISTRATION GUIDANCE : This include the type of product and dosage forms that can be registered.

a) Product:

- i. Natural or traditional medicines registered as herbal medicines are health products that come directly from natural sources such as plants, animals, natural minerals, algae, fungi and so on.
- ii. Dosage forms that can be registered under herbal medicines include: capsule, tablet, mixture, liquid, cream, balm, tinctures, oral liquids with alcoholic content not more than 5%.
- iii. Dosage forms that cannot be registered under Herbal medicines include: eye drops, ear drops, parenterals, narcotics and oral herbal products for vulnerable groups (pregnant women, nursing mothers and children less than 5 years) are not recommended except there is an adequate evidence of safety in these groups.

(b) Documentation:

- i. Application letter should be addressed to the Director-General (NAFDAC), Attention: Director, Drug Registration & Regulatory Affairs Directorate
- ii. Certificate of incorporation (Your TIN and RC numbers are needed to register new applicants on the NAPAMS platform)
- iii. Evidence of registration of brand name with Trade mark registry (Certificate of registration of trade mark or Trade mark acceptance letter), class 5
- iv. Coloured artwork and leaflet
- v. Copy of the certificate of analysis and toxicity test report from a government approved/certified public analyst having a signature, stamp, and seal of the analyst, and date of analysis
- vi. [HMTIST](#) (Ctrl click on link to access the Herbal Medicines Technical Information Submission Template). Download template, convert it to word document, fill the asterisked sections, save it as *pdf* document and upload.

2) [LABEL](#) (ctrl click for label guidance on herbal medicines)

3) NAPAMS

To register as a new client

- i. Click <https://registration.nafdac.gov.ng/>
- ii. Click Login
- iii. Click Login as clients
- iv. Click Register as a new client
- v. Fill information on company profile
- vi. Submit

To submit application on NAPAMS

1. Click <https://registration.nafdac.gov.ng/>
2. Click Login
3. Click Login as client and sign in with either TIN for ADMIN or email for staff with password
4. From the dashboard, click applications, choose either (a) New Product Registration- for new registration or (b) Data Capture – for renewal or variation.
5. Fill application form, for marketing category, fill as OTC, while for pharmacological class, fill Herbal remedy.
6. Upload all relevant document.
7. Make payment.
8. Submit application

To respond to compliance directive

- (i) From the dash board, Click – Compliance directive
- (ii) Make the necessary corrections
- (iii) Submit