NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT

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An Act to establish the National Agency for Food and Drug Administration and Control with the functions, among others, to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.

[1993 No. 15.J

[1*st October*, 1992]

[Cornrnencernent.]

PART 1

Establishment of the National Agency for Food and Drug Administration and Control and its Governing Council

1. Establishment of the National Agency for Food and Drug Administration and Control

There is hereby established a body to be known as the National Agency for Food and Drug Administration and Control (in this Act referred to as "the Agency") which-

(a) shall be a body corporate with perpetual succession and a common seal; and

(b) may sue and be sued in its corporate name.

2. Establishment of the Governing Council

(1) There is hereby established for the Agency, a Governing Council which shall consist of-

(a) a chairman who shall be appointed by the President on the recommendation of the Minister;

(b) the Permanent Secretary of the Federal Ministry of Health or his representative;

(c) the Director and Chief Executive of the National Institute for Pharmaceutical Research and Development or his representative;

(d) the Director-General of the Standards Organisation of Nigeria or his representative;

(e) the chairman of the National Drug Law Enforcement Agency or his representative;

(f) the chairman of the Pharmacists Board of Nigeria or his representative;

(g) one person to represent the Pharmaceutical Group of the Manufacturers Association of Nigeria;

(h) one person to represent the Food Beverages Group of the Manufacturers Association of Nigeria;

(i) the Director-General of the Agency; and

(j) three other persons to represent public interest to be appointed by the Minister.

(2) A member of the Council, other than the chairman, shall be appointed by the Minister on the recommendation of the body, if any, he represents.

(3) The members of the Council shall be paid such allowances as the Federal Government may, from time to time, approve.

(4) The provisions of the First Schedule to this Act shall have effect with respect to the proceedings of the Council and the other matters mentioned therein.

[First Schedule.]

3. Tenure of office

(1) A member of the Council appointed, otherwise than by office, shall hold office for a term of four years, and subject to the provisions of subsection (2) of this section, shall be eligible for reappointment for only one further term of four years.

(2) The office of a member of the Council shall become vacant if-

(a) he resigns as a member of the Council by notice in writing under his hand addressed to the Minister; or

(b) the Minister is satisfied that it is not in the interest of the Agency for the person appointed to continue in office and notifies the member in writing to that effect

4. Removal from office of members of the Council

(1) If it appears to the Council that a member of the Council, other than an *ex-officio* member, should be removed from office on the grounds of misconduct or inability to perform the functions of his office, the Council shall make a recommendation to the President

(2) If the President, after making such inquiries as he considers necessary, approves the recommendation, the Minister shall, in writing, declare the office of such a member vacant

(3) Notwithstanding the provisions of subsection (1) of this section, the President may remove any member of the Council if he is satisfied that it is in the public interest so to do.

PART II

Functions and powers

5. Functions of the Agency

The Agency shall have the following functions, that is, to-

(a) regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(b) conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals and their raw materials as well as their production processes in factories and other establishments;

(c) undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, including certificates of the production sites and of the regulated products;

(d) undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, incl uding certification of the production sites and of the regulated products;

(e) compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drug, cosmetics, medical devices, bottled water and chemicals;

(f) undertake the registration of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(g) control the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export;

(h) establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions under this Act;

(*i*) pronounce on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis;

(*j*) undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;

(k) grant authorisation for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances;

(l) collaborate with the National Drug Law Enforcement Agency in measures to eradicate drug abuse in Nigeria;

(m) advise Federal, State and local governments, the private sector and other interested bodies regarding the quality, safety, and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals;

(n) undertake and co-ordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(o) issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(p) compile and publish relevant data resulting from the performance of the functions of the Agency under this Act or from other sources;

(q) sponsor such national and international conferences as it may consider appropriate;

(r) liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency;

(s) determine the suitability or otherwise of medicines, drugs, food products, cosmetics, medical devices or chemicals for human and animal use; and

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(t) carry out such activities as are necessary or expedient for the performance of its functions under this Act.

6. **Functions of the Council**

The Council shall-

(a) advise the Federal Government generally on the national policies on the control and quality specifications of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(b) designate, establish and approve quality specifications in respect of food, drugs, cosmetics, medical devices, bottled water and chemicals, necessary for their certification;

(c) establish the relevant guidelines and measures for quality control of food, drugs, cosmetics, medical devices, bottled water and chemicals in conformity with the Agency's standard specifications;

(d) appoint, promote and discipline employees necessary for the proper discharge of the functions of the Agency;

(e) establish committees as may be expedient which shall be charged with specific functions delegated by the Council;

(j) establish appropriate programmes for the quality, safety and rational use of the food, drugs, cosmetics, medical devices, bottled water and chemicals;

(g) encourage and promote activities related to this process, standard specifications, guidelines on importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(h) utilise and promote the expansion of research, experiments, surveys and studies by public or private agencies, institutions and organisations concerning the quality, safety and use of food, drug, cosmetics, medical devices, bottled water and chemicals and such other matters related to this Act as the Agency may, from time to time, determine as necessary or useful;

(*i*) establish, encourage and promote training programmes for the employees of the Agency and other appropriate persons from public or private organisations; and

(j) carry out such other activities which are connected with its other functions.

7. Powers of the Council

The Council shall have power-

(a) to open and operate ordinary and domiciliary accounts for the Agency in recognised banking institutions in Nigeria;

(b) subject to section 8 of this Act, to specify the management system of the Agency, including financial approval ceilings for officers of the agency;

(c) to enter into agreement with public or private organisations and individuals to develop, utilise, co-ordinate and share such information as is determined to be appropriate by the Council for the performance of its functions under this Act; and

(d) to do such other things as are necessary for the successful performance of its functions under this Act.

PART III

Structure of the Agency

8. **Structure of the Agency**

The Agency shall have-

(a) an Administration and Finance Directorate to be headed by a Director, who shall serve as the secretary of the Agency;

(b) a Planning, Research and Statistics Directorate to be headed by a Director;

(c) a Narcotics and Controlled Substances Directorate to be headed by a Director;

(d) a Regulatory and Registration Directorate to be headed by a Director;

(e) an Inspectorate Directorate to be headed by a Director;

(j) a Laboratory Services Directorate to be headed by a Director; and

(g) such other Directorates as may be required for the proper performance of the functions of the Agency.

PART IV

Staff of the Agency

9. Appointment of Director-General and other staff of the Agency

(1) There shall be appointed for the Agency by the President, on the recommendation of the Minister, a Director-General who shall be a person with good knowledge of pharmacy, food and drugs.

(2) The Director-General shall be-

(a) the chief executive of the Agency;

(b) responsible for the day-to-day administration of the Agency and keep the books and records of the Agency; and

(c) subject to the supervision and control of the chairman and the Council.

(3) The Director-General shall hold office for a period of five years on such terms and conditions as may be specified in his letter of appointment and be eligible for re-appointment for another period of five years.

(4) The Council may, from time to time, appoint such other persons as members of staff of the Agency as it may deem necessary, to assist the Agency in the performance of its functions under this Act.

(5) The members of staff of the Agency appointed under subsection (4) of this section shall be appointed on such terms and conditions of service as the Council may, after consultation with the Federal Civil Service Commissions determine.

(6) The members of staff of the Agency shall be public officers as defined in the Constitution of the Federal Republic of Nigeria, 1999.

[Cap. C23.]

10. Pension

(1) Service in the Agency shall be approved service for the purpose of the Pensions Act and, accordingly, officers and other persons employed in the Agency shall be entitled to pensions, gratuity and other benefits as are prescribed thereunder.

[Cap. P4.]

(2) Notwithstanding the provisions of subsection (1) of this section, the Agency may appoint a person to any office on terms which preclude the grant of a pension, gratuity or other retirement benefits in respect of that office.

power exercisable thereunder by a Minister or other authority of the Government of the Federation, other than the power to make regulations under section 23 thereof, is hereby vested in and shall be exercisable by the Agency and not by any other person or authority.

11. Removal and discipline of senior staff

(1) If it appears to the Council that there are reasons for believing that any person employed as a member of the senior staff of the Agency, other than the Director-General, should be removed from office on grounds of misconduct or inability to perform the functions of his office, the Council shall-

(a) give notice of those reasons to the person concerned;

(b) afford the person an opportunity of making representation on the matter to the Council in person;

(c) if the person concerned or any three members of the Council so request within the period of one month beginning with the date of the notice, make arrangement-

(i) for a committee of the Council to investigate the matter and to report on it to the Council; and

(ii) for the person in question to be afforded an opportunity of appearing before and being heard by the investigating committee on the matter.

(2) If the Council, after considering the report of the investigating committee, is sarisfied that the person in question should be removed as aforesaid, the Council may remove the person concerned by an instrument in writing signed on the direction of the Council.

(3) The Director-General of the Agency may, in a case of misconduct by a member of staff which in the opinion of the Director-General is prejudicial to the interest of the Council, suspend such member of staff and any such suspension shall forthwith be reported to the Council.

(4) For good cause, any member of staff may be suspended from office or his appointment may be terminated by the Council and for the purposes of this subsection, **"good cause"** means-

(a) any physical or mental incapacity which the Council, after obtaining medical advice, considers to render the person concerned unfit for the discharge of the functions of his office; or

(b) conduct of a scandalous or other disgraceful nature which the Council considers to be such as to render the person concerned unfit to continue to hold his office; or

(c) conduct which the Council considers to be such as to constitute failure or inability of the person concerned to discharge the functions of his office or to comply with the terms and condition of his service.

(5) Any person suspended pursuant to this section shall be placed on half pay and the Council shall before the expiration of a period of three months after the date of such suspension consider the case against that person and come to a decision as to-

(a) whether to continue such person's suspension and if so on what terms (including the portion of his emoluments to be paid to him); or

(b) whether to reinstate such person to his office, in which case the Council shall restore his full emoluments to him with effect from the date of the suspension; or

(c) whether to terminate the appointment of the person in question in which case such a person shall not be entitled to the portion of his emolument withheld during the period of the suspension; or

(d) whether to take such lesser disciplinary action against such person (including the restoration of such portion of his emolument that might have been withheld) as the Council may determine.

(6) In any case where the Council, pursuant to this section, decides to continue a person's suspension or decides to take further disciplinary action against a person, the Council shall, before the expiration of a period of three months from such decision, come to a final determination in respect of the case concerning that person.

(7) It shall be the duty of any person who signed the instrument of removal by virtue of this section to serve or cause to be served on the person concerned, a copy of the instrument.

(8) Nothing in the foregoing provisions of this section shall prevent the Council from making such regulations for the discipline of other categories of staff and workers of the Council as it may think fit.

12. Discipline of junior staff

(1) If any junior member of the staff is accused of misconduct or inefficiency, the Director-General may suspend him for not more than three months and forthwith shall direct the matter to the Junior Staff Appointment and Promotion Committee to-

(a) consider the case; and

(b) make recommendation as to the appropriate action to be taken by the Director- General.

(2) In all cases under this section, the junior member of the staff shall be informed in writing of the charges against him and be given reasonable opportunity to defend himself.

(3) The Director-General may, after considering the recommendation made pursuant to subsection (1) *(b)* of this section, dismiss, terminate, retire or downgrade the junior members of the staff concerned.

(4) Any person aggrieved by the Director-General's decision under subsection (3) of this section may, within a period of 21 days from the date of receipt of the letter communicating the decision to him, address a petition to the Council to reconsider his case and the Council's decision thereon shall be final.

PART V

Financial provisions

13. Fund of the Agency

(1) The Agency shall establish a fund from which shall be defrayed all expenditure incurred by the Agency for the purposes of this Act.

(2) There shall be paid and credited to the fund of the Agency-

(*a*) fees charged for services rendered by the Agency;

(*b*) all sums accruing to the Agency by way of gifts, endowments, bequests or other voluntary contributions by persons and organisations;

(c) foreign aid and assistance from bilateral agencies; and

(d) subventions and extra-budgetary allocations from the Federal Government.

