GOVERNMENT NOTICE NO. 130

TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ORDINANCE, 1960

(*No.* 8 *of* 1960)

REGULATIONS

MADE BY THE GOVERNOR-GENERAL UNDER SECTION 25 OF THE FOOD AND DRUGS ORDINANCE, 1960

THE FOOD AND DRUGS REGULATIONS, 1965

PART I

1. These Regulations may be cited as the Food and Drugs Regulations, 1965.

2. These Regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality, or other property of the article of food, drug, cosmetic, or device, to which they refer.

INTERPRETATION

3. In these Regulations—

"acceptable method" means a method of analysis or examination indicated by the Minister as acceptable for use in the administration of the Ordinance;

"cubic centimetre" and its abbreviation "cc" shall be deemed to be interchangeable with the term "millilitre" and its abbreviation "ml";

"inner label" means the label on or affixed to an immediate container of a food, drug, cosmetic, or device;

"lot number" means any combination of letters or figures, or both, by which any food or drug can be traced in manufacture and identified in distribution;

"official method" means the method of analysis or examination designated by the Minister for use in the administration of the Ordinance;

"the Ordinance" means the Food and Drugs Ordinance, 1960;

"outer label" means the label on or affixed to the outside of a package of a food, drug, cosmetic, or device.

4. The Chief Chemist shall, upon request—

(*a*) furnish copies of official methods, and

(*b*) indicate that a method submitted to him for his ruling is acceptable or otherwise.

INSPECTORS

5. (1) Inspectors shall perform the functions and duties, and carry out the responsibilities, prescribed by the Ordinance, these Regulations and the Minister.

(2) The authority of an inspector extends to and includes the whole of Trinidad and Tobago.

6. A certificate that a person has been appointed as an Inspector shall be in the form set out as Form A in the Third Schedule, shall be signed by the Minister and the person appointed.

7. (1) An Inspector may take photographs of premises and articles as may be relevant to the administration of the Ordinance or these Regulations, in so far as they apply to unsanitary conditions.

(2) For the purposes of paragraph (1), the expression "articles" includes—

(*a*) food, drugs, cosmetics, and devices, and anything used for the manufacture, preparation, preservation, packaging or storing of such articles; and

(*b*) any labelling or advertising material.

IMPORTATIONS

8. (1) An Inspector may examine, take samples of, and detain pending further examination, any food, drug, cosmetic, or device, imported into Trinidad and Tobago but not delivered out of the charge of customs.

(2) Where a sample of a food, drug, cosmetic, or device is taken, the inspector shall, as soon as may be practicable thereafter, submit the sample to an analyst for examination or analysis.

9. (1) Subject to paragraph (2), where, as a result of an examination or analysis of a sample of a food, drug, cosmetic, or device, an analyst reports that the food, drug, cosmetic, or device would, if sold in Trinidad and Tobago, constitute a violation of the Ordinance or of these Regulations, the food, drug cosmetic, or device shall not be admitted into Trinidad and Tobago for use as a food, drug, cosmetic, or device, as the case may be, and the inspector shall send a report of the analysis or examination to the Comptroller of Customs and a copy to the importer.

(2) Where a food, drug, cosmetic, or device, sought to be admitted into Trinidad and Tobago would, if sold in Trinidad and Tobago, constitute a violation of the Ordinance or of these Regulations, the food, drug, cosmetic, or device may be admitted into Trinidad and Tobago for the purpose of re-labelling or re-conditioning under the supervision of an inspector in compliance with such written conditions as may be specified in the report of an

analyst, and where such re-labelling or re-conditioning is not satisfactorily carried out within three months after the report is made, or such lesser period as may be specified in the report, such food, drug, cosmetic, or device shall be exported, and, if not exported within a further period of three months, are forfeited to the Crown and may be disposed of as the Minister may direct; but the Minister may extend the time for complying with conditions or for exporting the said goods.

10. A certificate required under subsection (2) of section 32 of the Ordinance shall be a certificate in the English Language issued by the official body or Government Department having authority to issue such certificate in the country in which the article of food, drug, cosmetic, or device was manufactured or produced; and where no official body or Government Department has authority to issue such a certificate, the certificate may be issued by any person acceptable to the Minister.

SAMPLING

11. When taking a sample pursuant to section 21 of the Ordinance, an inspector shall, after procuring a suitable quantity of the article in question and paying for the same the usual price therefor, notify the owner thereof or the person from whom the sample was obtained of his intention to submit a sample thereof to an analyst for analysis or examination, and

(*a*) if the owner or the person from whom the sample was obtained, demands it, but not otherwise, then and there divide the quantity into three parts, and shall—

(i) cause each of the three parts to be marked and sealed in such manner as the nature of such sample will permit,

(ii) deliver one of the parts to the owner or person from whom the sample was obtained, or leave the same upon the premises wherein the sample was obtained, and

(iii) retain one of the parts for future comparison or verification, and shall submit the third part to the analyst for analysis or examination;

(*b*) if no demand is made for the division of the sample into three parts, the inspector shall—

(i) divide the same into two parts,

(ii) cause each of those parts to be marked and sealed in such manner as the nature of the sample will permit, and

(iii) retain one of the parts for future comparison or verification, and submit the other to the analyst for analysis or examination.

12. (1) Notwithstanding regulation 11, where in the opinion of the inspector division of the procured quantity of a sample would interfere with analysis or examination, the inspector may, subject to paragraph (2), seal and submit the entire sample for analysis or examination.

(2) Where the owner or person from whom the sample was obtained objects to the procedure provided for in paragraph (1) at the time the sample was obtained, and supplies at his own expense a sufficient quantity of the article, the inspector shall follow the procedure described in regulation 11.

CERTIFICATE OF ANALYSIS

13. A certificate of an analyst stating that he has analysed or examined an article or a sample submitted to him by an inspector shall be in the form set out as Form B in the First Schedule, with such variations as circumstances may require.

PART II—FOODS

14. In this Part—

"bulk container" means a container in which more than one duly labelled package of a food and its contents are placed for purposes of wholesale, but in which the packages and their contents are not intended to be retained;

"common name" means, with reference to a food, the name of the food printed in bold type in these Regulations, or, if the name of the food is not so printed, the name by which the food is generally known;

"flavouring preparation" includes any food for which a standard is provided in Division 5 of the Second Schedule;

"food colour" means those colours permitted for use in or upon food by Division 2 of the First Schedule;

"per cent." means per cent. by weight unless otherwise stated;

"preservative" means a substance classified as such in Division 7 of the First Schedule;

"sweetening agent" means a sugar, molasses, or honey.

15. No person shall sell a food that is not labelled in accordance with this Part.

16. Except as otherwise provided by this Part, the label of a package of food shall carry—

(*a*) on the main panel of the label :

(i) the brand or trade name, if any, of the food;

(ii) the common name of the food, and

(iii) a correct declaration of the net contents of the package in terms of weight, measure, or number, as is the usual practice in describing such article;

(*b*) grouped together on the main panel or on any panel other than the bottom of the package :

(i) a declaration by name of any Class II, Class III, or Class IV preservative therein,

(ii) a declaration of any food colour added thereto,

(iii) a declaration of any artificial or imitation flavouring preparation added thereto,

(iv) any other statement required by these Regulations to be declared; and

(*c*) on the main panel or on any panel other than the bottom of the package, the name and address of the manufacturer or packager.

17. Regulation 16 does not apply to a food which is—

(*a*) sold in an open or uncovered package;

(*b*) sold in a sealed package made of transparent, colourless, and flexible material;

(*c*) weighed, measured, or counted into the package in which it is sold, in the presence of the purchaser; or

(*d*) packaged from bulk at the place where the food is sold by retail.

18. Notwithstanding regulation 16, a bulk container of a food may carry a label with any or all of the following:

(*a*) the common name of the food,

(*b*) the brand or trade name of the food,

(*c*) the contents of the bulk container,

(*d*) the name of the manufacturer, importer, packager, or wholesaler,

(*e*) the address of the manufacturer, importer, packager, or wholesaler.

