ANALYSIS

1969, No. 7

An Act to consolidate and amend the law relating to the sale of food and drugs and medical devices and the law relating to medical advertisements [*22 July 1969*

BE IT ENACTED by the General Assembly of New Zealand in Parliament assembled, and by the authority of the same, as follows:

Preliminary

1. Short Title and commencement—(1) This Act may be cited as the Food and Drug Act 1969.

(2) Except as provided in section 10 of this Act, this Act shall come into force on the first day of April, nineteen hundred and seventy.

2. Interpretation—(1) In this Act, unless the context otherwise requires,—

"Advertisement" means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of any food or drug or medical device or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in any trade journal:

"Agent", in relation to any food or drug or medical device includes any person who, not being the owner of the food or drug or medical device, or a person appointed or employed as the agent or servant of the owner, is, with the consent or concurrence of the owner, for the time being in possession or control of the food or drug or medical device:

"Analyst" means a person appointed to be an analyst pursuant to section 19 of this Act:

"Appliance" includes the whole or any part of any utensil, machinery, instrument, apparatus, or article used or represented for use in or for the making, keeping, preparing, decorating, or supplying of any food or drug:

"Cosmetic" means any substance or mixture of substances, not being a therapeutic drug, used or represented for use for the purposes of beautifying, improving, protecting, altering, or cleansing the hair, skin, or com-

plexion of human beings; and includes any perfume, any deodorant, any insect repellant, and any dusting powder:

"Dentifrice" means any substance or mixture of substances, not being a therapeutic drug, used or represented for use for the purpose of cleansing the mouths or teeth (natural or artificial) of human beings; and includes any denture fixative:

"Description" includes any pictorial representation and "described" has a corresponding meaning:

"Detergent" means any cleansing agent, not being a therapeutic drug or a cosmetic, used or represented for use in contact with the skin of human beings, and includes any soap, soap powder, soap solution, synthetic detergent, alkaline solution or any mixture of any of these substances, with or without the addition of abrasives, bleaching agents, enzymes, surfactants, or inert material:

"Director-General" means the Director-General of Health appointed pursuant to the Health Act 1956:

"Drug" means—

(a) Any substance or mixture of substances used or represented for use, whether internally or externally, for the purposes of the prevention, diagnosis, or treatment of any disease, ailment, disorder, deformity, defect, or injury of the human body:

(b) Any substance or mixture of substances used or represented for use for the purpose of altering the shape or structure of the human body:

(c) Any substance or mixture of substances, including anaesthetics, used or represented for use for the purposes of influencing, inhibiting, or modifying any physiological process in human beings, or the desires or emotions connected with any such physiological process, or the desire for alcohol or tobacco:

(d) Any chemical contraceptive:

(e) Any material used or represented for use as surgical dressings:

(f) Any disinfectant, germicide, or antiseptic:

(g) Any tobacco prepared for smoking, chewing, or snuffing:

"Entertainment" includes any social gathering, amusement, exhibition, performance, game, sport, or trial of skill:

"Examine" includes weigh, count, and measure:

"Food" includes any article used or represented for use as food or drink for human beings, chewing gum, and any ingredient that is or is intended to be mixed with or added to any such thing for any purpose whatever:

"Local authority inspector" means any City Health Inspector, Borough Health Inspector, Town District Health Inspector, County Health Inspector, or Road District Health Inspector:

"Medical advertisement" means an advertisement relating or likely to cause any person to believe that it relates to any drug or medical device or method of treatment:

"Medical device" means any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, used or represented for use for any of the purposes specified in paragraphs (a), (b), or (c) of the definition of "drug" in this subsection:

"Method of treatment" means any method of treatment for reward undertaken or represented to be undertaken for any of the purposes specified in paragraphs (a), (b), or (c) of the definition of "drug" in this subsection:

"Minister" means the Minister of Health:

"Officer" includes any medical practitioner employed in the Department of Health, any Inspector of Health within the meaning of the Health Act 1956, and any person appointed to be an officer for the purposes of this Act pursuant to section 19 of this Act:

"Package" includes anything in or by which goods for carriage or for sale may be cased, covered, enclosed, contained, or packed; and, in the case of goods sold or carried or intended for sale or carriage in more than one package, includes every such package:

"Prescribed" means prescribed by regulations made under this Act:

"Publish" means—

(a) Insert in any newspaper or other periodical publication printed or published in New Zealand; or

(b) Send to any person through the Post Office or otherwise; or

(c) Deliver to any person or leave upon premises in the occupation of any person; or

(d) Broadcast within the meaning of the Broadcasting Corporation Act 1961; or

(e) Bring to the notice of the public in New Zealand in any other manner whatsoever;

but, for the purposes of sections 9 and 10 of this Act, does not include sending or delivering to any person, or leaving upon premises in the occupation of any person, unless such sending, delivering, or leaving is related to or results from or is consequential upon a publication within the meaning of paragraph (a), paragraph (d), or paragraph (e) of this definition:

"Therapeutic drug" means a drug within the meaning of paragraph (a) or paragraph (b) or paragraph (c) or paragraph (d) of the definition of "drug" in this subsection:

"Vehicle" includes an aircraft, a ship, or a train.

(2) Without prejudice to the definition of the term "drug" in subsection (1) of this section, for the purposes of the definitions of the terms "agent" and "appliance" in subsection (1) of this section and for the purposes of sections 3, 4, 6, 21 to 33, 40 to 42, and 47 and of paragraphs (a) to (c), (e), (f), (i), (t), and (x) of subsection (1), and subsections (3) to (5), of section 46 of this Act, the term "drug" includes any cosmetic, dentifrice, or detergent.

Cf. 1947, No. 7, ss. 2, 31, 31A; 1962, No. 50, ss. 2, 15; 1942, No. 11, s. 2

3. What constitutes "sale"—(1) In this Act, unless the context otherwise requires, "sell" means sell for human consumption or use and includes—

(a) Selling for resale for human consumption or use;

(b) Offering or attempting to sell, or receiving for sale, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or permitting to be sold, offered, or exposed for sale;

(c) Barter;

(d) Supplying pursuant to a contract, together with accommodation, service, or entertainment, in consideration of an inclusive charge for the article supplied and the accommodation, service, or entertainment;

(e) In the case of drugs, export in the course or for the purpose of sale;

and "sale" and "sold" have corresponding meanings.

(2) For the purposes of this Act any article of food which is part of, or supplied with, any meal or food for which payment is made or required to be made, and which is supplied

for consumption in any shop, hotel, restaurant, or eatinghouse, or at any stall or other place, or in any vehicle, shall be deemed to have been sold or offered or exposed for sale.

(3) For the purposes of this Act, every person shall be deemed to sell or to intend to sell any food or drug if he sells or intends to sell for human consumption or use any article of which the food or drug is a constituent.

(4) When any food or drug is sold or offered or exposed for sale it shall be deemed to be sold or, as the case may require, offered or exposed for sale, for human consumption or use, unless the contrary is proved.

