



FOOD, DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) ACT

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FOOD, DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) ACT

An Act to regulate the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs and related products and registration thereof.

[27th January, 1993] [Commencement.]

1. Prohibition of the manufacture, etc., of unregistered processed food, drugs, etc.

- (1) No processed food, drug, drug product, cosmetic, medical device or water shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of this Act or regulations made under it.
- (2) Notwithstanding the provisions of subsection (1) of this section, the National Agency for Food and Drug Administration and Control (in this Act referred to as "the Agency") may grant a permit for the importation or manufacture of a sample of drug, drug product, cosmetic or medical device for the purpose of registration or clinical trial, and the importation or manufacture shall be in accordance with the conditions specified in the permit.

2. Application for registration

- (1) Application for the registration of a processed food, drug, drug product, cosmetic or medical device shall be made in writing to the Agency in such form as the Agency may, from time to time, prescribe and shall-
 - (a) contain the particulars and description of the processed food, drug, drug product, cosmetic or medical device in respect of which the application is made;
 - (b) be accompanied by such fee as the Agency may, from time to time, prescribe.

- (2) The Agency, in considering an application-
- (a) may ask the applicant to supply such other information as it may require to enable it to reach a decision on the application;
 - (b) shall satisfy itself that there is need to have the processed food, drug, drug product, cosmetic or medical device registered in Nigeria.
- (3) Where the Agency is satisfied that there is need to register the processed food, drug, drug product, cosmetic or medical device it shall do so and issue to the applicant a certificate of registration, subject to such conditions as it may deem necessary.
- (4) The registration of a processed food drug, drug product, cosmetic or medical device under this Act shall, unless cancelled earlier, be valid for a period of five years and may be renewed.
- (5) The Agency shall, from time to time, publish a notice in the *Gazette* notifying the registration of a processed food, drug, drug product, cosmetic or medical device under this Act.

3. Disclosure of information supplied by applicant

No person shall disclose an information supplied to the Agency in pursuance of section 2 of this Act except-

- (a) with the written consent of the person who supplied the information; or
- (b) in accordance with the directive of the Agency; or
- (c) for the purpose of a proceeding under this Act.

4. Suspension or cancellation of certificate of registration

- (1) The Agency may suspend or cancel the registration of a processed food, drug, drug product, cosmetic or medical device if-
- (a) the grounds on which the processed food, drug, drug product, cosmetic or medical device was registered were later found to be false or incomplete; or

- (b) the circumstances under which the processed food, drug, drug product, cosmetic or medical device was registered no longer exist; or
 - (c) any of the conditions under which the processed food, drug, drug product, cosmetic or medical device was registered has been contravened; or
 - (d) the standard of quality, safety or efficacy as prescribed in the documentation for registration is not being complied with; or
 - (e) the premises in which the processed food, drug, drug product, cosmetic or medical device or part thereof is manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, assembling or storage of the processed food, drug, drug product, cosmetic or medical device.
- (2) Where the registration of a processed food, drug, drug product, cosmetic or medical device is suspended or cancelled, the Agency shall order the withdrawal from circulation of that processed food, drug, drug product, cosmetic or medical device and shall accordingly cause the suspension, cancellation or withdrawal to be published in the *Gazette*.

5. Clinical trials

- (1) No person shall, in the course of his business-
- (a) import or supply a drug, drug product, cosmetic or medical device; or
 - (b) procure the importation or supply of a drug, drug product, cosmetic or medical device; or (c) procure the manufacture or assembly of a drug, drug product, cosmetic or medical device,

for the purpose of a clinical test, unless he is a holder of a valid clinical trial, certificate and the trial is to be carried out in accordance with the terms of the certificate and the provisions of any regulation in force.

(2) Application for a clinical trial, certificate shall be made to the Agency in such form and manner as the Agency may prescribe by regulations.

6. Offences

- (1) A person who contravenes a provision of this Act or a regulation made under it is guilty of an offence and liable on conviction-
- (a) in the case of an individual, to a fine not exceeding ₦50,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment; and
 - (b) in the case of a body corporate, to a fine not exceeding ₦100,000.