19. Notwithstanding subparagraph (iii) of paragraph (*a*) of regulation 16, a declaration of net contents is not required on—

(*a*) a package of food the weight of which including the package, is less than two ounces, or

(*b*) fluid dairy products sold in glass containers of one-half pint, one pint, one quart, one-half gallon, three quarts, or one gallon capacity.

20. Notwithstanding subparagraph (ii) of paragraph (*b*) of regulation 16—

(*a*) no label declaration is required to indicate the presence of food colour in the following:

(i) bakery products, except brown bread,
(ii) butter,
(iii) cheese,
(iv) confectionery,
(v) ice cream,
(vi) icing sugar,
(vii) liqueurs and alcoholic cordials,
(viii) sherbets,
(ix) carbonated beverages,
(x) soft drinks; and

(*b*) no label declaration is required to indicate the presence of caramel as a food colour in the following :

(i) non-excisable fermented beverages,
(ii) sauces,
(iii) spirituous liquors, except gin,
(iv) vinegar,
(v) dilute acetic acid (food grade),
(vi) wine.

21. Notwithstanding subparagraph (iii) of paragraph (*b*) of regulation 16, no label declaration is required to indicate the presence of artificial or imitation flavouring preparations in the following :

(i) bakery products,
(ii) confectionery,
(iii) ice cream,
(iv) sherbets,
(v) liqueurs and alcoholic beverages,
(vi) soft drinks,
(vii) carbonated beverages.

22. A food containing saccharin or cyclohexylsulphamic acid, or the salts of either of them, shall carry on the label a statement indicating that the food contains a synthetic sweetener (naming it), and is intended to be used by persons who must restrict their intake of ordinary sweetening agents.

23. No reference direct or indirect, to the Ordinance, to those Regulations, or to the Ministry of Health, shall be made upon any label, or in any advertisement, of a food unless such reference is a specific requirement of the Ordinance or of these Regulations.

24. Where a standard for a food is provided in this Part, only those ingredients named in the standard shall be used in the food.

25. For the purposes of the Ordinance and these Regulations, a food is adulterated if any of the following substances or classes of substances is present therein or has been added thereto :

(i) mineral oil or paraffin wax, or any preparation thereof,

(ii) coumarin or an extract of tonka beans, the seed of *Dipteryx odorata Willd.* or *Dipteryx oppositifolia Willd.;*

(iii) synthetic sweetening agents, other than saccharin or cyclohexyl-sulphamic acid or their salts;

(iv) iso-propyl alcohol.

26. Notwithstanding regulation 25—

(*a*) a food is not adulterated by reason only that it contains mineral oil not exceeding 0.3 per cent., if good manufacturing practice required its use; and

(*b*) chewing gum is not adulterated by reason only that it contains a paraffin wax base.

27. (1) Where the contents of a package of food are expressed in terms of weight, measure, or number, no variations below the quantity declared on the label are permitted except, subject to paragraph (2)—

(*a*) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing, and

(*b*) variations in weight, measure, or number, that unavoidably result from the ordinary and customary exposure of the package to evaporation, or to the absorption of water, under normal atmospheric conditions.

(2) Where the contents of a package of food are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

28. (1) All information required by this Part to be carried on a label shall be—

(*a*) clearly and prominently displayed thereon, and

(*b*) readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

(2) For the purpose of paragraph (*a*) of regulation 16, a common name consisting of more than one word shall be deemed to be clearly and prominently displayed on the main panel of the label if each word (other than article, conjunction, or preposition) is in identical type and identically displayed.

(3) On any label of or in any advertisement of an artificial, imitation, substitute, or synthetic food, the word "artificial", "imitation", "substitute", "synthetic", or other appropriate word shall be stated in full, and shall—

(*a*) be an integral part of the name of such food, and

(*b*) be in identical type and be identically displayed with such name.

(4) Where inner and outer labels are employed on a package of food, all label declarations required by this Part shall appear on both the inner and outer labels.

First Schedule

29. The provisions of the First Schedule shall be read as one with this Part.

30. A person who contravenes or fails to comply with a provision of this Part is liable on summary conviction to a penalty of one hundred dollars or to imprisonment for three months.

PART III—DRUGS

General

31. In this Part—

Ch. 12. No. 8.

"antibiotic" means any of the substances whether made by the action of micro-organisms or synthetically, specified in the Schedule to the Antibiotics Ordinance, and includes all compounds of, and all medicinal preparations containing any of such substances;

"common name" means, with reference to a drug, the name in English by which the drug is commonly known, or the name by which the drug is commonly known in Trinidad and Tobago;

Second Schedule

"controlled drug" means any of the drugs classified as such in Division 2 of the Second Schedule, and includes a preparation;

"dentist" means a person qualified by law to practice dentistry in Trinidad and Tobago;

"expiration date" means the date after which a drug is not recommended by the manufacturer for use;

"hospital" means any public hospital or licensed private hospital;

"internal use" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane;

No. 27 of 1961

"narcotic drug" means any of the substances specified in the Schedule to the Narcotics Control Ordinance;

"official drug" means any drug for which a standard is provided—

(*a*) in this Part, or

(*b*) in any of the publications mentioned in the Second Schedule to the Ordinance;

"parenteral use" means administration of a drug by means of a hypodermic syringe, needle, or other instrument, through or into the skin or mucous membrane; and "parenteral" shall be construed accordingly;

"Patent or Proprietary Medicine" means any drug which—

(*a*) is intended for internal or external use by man, and the name, composition, or definition of which is not to be found in any of the publications mentioned in the Second Schedule to the Ordinance, or in any formulary, pharmacopoeia, or publication issued by any official body approved by the Minister; and

(*b*) is sold and labelled with a trade name or registered trade mark indicating that the drug is manufactured by a particular person or company;

and includes any drug approved as a Patent or Proprietary Medicine by the Pharmacy Board of Trinidad and Tobago;

"per cent." means per cent. by weight unless otherwise stated;

"pharmacist" means a person who is registered as a member of the Pharmacy Board of Trinidad and Tobago;

"pharmacy" means an establishment where drugs or devices are dispensed or prepared or sold by retail;

"physician" means a person who is registered as a member of the Medical Board of Trinidad and Tobago;

"poisonous drug" means a drug mentioned in the Third Schedule to Pharmacy Board Ordinance; No. 7—1960

"practitioner" means a dentist, physician, or veterinary surgeon;

"preparation" means a drug that contains in a recognised therapeutic form, a controlled drug and one or more drugs other than controlled drugs;

"prescription" means a direction given in writing, and dated and signed, by a practitioner, that a stated amount of a drug or mixture of drugs be dispensed for the person named therein;

"proper name" means with reference to a drug—

(*a*) the name in English that is assigned to the drug by this Part,

(*b*) the name in English of the drug printed in bold type in this Part, and, where the drug is dispensed in a form other than described in this Part, the name of the dispensing form,

(*c*) the name published by—

(i) the British Pharmacopoeia Commission of the General Medical Council of the United Kingdom as the approved name, or

(ii) the Adopted Name Council of the United States Pharmacopeial Convention as the adopted name of the drug; or

(*d*) in the case of a drug not included in paragraph (*a*), (*b*), or (*c*), the name in English assigned to the drug in any of the publications mentioned in the Second Schedule to the Ordinance; or

(*e*) international non-proprietary names proposed by the World Health Organization;

Ch. 12. No. 7 "sulphonamide drug" includes a drug mentioned in the Schedule to the Sulphonamide Drugs Ordinance;

"Third Schedule drug" means any drug mentioned in the Third Schedule to the Ordinance;

"veterinary drug" means a drug sold for veterinary use, and includes a drug supplied on a prescription given by a Veterinary Surgeon;

Ch. 25. No. 1 "veterinary surgeon" means a person who is registered under the Veterinary Surgeons (Registration) Ordinance.