(5) For the purposes of this Act, the sale of any food or drug for the purpose of being mixed with any other food or drug, or with a food or drug of the same kind, shall be deemed to be a sale for human consumption or use if the bulk or product produced by the mixing, or any part thereof, is intended to be sold for human consumption or use.

(6) The purchase and sale, under the provisions of this Act, of a sample of any food or drug for the purpose of analysis shall be deemed to be a purchase and sale of the food or drug for human consumption or use, unless the seller proves that the bulk from which the sample was taken was offered, exposed, or intended for sale for purposes other than human consumption or use.

(7) When a sample of any milk is taken from a container, the sample shall be deemed for the purposes of this Act to be a sample of any bulk of which the milk in that container forms part notwithstanding that the milk was intended to be mixed with milk in any other container or containers before being sold.

Cf. 1947, No. 7, s. 3; 1949, No. 51, s. 16

4. Food and drugs offered as prizes—(1) Where any food which is intended for human consumption or any drug is offered as a prize or reward in connection with any entertainment to which the public are admitted, whether on payment of money or not, this Act shall apply in relation to the food or drug, as the case may be, as if it were, or had been, exposed for sale by each person concerned in the organisation of the entertainment.

(2) Where any food which is intended for human consumption or any drug is offered as a prize or reward or given away for the purpose of advertisement, or in furtherance of any

trade or business, this Act shall apply in relation to the food or drug, as the case may be, as if it were, or had been, exposed for sale by the person offering it or giving it away.

Cf. Food and Drugs Act 1955 (U.K.), s. 10

5. Act to bind the Crown—This Act shall bind the Crown.

Cf. 1947, No. 7, s. 32

Sales and Advertisements

6. General prohibitions on sales—(1) If a standard is prescribed in respect of the composition of any kind of food or drug or medical device, no person shall sell any article under such a name or description as to lead an intending purchaser to believe that he is purchasing that kind of food or drug or medical device unless the article complies with the standard.

(2) If a person sells an article to a purchaser in response to a request for a food or a drug or a medical device of a kind for which a standard is prescribed, he shall be deemed to sell a food, drug, or medical device of that kind and under such a description as is specified in subsection (1) of this section unless he clearly notifies the purchaser at the time of sale that the article is not of that kind.

(3) Notwithstanding that a food or drug or medical device otherwise complies with the standard prescribed for that kind of food or drug or medical device, it shall be deemed not to comply with that standard if anything has been added to it—

(a) The addition of which to that kind of food or drug or medical device is not expressly required or permitted by regulations made under this Act; or

(b) In a quantity or proportion greater than that so required or permitted; or

(c) Which does not comply with the standard, if any, prescribed for that kind of thing.

(4) No person shall sell—

(a) Any food which is unsound or unfit for human consumption; or

(b) Any food or drug containing or having attached to it or enclosed with it any extraneous thing which is harmful or dangerous, or which is offensive.

Cf. 1947, No. 7, s. 6 (2), (2A), (5), (5A); 1949, No. 51, s. 17; 1956, No. 37, s. 2; Food Standards (General Provisions) Order 1944 (U.K.)

7. Misleading branding—No person shall sell any food or drug or medical device—

(a) Which bears or has attached to it, or is contained in a package which bears or has attached to it, any false or misleading statement, word, brand, picture, label, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion, of the article, or of the article contained in the package, as the case may require, or of any ingredient thereof; or

(b) Which has been packaged, processed, or treated in a manner which is false or misleading in relation to any of the matters (other than the nature or quantity) mentioned in paragraph (a) of this section.

Cf. 1947, No. 7, s. 6 (3); 1962, No. 50, s. 4; Food and Drugs Act (Canada), s. 5

8. General restrictions on advertisements—(1) No person shall, for the purpose of effecting or promoting the sale of a food or drug or medical device, publish or cause to be published, either on his own account or as the servant or agent of the person seeking to effect or promote the sale, any advertisement relating or likely to cause any person to believe that it relates to the food or drug or medical device, or to any ingredient or component thereof; which—

(a) Directly or by implication qualifies or is contrary to any particulars required by regulations made under this Act to be marked on or attached to that kind of food or drug or medical device or on or to packages containing that kind of food or drug or medical device; or

(b) Is prohibited by any such regulations from being marked on or attached to that kind of food or drug or medical device or on or to packages containing that kind of food or drug or medical device; or

(c) Omits from the name or description of the food or drug or medical device any word or words required by any such regulations to be included in the name or description marked on or attached to that kind of food or drug or medical device or on or to packages containing that kind of food or drug or medical device; or

(d) Is likely to deceive a purchaser with regard to the nature, quality, strength, purity, composition, origin, age, or effects of the food or drug or medical device or of any ingredient thereof.

(2) For the purposes of subsection (1) of this section, any words, the inclusion of which in an advertisement are necessary in order to avoid a contravention of that subsection, shall, where they appear in an advertisement published by television or otherwise in a transitory manner on a screen, be disregarded unless they are exposed in clearly legible lettering for a length of time sufficient to enable them to be read and understood by the ordinary viewer.

(3) Without prejudice to his liability in respect of any offence against any regulations made under this Act, every person who contravenes any provision of subsection (1) of this section commits an offence.

Cf. 1947, No. 7, s. 9 (1); 1948, No. 77, s. 19; 1962, No. 50, s. 5

9. Medical advertisements to contain true name of advertiser—(1) No person shall publish, or cause or permit to be published, any medical advertisement unless the advertisement contains a statement setting forth the true name of the person for whom or on whose behalf the advertisement is published and the address of his place of residence or business:

Provided that where that person is a company it shall be sufficient if instead of the address of the company's place of business the statement sets forth the name of the place where the company has its registered office.

(2) Any statement which is contained in a medical advertisement and purports to set forth the name of the person for whom or on whose behalf the advertisement is published, shall, until the contrary is proved, be sufficient evidence of the name of the person for whom or on whose behalf the advertisement has been published.

(3) Nothing in this section shall apply to any advertisement which complies with any regulations made under this Act relating to the disclosure or otherwise of the name and address of the place of residence or business of the manufacturer or seller of the drug or medical device advertised or the agent of either of them or to any advertisement relating to any drug or medical device in respect of which an exemption granted under or by virtue of this Act from the material provisions of any such regulations is for the time being in force.