14. Expenditure of the Agency

The Agency shall, from time to time, apply the funds at its disposal to-

(a) the cost of establishing and maintaining the head office of the Agency at the Federal Capital Territory, Abuja and its other offices located in other places in Nigeria;

(b) pay allowances and other benefits of members of the Council and of its committee;

(c) pay the emoluments and entitlement of the Director-General and other members of staff of the Agency;

(d) pay the personnel, overhead, allowances, benefits and other administrative costs of the Agency;

(e) the training of members of staff of the Agency;

(f) provide scholarship and awards for specialised training of personnel;

(g) publicise and promote the activities of the Agency;

(h) support national and international scientific and professional organisations and pay annual and other contributions to such bodies;

(i) undertake any other activity in connection with all or any of the functions of the Agency.

15. Exemption from income tax

All income derived by the Agency from the sources specified in section 13 (2) of this Act shall be exempt from income tax and all contributions to the fund of the Agency shall be tax deductible.

16. Capital production income

Subject to the approval of the Minister, the Agency may invest in the profitable production of capital goods by joint-venture, partnership, shareholding or as sole proprietor, as the case may be, and the net incomes so generated shall be paid into the fund of the Agency.

17. Disposal of surplus funds

The Council may invest any surplus funds in profit yielding ventures, and notwithstanding that power, the Minister may issue to the Agency directives as he may think necessary as to the disposal of any surplus funds of the Agency.

18. Annual estimates

The Council shall submit to the Minister, not later than 31 October each year, its programme of work and estimates of its income and expenditure for the following year.

19. Accounts and audit

(1) The Council shall keep proper accounts of the Agency and proper records in relation to those accounts.

(2) The accounts of the Agency shall be audited, not later than six months after the end of the year to which it relates, by auditors appointed by the Agency from the list and in accordance with the guidelines supplied by the Auditor-General for the Federation.

20. Annual report

The Agency shall prepare and submit to the Minister, not later than 30 June in each year, a report on the activities of the Agency during the immediately proceeding year, and shall include in such report a copy of the audited accounts of the Agency for that year and the auditor's report thereon.

PART VI

Miscellaneous

21. Offices and premises

(1) For the purpose of providing offices and premises necessary for the performance of its functions, the Agency may, subject to the Land Use Act-

[Cap. L5.]

(a) purchase or take on lease any interest in land, building or property; and

(b) build, equip and maintain offices and premises.

(2) The Agency may, subject to the Land Use Act, sell or lease out any office or premises held by it, which is no longer required for the performance of its functions under this Act.

22. Power to borrow

(1) The Agency may, from time to time, borrow by overdraft or otherwise such sums as it may require for the performance of its functions under this Act.

(2) The Agency shall not, without the approval of the Minister, borrow money which exceeds, at any time, the limit set by the Minister.

(3) Notwithstanding subsection (1) of this section, where the sum to be borrowed is in foreign currency the Agency shall not borrow the sum without the prior approval of the Minister.

23. Power to accept gifts

(1) The Agency may accept gifts of land, money or other property, upon such terms and conditions, if any, as may be specified by the person or organisation making the gift.

(2) The Agency shall not accept any gifts if the conditions attached by the person or organisation making the gift are inconsistent with the functions of the Agency.

24. Power to enter the premises, etc.

(1) An officer of the Agency may, in the course of his duty, at any reasonable time and on production of his certificate of designation if so required-

(a) enter (if need be by force) any premises in which he reasonably believes that any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged, stored or sold;

(b) examine any article in the premises which appears to him to be an article to which this Act or the regulations apply or anything in the premises which he reasonably believes is used or is capable of being used for the manufacture, preparation, preservation, packaging, storage or sale of any such article;

(c) take a sample or specimen of any article to which this Act or the regulations apply or which he has power to examine under paragraph *(b)* of this subsection;

(d) open and examine, while on the premises, any container or package which he reasonably believes may contain anything to which this Act or the regulations apply or which may help in his investigations;

(e) examine any book, document or other record found on the premises which he reasonably believes may contain any information relevant to the enforcement of this Act or the regulations and make copies thereof or extracts therefrom; and

(j) seize and detain for such time as may be necessary for the purpose of this Act, any article by means of or in relation to which he reasonably believes any provision of this Act or regulations has been contravened.

(2) The owner or person in charge of any premises entered by an officer of the Agency in pursuant of this section, and every person found thereon, shall give all reason-

able assistance in their power to the officer and shall make available to the officer all such information as the officer may reasonably require for the purposes of this Act.

(3) Any article seized under this Act shall be kept or stored in such a place as the officer of the Agency may direct and shall be returned to the owner or the person from whom it was seized if the article upon analysis or examination is found to conform with the requirements of this Act and regulations.

(4) Any article seized by an officer of the Agency pursuant to this Act or the regulations may be submitted to an analyst for analysis or examination and the analyst upon making such analysis or examination shall issue a certificate or report in the prescribed form setting forth the result of such analysis or examination, and the officer of the Agency shall on demand deliver a copy of such certificate or report to the owner of the article if the article is to be the subject of a proceeding under this Act.

(5) In this section, the expression **"article to which this Act or the regulations apply"** means-

(a) any food, drug, cosmetics, medical devices, bottled water or chemical;

(b) anything used for the manufacture, preparation, preservation, packaging or storage of any food, drug, cosmetics, medical device, bottled water or chemical; and

(c) any labelling or advertising material relating to or for use in connection with any food, drug, cosmetics, medical device, bottled water or chemical, but does not include a live animal.

25. Offences

(1) A person who obstructs an officer of the Agency in the performance of his duties under section 24 of this Act shall be guilty of an offence and liable on conviction to a fine of ₦5,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

(2) Any person who contravenes the provisions of any regulations made under this Act is guilty of an offence and liable on conviction to the penalties specified in the regulations.

[1999 No. 19.)

(3) Where no penalty has been specified, the person shall be liable to a fine of ₦50, 000 or imprisonment for a term of one year or to both such fine and imprisonment.

(4) Where an offence under this Act which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, he, as well as the body corporate, shall be deemed to be guilty of the offence and shall be liable on conviction to a fine of ₦ 100,000.

(5) The Federal High Court shall have exclusive jurisdiction to try offences under this Act.

[1999 No. 62.)

26. Conduct of proceedings

(1) Subject to the provisions of section 174 of the Constitution of the Federal Republic of Nigeria 1999 (which relates to the power of the Attorney-General of the Federation to institute, continue or discontinue criminal proceedings against any person in a court of law), any officer of the Agency may, with the consent of the Attorney-General of the Federation, conduct criminal proceedings in respect of offences under this Act or regulations made under this Act.

[1999 No. 19. Cap. C23.)

(2) In a judicial proceeding for an offence under this Act or any regulation made under it, the provisions of the Criminal Procedure Act or depending on the venue, the Criminal Procedure Code shall, with such modifications as the circumstance may require,

apply in respect of such matter to the same extent as they apply to the trial of offences generally.

[1999 No. 19.)

27. Legal proceedings

(1) No suit shall be commenced against the Agency before the expiration of a period of one month after written notice of intention to commence the suit shall have been served on the Agency by the intending plaintiff or his agent and the notice clearly and explicitly states-

(a) the cause of action;

(b) the particulars of the claim;

(c) the name and place of abode of the intending plaintiff; and

(d) the relief which he claims.

(2) The notice referred to in subsection (1) of this section and any summons, notice or other document required or authorised to be served on the Agency under the provisions of this Act or any other enactment or law, may be served by-

(a) delivering the same to the Director-General; or

(b) sending it by registered post addressed to the Director-General at the head office of the Agency.

(3) In any action or suit against the Agency, no execution or attachment or process in the nature thereof shall be issued against the Agency, but any sums of money which may, by the judgment of the court, be awarded against the Agency shall, subject to any directives given by the Agency, be paid from the fund of the Agency.

28. Power of Minister to give directives

The Minister may give directives of a general or special character to the Agency relating to the performance by the Agency of any or all of its functions under this Act, and it shall be the duty of the Agency to comply and give effect to the directives.

29. Dissolution of Food and Drug Administration and Control Department

(1) On the commencement of this Act, the Food and Drug Administration and Control Department of the Federal Ministry of Health (in this section referred to as "the Department") shall cease to exist.

(2) Accordingly, the Department is hereby dissolved and the provision of the Second Schedule to this Act shall apply in relation to the employees in the Department, the assets and liabilities of the Department and the other matters connected with the Department set out therein.

[Second Schedule.]

30. Power to make regulations

The Council may, with the approval of the Minister, make regulations-

(a) to prescribe the methodologies for private sector payments into the fund of the Agency;

(b) to prescribe the fees to be paid for services rendered by the Agency;

(c) generally for the purposes of carrying out or giving full effect to the provisions of this Act

31. Interpretation

In this Act-

"**Agency**" means the National Agency for Food and Drug Administration and Control established by section 1 of this Act;

"**Council**" means the Governing Council of the Agency established by section 2 of this Act;

"**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;

"**chairman**" means the chairman of the Council;

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

[1999 No. 19.]

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

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

[1999 No. 19.]

"**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;

"**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;

"**member**" means a member of the Council and includes the chairman;

"**Minister**" means the Minister charged with matters relating to health;

"**President**" means the President of the Federal Republic of Nigeria;

"**public service**" has the meaning assigned to it in the Constitution of the Federal Republic of Nigeria 1999; and

[Cap. C23.]

. "**regulated products**" means food, drugs, cosmetics, medical devices, detergents bottled water and chemicals.

[1999 No. 19.]

32. Short title

This Act may be cited as the National Agency for Food and Drug Administration and Control Act.

SCHEDULES

FIRST SCHEDULE

[Section 2 (4).]

Supplementary provisions relating to the Council and the Agency

Proceedings of the Council

1. Subject to this Act and section 27 of the Interpretation Act, the Council may make standing orders regulating the proceedings of the Council and any committee thereof.

[Cap. 123.]

2. Every meeting of the Council shall be presided over by the chairman and if the chairman is unable to attend a particular meeting, the members present at the meeting shall elect one of their number to preside at the meeting.

3. The quorum at a meeting of the Council shall consist of the chairman (or in an appropriate case, the person presiding at the meeting pursuant to paragraph 2 of this Schedule) and six other members.

4. The Council may on any special occasion, co-opt any person to be member of the Council for as many meetings as it may deem necessary, and that person while so co-opted shall have all the rights and privileges of a member, except that he shall not be entitled to vote or count towards a quorum.

Committees

5. (1) Subject to its standing orders, the Council may appoint such number of standing and *ad hoc* committees as it thinks fit to consider and report on any matter with which the Agency is concerned.

(2) Every committee appointed under the provisions of sub-paragraph (1) of this paragraph shall be presided over by a member of the Council and shall be made up of such number of persons, not necessarily members of the Council, as the Council may determine in each case.

6. The decision of a committee shall be of no effect until it is confirmed by the Agency.

Miscellaneous

7. The fixing of the seal of the Agency shall be authenticated by the signature of the chairman and of the Director-General of the Agency or such other member authorised generally or specially by the Council to act for that purpose.

8. Any contract or instrument, which, if made by a person not being a body corporate, would not be required to be under seal, may be made or executed on behalf of the Agency by the Director-General or by any other person authorised generally or specifically by the Council to act for that purpose.

9. Any document purporting to be a contract, an instrument or other document signed or sealed on behalf of the Agency shall be received in evidence and, unless the contrary is proved, be presumed without further proof, to have been so signed or sealed.

10. The validity of a proceeding of the Council or of a committee thereof shall not be adversely affected-

(a) by any vacancy in the membership of the Council; or

(b) by any defect in the appointment of a member of the Council; or

(c) by reason that a person not entitled to do so took part in the proceeding.

11. A member of the Council or committee who has a personal interest in any contract or arrangement entered into or proposed to be considered by the Council or committee shall forthwith disclose his interest to the Council or committee and shall not vote on any question relating to the contract or arrangement.

SECOND SCHEDULE

[Section 29 (2).]

Transitional provisions relating to the employees, assets and liabilities of the Food and Drugs Administration and Control Department of the Federal Ministry of Health

1. By virtue of this Act, there shall be vested in the Agency immediately at the commencement of this Act, without further assurance, all assets, funds, resources and other movable or immovable property which immediately before the commencement of this Act were vested in the Food and Drugs Administration and Control Department of the Federal Ministry of Health (in this Schedule referred to as "the Department").