32. No person shall sell a drug that is not labelled as required by this Part.

33. Except as provided in this Part, the label of a drug shall carry—

(*a*) on the main panel of both the inner and the outer labels :

(i) the proper name and the standard under which the drug was manufactured which, if the standard is contained in any publication mentioned in the Second Schedule to the Ordinance, shall be stated in full or by the abbreviation therein provided, or

(ii) if there is no proper name, the common name;

(*b*) on both the inner and outer labels:

(i) the name of the manufacturer or distributor of the drug,

(ii) the address of the manufacturer or distributor, except that where the immediate container contains five millilitres or less, this statement need not be made on the inner label,

(iii) where a drug is intended for internal or parenteral use, the lot number, the number being preceded by the words "Lot number", "Lot No.", "Lot", or "L", except on labels of Patent or Proprietary Medicines,

(iv) adequate directions for use,

(v) the proper name, or, if there is no proper name, the common name, of each medicinal ingredient contained therein, except on shipping cases, wrapping material, official drugs, and Patent or Proprietary Medicines; and

(*c*) on the outer label:

(i) a correct statement of net contents in terms of weight, measure, or number, and

(ii) where the drug is intended for parenteral use, the name and proportion of any preservative present therein.

34. The provisions of regulation 33 do not apply—

(*a*) to the label of a drug sold on a prescription where the label carries—

(i) the name and address of the pharmacist or pharmacy;

(ii) the date and number of the prescription;

(iii) adequate directions for use;

(iv) the name of the person for whom the drug is dispensed or prescribed;

(v) the name of the physician, dentist, or veterinary surgeon, issuing the prescription;

(vi) where the drug is a Third Schedule drug or a controlled drug and unless otherwise directed by the person issuing the prescription, the name of the drug; and

(*b*) to the label of a drug packaged from bulk on the premises where the drug is retailed, if the label carries:

(i) the name of the drug, and

(ii) the name and address of the pharmacist or pharmacy.

35. Notwithstanding subparagraph (v) of paragraph (*b*) of regulation 33, where a Patent or Proprietary Medicine contains a narcotic drug, a Third Schedule drug, or a controlled drug, the name and proportion of such drug shall, subject to regulation 34, be stated on the label.

36. Where a package of a drug has only one label, that label shall contain all the information required by these Regulations to be shown on both the inner and outer labels.

37. All information required by this Part to be carried on a label of a drug shall be clearly and prominently displayed thereon, and readily discernible to the purchaser or consumer under the customary conditions of purchase or use.

38. No reference, direct or indirect, to the Ordinance, to these Regulations, or to the Ministry of Health, shall be made upon any label or in any advertisement, of a drug unless such reference is a specific requirement of the Ordinance or of these Regulations.

39. Where by any law in force in Trinidad and Tobago, a standard is prescribed for a drug and that standard is given a name or designation by such law, no person shall use that name or designation on a label, or in any advertisement, of that drug, unless the drug conforms to the standard.

40. Where it is necessary to provide adequate directions for the safe use of parenteral drugs, Third Schedule drugs, or controlled drugs, that are used in the treatment or prevention of any of the diseases, disorders, or abnormal physical states, mentioned in the First Schedule to the Ordinance, such diseases, disorders, or abnormal physical states may be mentioned in the inserts accompanying such drugs, and, to such extent, such drugs are hereby exempted from the provisions of subsection (1) of section 4 of the Ordinance.

41. A drug when distributed in accordance with subsection (2) of section 13 of the Ordinance is hereby exempted from the provisions of subsection (1) of section 4 of the Ordinance as regards any inserts accompanying such drug.

42. (1) No person shall sell a drug in the form of a tablet which is intended to be swallowed whole, unless the tablet disintegrates in not more than 60 minutes when tested by the official method.

(2) Paragraph (1) does not apply to tablets which are represented on the label as being enteric coated, or as having delayed action.

43. (1) Where the contents of a package of a drug are expressed in terms of weight, measure, or number, no variations from the quantity declared on the label are permitted except, subject to paragraph (2)—

(*a*) variations due exclusively to weighing, measuring, or counting, that occur in packaging conducted in accordance with good commercial practice, which variations are, except where the contents are expressed in terms of number, not to be such that the average content is less than the quantity declared on the label, as determined by the official method,

(*b*) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing,

(*c*) variations in weight or measure that unavoidably result from the ordinary and customary exposure of the package to evaporation, or to the absorption of water, under normal atmospheric conditions, and

(*d*) where a drug, other than an official drug, consists of several ingredients, the amount of each ingredient so dispensed shall be not less than 90 per cent. and not more than 110 per cent. of the amount calculated from the label description.

(2) Where the contents of a package of a drug are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

44. No person shall sell a drug—

(*a*) that contains salicylic acid or its salts, acetylsalicylic acid or its salts, or salicylamide, and

(*b*) that is recommended for children,

unless both the inner and the outer labels carry a cautionary statement to the effect that the drug is not to be administered to children under two years of age except on the advice of a physician.

45. No person shall advertise to the general public for human use, a Third Schedule drug, or a controlled drug.

46. The importation and sale of Thalidomide is prohibited.

47. The provisions of the Second Schedule shall be read as one with this Part.

48. A person who contravenes or fails to comply with a provision of this Part is liable on summary conviction to a penalty of one hundred dollars or to imprisonment for three months.

49. These regulations have effect from 1st January, 1965.

FIRST SCHEDULE (Regulation 29)

Division 1—Baking Powder

1. *Baking Powder* shall be a combination of sodium bicarbonate, an acid-reacting material mentioned in paragraph 2, and starch or other neutral material, and shall yield not less than 8 per cent. of its weight of carbon dioxide as determined by the official method.

2. The acid-reacting material of baking powder shall be—

(*a*) tartaric acid or its salts, or both; or

(*b*) acid salts of phosphoric acids.

Division 2—Food Colours

1. In this Division—

(*a*) "pure dye" means the synthetic dye contained in a synthetic food colour;

(*b*) "preparation" means a preparation of one or more synthetic food colours containing less than 15 per cent. pure dye and sold for household use in containers of two ounces net or less.

2. No person shall sell for use in or upon food any colour other than the following:—

(*a*) natural colours, being cochineal, vegetable colours and vegetable colour extractives, or their colouring principles whether isolated from natural sources or produced synthetically;

(*b*) caramel;

(*c*) specially purified charcoals, carbon blacks, iron oxide, and titanium dioxide;

(*d*) synthetic food colours approved by the Minister.

3. No person shall sell a food having in or upon it any added colour other than the following:—

(*a*) natural colours, being cochineal, vegetable colours, and vegetable colour extractives, or their colouring principles whether isolated from natural sources or produced synthetically;

(*b*) caramel;

(*c*) specially purified charcoals, carbon blacks, iron oxide, and titanium dioxide;

(*d*) synthetic food colours approved by the Minister.

4. No person shall sell a colour for use in or upon food that contains more than—

(*a*) 2 parts per million of arsenic, calculated as arsenic; or

(*b*) 10 parts per million of lead, calculated as lead, as determined by the official method; or

(*c*) except in the case of iron oxide, a total of 100 parts per million of iron and copper, calculated as iron and copper;

and if other heavy metals are present, the colour shall be deemed to be adulterated.

5. (1) No person shall import a synthetic food colour or a mixture or preparation of synthetic food colours for use in or upon food unless it has been certified by the Minister, or by another agency acceptable to the Minister, that such synthetic food colour or such mixture or preparation of synthetic food colours meets the requirements of paragraph 4, and, if certified by an agency, a copy of the certificate has been submitted to and approved by the Minister.

(2) For the purpose of subparagraph (1), a synthetic food colour or a mixture or preparation of synthetic food colours meets the requirements of paragraph 4 if the provisions thereof will not be contravened in a sale of the synthetic food colour or the mixture or preparation.