Cf. 1942, No. 11, s. 10; 1945, No. 40, s. 46

10. Special prohibitions on medical advertisements—(1) No person shall publish or cause or permit to be published any medical advertisement which—

(a) To the knowledge of that person, is false or misleading, in a material particular; or

(b) Includes any words or matters the mention of which in that advertisement is prohibited by regulations made under this Act, or omits any statement, warning, or other words required to be included in that advertisement by any such regulations; or

(c) Invites correspondence or the sending of hair, blood, urine, or other bodily specimens for the purposes of diagnosis or consultation concerning any complaint or condition; or

(d) Directly or by implication claims, indicates, or suggests that the article or method of treatment advertised will prevent, alleviate, or cure any disease or disorder specified, or belonging to a class of disease or disorder specified, in Part I of the First Schedule to this Act; or

(e) Directly or by implication claims, indicates, or suggests that the article or method of treatment advertised will prevent or cure any disease or disorder specified, or belonging to a class of disease or disorder specified, in Part II of the First Schedule to this Act; or

(f) Directly or by implication claims, indicates, or suggests that the article or method of treatment advertised—

(i) Is a panacea or infallible; or

(ii) Is or has been used or recommended by a person (other than the person by or on whose behalf the advertisement is published or whose services are advertised) practising chiropody, dentistry, medicine, midwifery, nursing, occupational therapy, optical dispensing, or physiotherapy, or practising as a chiropractor, dental technician, dietitian, or optician, or carrying on business as a pharmaceutical chemist, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

(iii) Being a therapeutic drug or a medical device or a method of treatment, has beneficially affected the health of a particular person or class of persons, whether named or not named and whether real or fictitious, referred to in the advertisement.

(2) The provisions of this section shall be in addition to and not in substitution of the provisions of section 8 of this Act.

(3) Nothing in this section shall apply in respect of anything done before the first day of January, nineteen hundred and seventy-one, unless the doing of that thing would have been an offence if this Act had not been passed.

Cf. 1942, No. 11, s. 11; Medical Advertisements Regulations 1943, regs. 12, 13, 14

11. Exemption of certain medical advertisements—Nothing in section 9, or in paragraphs (c) to (f) of subsection (1) of section 10 of this Act, and nothing in any regulations made under the Medical Advertisements Act 1942 which continue in force after the commencement of this Act, shall apply to any advertisement which is distributed only to members of the professions or occupations referred to in subparagraph (ii) of paragraph (f) of subsection (1) of section 10 of this Act or which is contained in a publication which in the ordinary course circulates solely or mainly or is distributed solely or mainly to members of those professions or occupations.

Cf. 1942, No. 11, s. 16

Special Provisions as to Therapeutic Drugs

12. Distribution of new therapeutic drugs restricted—(1) Except as provided in subsection (7) of this section, this section applies to—

(a) Any therapeutic drug which has not previously been distributed in New Zealand:

(b) Any therapeutic drug which has been referred to the Minister pursuant to subsection (5) of section 14 of this Act.

(2) No person shall sell, or distribute by way of gift, loan, or sample or in any manner whatsoever, or advertise for sale, or advertise the availability of, any therapeutic drug to which this section applies before the consent of the Minister to the distribution of the drug has been notified in the *Gazette*.

(3) Before deciding whether or not to consent to the distribution of a therapeutic drug pursuant to subsection (2) of this section, the Minister shall consider all the particulars and information relating to the drug submitted under section 13 of this Act and such other matters as appear to him to be relevant, and shall, as far as practicable, weigh the likely therapeutic value of the drug against the risk, if any, of the use of the drug injuriously affecting the health of any person.

(4) In any proceedings for an offence against this section, in which it is alleged that this section applies to a drug by reason of paragraph (a) of subsection (1) of this section, it shall be presumed that the drug is a therapeutic drug to which this section applies until the contrary is proved.

(5) No consent given under this section shall be deemed to warrant the safety or efficacy of the drug to which the consent relates.

(6) The provisions of this section shall be in addition to, and not in substitution of, the provisions of any other enactment prohibiting, regulating, or restricting the sale or distribution of therapeutic drugs, and nothing in any such other enactment shall authorise any person to act in contravention of the provisions of this section but in the event of any conflict the provisions of this section shall prevail.

(7) Nothing in this section shall apply to any drug in respect of which a notice has been deposited with the Director-General under section 11B or section 11C of the Food and Drugs Act 1947 (as inserted by section 14 of the Food and Drugs Amendment Act 1962) before the commencement of this Act, and the provisions of those sections, and of section 11D and section 11E of the first-mentioned Act (as so inserted) shall continue to apply in respect of any such drug notwithstanding the repeal of those Acts by this Act.

Cf. 1947, No. 7, s. 11B (2), (5); 1962, No. 50, s. 14

13. Applications for consent—(1) An application for the consent of the Minister under section 12 of this Act to the distribution of a therapeutic drug shall be made by the manufacturer, importer, or proprietor or proposed manufacturer, importer, or proprietor in New Zealand of the drug, or the duly authorised agent of those persons, and shall be addressed to the Director-General and shall be in the true name of the person making the application and shall set out or be accompanied by—

(a) The address of that person and, if he is not the manufacturer, the true name and address of the manufacturer:

(b) The name under which the drug will be distributed:

(c) A full statement of the ingredients, named by the descriptive or non-proprietary names, including details of the quantities in which they are contained in the drug:

(d) A description of the form or forms of the drug:

(e) The proposed or recommended dosage and frequency of dose, and the manner in which the drug will be recommended to be administered, applied, or otherwise used:

(f) The purposes for which the drug will be recommended to be used, and the claims to be made in respect of its usefulness:

(g) Reports of any tests made to establish the safety of the drug for the purposes for which and in the manner in which it is intended to be used:

(h) Reports of any tests made to control the strength, quality, purity, or safety of the drug and of the method of testing:

(i) Any reports tending to demonstrate the efficacy of the drug:

(j) A translation into the English language, authenticated in such manner as the Director-General may require, of any report referred to in paragraph (g), paragraph (h), or paragraph (i) of this subsection which is not in that language:

(k) Any evidence to show that the distribution of the drug in the form and for the purposes that it is proposed to be distributed in New Zealand has been approved or consented to by the appropriate authorities in a country or countries other than New Zealand:

(l) The intended method of distribution of the drug in New Zealand:

(m) A specimen of every label and other descriptive matter proposed to be used on or to be included in or to accompany packages containing the drug:

(n) If the drug is to be manufactured, prepared, or packed in New Zealand, the name and address of the place or places where the manufacture, preparation, or packing is intended to be carried out.

(2) Notwithstanding anything in subsection (1) of this section, in the case of a drug to which section 12 of this Act applies by virtue of paragraph (b) of subsection (1) of that section the notice deposited with the Director-General under section 14 of this Act shall, subject to subsections (3) and (4) of this section, be a sufficient application for the consent of the Minister under the said section 12.

(3) At any time before the publication of a notice in the *Gazette* signifying the consent of the Minister to the distribution of a drug in respect of which an application under section 12 of this Act has been made the Director-General may

by notice in writing, given to the person in whose name the application was made, require that person to supply such samples of and further information or particulars concerning the drug, or the manufacture or intended sale, distribution, or advertising thereof, as may be set out in the last-mentioned notice.

(4) The Director-General may, if he thinks fit, require any person to verify by statutory declaration any statement in an application made, or in any further information or particulars supplied, under this section and signed by that person.