2. As from the commencement of this Act-

(a) all rights, interests, obligations and liabilities of the Department existing immediately before the commencement of this Act under any contract or instrument, or at law or in equity apart from any contract or instrument, shall by virtue of this Act be assigned to and vested in the Agency;

(b) any contract or instrument as mentioned in sub-paragraph *(a)* of this paragraph shall be of the same force and effect against or in favour of the Agency and shall be enforceable as fully and effectively as if, instead of the Department, the Agency has been named therein or had been a part thereto; and

(c) the Agency shall be subject to all obligations and liabilities to which the department was subject immediately before the commencement of this Act, and all other persons shall as from the commencement of this Act have the same

rights, powers and remedies against the Agency as they had against the Department immediately before the commencement of this Act.

3. Any proceeding or cause of action pending or existing immediately before the commencement of this Act by or against the Department in respect of any right, interest, obligation or liability of the Department may be commenced, continued or enforced by or against the Agency as if this Act had not been made.

4. Notwithstanding the provisions of this Act but subject to such directions as may be issued by the Agency, any person who immediately before the date of commencement of this Act held office in the Department shall be deemed to have been transferred to the Agency on terms and conditions not less favourable than those obtaining immediately before the commencement of this Act, and service under the Department shall be deemed to be service under the Agency for purposes of pension.

5. The Minister, if he thinks fit, may, within the twelve months after the commencement of this Act by order published in the *Gazette,* make additional or saving provisions for the better carrying out of the objectives of this Schedule.

CHAPTER N1

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT

SUBSIDIARY LEGISLATION

List of Subsidiary Legislation

I. National Agency for Food and Drug Administration and Control Tariff Charges Regulations.
2. Drug Products Advertisement Regulations.
3. Pre-Packaged Food (Labelling) Regulations.
4. Bottled Water (Advertisement) Regulations.
5. Cosmetic Product (Prohibition of Bleaching Agents, etc.) Regulations.
6. Food Products Registration Regulations.
7. Bottled Water (Labelling) Regulations.
8. Pesticide Registration Regulations.
9. Non-nutritive Sweeteners in Food Products Regulations.
10. Non-nutritive Sweeteners in Drug Products (Prohibition) Regulations.
11. Food Products (Advertisement) Regulations.
12. Food Grade (Table or Cooking) Salt Regulations.
13. Cosmetics and Medical Devices (Advertisement) Regulations.
14. Bottled Water Registration Regulations.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL TARIFF CHARGES REGULATIONS

[S.l. 3 of 1994.]

under section 29

[1st November, 1993]

[Commencement.]

Tariff charges to be paid for services rendered by the Directorates of the Agency

1. Tariff charges

The following tariff charges are payable in respect of services rendered by the Directorates of the Agency respectively set out as follows-

PART (A)

Narcotics and Controlled Substances Directorate

	₦
Import Permit for Psychotropic Substances	500
Dangerous Drugs Import Authorisation	500
Conditional Releases of Controlled Drugs (with incomplete documents)	1,000
Conditional Release of Controlled Drugs (without permit)	20,000.
Application Form for Chemical Import Permit	250.
Chemical Import Permit	3,500

PART (B)

Regulatory and Registration Directorate

	₦
Form for Product Registration	250 (Food, medical devices and cosmetics) 500 (Drugs)
Product Licences	10,000 (Licence valid for 5 years)
Forms for Product Advertisement	250
Advertisement Approval Letter	5,000
Revalidation of Advertisement Approval	3,000
Renewal of Product Licence Registration	10,000
Application Form for Clinical Trials	500
Clinical Trials Permit	20,000

PART (C)

Inspectorate Directorate

	₦
Pre-production Inspection of Drug Manufacturing Establishments	5,000
Inspection of establishment prior to product registration (included in charges for registration)	2,500
Port Inspection per consignment	5,000
Certificate of Manufacture and Free Sale (per consignment)	5,000
Radiation Certificate (including handling charges)	7,500
Endorsement for the release of consignment through NIPOST	5,000
Issuance of Clearance Certificate for Siting of Industries	2,500
Ports Inspection of Chemicals	3, 500

PART (D)

Laboratory Services Directorate

Special Chemical Analysis per samples 2,500

Special Biological Analysis per sample 2,500

Use of physical instruments (per single use) 1,000

(a) U/V, IR, GLC, HPLC, etc.

(b) Atomic Absorption Spectrephetemeter 1,500

(c) Gas Chromatograph, Mass Spectrometer N.M.R. 2,500

Attachment to laboratory for training

(a) For one week 1,000

(b) For one month 2,500

(c) For 3 months 5,000

(d) For 12 months 10,000

2. Citation

These Regulations may be cited as the National Agency for Food and Drug Administration and Control Tariff Charges Regulations.

DRUG PRODUCTS ADVERTISEMENT REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

SCHEDULE

DRUG PRODUCTS ADVERTISEMENT REGULATIONS

[S.1. 15 of 1995.]

under sections 5 and 29

[16th August, 1995]

[Commencement.]

1. Advertisement of registered product only

(1) These Regulations apply to all advertisements or promotion of drug products (both single entity and compound) imported into Nigeria or locally manufactured, distributed or sold in Nigeria.

(2) No person shall advertise any drug product unless it has been registered by the Agency.

2. Clearance to be obtained before advertisement

No person shall advertise any drug product unless the advertisement has the pre-clearance and approval of the Agency.

3. Nature of advertisement

The advertisement in Nigeria of any drug product shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners, therefore statements or illustrations shall not mislead directly or by implication.

4. Non-referential advertisement

No advertisement of a drug product shall-

(a) imitate the general layout, text, slogan or visual presentation of another drug product in a way likely to mislead or confuse the consumer; or

(b) be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers causing them to purchase the drug product being advertised.

5. Application for the approval of advertisement

(1) All advertisement materials including scripts, story-boards, art work, radio, video tapes, etc., shall be submitted under confidential cover along with an application, to the Director-General of the Agency.

(2) Where advertisement materials are submitted through any of the State offices of the Agency, it shall still be subject to the approval of the Director-General of the Agency.

6. Particulars of application

(1) An application submitted by an advertisement agent, distributor, manufacturer or the sponsor of the advert shall contain the following information-

(a) the brand name of the drug;

(b) the generic name of drug;

(c) the dosage form available where applicable;

(d) the place of importation or local manufacturer;

(e) the name and location address of the manufacturer;

(*j*) the name and location address of the local distributor;

(g) the name and location address of the advertising company;

(h) the dale of first introduction of the drug to the Nigerian market;

(*i*) any previous advertisement of the drug in Nigeria;

(*j*) a copy of the old script (if any);

(k) the proposed media for the advertisement;

(l) a copy of the registration certificate of the drug;

(m) a copy of the registration certificate of the premises of the sponsors;

(n) scripts, art works, radio, video tapes and story-board of the advert; and

(o) justification for any special claims on the drug.

(2) The advertisement materials on the drug shall be authenticated by the superintendent pharmacist of the pharmaceutical company and the chief executive of the drug company sponsoring the drug.

7. Validity of approval

The approval of an advert shall be valid for a period of one year beginning from the date of the approval.

8. Alteration in approved script

Any alteration in the format of the approved script, story-board, art work, radio or video tapes without the approval of the Agency shall render the approval null and void.

9. Unacceptable advertisement

Where an advertisement is considered unacceptable by the Agency the words "Unacceptable as presented" shall be stamped on it and it shall be returned to the advertiser with the unacceptable information or illustration clearly identified.

10. Appeal in case of withdrawal of approval within the one year specified

If the approval of an advertisement is withdrawn during the one year period of approval, an appeal shall be lodged within thirty days after the receipt of the withdrawal to the Governing Council of the Agency in writing and accompanied by supportive information.

11. Advertisement to effect caution in drug usage

Drug advertisements shall reflect an overall attitude of the caution in respect to the drug usage with emphasis on national drug therapy and shall also provide sufficient and balanced information to permit assessment of risk or benefit.

12. Drug advertisement not to state that a product is "safe", "non-toxic", etc.

(1) No advertisement for over the counter drugs shall state or imply in absolute terms or by quotations taken out of context, that any pharmaceutical product is "safe" or has "guaranteed efficacy" or special status.

(2) Any statement claiming or implying a superlative function such as "most effective", "Ieast toxic", "least tolerated", or special status such as "the drug of choice", etc., for a product shall not be used unless it can be adequately substantiated.

13. Restriction

No advertisement for any drug product shall contain-

(a) any false or misleading information;

(b) half-truths, inadequate qualification and limitations regarding safety or effectiveness of the drug;

(c) vague, unsubstantiated statements, or suggestions of superiority over other competing drugs; or

(d) any false impression that the advertised drug is for universal cure or should be regarded as a more effective and safer alternative to other related drugs.

Prescription drugs

14. Labelling advertisement. Prescription drugs and particulars of prescription

(l) No person shall advertise any prescription drug to the public and the drug shall be properly labelled with the following information on the package label-

(a) the name of the pharmaceutical product, the brand name or chemical names whichever is applicable;

(b) a quantitative listing of all the ingredients of the drug;

(c) indication for which the drug is intended;

(d) an accurate statement of dosage (per tablets, capsule, etc.);

(e) the daily dose;

(j) the frequency of administration;

(g) the preparation for use (shaking, dilution, refrigeration, etc.);

(h) the expiry date, date of manufacture, storage temperature requirement and lot or batch;

(i) the route or method of administration;

(j) adequate warning, where necessary, for the protection of the patient as provided in the drug labelling guidelines;

(k) the name and location address of manufacturer or packer; and

(*l*) if an imported drug, the name and address of the local packer or distributor shall appear on the label in such a manner as to identify the connection between the manufacturer and the local packer or distributor such as "manufactured for" ....."distributed by" .....

(2) Prescribing information shall be legibly presented in a type face not smaller than six points and shall provide good contrast on the packaging.

(3) The indications for use of any therapeutic agent shall conform to the product monograph and label indication approved by the Agency.

(4) The main advertising message and the prescribing information shall be adjoining or page referenced in such a manner as to be liable to be read at the same time one after the other.

(5) All labelling information shall be in English language.

15. Data comparison misrepresentation

(1) No comparison on a drug packaging shall mislead directly or by implication and any such comparison shall be supported by reliable current data.

(2) Any reference to a competitive manufacturer or their specialities shall be restricted to factual comparisons without the use of identifiable products or brand names.

(3) All data illustrations presented in the advertisement including charts, graphs, tables, etc., extracted from reference studies or other sources or reproduced by art work shall be accurate, complete and clear with their source specifically identified.

(4) Data illustrations shall not be misleading or ambiguous or distort the originally intended meaning or interpretation either directly or by implication.

16. Side effect and contra-indications

(1) Advertisement for all drugs shall present information that is reasonably balanced, between indications, effectiveness, safety, side effects and contra-indications.

(2) Advertisement of all drugs for use during pregnancy shall state any known effects of the drug on a pregnant woman, foetus and lactation.

17. Contents of advertisements with specific therapeutic claims

Advertisement of drugs which contain specific therapeutic claims shall contain within the advertisement-

(a) the brand name and non-proprietary or general names of the pharmaceutical product;

(b) the therapeutic classification of the pharmaceutical product;

(c) a quantitative list of the actual medical ingredients contained in each dose or unit;

(d) the indication for use;

(e) the recommended dosage, methods of use and routes of administration for all stated indications;

(*f*) a list of adverse reactions (with some indication or expected incidence if known) the precaution to be taken by any member of the health profession and the contra-indications and warning of the pharmaceutical product;

(g) a statement that the product monograph or full prescribing information is

readily available from a stated Nigerian address; and

(h) the full name and location address of manufacturer and the Nigerian packer.

18. Accurate interpretation of research findings

A copy of an advertisement shall be written in a manner which accurately interprets valid and representative research findings, also statistics shall be written in a manner which reflects only their true validity and significance.

19. Claims and quotations from scientific literature to be mentioned

(1) Claims and quotations from the scientific literature concerning the efficacy, safety and adverse reactions, use in very young children, use in pregnancy, etc., with the constraints of the accepted products monograph, shall specify the scientific source(s) of information.