6. For the purposes of this Division the following synthetic food colours shall, subject to paragraph 7, be deemed to be approved by the Minister—

(*a*) food colours certified by the Food and Drug Directorate of Canada;

(*b*) food colours certified by the Food and Drug Administration of the United States of America;

(*c*) colours permitted for use in food in the United Kingdom;

(*d*) synthetic food dyes approved for use in food by the Food and Agriculture Organisation of the United Nations and by the World Health Organisation;

(*e*) synthetic food dyes approved for use in food by the Australian Commonwealth Food Additives Committee.

7. Notwithstanding paragraph 6, the Minister may, by notice published in the *Gazette*, withdraw approval with respect to any synthetic food colour which he is satisfied is toxic or is capable of producing toxic effects; and upon publication of the notice, paragraph 6 shall cease to apply with respect to that synthetic food colour.

Division 3—Dairy Products

1. The foods referred to in this Division are included within the term "dairy product".

2. Except as provided in this Division, a dairy product that contains a fat other than milk fat is adulterated.

Milk

3. *Milk or* (*Whole Milk*) shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus Bos, and shall be free from colostrum, and shall contain—

(*a*) not less than 3.0 per cent. of milk fat;

(*b*) not less than 8.5 per cent. of milk solids not fat; and

(*c*) not more than 20 parts per million of dirt.

By dirt is meant all matter insoluble in, and foreign to, milk as it leaves the cow's udder.

The milk from animals other than bovine species shall be given a designation appropriate to its source.

4. *Milk Products* shall be products of which the components are exclusively derived from milk, and may contain added substances necessary for manufacture or intended to enrich the natural vitamins and salts in the products if these added substances do not replace, either completely or partly, any constituent whatsoever of milk.

5. *Reconstituted Milk* shall be labelled as such, and shall be a milk product resulting from the combining of milk constituents with water, and shall contain not less than :—

(*a*) 3.0 per cent. of milk fat, and

(*b*) 8.5 per cent. of milk solids not fat.

6. *Milk Fat or Butter Fat* shall be the fat of cow's milk, and shall have :—

(*a*) a specific gravity of not less than 0.905 at a temperature of 40°C. ;

(*b*) a Reichert-Meissl number not less than 24 ; and

(*c*) a Polenske number not exceeding 10 per cent. of the Reichert-Meissl number, and in no case shall the Polenske number exceed 3.5 ; and

where the Polenske number exceeds 10 per cent. of the Reichert-Meissl number, there shall be deemed to have been an addition to the milk fat of fat other than that of cow's milk.

7. *Sterilized Milk* shall be milk, or a milk product, that has been heated to a temperature of at least 100°C. for a length of time sufficient to kill all the organisms present, and shall be delivered to the consumer in hermetically sealed containers, and shall contain not less than :—

(*a*) 3 per cent. of milk fat, and

(*b*) 8.5 per cent. of milk solids not fat.

8. *Flavoured Sterilized Milk* shall be sterilized milk with cocoa, chocolate, or a flavouring preparation and shall contain not less than :—

(*a*) 2.5 per cent. of milk fat ; and

(*b*) 8.5 per cent. of milk solids not fat ;

and may contain stabilizer and sugar.

9. *Condensed Milk or Sweetened Condensed Milk* shall be milk, or a milk product, from which water has been evaporated and to which sugar has been added, and shall contain not less than :—

(*a*) 28 per cent. of milk solids ; and

(*b*) 8 per cent. of milk fat ;

and may contain added vitamin D.

10. *Evaporated Milk or Unsweetened Condensed Milk* shall be milk, or a milk product, from which water has been evaporated, and shall contain not less than :—

(*a*) 25.0 per cent. of milk solids ;

(*b*) 7.5 per cent. of milk fat ;

and may contain :—

(*c*) added vitamin D ;

(*d*) disodium phosphate, or sodium citrate, or both, added in a total quantity of not more than 0.1 per cent. of the finished product.

11. *Skim Milk* shall be milk from which all or most of the milk fat has been removed.

12. *Milk Powder, Dry Milk, Dry Whole Milk, Powdered Milk or Powdered Whole Milk* shall be dried milk, and shall contain not less than :—

(*a*) 95 per cent. of milk solids ; and

(*b*) 26 per cent. of milk fat ;

and may contain added vitamin D.

13. *Skim Milk Powder, Dry Skim Milk or Powdered Skim Milk* shall be dried skim milk and shall contain not less than 95 per cent. of milk solids, and may contain added vitamin D.

14. *Butter* shall be the food, prepared by gathering the milk fat of milk or cream into a mass that may also contain a portion of the other milk constituents not separated in good manufacturing practice, and shall contain :—

(*a*) not less than 80 per cent. of milk fat ; and

(*b*) not more than 16 per cent. of moisture ;

and may contain salt and food colour.

15. *Cooking Butter* shall be labelled as such, and shall be butter prepared as described in paragraph 14, and shall contain :—

(*a*) not less than 75 per cent. of milk fat ; and

(*b*) not more than 12 per cent. of salt,

and may contain food colour.

16. *Ghee* shall contain not less than 98 per cent. of milk fat, without any admixture of other fat.

17. *Ice Cream* shall be the frozen food made from milk or milk products and sweetened with sugar, and shall contain not less than :—

(*a*) 8 per cent. of fat ;

(*b*) 36 per cent. of solids ;

(*c*) 1.8 parts of solids per Imperial gallon ;

and may contain :—

(*d*) edible oil or fat ;

(*e*) egg ;

(*f*) flavouring preparation ;

(*g*) cocoa or chocolate syrup ;

(*h*) food colour ;

(*i*) acid-reducing salts ;

(*j*) fruit, nuts, confections ; and

(*k*) stabilizer, but not more than 0.5 per cent.

Division 4—Edible Oils and Fats

1. *Cooking Oil or Edible Oil* shall be a refined product of coconut oil, and shall contain not more than 0.08 per cent. of acid expressed as lauric acid, and may contain such other oil as may be approved by the Minister.

2. *Cooking Butter Substitute* shall be labelled as such, and shall contain—

(*a*) not less than 75 per cent. of fat, and

(*b*) not more than 12 per cent. of salt,

and may contain food colour, preservative, and added vitamins.

3. *Margarine* shall be labelled as such and shall contain not less than 80 per cent. of fat, and may contain food colour, preservative, salt, and added vitamins.

4. *Phalka Ghee, Ghee Substitute, or Vegetable Ghee* shall contain not less than 98 per cent. of fat other than animal fat.

5. *Olive Oil* shall be the oil of the fruit of the olive tree and shall have—

(*a*) a specific gravity at 20°/20°C. of not less than 0.910 and not more than 0.918;

(*b*) a refractive index at 40°C. of between 1.4605 and 1.4635,

(*c*) an Iodine value (Hanus) of not less than 78 and not more than 88, and

(*d*) a saponification value of not less than 190 and not more than 195.

Division 5—Flavouring Preparations

1. A flavouring extract or essence shall be a solution in ethyl alcohol, glycerol, or propylene glycol, or any combination of these, of sapid or odorous principles, or both, and shall be derived from the plant after which the flavouring extract or essence is named, and may contain—

(*a*) water;

(*b*) a sweetening agent;

(*c*) food colour; and

(*d*) a Class II or Class IV preservative.

2. Where a flavouring extract or essence is mixed with other flavouring extracts or essences, the label shall carry a statement of the names of all the extracts or essences so mixed and each of those names shall be deemed to comprise the name of the extract or essence.

3. An artificial, imitation, substitute, or synthetic flavouring extract or essence shall be a flavouring extract or essence, except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named.