(5) For the purposes of section 27 of the Poisons Act 1960, every application made under this section shall be deemed also to be a notice to the Registrar satisfying the requirements of subsections (1) and (2) of that section.

Cf. 1947, No. 7, ss. 11B (1), (3), (4), 11D (1); 1962, No. 50, s. 14

14. Distribution of changed therapeutic drugs restricted—(1) If at any time a material change is made by the manufacturer of any therapeutic drug, whether in New Zealand or elsewhere and whether or not he was a manufacturer of the drug before the change was made, in—

(a) The purpose for which the drug is represented to be used, or the recommended dosage, or the recommended manner of administration; or

(b) The labelling of the drug or of any package containing it or any descriptive matter accompanying or contained in any such drug or package; or

(c) The pharmaceutical form of the drug; or

(d) The strength, quality, or purity of the drug; or

(e) The methods of manufacture, or the facilities for testing the strength, quality, purity, or safety of the drug; or

(f) The formula under which the drug is manufactured or intended to be manufactured—

the importer into New Zealand of the drug, or its manufacturer in New Zealand, shall, unless he is of the opinion that the drug is a therapeutic drug to which section 12 of this Act applies by virtue of paragraph (a) of subsection (1) of that section, deposit with the Director-General a notice in writing in the English language describing the change and giving particulars, so far as they are known to him, of any effect that the change might have on the safe consumption or use of the drug.

(2) Except with the prior consent in writing of the Director-General, no person shall sell any therapeutic drug, to which section 12 of this Act does not apply and in respect of which any such change as aforesaid has been made, or distribute it by way of gift, loan, or sample or in any manner whatsoever until after the expiry of at least ninety days from the date of the deposit with the Director-General of such notice as aforesaid.

(3) Within thirty days after the deposit of any notice which satisfies subsection (1) of this section the Director-General may by notice in writing given to the person in whose name the first-mentioned notice was deposited require him to supply such further information or particulars as the Director-General may require with respect to any matter set out in that notice.

(4) Every person to whom notice is given under this section shall, within thirty days after the receipt by him of the notice, comply with the requirements set out therein, so far as he is able to do so.

(5) If the Director-General, after considering the particulars and information relating to the drug required by or under subsection (1) or subsection (3) of this section, is of the opinion, at any time within the period specified in subsection (2) of this section, that any change of a kind specified in subsection (1) of this section and made in respect of that drug is of such a character or degree that the drug ought not to be distributed in New Zealand without the consent of the Minister, he shall refer the drug to the Minister and shall forthwith by notice in writing inform the person in whose name the notice under subsection (1) of this section was deposited that he has so referred the drug.

Cf. 1947, No. 7, ss. 11C, 11D; 1962, No. 50, s. 14

15. Exemption for investigation—(1) Notwithstanding anything in section 12 or section 14 of this Act, but subject to the provisions of this section, any therapeutic drug may be distributed by the importer or manufacturer, for the sole purpose of obtaining clinical and scientific information with respect to its safety, stability, appropriate dosage, or efficacy, to persons who are for the time being approved by the Director-General, on the recommendation of the Medical Research Council of New Zealand, as being qualified, either generally or in relation to any particular drug or class of drugs or in any particular circumstances or class of circumstances, to use the drug for that purpose.

(2) The distribution of any drug under this section shall be subject to the following conditions, namely:

(a) That the Director-General shall be informed, before the drug is so distributed, of the identifying name or mark by which it may be recognised:

(b) That every label on every package of the drug shall bear the words "To be used by qualified investigators only":

(c) That the importer or manufacturer shall, before so distributing the drug, take all reasonable steps to ensure that every person to whom it is supplied is approved under this section as a person qualified to carry out, and has available the necessary facilities for, the investigation to be conducted by him, and that the drug will be used solely by that person or under his direction for the purposes of such investigation:

(d) That the importer or manufacturer shall keep complete and accurate records of all quantities of the drug so supplied and of the results of the investigation, and shall make copies of those records available to the Director-General when required to do so.

Cf. 1947, No. 7, s. 11E; 1962, No. 50, s. 14

16. Exemption for therapeutic drugs required by medical practitioner—Nothing in section 12 or section 14 of this Act shall prevent the supply by any person to any medical practitioner, on his request, of any therapeutic drug required by him for the treatment of a patient under his care, or the administration by any medical practitioner of any such drug to any such patient.

Cf. 1947, No. 7, s. 11F; 1962, No. 50, s. 14

17. Duty of importer or manufacturer to report untoward effects of therapeutic drugs—(1) If at any time the importer into New Zealand of any therapeutic drug, or the manufacturer in New Zealand of any therapeutic drug, has reason to believe that any substantial untoward effects have arisen from the use of the drug, whether in New Zealand or elsewhere, he shall forthwith notify the Director-General of the nature of those effects and the circumstances in which they have arisen, so far as they are known to him.

(2) Subsection (1) of this section shall not apply in any case where particulars of such effects and circumstances as aforesaid have been published in the English language in any

medical or pharmaceutical publication or periodical which in the ordinary course is circulated among or distributed to members of the medical and pharmaceutical professions in New Zealand.

Cf. 1947, No. 7, s. 11A; 1962, No. 50, s. 14

18. General restrictions on sale of therapeutic drugs— (1) Every person commits an offence against this Act who sells any therapeutic drug by means of a vending machine or by auctioning the drug.

(2) Without prejudice to subsection (1) of this section, every person commits an offence against this Act who sells any therapeutic drug except a therapeutic drug the sale of which by that person is permitted by regulations under this Act and in accordance with any conditions that may be prescribed.

(3) Nothing in subsection (2) of this section shall apply to sales by or on behalf of—

(a) The Crown or a Hospital Board;

(b) A medical practitioner, dentist, or veterinary surgeon in the course of his practice;

(c) The proprietor of a pharmacy registered under the Pharmacy Act 1939, if the sale is carried out at the pharmacy by that proprietor or by a person employed by him in the course of that employment;

(d) The proprietor or licensee of a private hospital licensed under the Hospitals Act 1957 in the course of carrying on that hospital;

(e) The licensee of an old people's home if the home is licensed under regulations made pursuant to section 120A of the Health Act 1956 and if the sale is made in the course of carrying on that home;

(f) A manufacturer of or a wholesale dealer in therapeutic drugs to a manufacturer of therapeutic drugs, for the purpose of use in such manufacture, or to a wholesale dealer in therapeutic drugs, or other person entitled to sell the particular therapeutic drugs, for the purpose of resale;

(g) Any other person—

(i) For the purpose of the lawful treatment of any patient personally consulting him and under his care; or

(ii) Of any drug not being or containing a poisonous substance or toxic substance within the meaning of the Poisons Act 1960; or

(iii) Of any drug which that person is licensed or otherwise authorised to sell by or under the provisions of any other enactment.