(2) Copies of all references cited shall be submitted to the Agency for verification.

20. Scientific articles and literature to contain both positive features and negative findings

(1) Claims based on, or quotations that have been selected from a scientific article or series of articles which emphasise only the positive features other than negative findings of the drug, shall not be acceptable.

(2) Accordingly all claims and quotations shall contain both negative and positive findings and shall be verifiable by the Agency or its representative(s).

21. Restriction or selection of quotation

No selected quotation shall refer to another brand of the same pharmaceutical entity, or to a different formulation of the same active ingredients unless data of accepted methodology are available to warrant "cross reference" between the drugs.

22. Prohibition of advertisement for certain diseases

No person shall advertise a drug as a treatment, prevention or cure for any disease, disorder or abnormal physical state as speci tied in the Schedule to these Regulations.

Over-the-counter drugs

23. Labelling particulars and information for over-the-counter drugs

The advertisement of an over-the-counter drug in Nigeria shall be properly labelled with the following information included on the package-

(a) the generic and brand if applicable (names of the drug);

(b) the generic and brand (if applicable) names shall be conspicuously placed one above the other with a prefix "Brand of" in between (where necessary);

(c) a quantitative list of the ingredients of the drug;

(d) the conditions, purpose of or use of the drug;

(e) an accurate statement of the dosage strength (per tablet, capsule, teaspoon, etc.);

(j) the daily dose;

(g) the route or method of administration;

(h) the preparation for use (shaking, dilution, refrigeration, etc.);

(*i*) adequate warnings, when necessary for the protection of users such as "keep out of the reach of children";

(j) the name and location address of manufacturer or packer;

(k) if an imported drug, the name and location address of the local packer or distributor shall appear on the label in such a manner as to identify the connection between the manufacturer and the local packer or distributor such as "manufactured for. ..... distributed by ....."; and

(l) the date of manufacture, date of expiration, unless exempted, storage temperature and batch or lot number.

24. Labelling of over-the-counter drugs

(1) Over-the-counter drugs shall carry package leaflets with complete label information in addition to the contra-indications and the labelling shall not contain any statement which is false, misleading or exaggerated as to amount to a misrepresentation.

(2) Where the bottle, jar or other "immediate container" of the drug has an outer wrapper or carton, such outer wrapper or carton shall bear all the information required to be specified on the label.

(3) All labelling information shall be in English language.

25. Advertisement to contain certain information

The advertisement of a drug which shall not carry any false or misleading information shall contain the following information-

(a) the name of the drug;

(b) the pack size(s) being promoted and their corresponding prices;

(c) the different forms in which the drug is available (if necessary); and

(d) the name and location address of the sellers and manufacturer.

26. Restriction on use of advertisement

No over-the-counter drugs advertisement shall-

(a) contain such words as "magic", "miracle", or an exotic description such as "upper potency" or such other words as to induce the daily or continuous use of the drug;

(b) imply that if the reader, viewer or listener is suffering from any ailment or disease he shall suffer more severely from the illness, ailment or disease on failure to use that particular drug;

(c) over dramatise any symptoms by way of drawing a picture of a pregnant woman, patient with backache, or use throbbing sounds like heartbeats, coughing or agonising cries; and

(d) denigrate or attack unfairly any competitive products, goods or services.

27. Advertisement of over-the-counter drugs in mass media

No person shall advertise any drug unless such advertisement states clearly both the generic and brand (if applicable) names of the drug.

28. Interpretation

In these Regulations, unless the context otherwise requires-

"advertising" means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, and any other documents) made orally or otherwise or by means of projected light and sound recordings;

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

"claim" means any representation which states, suggests or implies that the drug has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality;

"Director-General" means the Director-General of the Agency;

"justification" in respect of any claim shall be in the light of current knowledge acceptable to the Agency;

"label" means a display of written, printed or graphic matter upon the immediate containers to the drug;

"location address" means a place where the business of manufacture, sale, distribution, storage and display of pharmaceutical products is carried out which includes the house number, plot number, street name, town or city, state, country, etc.;

"package labelling" includes the label on the immediate container of the drug and all other printed matter such as outer wrapper, carton or leatlet associated with the package;

"prescription drug" means a drug which can only be made available to a patient through a written prescription signed by a duly qualified and registered medical practitioner and dispensed by a registered and licensed pharmacist; such drug shall not be made available or sold directly to the general public without the said prescription and shall be identified by chemical or generic name(s);

"pharmaceutical product" means a substance or mixture of substances manufactured, sold or prescribed for invivo use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state of the symptoms thereof, or in restoring, correcting or modifying organic function in man or animals but excluding mechanical devices and cosmetics;

"rational drug therapy" means appropriate therapy recommended or prescribed which logically may be expected to remedy or ameliorate a disordered state of physical or mental health, and shall include logical use for a diagnostic and prophylactic purpose to prevent or lower the incidence of illness;

"therapeutic classification of pharmaceutical product" means either the accepted pharmacological classification (e.g. anxiolytic, diuretic, analgestic, antibiotic, etc.) or the identity of the purpose(s) for which the pharmaceutical product is intended (migraine, hypertension, etc.,) or both.

29. Citation

These Regulations may be cited as the Drug Products Advertisement Regulations.

SCHEDULE

[Regulation 22.]

Alcoholism
Appendicitis
Arteriosclerosis
Asthma
Blood disorders
Cancer
Cataract
Cholera
Diabetes
Diphtheria
Disorders of menstrual flow
Disorders of prostate gland
Dysentery
Encephalitis
Enteric fever
Epilepsy
Erysipelas
Filariasias
Gallstones, kidney stones and bladder stones
Gangrene
Any genital or urinary diseases not mentioned elsewhere in the Schedule
Glaucoma
Goitre

Hay fever
Heart disease
Hernia
High blood pressure
Infective hepatitis
Influenza and flu
Jaundice
Kidney disease
Leprosy
Locomotor ataxis
Loss of youth
Measles
Meningitis
Mental conditions
Mumps
Nervousness
Nutritional disorders
Obesity
Onchocerciasis
Paralysis
Plague
Pleurisy
Pneumonia
Poliomyelitis
Rabies
Rheumatic fever
Schistosomiasis
Sexual impotence, loss of virility or sterility
Sleeping sickness
Small pox
Snake bite
Syphilis
Tetanus
Trachoma
Tubercu losi s
Tumours
Typhoid fever
Undulant fever
Ulcers of the gastro-intestinal tract
Venereal diseases
Yaws
Yellow fever

PRE-PACKAGED FOOD (LABELLING) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

PRE-PACKAGED FOOD (LABELLING) REGULATIONS

[S.I. 16 of1995.]

under sections 5 and 29

[16*th August*, 1995]

[Commencement.]

1. Sale of unlabelled pre-packaged food prohibited

No person shall sell a pre-packaged food unless a label has been affixed thereto.

2. **Pre-packaged food not to be described falsely, etc**.

A pre-packaged food shall not be described or presented on any label-

(a) in a manner which is false, misleading, deceptive or is likely to create an erroneous impression regarding its character, quality, quantity and origin;

(b) by words, pictorial or other means which refer to any other product or suggests either directly or indirectly, that the food is connected with such other product.

3. Pre-packaged food to bear certain information

The label of a pre-packaged food shall be required to bear the following information-

(a) the name of the food item which shall indicate the accurate nature of the food;

(b) where a name has been established for the food item it shall be the only name used by that food item;

(c) where no name exists for a food item, an appropriate descriptive name shall be affixed thereto;

(d) where a coined or fanciful name is used for the food item, the name shall not be misleading and shall be accompanied by an appropriate descriptive term.

4. List of ingredients

(1) A complete list of ingredients used in preparing the food item shall be declared on the label in descending order of their proportion, except in the case of a dehydrated food item intended to be reconstituted by the addition in order of proportion in the reconstituted product:

Provided that the list of ingredients shall be headed by a statement such as ingredients when reconstituted.

(2) Where the ingredients of a food item has more than one component the name of the components shall be included in the list of ingredients.

(3) Every ingredient contained in such list other than the ingredients specified in Schedule I to these Regulations and substances falling within the classes specified in Schedule 2 to these Regulations, shall bear a specific name or the specific item written in parenthesis.

[Schedules I and 2.]

(4) Any added water shall be declared in the list of ingredients if such a declaration would result in a better understanding of the food composition by the consumer, except when the water forms part of ingredients such as-

(a) brine;

(b) syrup; and

(c) both are used in the compound food item.

5. Net content of pre-packaged food

(1) The average net content of every pre-packaged food item shall be declared in the metric system.

(2) The declaration of the average net content of the food item shall be required to be made in the case of-

(a) liquid food in volume;

(b) solid food by weight and number or count (where applicable);

(c) semi-solid or viscous food by weight or volume.

(3) Any food pre-packaged in liquid form normally discarded before consumption, shall carry or a declaration of the drained weight of the food item.

6. Name, address and country of manufacturer, etc., to be declared

(1) The name and location address of the manufacturer, packer, distributor, importer or vendor of a pre-packaged food shall be specified on the label.

(2) The country of the manufacturer of a pre-packaged food shall be specified on the label.

(3) When a pre-packaged food item undergoes any processing which affects its contents in another country, such a country shall be considered as the country of manufacture for the purpose of labelling.

7. Clear prominent, etc., statements

(1) Any statement required to appear on the label of a food item shall be clear, prominent and legible to the consumer and be of contrasting colour to that of the background.

(2) No information shall be obscured by design or by other written, printed or graphic matter contained on the label.

(3) The letters of the name of the food item and the net content shall be of a size reasonably related to the most printed matter on the label.

(4) Where a pre-packaged food container is covered by a wrapper, the wrapper shall carry the required information and the label shall be readily legible through the outer wrapper and not be obscured by it.

8. Date marking instructions

(1) For any pre-packaged food item, the date of minimum durability shall be specified and legibly displayed.

(2) Where the date of minimum durability is specified, it shall be preceded by the words "best before", "use by" or "expiry" and shall be legibly displayed as required by the Agency.

(3) Unless otherwise specified for pre-packaged food items the day, month and year of manufacture shall to be stated in an uncoded chronological order on the label.

9. Storage condition

The required special storage conditions shall be specified on the label.

10. Batch number

The batch number shall be indicated on the label of all pre-packaged food.

11. Trademark

The trademark (if any) shall be displayed on the label such that the trademark shall not give a wrong impression of the nature, quality or substance of the food item.

12. Language

Any declaration required to be made under these Regulations shall be in English language.

13. Particulars of physical condition of food and specific treatment

Any special treatment which a particular pre-packaged food item has undergone, shall be indicated in all cases where an omission of such information may create confusion in the mind of the consumer.

14. Ionising radiation

A pre-packaged food item, which has been treated with ionising radiation, shall be so declared and the nature of the ionising radiation shall be stated on the label.

15. Frozen food

The form of freezing of a pre-packaged food item shall be indicated on the label.

16. Directions for use

Directions for use, including reconstitution, where applicable, shall be included on the label to ensure correct utilisation of the food item.

17. Nutritional labelling

(1) Any nutritional claim shall be justified expressly on the label.

(2) A nutrient labelling shall be mandatory for any pre-packaged food item for which a nutrition claim is made by the manufacturer.

(3) Where nutrient declaration is applied, the declaration of the following shall be mandatory-

(a) energy value;

(b) the amounts of protein available, carbohydrate (excluding dietary fibre) and fat; and

(c) the amount of any other nutrient for which a nutrient claim is made.

(4) When nutrient labelling is applied, the amount of vitamins and minerals considered to be of negligible importance may not be listed.

(5) The list of ingredients and the specification of the quantities of certain nutrients on the label as required by the Act or of any Regulations made thereunder shall not constitute a claim.

18. Display of information, etc., not in conflict with mandatory requirement

Any information required to be displayed on a label which misleads or deserves a consumer in any way shall constitute an offence under these Regulations.

19. Grade designation

Where a grade designation is used, it shall be readily understandable and not be misleading or deceptive in anyway.