DIVISION 6—POISONOUS SUBSTANCES IN FOOD

1. No person shall sell any food in a container that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

2. Except as otherwise provided, a food named in the Table herein set forth, which contains in or upon it—

(*a*) any or all of the poisonous or harmful substances listed in the said Table, in amounts not exceeding the quantities stated therein in parts per million (p.p.m.) for that food, as determined by an acceptable method, and either

(*b*) no other poisonous or harmful substances; or

(*c*) other poisonous or harmful substances in amounts not considered by the Minister likely to be injurious to health;

is hereby exempted from the provision of paragraph (*a*) of section 5 of the Ordinance.

FOOD	SUBSTANCE			
	Arsenic p.p.m.	Lead p.p.m.	Copper p.p.m.	Zinc p.p.m.
Citric Acid	1	10	50	50
Tartaric Acid...	1	10	50	50
Cream of Tartar	2	20	50	50
Sodium Bicarbonate	2	5	50	50
Baking Powder	2	10	50	50
Phosphoric Acid	4	5	30	30
Calcium Phosphate	4	5	30	30
Sodium, Potassium and Ammonium Phosphates ...	4	5	30	30
Sodium and Potassium Nitrates	1	10	50	50
Sodium Nitrate	1	20	50	50
Marine and Fresh Water Animal Products ...	5	10	100	100
Fresh Fruits	2	7	50	50
Fresh Vegetables	1	2	50	50
Gelatin	2	7	30	100
Gelling agents except Gelatin	2	20	50	200
Dried Herbs and Spices	5	10	50	50
Apple Juice, Cider, Wine and Beer	0.2	0.5	2	5
Fruit Juice except Apple Juice	0.1	0.2	2	5
Beverages	0.1	0.2	2	5
Tea	1	10	150	50

3. Except as otherwise provided, a food not named in the Table to paragraph 2 which contains in or upon it—

(*a*) not more than—

(i) one part per million of arsenic,

(ii) two parts per million of lead,

(iii) twenty parts per million of copper, or

(iv) fifty parts per million of zinc. as determined by an acceptable method and either

(*b*) no other poisonous or harmful substances, or

(*c*) other poisonous or harmful substances in amounts not considered by the Minister likely to be injurious to health,

is hereby exempted from the provision of paragraph (*a*) of section 5 of the Ordinance.

DIVISION 7—PRESERVATIVES

1. For the purposes of this Division—

(*a*) Class I preservatives comprise the following :

(i) ethyl alcohol,
(ii) ascorbic acid, iso-ascorbic acid, and their salts,
(iii) glucose,
(iv) potassium nitrate,
(v) common salt,
(vi) sodium nitrate,
(vii) sodium nitrite in preserved meat only, in an amount not exceeding 200 parts per million of the finished product,
(viii) spices,
(ix) cane sugar,
(x) vinegar,
(xi) wood smoke,

(*b*) Class II preservatives comprise the following:

(i) benzoic acid, including salts thereof,
(ii) sulphurous acid, including salts thereof,
(iii) sorbic acid, including salts thereof,

(*c*) Class III preservatives comprise the following:

(i) propionic acid, including salts thereof,
(ii) sodium diacetate,
(iii) sorbic acid, including salts thereof,

(*d*) Class IV preservatives comprise the following, whether used with or without a harmless carrier:

(i) gum guaiacum,
(ii) vegetable oils containing tocopherols,
(iii) lecithin,
(iv) citric, tartaric, or ascorbic acid,
(v) monoisopropyl citrate,
(vi) ascorbyl palmitate,
(vii) n-propyl gallate, or n-octyl gallate, or n-dodecyl gallate,
(viii) nordihydroguaiaretic acid,
(ix) butylated hydroxyanisole,
(x) butylated hydroxytoluene.

2. Where any Class II, Class III, or Class IV preservative is sold for use as a preservative for food, the label shall carry adequate directions for use in accordance with the limits prescribed for such preservative in this Division.

3. Notwithstanding subparagraph (i) of paragraph (*b*) of regulation 16—

(*a*) no label declaration is required for the presence of sulphurous acid or its salts in or upon the following:

(i) sweetening agents,
(ii) beer and stout,
(iii) syrups,
(iv) wine,
(v) confectionery; and

(*b*) no label declaration is required for the presence of a Class III preservative, in or upon the following:

(i) bakery products,
(ii) cheese.

4. No person shall—

(*a*) use as a preservative in or upon food, or sell as a preservative for food, any substance other than Class I, Class II, Class III, or Class IV preservatives.

5. No person shall sell—

(*a*) benzoic acid or its salts,

(*b*) sulphurous acid or its salts,

(*c*) n-propyl gallate, n-octyl gallate or n-dodecyl gallate,

(*d*) butylated hydroxyanisole,

(*e*) nordihydroguaiaretic acid, or

(*f*) butylated hydroxytoluene,

for use as a preservative for food, unless the label carries a quantitative statement of the amounts of such preservative present.

6. No person shall use in or upon a food more than one Class II preservative.

7. No person shall use in or upon a food, more than—

(*a*) 1,000 parts per million of benzoic acid or its salts, calculated as benzoic acid, or

(*b*) 1,000 parts per million of sorbic acid or its salts, calculated as sorbic acid.

8. Except as provided in this Division, no person shall use sulphurous acid or its salts, calculated as sulphur dioxide, in amounts greater than—

(*a*) 100 parts per million in beverages as prepared for consumption,

(*b*) 2,500 parts per million in or upon dried fruits and vegetables, or

(c) 500 parts per million in or upon other foods.

9. No person shall use in or upon a food, more than—

(*a*) 2,000 parts per million of propionic acid or its salts, calculated as propionic acid;

(*b*) 3,000 parts per million of sodium diacetate; or

(*c*) 1,000 parts per million of sorbic acid or its salts, calculated as sorbic acid.

10. No person shall use in or upon a food, Class IV preservatives, singly or in combination, including the carrier, in an amount greater than 0.2 per cent. of the finished product.

11. No person shall use in or upon food more than—

(*a*) 0.01 per cent. of n-propyl gallate, n-octyl gallate, or n-dodecyl gallate,

(*b*) 0.01 per cent. of nordihydroguaiaretic acid,

(*c*) 0.02 per cent. of butylated hydroxyanisole,

(*d*) 0.02 per cent. of butylated hydroxytoluene, or

(*e*) 0.02 per cent. of a combination of not more than three of the Class IV preservatives listed in subparagraphs (*a*), (*b*), (*c*) and (*d*) of this paragraph.

12. No person shall use in or upon a food combination of nordihydro guaiaretic acid and n-propyl gallate or n-octyl gallate or n-dodecyl gallate.

Division 8—Vinegar and Dilute Acetic Acid (Food Grade)

1. *Vinegar* shall be the liquid obtained by the acetous fermentation of an alcoholic liquid, and subject to paragraph 7, shall contain not less than 4.0 per cent., nor more than 12.0 per cent. of acetic acid.

2. *Wine Vinegar* shall be vinegar made from wine, and may contain caramel.

3. *Spirit Vinegar or Alcohol Vinegar, Distilled Molasses Vinegar, White Vinegar, or Grain Vinegar* shall be vinegar made from diluted distilled alcohol.

4. *Malt Vinegar* shall be vinegar made from an infusion of malt undistilled prior to acetous fermentation, and may contain other cereals and caramel.

5. *Cider Vinegar or Apple Vinegar* shall be vinegar made from the liquid expressed from apples, and may contain caramel.

6. If any reference is made to the strength of a vinegar by any statement, mark, or device on the label of or in any advertisement of a vinegar, the label shall carry a statement of the strength of the vinegar declared in per cent., and the strength of the vinegar shall be calculated in terms of acetic acid.

7. The maximum limit for the acetic acid content of vinegar does not apply to vinegar sold for manufacturing use only, if such vinegar is so identified by the use of the words, " For Manufacturing Use Only " on the label of the package.