(4) The following enactments are hereby consequentially repealed:

(a) Sections 32, 33, and 36 of the Pharmacy Act 1939 and the First Schedule to that Act:

(b) Section 47 of the Statutes Amendment Act 1947:

(c) Section 18 of the Pharmacy Amendment Act 1954.

Cf. 1939, No. 33, ss. 32, 33, 36, First Schedule; 1947, No. 60, s. 47; 1954, No. 81, s. 18

Administration and Enforcement

19. Appointments of analysts and officers—(1) There shall from time to time be appointed under the State Services Act 1962 such analysts and officers as may be required for the purposes of this Act.

(2) The Governor-General may from time to time appoint any person, not being an officer of the Public Service, as an analyst or officer for the purposes of this Act.

(3) No person appointed as an analyst or officer under subsection (2) of this section shall be deemed by reason only of that appointment to be employed in the service of Her Majesty for the purposes of the State Services Act 1962 or of the Superannuation Act 1956.

Cf. 1947, No. 7, s. 5

20. Advisory and technical committees—(1) The Minister may from time to time appoint such advisory or technical committees as he thinks fit to advise him for any of the purposes of this Act, and may from time to time determine the functions of any such committee.

(2) There may be paid out of money appropriated by Parliament for the purpose to the members of any committee appointed under this section remuneration by way of fees, salary, or allowances and travelling allowances and expenses in accordance with the Fees and Travelling Allowances Act 1951, and the provisions of that Act shall apply accordingly as if the committee were a statutory Board within the meaning of that Act.

(3) Subject to the provisions of this Act and of any regulations made under this Act, every such committee may regulate its own procedure.

Cf. 1947, No. 7, s. 5A; 1962, No. 50, s. 3

21. Powers of officers—(1) For the purposes of this section, the expression "article to which this section applies" includes any food, drug, medical device, appliance, and any labelling or advertising material, and any package containing any such article.

(2) An officer may at any reasonable time—

(a) Enter and inspect any place or vehicle where he reasonably believes any article to which this section applies is manufactured, prepared, preserved, packed, stored or kept for sale:

(b) Examine any article to which this section applies, and subject to section 23 and section 24 of this Act, take or purchase samples of any food or drug which appears to him to be intended for sale or to have been sold or of any labelling or advertising material which appears to him to be intended for use in connection with the sale of any such article or to have been so used:

(c) Open and examine any medical device or any appliance, receptacle, or package that he reasonably believes contains any article to which this section applies:

(d) Examine any books, documents, or other records found in a place or vehicle referred to in paragraph (a) of this subsection that he reasonably believes contain information relevant to the enforcement of this Act or any regulation made under this Act and make copies thereof or extracts therefrom:

(e) Seize and detain any article to which this section applies by means of or in relation to which he or another officer superior to him reasonably believes an offence against this Act or against any regulation made under this Act has been committed.

(3) Any local authority inspector may in respect of any food exercise, within the district or districts in which he is employed, the powers of entry and examination conferred on an officer by paragraph (a) or paragraph (b) of subsection (2) of this section and the powers conferred on an officer by paragraph (c) or paragraph (e) of that subsection or by subsection (9) of this section, and for this purpose the word "officer" in this section includes a local authority inspector.

(4) Every officer exercising any power conferred by this section shall identify himself and produce evidence that he is an officer to any person in the place or vehicle, or claiming

an interest in the article, in or in respect of which the power is exercised, who questions the right of the officer to exercise that power.

(5) If any article to which this section applies is seized in any place or vehicle which is not in the occupation or use of the owner of the article, the officer making the seizure shall forthwith give notice in writing of the seizure to the owner, or to the consignor or consignee, or to the agent of the owner, of the article, if his name and address are attached thereto or are otherwise known to the officer and the address is that of a place in New Zealand.

(6) Any article seized under paragraph (e) of subsection (2) of this section may at the option of the officer be detained in the place or vehicle where it was seized or removed to another place and detained there.

(7) An officer shall release any article seized by him under paragraph (e) of subsection (2) of this section when he or another officer superior to him or acting in his place is satisfied that all the provisions of this Act and of any regulations made under this Act, to the extent that they are material, have been complied with in respect of that article and that that article is fit for the purpose for which it is intended to be sold or used.

(8) If, within the time limited by subsection (1) of section 22 of this Act, the article seized has not been released and no application for disallowance of that seizure has been made under that section, or if any such application has been dismissed, the article seized shall, if the seizure was made by an officer other than a local authority inspector, become the property of the Crown, or, if the seizure was made by a local authority inspector, become the property of the corporation of the local authority in whose district he was employed at the time of the seizure:

Provided that, if the article is not destroyed or otherwise disposed of, it may be returned to the person from whom it was seized at any time after the officer who made the seizure, or another officer superior to him or acting in his place, is satisfied in terms of subsection (7) of this section.

(9) Notwithstanding anything in subsections (1) to (8) of this section, an officer may at any time seize and destroy any food or drug which is decayed or putrified.

(10) It shall be the duty of every local authority to furnish to the Medical Officer of Health from time to time such

reports relating to the exercise of the powers of local authority inspectors under this section as the Director-General or the Medical Officer of Health may require.

Cf. 1947, No. 7, s. 12 (1) (a)–(d), (1A), (3), (4), (5), (6); 1962, No. 50, s. 6; Food and Drugs Act (Canada), ss. 21 (1), (2), (3), (8), 22 (1), (2); Food and Drugs Act 1955 (U.K.), s. 91 (2), (3)

22. Disallowance of seizure—(1) Any person claiming an interest in any article seized under paragraph (e) of subsection (2) of section 21 of this Act, may, within three days thereafter, apply to a Magistrate's Court for an order—

(a) That the seizure be disallowed and that the article be returned or otherwise made available to him:

(b) That the Crown or the local authority, as the case may be, shall pay to him such sum by way of compensation for any depreciation in the value of the article resulting from its seizure, detention, or removal as the Court thinks fit.

(2) On any such application the Court may dismiss the application, or order that the seizure be disallowed in whole or in part, or that the detention of the article be terminated in whole or in part, or that compensation be paid by the Crown or the local authority for any depreciation in the value of the article as aforesaid, and any such order may be made upon and subject to such terms and conditions, in relation to the return of the article or otherwise, as the Court thinks fit:

Provided that—

(a) No order that the seizure of the article be disallowed or that the detention of the article be terminated, in whole or in part, shall be made if the Court is of the opinion that the purpose to which that article or that part is intended to be put will probably involve the commission of an offence against this Act, or any regulation made under this Act, or that the continued detention of that article or that part is expedient for the purposes of its production in any pending proceedings under this Act:

(b) No order for the payment of compensation shall be made except in respect of an article or part which in the opinion of the Court, ought not to have been seized or continued to be detained, as the case may be, and except to the extent that the Court disallows the seizure or terminates the detention.

(3) Where the Court makes an order for the payment of any sum by way of compensation to any person under this section, the sum so awarded shall be recoverable by that person as a debt due from the Crown or the local authority.