20. Removal, etc., of label

No person shall remove, add to, alter, deface or render illegible any statement upon a label printed on or attached to a wrapper or container in pursuance of these Regulations.

21. Sanctions

If any person fails to comply with the provisions of these Regulations, the Agency may prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale of or use of the pre-packaged food item either absolutely or for such a period of time as the Agency may declare, in addition to the payment of a fine of ₦50,000.00.

22. Interpretation

In these Regulations, unless the context otherwise requires-

"Act" means National Agency for Food and Drug Administration and Control Act; [Cap. Nl.]

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

"container" means any form of packaging of food for sale as a single item whether by completely or partially enclosing the food and includes wrappers, but does not include leaves traditionally used as food wrappers;

''food'' means any article manufactured, sold or advertised for use as food or drink and includes drinking water, chewing gum, and such other ingredients as may be mixed with food for any purpose whatsoever including supplements processed for addition to animal and poultry feeds;

''food additives" means any substance not usually consumed as food by itself but used as an ingredient of that food, whether or not it has nutritive value;

"ingredient" includes additives used in the manufacture of preparation of food;

"label" includes any writing, printed or graphic matter relating to and accompanying the food item;

"location address" means a place where the business of manufacture sale, distribution, storage and display of pre-packaged food item is carried out which includes the house number, plot number, street name, town/city, state, country, etc.;

"pre-packaged" means packed or made in advance ready for retail sale in a wrapper or container.

23. Citation

These Regulations may be cited as the Pre-packaged Food (Labelling) Regulations.

SCHEDULES

SCHEDULE I
[Regulation 4 (3).]

Class names

"Oil" together with either the term "vegetable" or "animal" qualified by the term "hydrogenated" or "partially hydrogenated" as appropriate; "fat" together with either the term "vegetable or animal" as appropriate:

"Starch"

"Fish"

"Poultry meat"

"Cheese"

"Spice", "Spices" or

"Mixed spices" as appropriate

"Herbs" or "mixed herbs" as appropriate

"Gum base"

"Sugar"

"Dextrose" or "Glucose"

"Caseinates"

"Cocoa butter"

"Crystallized fruit"

SCHEDULE 2
[Section 4 (3).]

Class names

Anti-caking agents(s)

Anti-oxidant(s)

Colour(s)

Emulsifier(s)

Flavour enhancer(s)

Glazing agents(s)

Preservative(s)

Stabiliser (s)

Thickener(s) Gelling agent(s)

Anti-foaming agent(s)

Flour treatment agent(s)

Artificial sweetener(s)

Acidity regulator(s)

Propellant(s)

BOTTLED WATER (ADVERTISEMENT) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

BOTTLED WATER (ADVERTISEMENT) REGULATIONS

[S.l. 17 of l995.]

under sections 5 and 29

*[*16*th August*, 1995*]*

[Commencement.]

1. Advertisement of registered product only

No person shall advertise any bottled water imported into Nigeria or locally manufactured unless the bottled water has been registered by the Agency.

2. Clearance to be obtained before advertisement

No person shall advertise any bottled water unless the advert has the pre-clearance and approval of the Agency.

3. Nature of advertisement

All advertisements of bottled water in Nigeria shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners, accordingly statements or illustrations on the bottled water shall not mislead directly or by implication.

4. Non-referential advertisement

No advert bottled water shall-

(a) make reference directly or indirectly to any member of the health care profession, hospitals, clinic or pharmacy, etc.;

(b) imitate the general layout, text, slogan or visual presentation of devices of any other bottled water in a way likely to mislead or confuse the consumer;

(c) be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers causing them to purchase the bottled water being advertised.

5. Application for the approval of advertisement

(1) All advertisement materials including scripts, story-board, art work, radio, video tapes, etc., shall be submitted under confidential cover along with than application to the Director-General of the Agency.

(2) Where advertisement materials are submitted through any of the State offices of the Agency, it shall be subject to the approval of the Director-General of the Agency.

6. Particulars of application

(1) An application submitted by an advertising agent, distributor, manufacturer or the sponsor of the advert shall contain the following, that is-

(a) the brand name of the bottled water;

(b) the generic name of the bottled water;

(c) whether the bottled water is imported or locally manufactured (country of manufacture);

(d) the name and location address of the manufacturer;

(e) the name and location address of the local distributor;

(*f*) the name and location address of the advertising company;

(g) the date of first introduction of the bottled water to the Nigerian market;

(h) information about any previous advertisement of the bottled water in Nigeria;

(i) a copy of the old script (if any);

(j) the proposed media for the advertisement;

(k) a copy of the registration certificate of the bottled water;

(l) justification for any special claims on the bottled water;

(m) the scripts, story-board, art works, radio and video tapes of the advert; and

(n) such other materials as may be required by the Agency from time to time.

7. Validity of approval

The approval of an advertisement shall be valid for a period of one year beginning from the date of the approval.

8. Alteration in approved script

Any alteration in the format of the approved script, story-board, art work, radio or video tapes without the approval of the Agency shall render the approval null and void.

9. Unacceptable advertisement

Where an advertisement is considered unacceptable by the Agency, the words "Unacceptable as presented" shall be stamped on it and it shall be returned to the advertiser with the unacceptable information or illustration clearly identified.

10. Appeal in case of withdrawal of approval within the one year specified

If the approval for an advertisement is withdrawn during the one-year period of approval, an appeal shall be lodged within thirty days after the receipt of the withdrawal directed to the Governing Council of the Agency in writing and accompanied by supportive information.

11. Restriction

No advertisement for a bottled water shall contain-

(a) any false or misleading information;

(b) half-truths, inadequate qualification and limitations regarding safety or effectiveness of the bottled water;

(c) vague, unsubstantiated statements, suggestions of superiority over other competing bottled water;

(d) any false impression that the advertised bottled water is for universal cure or should be regarded as a more effective and safer alternative to other related products.

12. Data comparison misrepresentation

(1) No comparison shall mislead directly or by implication and any such comparison shall be supported by reliable current scientific data.

(2) Any reference to competitive manufacturer or their specialities shall be restricted to factual comparisons without the use of identifiable product(s) or brand name(s).

(3) All data illustrations presented in an advertisement including charts, graphs, tables, etc., extracted from reference studies or other source or reproduced by art work shall be accurate, complete and clear with their source specifically identified.

(4) Data illustrations shall not be misleading or ambiguous or distort the original intended meaning or interpretation either directly or by implication.

13. Accurate interpretation of research findings

Any copy of an advertisement shall be written in a manner which accurately interprets valid and representative research findings and statistics on the bottled water and shall be written in a manner which retlects only their true validity and significance.

14. Sanctions

If any person fails to comply with the provisions of these Regulations, the Agency may prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale of or use of the bottled water either absolutely or for such period of time as the Agency may declare in addition to the payment of a fine of ₦5,000.

15. Interpretation

In these Regulations, unless the context otherwise requires-

"advertising" means the publicity of goods and description of all products (which includes any form of notice in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines and any other document made orally or otherwise or by means of projected light and sound recordings);

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

"appropriate authority" means the Director-General of the Agency;

"bottled water" means any form of processed water packed for drinking purpose and enclosed in any form of container;

"claim" means any representation which states, suggests or implies that the bottled water has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality;

"Director-General" means the Director-General of the Agency;

"justification" in respect of any claim shall be in the light of current nutritional scientific knowledge acceptable to the Agency;

"label" means a display of written, printed or graphic matter upon the immediate bottled water container;

"location and address" means a place where the business of manufacture, sale, distribution, storage and display of bottled water is carried out which includes the house number, plot number, street name, town or city, state, country, etc.;

"package labelling" includes the label on the immediate bottled water container and all other printed matter such as outer wrapper or carton or leaflet associated with the package.

16. Citation

These Regulations may be cited as the Bottled Water (Advertisement) Regulations.

COSMETIC PRODUCT (PROHIBITION OF BLEACHING AGENTS, ETC.) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

SCHEDULE

COSMETIC PRODUCT (PROHIBITION OF BLEACHING AGENTS, ETC.) REGULATIONS

[S.1. 20 of 1995.)

under sections 5 and 29

[11*th August*, 1995]

[Cornmencernent.]

1. Sale of adulterated cosmetic products

(1) No person shall sell or offer for sale any cosmetic product which is adulterated or which contains any substance which when used according to the directions on the label accompanying the cosmetic product is likely to cause injury to the health of the user.

(2) No person shall manufacture, sell, offer for sale, distribute or cause to be distributed any cosmetic product which contains any of the skin bleaching agents listed in the Schedule to these Regulations.

(3) A person who contravenes the provisions of paragraph (1) or (2) of this regulation is guilty of an offence and liable on conviction to a fine of ₦5,OOO or imprisonment for a term of six months or to both such fine and imprisonment.

2. Meaning of adulterated cosmetic products

A cosmetic product shall be regarded as adulterated if it-

(a) contains more than a trace of mercury or any mercury salt which under normal condition of manufacturing practice is unavoidable; or

(b) contains more than a trace of mercury or any mercury salt calculated as the metal or preservative; or

(c) contains hydroquinone; or

(d) bears or contains any poisonous or deleterious substance as to render it injurious to a user under the conditions prescribed in its labelling or under such conditions of use as are customary or usual for the cosmetic product; or

(e) has been prepared, packed or held under insanitary conditions thereby rendering it likely to be injurious to health; or

(j) the container in which it is packed is composed in whole or part of poisonous or deleterious substance which may render the contents injurious to health; or

(g) contains more than the permissible limit of an ingredient.

3. Citation

These Regulations may be cited as the Cosmetic Products (Prohibition of Bleaching Agents, etc.) Regulations.

SCHEDULE

[Paragraph I (2).]

Skin bleaching agents

I. Hydroquinone.
2. Corticosteroids.
3. Mercury and mercury compounds.

FOOD PRODUCTS REGISTRATION REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

FOOD PRODUCTS REGISTRATION REGULATIONS

[S.1.7 of 1996.]

under sections 5 and 29

[2nd January, 1996]

[Commencement.]

1. Registration of every food manufactured, etc.

(1) Every food manufactured, imported, exported, advertised, sold or distributed in Nigeria shall be registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of sub-paragraph (1) of this regulation, the manufacture or importation of any food product as a sample for registration shall be undertaken with the approval of the Agency.

2. Application for registration

(1) The application for registration of any food product shall be made in such form as may be prescribed from time to time by the Agency.

(2) An application shall be accompanied by-

(a) a non-refundable fee as may be prescribed by the Agency;

(b) adequate samples of the food product;

(c) the original certificate of analysis of the food product;

(d) samples of the labels of the food product;

(e) evidence of any special labelling claims of the character, quality and safety of the food product;

(f) the original certificate of manufacture and free sale for the imported food product from the statutory body in charge in the country of origin responsible for the safety of the food product;

(g) the radio-active test certificate where demanded by the Agency;

(h) the power of attorney or an agreement from the manufacturer to register the food product in Nigeria if it is an imported food product and an undertaking that every advertisement of the food product shall be submitted to the Agency for approval before publication:

Provided that any person given a power of attorney shall be required to satisfy the Agency that he has the resources and facilities to execute an effective recall of the food product if the need arises.

3. Issuance of certificate of registration

(1) Where the Agency is satisfied that an application for registration has been made in the prescribed form and contains all the information as required under paragraph (2) of these Regulations, the food product shall be issued with a registration certificate and registration number.

(2) Where an application is unsatisfactory the applicant shall be notified and the defects specified.

4. Validity of approval

The certificate of registration of food product shall be valid for a period of five years.

5. Invalidation of certificate of registration

The Agency may suspend, withdraw or cancel the certificate of registration of a food product if-

(a) the grounds on which the food product was registered were found to be false or incomplete; or

(b) the circumstances under which the food product was registered no longer exist; or

(c) any of the conditions or undertaking under which the food product 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 food product is imported, processed, manufactured or stored by or on behalf of the holder of the certificate of registration are unsuitable for the importation, processing, manufacturing or storage of the food product.

6. Demand for the certificate of registration

A manufacturer or importer of a food product shall produce the original certificate of registration in respect of any food product manufactured or imported by him within 48 hours of its demand by any person duly authorised by the Agency.