8. Solutions of acetic acid prepared by diluting concentrated or glacial acetic acid with water, with or without the addition of food colour or other material, shall not be sold in any package bearing on the label the word " vinegar " or the words " salad dressing ", or any other word or words which may lead the purchaser to believe that the contents consist either wholly or in part of vinegar as defined in paragraph 1.

9. Solutions of acetic acid prepared as described in paragraph 8 shall, subject to paragraph 10, be labelled " Dilute Acetic Acid (Food Grade) " and shall contain not less than 4.0 per cent., nor more than 12.0 per cent. of acetic acid.

10 Paragraph 9 does not apply to the preparation and sale in registered pharmacies of acetic acid solutions for medicinal purposes.

Division 9—Fruit Juices

1. *Canned Fruit Juice* shall be the unfermented liquid expressed from sound, ripe, fresh fruit, and may contain—

(*a*) sweetening agent; and

(*b*) a Class II preservative;

and shall be packed in hermetically sealed metal container.

2. *Canned Grapefruit Juice* shall be the fruit juice obtained from grapefruit, and shall contain, in 100 mililitre measured at a temperature of 20°C.—

(*a*) not less than 9.5 grams of soluble solids before addition of any sweetening agent;

(*b*) not less than 0.3 grams of ash; and

(*c*) not less than 1.0 gram and not more than 2.2 grams of acid calculated as anhydrous citric acid;

and shall be packed in hermetically sealed metal containers.

3. *Canned Orange Juice* shall be the fruit juice obtained from oranges, and shall contain in 100 millilitres measured at a temperature of 20°C.—

(*a*) not less than 10 grams of soluble solids before addition of any sweetening agent

(*b*) not less than 0.4 grams of ash, and

(*c*) not less than 0.5 grams and not more than 1.9 grams of acid calculated as anhydrous citric acid,

and shall be packed in hermetically sealed metal containers.

4. The label of canned fruit juice shall carry a declaration by name, and in per cent. by weight, of any added sweetening agent.

Division 10—Coffee

1. *Green Coffee, Raw Coffee, or Unroasted Coffee* shall be the seed of Coffea arabica L., C. liberica Hiern., or C. robusta chev., freed from all but a small portion of its spermoderm.

2. Coffee (Roasted Coffee) shall be roasted green coffee, and shall contain:—

(i) no other added or extraneous matter, except added sugar to the extent of not more than 10 per cent.,

(ii) not more than 6 per cent. of total ash, and

(iii) not more than 25 per cent. of water-soluble extract before addition of any sugar, as determined by an acceptable method.

3. *Instant Coffee* shall be a dried, aqueous extract of pure coffee, and may contain such added carbohydrate material as may be found necessary or desirable for good manufacturing practice.

4. Notwithstanding regulation 17, no person shall sell any coffee containing added sugar in a package unless such package is distinctly labelled with the words " contains added sugar ".

DIVISION 11—CARBONATED BEVERAGES

1. For the purposes of this Division—

" carbonated beverage " means a non-alcoholic beverage that is impregnated with carbon dioxide under pressure and is sold in hermetically sealed containers.

2. No carbonated beverage shall contain saccharin, cyclohexylsulphamic acid or their salts.

3. No person shall sell a carbonated beverage that contains saccharin, cyclohexylsulphamic acid, or their salts.

SECOND SCHEDULE (Regulation 47)

DIVISION I—THIRD SCHEDULE DRUGS

1. No person shall sell a Third Schedule drug unless he has received a prescription therefor; and such prescription shall show—

(*a*) the name and address of the person for whom the drug may be dispensed,

(*b*) the name and quantity of the drug specified therein,

(*c*) the directions for use given therewith,

(*d*) the date of the prescription, and

(*e*) the signature of the practitioner, who issued the prescription,

and where such signature is not known to the dispenser of the prescription, the signature shall be first verified by him.

2. A record of every prescription for a Third Schedule drug shall be retained by the dispenser thereof for a period of at least two years, and shall show—

(*a*) the name and address of the person named in the prescription,

(*b*) the name and quantity of the drug specified therein,

(*c*) the name of the practitioner who issued the prescription,

(*d*) the date and number of the prescription,

(*e*) the directions for use given therewith.

3. No person shall refill a prescription for a Third Schedule drug unless the practitioner so directs on the prescription, and specifies the number of times that the same may be refilled.

4. No person other than—

(*a*) a practitioner,

(*b*) a drug manufacturer,

(*c*) an importer, wholesaler, jobber, or agent, dealing in drugs,

(*d*) a pharmacist; or

(*e*) a resident of a foreign country while a visitor in Trinidad and Tobago,

shall import a Third Schedule drug.

5. The provisions of paragraph 1 do not apply on the sale of a Third Schedule drug to—

(*a*) a drug manufacturer,

(*b*) a practitioner,

(*c*) an importer, wholesaler, jobber, or agent, dealing in drugs,

(*d*) a pharmacist,

(*e*) a hospital; or

(*f*) any Department of the Government upon an order signed by the Minister thereof or his duly authorised representative.

6. The provisions of paragraphs 1, 2, 3, and 4, do not apply to a drug listed or described in Part II of the Third Schedule to the Ordinance, if—

(*a*) the drug is in a form not suitable for human use, or

(*b*) the main panel of both the inner and the outer labels carries, immediately preceding or following the proprietary, brand, proper, or common name of the drug, the words " Agricultural Use Only ", or " Veterinary Drug ", or " Veterinary Use Only ", or " Not for Human Use ", or some other form of words indicating that the drug is not to be used in treating humans.

7. The drugs contained in Parts I and II of the Third Schedule to the Ordinance are hereby deleted therefrom, and the following drugs substituted therefor :

" *Part I*

Amitriptyline and its salts
Bemegride
Bromal and the following derivatives :
  Bromal hydrate
  Brometone
  Bromoform
Carbromal and the following derivatives :
  Acetylcarbromal
  Allylisopropylacetylurea
  Bromisoval
  Diethylbromacetamide
Chloral and the following derivatives :
  Butyl chloral hydrate
  Alpha-chloralose
  Chloral hydrate (except in preparations for external use containing not more than 1 per cent.)
  Chloralformamide
  Chloralimide
Chlordiazepoxide and its salts
Diazepam
Disulfiram
Glutethimide
Imipramine and its salts
Iproniazid and its salts
Isocarboxazid and its salts
Metaldehyde
Methaqualone and its salts
Methylphenidate and its salts
Nialamide and its salts
Paraldehyde
Pemoline and its salts
Phendimetrazine and its salts
Phenelzine and its salts
Pheniprazine and its salts
Phenmetrazine and its salts
Pipamazine and its salts
Pipradol and its salts
Sulphonal and alkyl sulphonals

Part II

Adrenocortical hormones and their salts and derivatives
Aminopterin and its salts
4-aminopteroylaspartic acid and its salts
4-aminopteroyl-N-methyglutamic acid and its salts
Aminopyrine and its derivatives and their salts
Anticoagulants, the following :
  Bishydroxycoumarin, its salts and derivatives
  4-hydroxycoumarin and its derivatives when sold or recommended for use as anticoagulants
  Phenylindanedione and its derivatives
Azacyclonol
Benactyzine
Busulfan
Captodiame

Chlorambucil and its salts and derivatives
Chlorprothixene and its salts
Cinchophen and its salts
Cyclizine and its salts
Cyclophosphamide
2, 4-dinitrophenol and its salts
Emylcamate
Ergot alkaloids and their salts
Hydantoin derivatives and their salts (except in preparations for external use only)
Hydroxyzine
Isoniazide
Mebanazine and its salts
Mephenoxalone
Meprobamate
6-mercaptopurine
Mustine (or Mecloreth amine) and its salts
Neocinchophen and its salts
Paramethadione
Pargyline and its salts
Phenothiazine derivatives, the following and their salts—
Acepromazine
Chlorpromazine
Fluphenazine
Levomepromazine (or Mepromazine or Methotrimeprazine)
Perphenazine
Pecazine (or Mepazine)
Prochlorperazine
Promazine
Thiethylperazine
Thiopropazate
Thioproperazine
Thioridazine
Trifluoperazine
Trifluopromazine
Trimeprazine
Phenylbutazone and its salts
Primidone
Prothipendyl hydrochloride
Pyrazinamide
Rauwolfia, and the following Rauwolfia alkaloids and their salts—
Deserpidine
Raubasine
Rescinnamine
Reserpine
Sex hormones, (except for cosmetic preparations of sex hormones which are demonstrated to be free from systemic effects)
Sulphinpyrazone and its salts
Tetrabenazine
Thiotepa
Thiouracil and its derivatives
Thyroid
Thyroxin and its salts
Tolbutamide and its salts and derivatives
Tranylcypromine
Tretamine
l-triiodothyronine
Trimethadione ".