(4) Every application to the Court under this section shall be made and dealt with by way of originating application, on notice, under the rules of procedure for the time being in force under the Magistrates' Courts Act 1947, and the provisions of those rules shall apply accordingly.

(5) Every order made by the Court under this section shall be final and binding on all parties.

Cf. 1947, No. 7, s. 12 (2); 1960, No. 97, s. 32; Food and Drugs Act 1955 (U.K.), s. 9 (4)

23. Procuring samples for analysis—(1) When an officer intends to procure a sample of a food or drug for the purposes of analysis, he shall—

(a) Pay or tender the current market value of the sample to the owner thereof or the person from whom the sample is obtained:

(b) Before or forthwith after obtaining the sample inform the owner of the sample or the person from whom the sample is obtained of his intention to submit a sample to an analyst:

(c) Thereafter deal with the sample in the manner set out in section 24 of this Act.

(2) For the purposes of subsection (1) of this section, an officer may require the person in possession of a food or drug, or his servant or agent, to show and permit the inspection of any package containing the food or drug and to take therefrom the sample demanded.

(3) Where any food or drug is kept for retail sale in an unopened package, no person shall be required by any officer to sell less than the whole of the contents of the package.

(4) Nothing in this section or in section 24 of this Act shall apply to the procuring of a sample of a food or drug from a vending machine if the officer obtains the sample by properly making payment for it and no person present admits to being in charge of the machine.

(5) Notwithstanding anything in this section or in section 24 of this Act—

(a) An officer shall not be obliged to submit to an analyst any sample which he has obtained:

(b) An officer may inspect, select, and take or purchase any sample for the purposes of analysis without complying with those sections, but in that event no regard shall be had to the results of any such analysis in any proceedings before any Court in respect of an offence against this Act or against any regulations made under this Act.

Cf. 1947, No. 7, ss. 12 (1) (e), 15 (1), (2), (3), 16 (1)

24. How samples to be taken—(1) When an officer has procured a sample pursuant to section 23 of this Act, he shall divide the sample into three parts, and shall mark and seal or fasten up each part in such manner as its nature will permit, and shall leave one part with the owner of the food or drug from which the sample was taken or the person from whom the sample was procured.

(2) When any food or drug is contained in a package in such quantity that its division into three parts as aforesaid would, in the opinion of the officer, furnish parts insufficient for accurate analysis, additional packages which purport to contain a similar food or drug under the same brand or label may be taken or obtained, and the contents of two or more packages may be mixed together and the mixture divided and submitted for analysis as provided in this section.

(3) If the officer who has procured the sample considers that it should be analysed he shall submit one part of the sample to an analyst for this purpose and shall retain the third part.

(4) Notwithstanding anything in this section, where—

(a) A sample of milk, cream, ice cream, or any other perishable food being a product of milk is procured only for bacteriological analysis; or

(b) A sample of milk is procured only for examination by the freezing point test for added water; or

(c) A sample of milk is procured for bacteriological analysis and examination by the freezing point test as aforesaid,—

the officer may submit the whole sample to the analyst instead of dividing it into parts, unless the owner of the food from which the sample was taken or the person from whom the sample was procured requires him to leave a part with such owner or person, in which case the officer shall divide the

sample into two parts and, after marking and sealing them as aforesaid, leave one part with the person requiring it and submit the other to an analyst:

Provided that if the food is bottled milk or bottled cream or packaged ice cream or any other frozen confection and the officer is required to leave a part as aforesaid, it shall be sufficient compliance with that requirement if the officer selects, marks, and seals two bottles of milk or cream, or two packages which purport to contain similar ice cream or a similar frozen confection under the same brand or label, as the case may require, and leaves one of them.

(5) Notwithstanding anything in this section, if the officer reasonably believes that the food or drug of which he seeks to procure a sample is of such a nature or so packed that there is a risk of its quality being affected in the course and by reason of the procedure prescribed in subsection (1) of this section, the officer may submit the whole sample to the analyst instead of dividing it into three parts:

Provided that if the owner of the food or drug or the person from whom the sample was procured so requires, the officer shall select, mark, and seal one other package which purports to contain a similar food or drug under the same brand or label, as the case may require, and leave it with that owner or person.

Cf. 1947, No. 7, s. 16 (2), (3), (5), (6); 1951, No. 81, s. 12; 1962, No. 50, s. 9 (2); Food and Drugs Act 1955 (U.K.), s. 92 (1)

25. Analysis of sample and certificate of analyst—(1) The certificate of the analyst shall be in the prescribed form.

(2) Where any method of analysis for the analysis of any food or drug is prescribed, any analyst shall in his certificate of analysis declare that the prescribed method has been followed in the analysis.

(3) Any certificate of the result of an analysis given by an analyst in pursuance of this section shall be signed by the analyst but the analysis may be made by any person acting under the direction of the analyst.

(4) When any sample of a food or drug is procured by an officer under this Act and submitted for analysis, the person from whom the sample was procured may, on payment of a fee not exceeding fifty cents, obtain a copy of the analyst's certificate or, if there is no such certificate, a copy of the report made by the analyst in respect of the sample. Except

as provided in this subsection, no person shall be entitled to obtain a copy of any analyst's certificate or report given in respect of any sample procured and submitted for analysis by an officer under this Act.

(5) Every person commits an offence against this Act who causes or permits any copy of an analyst's certificate or report furnished for the purposes of this Act to be used in any advertisement.

Cf. 1947, No. 7, s. 17; 1962, No. 50, s. 10

26. Duty of officer to procure sample for analysis on request—Every officer shall, on being requested in writing by any person to procure a sample of any food or drug and submit it for analysis, and on payment by that person of the prescribed fee together with the cost of the sample, procure or arrange that another officer shall procure a sample of the food or drug and submit it for analysis. The provisions of sections 23 to 25 of this Act shall, so far as applicable and with the necessary modifications, apply with respect to the procuring and analysis of the sample.

Cf. 1947, No. 7, s. 18

27. Power of Medical Officer of Health to require information—(1) Without prejudice to any power conferred on an officer by section 21 of this Act, if in the opinion of a Medical Officer of Health, within the meaning of the Health Act 1956, there is reasonable ground for suspecting that any person is in possession of any food or drug or medical device for the purpose of sale or is in possession of any substance or article for the purpose of manufacturing, preparing, or selling any food or drug or medical device, in breach of this Act or of any regulation made under this Act the Medical Officer of Health may require that person to produce for his inspection, or to produce to any officer specially authorised by the Medical Officer of Health in that behalf, any books, documents, or other records dealing with the reception, possession, purchase, sale, or delivery of any such food, drug, medical device, substance, or article.

(2) The Medical Officer of Health may make or cause to be made copies of or extracts from any such books, documents, or other records.

(3) Every officer commits an offence against this Act who does not maintain the secrecy of all matters which come to his knowledge in the performance of his official duties under this section, or under paragraph (d) of subsection (2) of section 21 of this Act, or who communicates any such matters to any person, except for the purpose of carrying into effect the provisions of this Act.

