

DRUG REGULATORY MECHANISM IN NIGERIA

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OUTLINE

- The NAFDAC Act
- Organisational chart
- Requirements for Registration

THE NAFDAC ACT

- NAFDAC was established by decree 15 of 1993 as amended by decree 19 of 1999 and now encapsulated in the NAFDAC Cap N1 Laws of the Federation of Nigeria(LFN)
- This Act empowers the Agency to regulate and control manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, medical devices, detergents and packaged water.

STRUCTURE OF NAFDAC

- There are 9 Directorates, each headed by a Director:
- Registration And Regulatory Affairs
- Establishment Inspection
- Laboratory Services
- Port Inspection
- Enforcement
- Narcotics and Controlled Substances

STRUCTURE CONT.....

- Planning Research and Statistics
- Finance and Accounts
- Administration and Human Resources
- 6 other Units in the DGs office

REGISTRATION PROCEDURE FOR MEDICINES

- Applications/Forms
- Power of Attorney
- COPP
- Invitation For Inspection
- Labelling Requirements
- Trade Mark requirements
- Vetting Samples/samples for registration purposes
- Lab Analyses

REGISTRATION PROCEDURE CONT....

- Certificate of Registration
- Fees
- Time lines for completing registration
- Herbal medicines
- Nutraceuticals
- Biologicals
- Food
- Enquiries.....www.nafdacnigeria.gov.ng