DIVISION 2—CONTROLLED DRUGS

1. In this Division—

" controlled drug " means any of the drugs classified as such in paragraph 2 and includes a preparation ;

" licence " means a licence issued under paragraph 5 ;

" licensed dealer " means the holder of a licence ;

" permit " means a permit issued under paragraph 5 ;

" preparation " means a drug that contains less than five per centum of barbituric acid, any derivative thereof or any salt thereof, a controlled drug and one or more drugs, other than a controlled drug, in a recognised therapeutic form ;

" written order " means an order given in writing, and dated and signed by a person to whom a licensed dealer is permitted to sell or supply a controlled drug pursuant to a written order.

2. For the purposes of this division, the following substances are classified as controlled drugs :—

(*a*) Amphetamine and its salts,

(*b*) Barbituric acid, any derivative thereof, and any salt thereof,

(*c*) Lysergide,

(*d*) Mescaline and its salts,

(*e*) Methamphetamine, its derivatives and salts,

(*f*) Methysergide.

3. Subject to this division no person shall manufacture or sell a controlled drug unless he is a licensed dealer.

4. No person shall import or export a controlled drug unless he is a licensed dealer and has first obtained a permit to do so from the Minister.

5. The Minister may, on application therefor—

(*a*) issue a licence to any person to sell controlled drugs; or

(*b*) issue a permit to any licensed dealer to import or export a controlled drug.

6. A licence or permit is subject to the condition that the person to whom it is issued, will comply with the provisions of this Division.

7. The Minister may revoke or suspend a licence or a permit issued under this Division if in his opinion the person to whom it is issued, or any person in his employ, has violated or failed to comply with any term or condition thereof or any provision of this Division except that a licence shall not be revoked where the violation is by an employee unless that violation is in connection with controlled drugs in the possession, or under the control, of the licensed dealer.

8. A licence unless it is sooner revoked expires on the 31st day of December next following the day on which it was issued; and where a licence is suspended it has no validity during the period of suspension.

9. A permit is valid only for the importation or exportation in respect of which it is issued.

10. Subject to the terms of his licence and to the provisions of this Division, a licensed dealer may only sell or supply a controlled drug to—

(*a*) another licensed dealer;

(*b*) a practitioner; or

(*c*) a hospital.

11. No licensed dealer shall sell or supply a controlled drug to any person referred to in subparagraph (*a*) or (*b*) of paragraph 10 unless—

(*a*) he has received a written order therefore from such person; and

(*b*) he has first verified the signature of that person if the signature is unknown to him.

12. No licensed dealer shall sell or supply a controlled drug to a hospital unless—

(*a*) he has first received a written order therefore from the pharmacist in charge of the hospital dispensary or from a physician or dentist authorised by the hospital to sign such order; and

(*b*) he has first verified the signature of that person if the signature is unknown to him.

13. A licensed dealer who is a pharmacist carrying on the business of a pharmacy, or any pharmacist employed by him for the purposes of that business, may sell a controlled drug to any person if—

(*a*) the drug forms part of the stock in trade of the pharmacy;

(*b*) he has first received a prescription in writing authorising the dispensing of the drug;

(*c*) the prescription has been dated and signed by the practitioner who issued it; and

(*d*) the signature of the practitioner is first verified if the signature is unknown to him.

14. Every licensed dealer and every pharmacist in control of a place of business for the purposes of section 26 of the Pharmacy Board Ordinance, 1960, shall keep a separate book or register in which he shall enter or cause to be entered—

(*a*) the name, quantity and form of any controlled drug received by him, the name and address of the person who supplied it and the date on which it was received;

(*b*) the name, quantity and form of any controlled drug sold or supplied, the name and address of the person to whom it was sold or supplied, (or, if supplied pursuant to a prescription, the name of the person for whom it was dispensed and the name of the practitioner who issued the prescription), and the date on which it was sold or supplied;

(*c*) the name and quantity of any controlled drug used in manufacturing, the name and quantity of any controlled drug manufactured and the date any manufactured controlled drug was placed in stock; and

(*d*) the name, quantity and form of any controlled drug he had in stock at the end of each month;

and every required entry shall be made within 48 hours of the receipt or disposition of the controlled drug.

15. A licensed dealer who carries on the business of a wholesaler dealing in drugs and the business of a pharmacy shall keep separate registers, as required by paragraph 14, in respect of each such business.

16. No pharmacist shall refill a prescription for a controlled drug unless the practitioner so directs in the prescription and specifies the number of times it may be refilled and the dates on which it may be refilled.

17. Every pharmacist who dispenses a controlled drug shall initial the prescription therefor; and the pharmacist in control of a pharmacy for the purposes of section 26 of the Pharmacy Board Ordinance, 1960, shall maintaina special prescription file in which he shall file or cause to be filed in sequence as to date and number, all written orders and prescriptions for controlled drugs dispensed, sold, or supplied, and such orders and prescriptions shall be kept in the file for a period of at least two years from the date on which they were filled.

18. Every licensed dealer shall keep on his premises for a period of at least two years full and complete records respecting any controlled drug and any prescriptions therein and such records shall be kept in a manner that will enable an audit thereof to be made, at any time.

19. Every licensed dealer shall take all necessary steps to protect controlled drugs in his possession or under his control against loss or theft and shall report to the Director any such loss or theft of a controlled drug within ten days of the discovery thereof.

20. Nothing in this Division prohibits the sale to the Government by a licensed dealer of controlled drugs for its medical supplies but every officer in charge of Government medical supplies shall keep a seperate register in which he shall enter or caused to be entered—

(*a*) the name, quantity and form of any controlled drug received by him;

(*b*) the name, quantity and form of any drug distributed or supplied by him to any authorised person or institution.

In this paragraph " authorised person or institution " means any person or institution to whom the officer is authorised by the Chief Technical Officer, Medical, to distribute such drugs.

DIVISION 3—NEW DRUGS

1. In this division—

"appointed day" means the day appointed pursuant to subsection (2) of section 2 of the Ordinance as the day on which the Ordinance shall come into operation.

"new drug" means—

(*a*) a drug that contains or consists of a substance whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component that has not been imported into Trinidad and Tobago for use as a drug prior to the appointed day;

(*b*) a drug that is a combination of two or more drugs with or without other ingredients, and that has not been imported into Trinidad and Tobago prior to the appointed day in that combination or in the proportion in which those drugs are combined; or

(*c*) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, demonstration or duration of action, and that has not been imported into Trinidad and Tobago prior to the appointed day for that use or condition of use;

"notice of approval" means notice of approval in respect of a new drug given by the Minister pursuant to paragraph 7.

2. No person shall import, sell or advertise for sale a new drug unless he has been granted permission in accordance with paragraph 11 or unless—

(*a*) the manufacturer or importer has filed with the Minister in duplicate a new drug submission in respect of that drug; and

(*b*) the Minister has issued a notice of approval in respect of the new drug to the manufacturer or importer and such approval has not been withdrawn in accordance with paragraph 8.