(4) The liability imposed on an officer by subsection (3) of this section shall be without prejudice to his liability under any other Act in respect of the same matter.

Cf. 1947, No. 7, s. 13

28. Power to require name and address of seller—(1) Any officer acting in the exercise of any of his powers under this Act may require any person who is in possession of any food or drug or medical device for sale, or for delivery upon sale, to state correctly his name and address and, so far as he is aware of them, the name and address of the person from whom he obtained the food or drug or medical device.

(2) In this section the word "officer" includes a local authority inspector.

Cf. 1947, No. 7, s. 13A; 1962, No. 50, s. 8

29. Obstruction of officers—(1) Every person commits an offence against this Act who in any way resists, obstructs, or deceives any officer in the exercise of any powers conferred on that officer by or pursuant to this Act.

(2) Without prejudice to the generality of subsection (1) of this section, every person shall be deemed to have obstructed an officer who—

(a) Except with the authority of an officer or pursuant to an order of a Court, removes, alters, or interferes in any way with any article seized and detained under this Act; or

(b) Except with the authority of an officer or of an analyst or pursuant to an order of a Court, erases, alters, opens, breaks, or removes any mark, seal, or fastening placed by an officer pursuant to this Act on any sample or part of a sample procured under this Act other than a part of a sample, or a bottle or package, left with the owner of the food or drug from which the sample was taken or the person from whom the sample was procured; or

(c) Refuses to sell to an officer, or to allow the officer to take, any food or drug, which appears to the officer to be intended for sale or to have been sold, or any labelling or advertising material, which appears to the officer to be intended for use in connection with the sale of any article to which section 21 of this Act applies or to have been so used, in the quantity which the officer reasonably requires as a sample; or

(d) Refuses or neglects to give to an officer any assistance which that officer may reasonably require him to give or to give to an officer any information, or to produce or permit an officer to examine and make copies of and extracts from any books, documents, or other records, which that officer is expressly authorised by this Act to require to be given or produced or to examine or make or may reasonably require to be given or produced or to examine or make, or when required to give any such information or to produce any such books, documents, or other records, knowingly makes any misstatement in respect thereof.

(3) In this section the word "officer" includes a local authority inspector.

Cf. 1947, No. 7, ss. 13 (3), 13A (2), 15 (4), 21, 22; 1962, No. 50, s. 8; Food and Drugs Act (Canada), s. 21 (4)-(7); Food and Drugs Act 1955 (U.K.), s. 105 (2) and (3)

Legal Proceedings

30. Liability of principals and agents—(1) For the purposes of this Act and of any regulations made under this Act, a person shall be deemed to sell a food or drug or medical device if he sells that food or drug or medical device either on his own account or as the agent or servant of another person.

(2) Subject to section 31 and section 32 of this Act, if an offence is committed against this Act or against any regulation made under this Act by any person acting as the agent or servant of another person, that other person shall, without prejudice to the liability of the first mentioned person, be liable under this Act in the same manner and to the same extent as if he had personally committed the offence.

(3) Where any body corporate is convicted of an offence against this Act or against any regulation made under this

Act, every director and every person concerned in the management of the body corporate shall be guilty of a like offence if it is proved that the act which constituted the offence took place with his authority, permission, or consent.

Cf. 1947, No. 7, s. 11; 1960, No. 97, ss. 2 (2), 51

31. Strict liability—(1) In any prosecution for selling a food or drug or medical device contrary to any provision of this Act or of any regulation made under this Act it shall not be necessary for the prosecution to prove that the defendant intended to commit an offence.

(2) Subject to subsection (3) of this section, it shall be a good defence in any such prosecution if the defendant proves that he did not intend to commit an offence against this Act or any regulation made under this Act, and that he took all reasonable steps to ensure that the sale of the article would not constitute any such offence.

(3) Except as provided in subsection (4) of this section, subsection (2) of this section shall not apply unless within seven days after the service of the summons the defendant has delivered to the prosecution a written notice—

(a) Stating that he intends to rely on subsection (2) of this section; and

(b) Specifying the reasonable steps which he will claim to have taken.

(4) In any prosecution as aforesaid evidence that the defendant took a step not specified in the written notice required by subsection (3) of this section shall not, except with the leave of the Court, be admissible for the purpose of supporting a defence under subsection (2) of this section.

Cf. 1947, No. 7, s. 7

32. Further defences—(1) Subject to subsection (2) and subsection (4) of this section, it shall be a good defence in a prosecution for selling any food or drug or medical device contrary to any provision of this Act or of any regulation made under this Act if the defendant proves—

(a) That he purchased the article sold by him in reliance on a written warranty or other written statement as to the nature of the article purchased, signed by or on behalf of the person from whom the defendant purchased the article; and

(b) That if the article had truly conformed to the warranty or statement the sale of the article by the defendant would not have constituted the offence charged against him; and

(c) That he had no reason to believe or suspect that the article sold by him did not conform to the warranty or statement; and

(d) That at the time of the commission of the alleged offence the article was in the same state as when he purchased it.

(2) No warranty or statement shall be any defence under this section unless—

(a) It was given or made by or on behalf of a person resident in New Zealand or a company having a registered office in New Zealand or a firm having a place of business in New Zealand; and

(b) The signature thereto is written by hand; and

(c) The defendant proves that at the time he received the warranty or statement he took reasonable steps to ascertain, and did in fact believe, that the signature was that of the person from whom he purchased the article, or, as the case may be, of some person purporting to sign on behalf of the person from whom the defendant purchased the article.

(3) Subject to subsection (4) of this section, it shall be a good defence in a prosecution for selling any food or drug or medical device contrary to any provision of this Act or of any regulation made under this Act if the defendant proves—

(a) That he purchased the article sold by him in a package and sold it in the same package and in the same condition as the article was at the time when he purchased it; and

(b) That he could not with reasonable diligence have ascertained that the sale of the article would constitute the offence charged against him.

(4) Neither subsection (1) nor subsection (3) of this section shall apply unless within seven days after the service of the summons the defendant has delivered to the prosecution a copy of the warranty or statement, if any, and a written notice to the effect that he intends to rely thereon or on subsection (3) of this section, as the case may require, and specifying the name and address of the person from whom he received the warranty or statement or package, and has also within the same time sent by post a like notice of his intention to that person.

(5) When the defendant is a servant or agent of the person who purchased the article under such a warranty or statement or in a package as aforesaid, he shall be entitled to the benefit of this section in the same manner and to the same extent as his employer or principal would have been if he had been the defendant.