7. Penalty

If any person contravenes any of the requirements of these Regulations, the Agency shall prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale or use of the food product either absolutely or for such a period of time as the Agency may declare, in addition to a fine of NSO,OOO.

8. Application

The provisions of these Regulations shall be applicable to food products manufactured in an approved establishment.

9. Interpretation

For the purposes of these Regulations, unless the context otherwise requires-

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

"Director-General" means Director-General of the Agency;

"establishment" means any place, building and any forecourt or yard where any operation for the purpose of manufacturing a food product is carried out;

"label" in relation to any food product or food product as packaged includes any legend, word or mark attached to, included in, belonging to or accompanying that food product or a package of it.

10. Citation

These Regulations may be cited as the Food Products Registration Regulations.

BOTTLED WATER (LABELLING) REGULATIONS

ARRANGEMENT OF REGULATIONS

BOTTLED WATER (LABELLING) REGULATIONS

[S.l. 8 of 1996.]

under sections 5 and 29

[2*nd January*, 1996]

[Commencement.]

1. Labelling of bottled water

(1) No person shall under these Regulations sell bottled water unless a label has been affixed to it.

(2) Such label shall not describe or present bottled water-

(a) in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding the character, quality, quantity and origin of a bottled water;

(b) by words, pictorial or other means as to refer to any other product or to suggest either directly or indirectly, that the bottled water is connected with such other product.

2. Name

(1) Every bottled water shall have a name and such name shall indicate the accurate nature of the content of the bottled water.

(2) Where a name has been established for a bottled water in these Regulations, such a name only shall be used.

(3) Where no common name for a bottled water exists, an appropriate descriptive name shall be used.

(4) A coined or fanciful name may be used provided the name is not misleading and is accompanied by an appropriate descriptive term.

3. Net content of pre-packaged bottled water

(1) Every average net content of pre-packaged bottled water shall be declared in a metric system of measurement.

(2) The declaration required to be made under sub-paragraph (1) of this regulations shall be made, in the case of a bottled water, in volume.

4. Name and address of manufacturer

The name and location address of the manufacturer, packer, distributor, importer or vendor of a bottled water shall be declared on the label of every bottled water.

5. Country of manufacturer

The country of manufacture of a bottled water shall be declared on every bottled water.

6. Information on labels

(1) All statements on the label of every bottled water shall be clear, prominent and legible to a consumer and shall have a contrasting colour to that of the background.

(2) No information shall be obscured by design or by other written, printed or graphic matter.

(3) No person shall remove, add to, alter, deface or render illegible any statement upon a label printed on or attached to a wrapper or container of a bottled water in pursuance of these Regulations.

(4) Every label shall be firm and not easily detachable or defaceable.

7. Date marking instructions

(1) The date of minimum durability of every bottled water shall be specified and legibly displayed and shall be preceded by the words "best before", "use by" or "expiry" as required for the product by the Agency.

(2) Unless otherwise specified in any commodity regulations, the following shall apply for bottled water-

(a) the day, month and the year of expiry shall be stated in an uncoded chronological order;

(b) the date of manufacture, where applicable, shall be stated on the bottled water.

8. Batch number

The batch numbering shall be indicated on all bottled water.

9. Specific information

Every label of bottled water shall bear the information required by paragraphs 4,5, 6, 7, 8 and 9 of these Regulations.

10. Trade mark

The trade mark (if any) shall be displayed on all bottled water and such trade mark shall not give a wrong impression of the nature, quality or substance of the bottled water.

11. Language

All declarations required to be made under paragraphs 4 and 5 of these Regulations shall be in English.

12. Particulars on physical condition of bottled water and specific treatment

Any special treatment which a bottled water has undergone, shall be indicated in all cases where omission of such information may create confusion in the mind of the consumer.

13. Instructions for use

The directions for use, including reconstitulion where applicable, shall be included in the label to ensure correct utilisation of such bottled water.

14. Misleading information on label

Any information required to be displayed on a label of a bottled water which is misleading in any way shall constitute an offence under these Regulations.

15. Grade designation

Any grade designation used on a bottled water shall be readily understandable and shall not be misleading or deceptive in any way.

16. Penalty

If any person contravenes the requirements of these Regulations, the Agency may prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale or use of the bottled water either absolutely or for such period of time as the Agency may declare, in addition to the payment of a fine of N50,OOO.

17. Interpretation

For the purposes these Regulations, unless the context otherwise requires-

"bottled water" means any form of processed water packaged for drinking purposes enclosed in any container;

"label" includes any writing, printed or graphic matter relating to and accompanying the bottled water or a package of it.

18. Citation

These Regulations may be cited as the Bottled Water (LabelIing) Regulations.

PESTICIDE REGISTRATION REGULATIONS

ARRANGEMENT OF REGULATIONS

PESTICIDE REGISTRATION REGULATIONS

[1993 No. 15. S.l. 10 of 1996.]

[2*nd January*, 1996]

[Commencement.]

1. Prohibition

As from the commencement of these Regulations--

(i) no pesticide shall be manufactured, formulated, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of these Regulations;

(ii) notwithstanding the provisions of subsection (1) of this regulation the manufacture, formulation or importation of any pesticide as sample for registration shall be undertaken with the approval of the Agency.

2. Application for the registration of pesticide

(1) No person shall submit application for the registration of any pesticide unless such pesticide was manufactured or formulated in an establishment acceptable and approved by the Agency.

(2) The application for pesticide registration shall be made on a prescribed application form obtainable from the Agency.

(3) Each application form for the registration shall be accompanied by a non-refundable fee as prescribed in the current tariff of the Agency.

3. Submission of application

(a) The completed application form shall be submitted with the following--

(i) adequate samples of the pesticide product as determined by the Agency;

(ii) original certificate of analysis of the pesticide product;

(iii) certificate of manufacture and free sale of pesticide product if imported from the statutory body responsible for the safety of the product in the country of origin;

(iv) radio-active test certificate where demanded by the Agency;

(v) power of attorney or an agreement from the manufacturer to register the pesticide product in Nigeria if it is an imported pesticide;

(vi) an undertaking in writing that every advertisement of the pesticide shall be submitted to the Agency for approval before publication;

(vii) specimen labels of the pesticide product;

(viii) evidence for any special labelling claims on the character, quality and safety of the pesticide product.

(b) Product chemistry-

An application submitted to the Agency shall state--

(i) the product composition, normal concentration, physical and chemical characteristics; and

(ii) standard laboratory analytical methods for each active ingredient, impurity or inert ingredient that is toxicologically significant.

(c) Other studies--

The study conducted in respect of pesticide product shall include--

(i) environmental fate;

(ii) degradation;

(iii) metabolism of plant and animals;

(iv) mobility, that is, the stability thereof;

(v) accumulation;

(vi) hazards to human or domestic animals;

(vii) toxicity whether by oral, dermal and or inhalation;

(viii) teratogenicity or reproductive studies;

(ix) mutagenicity;

(x) hazard to non-target organisms including birds and fishes;

(xi) product performance including efficacy trials in Nigeria.

(d) Residue level-

Company should state the residue level for the pesticide in all its intended usage in the country. This will be compared with the tolerance level as may be determined by the Agency.

(e) Use of the pesticide product--

(i) dosage and direction for use;

(ii) fields of application;

(iii) methods of application.

(f) Storage conditions.

(g) Method of disposal of containers.

(h) Precautions including first-aid.

(i) Note to physician.

4. Issuance of certificate of registration

(1) Where the Agency is satisfied with the submissions in respect of the pesticide, the product shall be issued with a registration certificate.#

2) Where the submissions are unsatisfactory, the applicant shall be informed with reasons in writing.

5. Registration fee

The applicant shall pay a registration fee as may from time to time be prescribed in the approved tariff of the Agency.

6. Validity of approval

The registration of any pesticide product shall be valid for a period of five years.

7. Invalidation of certificate of registration

The Agency may suspend, withdraw or cancel the certificate of registration if-

(a) the grounds on which the pesticide product was registered were later found to be false or incomplete; or

(b) the circumstances under which the pesticide product was registered no longer exist; or

(c) any of the conditions or undertaking under which the pesticide product was registered has been contravened; or

(d) the standard of quality, safety or efficacy as prescribed in the documentation for registration are not being complied with; or

(e) the premises in which the pesticide product is imported, processed, manufactured, formulated or stored by or on behalf of the holder of the certificate of registration are unsuitable for the importation, processing, manufacturing, formulation or storage of the pesticide product.

8. Offences and penalty

If any person makes default in complying with the requirements of these Regulations, the Agency may prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale or use of the pesticide either absolutely or for such time the Agency declares, in addition to a fine of ₦100,000.00.

9. Interpretation

For the purposes of these Regulations, unless the context otherwise requires--

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

"Director-General" means the Director-General of the Agency;

"growth regulator" means any substance or mixture of substances intended through physiological action for accelerating or retarding the growth and development of organisms.

"pest" means any insect, rodent, nematode, fungus, weed or any other form of plant or animal or virus or bacteria or other micro-organisms which the Director-General declares to be a pest;

"pesticide" means any chemical substance or mixture of substances intended for preventing, destroying, repelling or mitigating the effect of any pest of plants and animal and

shall include herbicides insecticides, rodenticides, fungicides, molluscides, nematocides, repellants, attractants, insect growth regulators used in agriculture, public health, horti-culture, food storage or a chemical substance used for similar purpose;

"residue" means the amount of pesticides that may remain in or on food, animal feed and the environment;

"tolerance level" means the maximum permissible amount of pesticides that may remain in or on food and animal feed.

10. Citation

These Regulations may be cited as the Pesticide Registration Regulations.

NON-NUTRITIVE SWEETENERS IN FOOD PRODUCTS REGULATIONS

ARRANGEMENT OF REGULATONS

REGULATION

NON-NUTRITIVE SWEETENERS IN FOOD PRODUCTS REGULA TIONS

[S.l. 11 of 1996.)

[2*nd January*, 1996]

[Commencement.]

1. Prohibition of use of non-nutritive sweeteners in food/beverages

(1) No person shall manufacture, import, export, advertise, sell or present any food item or beverage containing a non-nutritive sweetener for human consumption, except as provided for in these Regulations.

(2) Non-nutritive sweeteners shall not be used for foods/beverages presented for in-fants and children consumption.

2. Conditions for use of non-nutritive sweeteners

Non-nutritive sweeteners may only be used in special dietary foods/beverages such as energy reduced foods or low calories foods/beverages. The use of non-nutritive sweeten-ers in foods shall be as authorised by the Agency.

3.**Declaration on label for foods / beverages containing non-nutritive sweetener**

Where the Agency permits the use, a declaration as to the identity and quantity of the sweetener shall be made on the labels of such food products/beverages.

4. Offence

(1) A person who contravenes a provision of these Regulations shall be liable on conviction to a fine of ₦ l00, 000 or one year imprisonment or to both such fine and im-prisonment.

(2) The Agency shall have the power to seize, confiscate, destroy or dispose of in any manner whatsoever the product containing the non-nutritive sweeteners in respect of which an offence has been committed.

5. Interpretation

In these Regulations unless the context otherwise requires--

"Agency" means National Agency for Foods and Drug Administration and Control;

"non-nutritive sweetener" means any substance having non-nutritive properties, which when added to food is capable of imparting sweetness to the food.

6. Citation

These Regulations may be cited as Non-nutritive Sweetener in Food Products Regulations.

NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS (PROHIBITION) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

NON-NUTRITIVE SWEETENERS IN DRUG PRODUCTS (PROHIBITION) REGULATIONS

[S.1. 12 of 1996.]

[2*nd January*, 1996]

[Commencement.]

1. Prohibition of use of non-nutritive sweeteners in drugs products

(1) No person shall manufacture, import, export, advertise, sell, distribute or cause to be distributed any drug product which contains non-nutritive sweeteners.

2. Adulterated products

A drug product shall be regarded as adulterated and hazardous to health if it contains nun-nutritive sweeteners.

3. Conditions for use of non-nutritive sweeteners

Without prejudice to section I of these Regulations, the Agency may authorise the manufacture, importation, exportation, sale, distribution, advertisement and use of a registered/permitted non-nutritive sweetener for special dietary requirements and or a formulation.