3. Subject to paragraph 4, a new drug submission in respect of a drug to be imported shall contain—

(*a*) a description of the new drug (including the manufacturer thereof), and a declaration of the proper name, if any, and the name under which it is proposed to be sold;

(*b*) a statement of all the ingredients, the route of administration, the proposed dosage, the claims to be made for the new drug, and the contra-indications and side-effects of the new drug if known, and a description of the pharmaceutical form under which the new drug is to be sold;

(*c*) details of the tests applied to control the potency, purity and safety of the new drug;

(*d*) a draft of every label proposed to be used in connection with the drug;

(*e*) samples of the new drug in the finished pharmaceutical form in which it is to be sold; and

(*f*) such samples of the components of the new drug as the Director may require, and shall include one or more of the following—

(*g*) a certified copy of a notice of compliance issued to the manufacturer by the Department of National Health and Welfare in Canada;

(*h*) a certificate from the Food and Drugs Administration of the Department of Health, Education and Welfare of the United States of America certifying that the new drug is approved for use in the United States of America under the conditions of use recommended and giving the conditions under which it may be sold in the United States of America;

(*i*) a certificate from the Ministry of Health of the United Kingdom certifying that the new drug is approved for use in the United Kingdom under the conditions of use recommended and giving the conditions under which it may be sold in the United Kingdom;

(*j*) a certificate from the Department of Health of Australia certifying that the drug is approved for use in Australia and giving the conditions under which it may be sold in Australia; or

(*k*) a certificate in the English language, respecting the safety of the new drug for conditions of use recommended and giving the conditions under which it may be sold, issued by an official body or Government Department having authority to issue such certificate, such official body or Government Department having experience and facilities for testing the safety of new drugs that are considered by the Minister as adequate to ensure the safety of the new drug under the conditions of use recommended;

but the Minister may accept a submission made in accordance with paragraph 4.

4. The Minister may in his discretion accept a new drug submission that contains the information specified in subparagraphs (*a*) to (*f*) of paragraph 3, and that includes—

(*a*) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use for which it is recommended; and

(*b*) such other information and material as the Minister may in any particular case require.

5. Notwithstanding paragraph 2 but subject to paragraph 12, no person shall import, sell or advertise for sale a new drug in respect of which notice of approval has been given if any material change has been made in—

(*a*) the conditions of use of the drug, including the indications for use and the route of administration;

(*b*) its labels;

(*c*) the pharmaceutical form in which it is sold;

(*d*) the dosage of the new drug; or

(*e*) the strength, purity or quality of the drug;

which is significantly different from the information contained in the new drug submission filed in respect thereof unless the manufacturer or importer has filed in duplicate with the Minister a supplement to the new drug submission that is satisfactory to the Minister and that describes the changes and gives all the particulars respecting the safety of the new drug and the revised conditions contained in the supplement.

6. Where notice of approval in respect of a new drug has been issued to a manufacturer or importer, another manufacturer or importer of the same new drug may provide the Minister with a submission that satisfies the provisions of paragraph 4.

7. The Minister on the recommendation of the Drug Advisory Committee shall, within one hundred and twenty days after the filing of a new drug submission or supplement thereto—

(*a*) notify the person filing the same whether the data and information submitted satisfied the requirements of paragraph 3, 4 or 5; and

(*b*) if these requirements are satisfied and it appears to the Minister after consultation with the Drug Advisory Committee, that the new drug is safe for use as a drug, issue a notice of approval in respect of that new drug.

8. The Minister may, after consultation with the Drug Advisory Committee, withdraw approval in respect of a new drug by sending notice to the manufacturer or importer of that new drug and such withdrawal may be made where—

(*a*) evidence obtained from clinical or other experience, or from tests by new methods or by methods not used before the approval was given, reveals that the new drug is not shown to be safe for the use represented in the submissions in respect of the new drugs which were filed with the Minister and on which the approval was based; or

(*b*) the submissions in respect of the new drug which were filed with the Minister and on which approval was based, contain any untrue statement of material fact; or

(*c*) the withdrawal is necessary in the interests of public health.

Notice of withdrawal of approval in respect of a new drug shall be published in the Gazette and at least one newspaper having daily circulation in Trinidad and Tobago.

9. Where any manufacturer or importer receives any report of any unexpected side-effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting a new drug, he shall inform the Minister as soon as possible of such side-effects, injury, toxicity, or sensitivity reaction.

10. Notwithstanding anything to the contrary in this Division, a new drug may be imported for the use of investigators qualified to use the drug for the sole purpose of obtaining clinical and scientific data with respect to its safety, stability, dosage, or efficacy, if—

(*a*) before the importation, the Minister is informed of the identifying name or mark by which the drug may be recognised;

(*b*) both the inner and outer labels on any package of such new drug carry the statement "To Be Used By Qualified Investigators Only";

(*c*) before the sale, the importer ensures that any person to whom the new drug is to be sold is a qualified investigator and has the facilities for the investigation to be conducted by him, and obtains in writing from that person an undertaking that the new drug will be used solely by that person or under his direction;

(*d*) the investigators have written authority from the Minister to carry out the investigation of the new drug and have the facilities for so doing.

11. A person who imports a new drug for the purposes of sale to qualified investigators shall keep accurate records of such sales, and make these records available for inspection on the request of the Minister.

12. Notwithstanding anything to the contrary in this Division the Minister may grant permission in writing to any person to import any specified quantity of a new drug, for the purpose of enabling that person to make a new drug submission or to file a supplement thereto.

DIVISION 4—OFFICIAL DRUGS

An official drug labelled as required by regulation 31 shall satisfy the standard mentioned on the label.

DIVISION 5—ANTIBIOTICS

Ch. 12 No. 8 An antibiotic which is imported, exported, manufactured, dispensed, or sold, in accordance with the Antibiotics Ordinance and any regulations made thereunder is exempt from the provisions of these Regulations.

DIVISION 6—NARCOTIC DRUGS

No. 27 of 1961 A narcotic drug which is sold, dispensed, imported, exported, or manufactured, in accordance with the Narcotic Control Ordinance and any regulations made thereunder, is exempted from the provisions of these Regulations except regulation 35.

DIVISION 7—SULPHONAMIDE DRUGS

Ch. 12 No. 7 A sulphonamide drug which is sold or used in accordance with the Sulphonamide Drugs Ordinance and any regulations made thereunder is exepmted from the provisions of these Regulations.

DIVISION 8—POISONOUS DRUGS

No. 7 of 1960 A poisonous drug which is sold by wholesale or retail, or dispensed in accordance with the Pharmacy Board Ordinance and any Regulations made thereunder is exempt from the provisions of these Regulations.

THIRD SCHEDULE

FORM A (Regulation 6)

CERTIFICATE OF APPOINTMENT OF INSPECTOR

(*Section 20 of the Food and Drugs Ordinance*, 1960)

This is to certify that *Official Stamp*

Mr.....

has been appointed as an Inspector under section 20 of the Food and Drugs Ordinance, 1960.

....

Signature of Inspector *Minister of Health*

FORM B

Laboratory No..... (Regulation 13)

THE FOOD AND DRUGS ORDINANCE, 1960

CERTIFICATE OF ANALYSIS

(*Under section* 30(*i*) *of the Food and Drugs Ordinance*, 1960)

I,....., being a person duly appointed as an analyst under section 20 of the Food and Drugs Ordinance, 1960, do hereby certify :—

(1) that on the.....day of.....19.....,

I received from.....a sealed package, which said package was unopened and the seals thereon unbroken;

(2) that I broke the seals and opened the said package and removed therefrom a sample, submitted as a sample of.....

taken from.....

.....of.....;

(3) that I duly analysed or examined the said sample for the purpose of determining if same conformed to the requirements of the Food and Drugs Ordinance, 1960, and the regulations thereunder, and I obtained the following results :—

As witness my hand this.....day of....., 19.....

.....
Analyst

Made this 31st day of December, 1964.

H. E. NELSON
Acting Secretary to the Cabinet