7. Offences by bodies corporate, etc.

Where an offence under this Act is committed by a body corporate or firm or other association of individuals

- (a) every director, manager, secretary or other similar officer of the body corporate; or
- (b) every partner or officer of the firm; or
- (c) every trustee of the body concerned; or
- (d) every person concerned in the management of the affairs of the association; or
- (e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this section,

is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

8. Forfeiture after conviction

- (1) A person convicted of an offence under this Act or regulations made under it shall forfeit to the Federal Government-

- (a) any asset or property constituting, or derived from any proceeds the person obtained, directly or indirectly, as a result of the offence;
 - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this section, "**proceeds**" means any property derived or obtained, directly or indirectly, through the commission of the offence.

9. Jurisdiction

- (1) The Tribunal established under the Special Tribunal (Miscellaneous Offences) Decree 1984, as amended, (in this Act referred to as "the Tribunal") shall have jurisdiction to try offenders under this Act.
- (2) The Tribunal shall have power, notwithstanding anything to the contrary in any other enactment, to impose the penalties provided for in this Act.
- (3) Any part-heard proceeding, relating to a matter for which the Tribunal has jurisdiction, which is pending before any court on the date of the making of this Act shall be continued and completed as if this Act had not been made.
- (4) All new proceedings shall be brought before the Tribunal in accordance with the provisions of the Special Tribunal (Miscellaneous Offences) Decree 1984.
- (5) A person who has been tried and convicted or acquitted for an offence charged under any other enactment shall not be tried a second time for the same offence, notwithstanding that he could be proceeded against in accordance with the provisions of this Act.

10. Forfeited drugs, etc.

Any processed food, drug, drug product, cosmetic, medical device or water seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Minister may, from time to time, determine.

11. Establishment of Food and Drug Registration Committee

- (1) There is hereby established a committee to be known as the Food and Drug Registration Committee (in this Act referred to as "the Committee") which shall consist of a chairman and such number of

other persons as the Agency may deem necessary, who possess the knowledge and experience relevant to this Act.

- (2) The Committee shall-
 - (a) evaluate the formation, method of preparation, packaging, labelling, safety, efficacy and usefulness of food, food products, drugs, drug products, cosmetics or medical devices for which application are made; and
 - (b) advise the Agency as appropriate in respect of those applications and the cancellation, withdrawal or suspension of any registration made in pursuance of the provisions of this Act.
- (3) The Agency shall, on the appointment of the chairman and members of the Committee, specify their tenure of office.
- (4) Subject to this section, the Committee shall determine its quorum and otherwise regulate its own procedure.

12. Regulations

The Governing Council of the Agency may, with the approval of the Minister, make regulations for the purpose of giving effect to the provisions of this Act.

13. Interpretation

In this Act, unless the context otherwise requires -

"Agency" means the National Agency for Food and Drug Administration and Control;

"cosmetic" includes any substance or mixture of substance intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder;

"detergent powder" means a cleansing agent in powder or granulated form used primarily for laundry purposes which-

- (a) contains suitable ionic and non-ionic surface-active agent; and

(b) is produced from either sulphuration of suitable hydrocarbon or the sulphuration of various hydroxyl compounds;

"drug" includes any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof manufactured, sold or advertised for use in-

(a) the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal;

(b) restoring, correcting or modifying organic functions in man or in animal;

(c) disinfection or the control of vermin, insects or pests; or

(d) contraception;

"drug product" means any formulating of a drug;

"food" includes any article manufactured, processed, packaged, sold or advertised for use as food or drink for human consumption, chewing gum and any ingredient which may be mixed with food for any purpose whatever and excludes-

(a) live animals, birds and fish;

(b) articles or substances used as drugs;

"medical device" means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal; **"Minister"** means the Minister charged with the responsibility for matters relating to health.

14. Short title

This Act may be cited as the Food, Drugs and Related Products (Registration, etc.) Act.

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SUBSIDIARY LEGISLATION

No Subsidiary Legislation



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