4. Offence

(1) A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction to a fine of ₦ I00,000 or one year imprisonment or to both such fine and imprisonment.

(2) The Agency shall have the power to seize, confiscate, destroy or dispose of in any manner whatsoever the product containing the non-nutritive sweeteners in respect of which an offence has been committed.

5. Interpretation

In these Regulations unless the context otherwise requires--

"adulterated drug" means a drug product which bears or contains non-nutritive sweeteners;

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

"drug product" means any formulation of a drug used for the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state or the symptoms thereof, in man or in animals; disinfection or the control of vermin, insects or pests, or contraception;

"non-nutritive sweetener" means any substance having non-nutritive properties, which when added to a drug product is capable of imparting sweetness to the drug product.

6. Citation

These Regulations may be cited as Non-nutritive Sweetener in Drug Products (Prohibition) Regulations.

FOOD PRODUCTS (ADVERTISEMENT) REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

FOOD PRODUCTS (ADVERTISEMENT) REGULATIONS

[1994 No. 15. S.1. 13 of 1996.]

[2*nd January*, 1996]

[Commencement.]

1. Application of Regulations

(1) The provisions of these Regulations shall apply to all advertisements of food products (both single entity or compound) imported into Nigeria or locally manufactured, distributed or sold in Nigeria.

2. Advertisement of unregistered products: Prohibition

No person shall advertise any food product unless it has been registered by the Agency.

3. Clearance to be obtained before advertisement

No person shall advertise any food product unless the advertisement has the pre-clearance and approval of the Agency.

4. Nature of advertisement

All advertisements of food products in Nigeria shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners and such statements or illustrations contained on the packaging shall not mislead directly or by implication.

5. Non-referential advertisement

No advertisement of any food product shall-

(a) make reference directly or indirectly to any member of the health care profession, hospitals, clinic or pharmacy, etc.;

(b) imitate the general layout, text, slogan or visual presentation or devices of other food products in a way likely to mislead or confuse the consumer; or

(c) be framed in such a manner as to make reference directly or indirectly to the medical or any of its allied professions.

6. Application for the approval of advertisements

(1) All advertisement materials including scripts, story-board, art work, radio, video tapes, etc., shall be submitted under confidential cover along with an application to the Director-General of the Agency.

(2) Where the advertisement materials are submitted through any of the State offices of the Agency, it shall be subject to the approval of the Director-General of the Agency.

7. Particulars of application

An application submitted by an advertising agent, distributor, manufacturer or the sponsor of the advert shall contain the followi ng, that is--

(a) the brand name of the food product;

(b) place of importation or local manufacture;

(c) the name and location address of the manufacturer;

(d) the name and address of the local distributor;

(e) the name and location address of the advertising company;

(f) the date of first introduction of the food product to the Nigerian market;

(g) information about any previous advertisement of the food product in Nigeria;

(h) a copy of the old script;

(i) the proposed media for the advertisement;

(j) a copy of the registration certificate of the food product;

(k) a justification for any special claims on the food product;

(l) scripts, story-board, art works, radio and video tapes of the advert; and

(m) such other materials as may be required by the Agency from time to time.

8. Validity of approval

The approval of an advertisement shall be valid for a period of one year beginning from the date of the approval.

9. Alteration in approved script

Any alteration in the format of the approved script, story-board, art work, radio or videos tapes without the approval of the Agency shall render the approval null and void.

10. Unacceptable advertisement

Where an advertisement is considered unacceptable by the Agency, the words "Unacceptable as presented" shall be stamped on it and it shall be returned to the advertiser with the unacceptable information or illustration clearly identified.

11. Appeal in case of withdrawal of approval within the one year specified

(1) If the approval for an advertisement is withdrawn during the one-year period of approval, an appeal shall be lodged within thirty days after the receipt of the withdrawal to the Governing Council in writing and accompanied by supportive information.

12. Restriction

No advertisement for a food product shall contain--

(a) any false or misleading information;

(b) half-truths, inadequate qualification and limitations regarding safety or effectiveness of the food product;

(c) vague, unsubstantiated statements, suggestions or superiority over other competing food products;

(d) any false impression that the advertised food product is for universal cure or should be regarded as a more effective and safer alternative to other related food products.

13. Data comparison misrepresentation

(1) No comparison shall mislead directly or by implication and any such comparison shall be supported by reliable current data.

(2) Any reference to competitive manufacturer or their specialties shall be restricted to factual comparisons without the use of identifiable product(s) or brand name(s).

(3) All data illustrations presented in an advertisement including charts, graphs, tables extracted from reference studies or other source or reproduced by art work shall be accurate, complete and clear with their source specifically identified.

(4) Data illustrations shall not be misleading or ambiguous or distort the original intended meaning or interpretation either directly or by implication.

14. Accurate interpretation of research findings

Any copy of an advertisement shall be written in a manner which accurately interprets valid and representative research findings and relevant statistics on the food product shall be written in a manner which reflects only their true validity and significance.

15. Prohibition of misleading statements in advertisement

No person shall-

(a) display, screen or otherwise present an advertisement of a food product unless in accordance with the provisions of these Regulations; or

(b) give to a food product a name which is capable of giving a false impression of the nutritional properties of the food product; or

(c) make any claim to assert, imply or otherwise convey the impression as to the suitability of the food product for use in the prevention, alleviation, management, treatment or cure of a disease, disorder or physiological condition; or

(d) make a claim that the food product contains a particular value when that value is not wholly contributed by the food products, but is partly contributed by other food products with which it may be consumed.

(2) All nutritional claims shall comply with Regulations of the Prepackaged Food (Labelling) Regulation 1995.

16. Energy intake in food product for adults and children

A person shall in advertising a food product or on a label of such food product, state--

(a) that the food product is a "source" or "dietary source" of energy if a reasonable daily intake of that food product by a person would result in the daily intake of not less than 450 kilo calories of energy;

(b) that the food product is a "good source" or "a good dietary source" of energy if a reasonable daily intake of that food product by a person would result in an intake of not less than 1,200 kilo calories of energy; and

(c) that the food product is "an excellent source" or "an excellent dietary source" of energy if a reasonable daily intake of that food product by a person would result in daily intake of not less than 2,250 kilo calories of energy.

(2) No person shall sell a food product for which an energy claim is made and represented as being solely for use in the feeding of children under two years of age, unless a reasonable daily intake of that food product by a child under two years of age would result in the total daily intake by the child of not less than 1,360 kilo calories of energy.

17. Ambiguous inference to tonic properties

No person shall advertise for the sale or have in his possession for the sale any food product which is described by a name or words calculated to indicate either directly or by ambiguity, commission or inference that the food product has tonic properties by reason only that such food product contains--

(a) alcohol; or

(b) protein or substances prepared from the hydrolysis of protein; or

(c) caffeine or purine derivatives.

18. Protein intake in food product

A person shall in advertising a food product or on a label of such food product, state--

(a) that the food product is Ha source" or Ha dietary source" of protein if a reasonable daily intake of that food product by a person would result in the daily intake by that person of not less than 9 grams of protein;

(b) that the food product is Ha good source" or "a good dietary source" of protein if a reasonable daily intake of that food product by a person would result in an intake of not less than 24 grams of protein; and

(c) that the food product is "an excellent source" or "an excellent dietary source" of protein if a reasonable daily intake of that food product by a person would result in daily intake by that person of not less than 45 grams of protein.

19. Penalties

If any person defaults in complying with the requirements of these Regulations, the Agency shall prohibit that person from carrying on the advertisement of food products either absolutely or for such period of time as the Agency may determine, in addition to a fine of ₦50,000.

20. Interpretation

In these Regulations, unless the context otherwise requires--

"advertising" means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, and any other documents) made orally or otherwise or by means of projected light and sound recordings;

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

"Director-General" means Director-General of the Agency;

"food" means any article manufactured, sold or advertised for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever, but does not include live animals, birds or fish, fodder or feeding stuff for ani-

mals, birds or fish other than supplements produced for addition to animal and poultry food stuff;

"food establishment" means any registered place where any operation for the purpose of manufacturing food is being carried on;

"label" means a display of written, printed or graphic matter upon the immediate containers;

"package labelling" includes the label on the immediate container and all other printed matter such as outer wrapper, carton or leatlet associated with the package.

21. Citation

These Regulations may be cited as the Food Products (Advertisement) Regulations.

FOOD GRADE (TABLE OR COOKING) SALT REGULATIONS

ARRANGEMENT OF REGULATIONS

SCHEDULES

FOOD GRADE (TABLE OR COOKING) SALT REGULATIONS

[1993 No. 15. S.1. 14 of 1996.]

[2*nd January*, 1996]

[Commencement.]

1. Application

(1) Any salt used as an ingredient of food for direct use to consumer, food manufacture or as a carrier of food additive shall meet the standard requirement for food grade salt as set out in this regulation.

(2) Notwithstanding the provisions of sub-paragraph (1) of this regulation, the requirement applies only to salt which is not a by-product of chemical industries.

2. **Standard for food grade salt**

(1) All food grade salt shall--

(a) be crystalline product consisting predominantly of sodium chloride;

(b) be obtained from the sea, from underground rock salt deposits or from natural brine;

(c) contain not less than 97,0% of sodium chloride on a dry matter basis exclusive of additives and not more than 0.2% of matter insoluble in water.

(2) *(a)* The remainder may comprise natural secondary products which are present in varying amounts depending on the origin and the method of production of the salt which shall compose mainly of calcium, potassium, magnesium, sodium sulphate, carbonates, bromides and of calcium, potassium and magnesium chlorides.

(b) Food grade salt may also contain natural contaminants, present in amounts varying with the origin and the method of production of the salt such that-

(i) the sulphate content shall not be more than (5g/kg) or (0.5%) expressed as S04;

(ii) the magnesium contents shall not be more than 3g/kg or 0.3% expressed as Mg;

(iii) the calcium content shall not be more than 3g/kg or 0.3% expressed as Ca.

(c) Food grade/salt shall be the fine grained, refined, white crystalline salt with the addition of anticaking agents and other additives the use and limits for which shall be as prescribed in Schedule A to these Regulations.

(d) The minimum level of iodine ex-factory and at the port of entry shall be 50 mg/kg. The minimum level of iodine at all retail outlets (markets, supermarkets, etc.) shall be 30 mg/kg.

3. Maximum limits of contaminants in food grade salt

Food grade salt shall not contain contaminants in amount and in such a form that shall be harmful to the health of the consumer: The maximum limits prescribed in Schedule B to these Regulations shall not be exceeded.

4. Hygiene of food grade salt

The method of production, packaging, storage and transportation of food salt shall be in accordance with the requirements of Good Manufacturing Practice (GMP).

5. Labelling of food grade salt

Notwithstanding the requirements of Prepackaged Food (Labelling) Regulations of 1995, the following specific provisions shall apply-

(a) the name of the product as declared on the label shall be "salt";

(b) the name "salt" shall have a prefix of "food grade" or "Table";

(c) where the salt contains one or more ferrocyanide salts added to the brine during the crystallisation step, the term "dendritic" shall be included to accompany the name;

(d) when the salt is used as a carrier of one or more nutrients and sold as such for public health reasons, the name (the product shall be declared properly on the label; for example, "Salt fluoridated", "Salt fortified with iron", "Salt fortified with vitamins" and so on as appropriate);

(e) sail (sodium chloride) meant for industrial use shall be labelled boldly in red: "INDUSTRIAL SALT NOT FOR HUMAN CONSUMPTION".

6. Interpretation

For the purpose of this Regulations, unless the context otherwise requires-

"component" means any substance which forms part of an ingredient;

"container" means any form of packaging of salt for sale as a single item whether by completely or partially enclosing the salt and includes wrappers;

"ingredient" means any substance, including a food additive used in the manufacture or preparation of salt and present in the final product;

"label" includes any tag, brand, mark, pictorial or other descriptive written, printed, stencilled, marked, embossed or impressed on or attached to a container of salt;

"labelling" includes the label and any written, printed or graphic matter relating to and accompanying the salt;

"prepackaged" means packaged or made up in advance ready for retail sale in a container.

7. Citation

These Regulations may be cited as the Food Grade (Table or Cooking) Salt Regulations.

SCHEDULES

SCHEDULE A

Permitted food additives and their maximum levels in food grade (table or cooking) salt

1. ANTICAKING AGENTS

(a) Coating Agents

Carbonates (Calcium and/or Magnesium)	20 g/kg singly or in combination
Magnesium Oxide, Phosphate (tricalcium), Silicon dioxide	20 g/kg singly or in combination

(b) Coating Hydrophilic Agents

Aluminium, calcium, magnesium, potassium or sodium salts of myristic, palmitic or stearic acids	20 g/kg singly or in combination

(c) Crystal Modifiers

Ferrocyanides, calcium potassium or sodium*	10 mg/kg singly or in combination or expressed as (Fe (CN) 6)

2. EMULSIFIERS

Polysorbate 80	10 mg/kg

3. PROCESSING AID

Dimethylpoly-silo-xane	10 mg of residue/kg

*Sodium and potassium ferrocyanides maximum level may be 20 mg/kg when used in the preparation of "dendritic" salt.

SCHEDULE B
[Regulation 3.]

I	Arsenic	0.5 mg/kg expressed as	As
2	Copper	2 mg/kg expressed as	Cu
3.	Lead	2 mg/kg expressed as	Pb
4	Cadmium	0.1 mg/kg expressed as	Cd
5	Mercury	0.1 mg/kg expressed as	Hg

COSMETICS AND MEDICAL DEVICES (ADVERTISEMENT) REGULATIONS

ARRANGEMENT OF REGULATIONS

COSMETICS AND MEDICAL DEVICES (ADVERTISEMENT) REGULA TIONS

[S.1. 17 of 1996.]

under sections 5 and 29

[*2nd January*, 1996]

[Commencement.]

1. Application of these Regulations

These Regulations apply to all advertisements and promotion of cosmetics and medical devices (in these Regulations referred to individually as "the product") (whether single entity or compound) imported into Nigeria or manufactured, distributed or sold in Nigeria.

2. Restriction on the product

No person shall advertise the product unless-

(a) the product has been registered by the National Agency for Food and Drug Administration and Control (in these Regulations referred to as the "Agency");

(b) the advertisement has been cleared and approved by the Agency.

3. Application for the approval of advertisement

An application for the approval of an advertisement shall be made by an advertisement agent, a distributor, manufacturer or the sponsor of the advertisement, through the State office of the Agency, to the Director-General of the Agency.

4. Particulars of application

(1) The application shall contain the following information, where applicable, that is-

(a) the brand name of the product;

(b) the generic name of the product;

(c) the dosage form of the product, if available;

(d) whether the product is imported or manufactured in Nigeria;

(e) the name and address of the manufacturer of the product;

(*j*) the name and address of the distributor of the product;

(g) the name and address of the advertising company;

(h) the date of first introduction of the product to the Nigerian market;

(i) any information on any previous advertisement of the product in Nigeria, if any;

(j) if any previous advertisement in Nigeria, a copy of that advertisement;

(k) the proposed media for the advertisement;

(l) a copy of the registration certificate of the product;

(m) justification for any special claims.

(2) The scripts and story-board art works, radio and video tapes of the advertisement shall be submitted with the application.

(3) All materials submitted under this Regulation shall be authenticated by the superintendent pharmacist of the pharmaceutical company and the Chief Executive of the cosmetics or medical devices company sponsoring the product.

5. Agency may grant an approval

Where the Agency is satisfied that there is need for an approval to be granted, it shall do so and issue to the applicant a certificate of approval, subject to such conditions as the Agency may deem necessary.

6. Validity of approval

An approval shall be valid for a period of one year from the date of the approval and may be renewed.

7. Alteration in approved script

Any alteration in the format of the approved script, art work or story-board without the written permission of the Agency shall render the approval null and void.

8. Nature of advertisement

An advertisement shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners, and accordingly, no illustration which is likely to mislead the general public either directly or by implication shall be accepted.

9. Unacceptable advertisement

Where an advertisement is considered unacceptable by the Agency, the words "Unacceptable as presented" shall be stamped on it and returned to the applicant with the unacceptable information or illustration clearly identified, and further clarification of the ruling shall be provided on request by the applicant.

10. Withdrawal of an approval

The Agency may withdraw the approval for an advertisement if-

(a) the grounds on which the approval was granted was later found to be false or incomplete; or

(b) any of the conditions under which the approval was granted has been contravened; or

(c) the standard or the advertisement contravenes the provisions of regulation 13, 14, 15, 16, 17, 18, 19, 20 or 21 of these Regulations.

11. Appeal in case of withdrawal of approval

(1) Where the approval for an advertisement is withdrawn during its validity, an appeal may be directed to the Agency within 30 days of the withdrawal.

(2) An appeal under paragraph (1) of this regulation shall be in writing and be accompanied with such materials and other information as may be necessary to support the appeal.

12. Prohibition of reference to member of health care profession, etc.

No advertisement shall make reference directly or indirectly to any member of the healthcare profession or to a hospital, clinic or any other health centre.

13. Contravention of ethical standards not permitted

No advertisement shall contravene the ethical standard of the health care profession.

14. Advertisement not to prejudice public confidence

No advertisement shall bring the pharmaceutical industry into disrepute, undermine or prejudice public confidence in medicine.

15. Unfairly disparage competition

No advertisement shall unfairly disparage any competitive company of its competitive products either directly or by implication.

16. Prohibition of imitation or misleading advertisement

No advertisement shall imitate the general layout, text, slogan or visual presentation of any other competing product in a way likely to mislead or confuse the consumer.

17. Exploitation of superstitious belief

No advertisement shall be framed in a manner as to exploit any superstitions or be calculated to induce fear, causing the public to purchase the product advertised.

18. Restriction

No advertisement shall contain-

(a) any false or misleading information; or

(b) half-truth, inadequate qualification and limitation regarding the safety or effectiveness of the product; or

(c) vague or unsubstantiated statement or suggestion or superiority over competing product; or

(d) any false impression that the product advertised is more effective or safer than any other competing product.

19. Prohibition of misleading comparison

(1) No comparison in an advertisement shall mislead the public either directly or by implication and where there is comparison it shall be supported by reliable current data.

(2) A reference to a competitive manufacturer or its specialties in an advertisement shall be restricted to factual comparison without the use of identifiable regulated product or product or brand name.

(3) A data illustration, including chart and graph, table extracted from reference study or other source or reproduced by art work, presented in an advertisement, shall-

(a) be accurate, complete and clear, with their source specifically identified;

(b) not be misleading or ambiguous or distort the original intended meaning or interpretation either directly or by implication.

20. Accurate interpretation of research findings

(1) A copy of an advertisement shall be so written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement shall be so written as to reflect only their true validity and significance.

(3) Any claim or quotation from a scientific literature concerning the efficacy, safety and adverse reaction, use in young children or during pregnancy or in any other situation with the constraints of the accepted products monograph, shall specify the scientific source of the claim or quotation.

(4) Copy of any reference cited by an applicant or in the advertisement shall be provided to the Agency for verification.

21. Scientific articles and literatures to contain both positive features and negative findings

(1) A claim or quotation shall contain both the negative and positive findings and shall be readily verifiable by the Agency.

(2) A claim based on, or quotation that has been selected from a scientific article or series of articles which emphasises only the positive features while ignoring negative findings, shall not be acceptable.

22. Offence

A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction to a fine of ₦50, 000.

23. Interpretation

(1) In these Regulations, unless the context otherwise requires-

"Act" means the National Agency for Food and Drug Administration and Control Act 1993;

[1993 No. 15.]

"advertising" means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, and any other documents) made orally or otherwise or by means of projected light and sound recordings;

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

"claim" means any representation which states, suggests or implies that the medical device has particular qualities relating to its origin, nature, processing, composition or any other quality;

"cosmetic" has the meaning assigned to it in the Drugs and Related Products (Registration, etc.) Act 1993;

[1993 No. 19.]

"Director-General" means the Director-General of the National Agency for Food and Drug Administration and Control;

"justification" in respect of any claim shall be in the light of current knowledge;

"label" means a display of written, printed or graphic matter upon the immediate medical device containers;

"package labelling" includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package;

"medical device" has the meaning assigned to it in the Act;

"product" means any cosmetic or medical device.

(2) Any word or expression used in these Regulations shall, unless the context otherwise requires, have the meaning assigned to it in the Act.

24. Citation

These Regulations may be cited as the Cosmetics and Medical Devices (Advertisement) Regulations.

BOTTLED WATER REGISTRATION REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

BOTTLED WATER REGISTRATION REGULATIONS

[S.l. 18 of 1996.]

under sections 5 and 29

[2*nd January*, 1996]

[Commencement.]

1. Registration of bottled water

(1) Every bottled water manufactured, imported, exported, advertised, sold or distributed in Nigeria shall be registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of sub-paragraph (1) of this regulation the manufacture or importation of any bottled water as a sample for registration shall be undertaken with the approval of the Agency.

2. Submission of application for registration

(1) An application for registration of a bottled water shall be-

(a) submitted only if the bottled water was manufactured in an establishment that has been approved by the Agency; and

(b) made on such form as may be prescribed from time to time by the Agency and on the payment of such non-refundable fee as may be prescribed by the Agency.

3. Forms, etc.

(1) A form submitted for registration of bottled water under these Regulations shall have attached thereto-

(a) adequate samples of the bottled water;

(b) the original certificate of analysis on the bottled water;

(c) the samples of the labels of the bottled water;

(d) the evidence of any special labelling claims of the character, quality and safety of the bottled water;

(e) the original certificate of manufacture and free sale for imported bottled water from the statutory body in charge in the country or origin responsible for the safety of the product;

(f) the radio-active test certificate where demanded by the Agency;

(g) the power of attorney or an agreement from the manufacturer to register the product in Nigeria if it is imported bottled water; and

(h) an undertaking that every advertisement of the bottled water shall be submitted to the Agency for approval before publication.

(2) A person given a power of attorney under sub-paragraph 3(1) *(g)* of this regulation shall be required to satisfy the Agency that he has the resources and facilities to execute an effective recall of the product if the need arises.

4. Issuance of certificate of registration

(1) Where the submissions in respect of a bottled water are satisfactory, the product shall be issued with a certificate of registration and a registration number.

(2) Where the submissions in respect of an application are unsatisfactory the applicant shall be informed of the reasons for the disapproval.

5. Validity or certificate of registration

The certificate of registration of a bottled water shall be for a period of five years.

6. Invalidity of certificate of registration

The Agency may suspend, withdraw or cancel the certificate of registration of a bottled water if-

(a) the grounds on which the bottled water was registered were false or incomplete; or

(b) the circumstances under which the bottled water was registered no longer exist; or

(c) any of the conditions or undertaking under which the bottled water was registered have 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 bottled water is imported, processed, manufactured or stored by or on behalf of the holder of the certificate of registration are unsuitable for the importation, processing, manufacturing or storage of the bottled water.

7. Demand for the certificate of registration

A manufacturer or importer of bottled water shall be required to produce the original certificate of registration in respect of any bottled water manufactured or imported by him within 48 hours of its demand by any person duly authorised by the Agency.

8. Penalty

If any person contravenes any of the requirements of these Regulations, the Agency shall prohibit that person from carrying on the importation, exportation, manufacture, distribution, sale or use of the bottled water either absolutely or for such period of time as the Agency may declare in addition to the payment of a fine of ₦5O,OOO.

9. Application

The provisions of these Regulations shall be applicable to any person seeking to register the manufacture, importation, exportation, advertisement, sale and distribution of bottled water in Nigeria.

10. Interpretation

For the purposes of these Regulations, unless the context otherwise requires-

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

"Director-General" means the Director-General of the Agency;

"establishment" means any place, building and any forecourt or yard where any operation for the purpose of manufacturing bottled water is carried out;

"label" in relation to any bottled water or as packaged, includes any legend, word or mark attached thereto, included in, belonging to or accompanying that bottled water or a package of it.

11. Citation

These Regulations may be cited as the Bottled Water Registration Regulations.