Cf. 1947, No. 7, s. 8; Food and Drugs Act (Canada), s. 28

33. Liability of persons named on labels—(1) If any food or drug or medical device is sold in the package in which it was contained when purchased by the person who sells the article, and which has not since that purchase been opened by that person or by any servant or agent of that person, every person who appears from any statement or label thereon or attached thereto to be the person who has manufactured, imported, or prepared the food or drug or medical device, or to be the person who is the owner of the rights of manufacture thereof or has enclosed it in the package, or to be the agent of any such person as aforesaid, shall, unless he proves the contrary, be deemed to have so manufactured, imported, prepared, or enclosed the food or drug or medical device or, as the case may require, to be such agent as aforesaid, and shall be liable in the same manner and to the same extent as if he had actually sold the food or drug or medical device at the time and place at which the sale was made and if that sale involved the commission of an offence shall be deemed to be a party to that offence.

(2) Subject to subsection (3) of this section, it shall be a good defence in a prosecution pursuant to subsection (1) of this section if the defendant proves—

(a) In the case of a prosecution relating to the condition of a food or drug or medical device, that when the package left his possession the food or drug or medical device was in such a condition that its sale then would not have involved the commission of the offence with which he is charged; or

(b) In the case of a prosecution relating to the condition of a food, that when or before the food left his possession, he gave notice to the person to whom he consigned or delivered the food that it was not intended for human consumption; or

(c) In the case of a prosecution relating to packing or labelling, that the offence with which he is charged arises from an alteration made to the package or labelling since the package left his possession.

(3) Subsection (2) of this section shall not apply unless within seven days after the service of the summons the defendant has delivered to the prosecution a written notice—

(a) Stating that he intends to rely on subsection (2) of this section; and

(b) Identifying the person to whom the defendant consigned or delivered the food or drug or medical device or explaining why he is unable to identify that person.

(4) Nothing in subsection (1) of this section shall apply in respect of any offence against section 18 of this Act.

Cf. 1947, No. 7, s. 10

34. Offences against section 7 or section 8 of this Act— (1) No prosecution for an offence against section 7 or section 8 of this Act shall be commenced except with the leave of the Director-General given in accordance with this section.

(2) The Director-General may give leave under subsection (1) of this section, without compliance by the Examiner with subsections (3) and (4) of this section, if he considers that an immediate prosecution is justified or necessary and shall give leave without such compliance if in his opinion the alleged offence may have damaged or endangered the health of any person.

(3) Subject to subsection (2) of this section, before the Director-General gives leave under subsection (1) of this section for the prosecution of any person, a notice in writing signed by a person (hereinafter called an Examiner) employed in the Department of Health and authorised by the Director-General, by name or office, to carry out the functions conferred on an Examiner by this section, shall be served on the first-mentioned person—

(a) Informing him of the alleged offence and the facts alleged to constitute an offence; and

(b) Inviting him to make his views in respect of the alleged offence known to the Examiner by serving on the Examiner within a period to be specified in the notice (being a period of not less than fourteen days after the service of the notice on that person), a written reply:

(i) Setting out those views; and

(ii) Stating whether or not he admits that if the offence alleged was committed he is a proper defendant; and

(iii) Stating whether or not he is prepared to confer with the Examiner.

(4) If any such person serves a written reply in accordance with paragraph (b) of subsection (3) of this section in which he both admits that if the offence alleged was committed he is a proper defendant and states that he is prepared to confer with the Examiner, the Examiner shall, unless he is then satisfied that it is not a proper case for a prosecution, serve on that person a notice in writing inviting him, within a period to be specified in the notice (being a period of not less than fourteen days after the service of the notice on him) to confer with the Examiner for the purpose of discussing the views set out in the reply and, if appropriate, entering into an agreement whereby the consequences of the offence, if any, will be mitigated as far as practicable and the repetition of the facts alleged to constitute an offence will be avoided.

(5) If any agreement entered into pursuant to subsection (4) of this section relates to an alleged offence against section 7 of this Act and includes a condition requiring goods to be withdrawn from sale, the Director-General shall cause particulars of the agreement, of the goods, and of the facts alleged to constitute an offence to be published in the *Gazette*; and thereupon that condition shall have the effect of an order under subsection (1) of section 35 of this Act and subsections (2) and (3) of that section shall apply accordingly with all necessary modifications.

(6) The Director-General may give leave under subsection (1) of this section—

(a) If any person on whom a notice has been served under subsection (3) of this section does not—

(i) Serve on the Examiner within the period specified in the notice, or within such further period as the Examiner may allow, a written reply complying with subparagraphs (i) to (iii) of paragraph (b) of that subsection; or

(ii) Include in his reply both an admission that if the offence alleged was committed he is a proper defendant and an offer to confer with the Examiner; or

(b) If any such person fails to confer with the Examiner within the period specified in the notice served on that person under subsection (4) of this section inviting him to do so or within such further period as the Examiner may allow; or

(c) If, after the Examiner has conferred with any person who has accepted an invitation under subsection (4) of this section, the Director-General considers that—

(i) A satisfactory agreement cannot be entered into under that subsection; or

(ii) There has been an undue delay in entering into an agreement and an agreement is not entered into within fourteen days after the Director-General has served on the person written notice of his intention to give leave for the commencement of a prosecution; or

(iii) Having regard to all the circumstances the person should be prosecuted; or

(iv) The person has failed to comply with the terms of an agreement entered into under that subsection.

(7) In any proceedings involving a prosecution for an offence to which subsection (1) of this section applies no question shall be raised as to whether any condition set out in subsections (2) to (6) of this section has been satisfied, or as to whether any requirement set out in those subsections has been complied with, and no reference shall be made to the fact that any negotiations have or have not taken place, or to the nature and content of any such negotiations, or to any admission made for the purposes of any such negotiations, or to any refusal or failure to confer with the Examiner, or to the application of any other provision of subsections (2) to (6) of this section.

(8) Any notice under this section may be served on any person in accordance with section 131 of the Health Act 1956.

35. Court may order withdrawal of goods from circulation—(1) If any person who packages goods or any importer of packaged goods is convicted of an offence against section 7 of this Act, the Court may in its discretion order that person to withdraw from sale all goods in respect of which the offence was committed until the matter in relation to which the offence was committed has been remedied.

(2) If the Court makes an order under subsection (1) of this section the Director-General shall cause particulars of the order and of the offence in relation to which the order was made to be published in the *Gazette*; and thereupon every distributor, trader, or retailer who has in his possession any goods of the same kind labelled and packaged in the same way as the goods in relation to which the offence was committed shall withdraw them from sale and may—

(a) Return the goods to the person who supplied them; or

(b) Remedy the matter in relation to which the offence was committed.

(3) Every distributor, trader, or retailer who takes action in accordance with paragraph (a) or paragraph (b) of subsection (2) of this section may recover all the costs and expenses incurred by him in so acting (including, if action is taken under the said paragraph (a), the purchase price of the goods) from the person who supplied the goods as a debt due by that person to the distributor, trader, or retailer.

(4) Where any person referred to in subsection (1) of this section is convicted of an offence against section 7 or section 8 of this Act, the Director-General may cause particulars of the offence and a description of the goods in relation to which the offence was committed to be published in the *Gazette*.

36. Evidence—(1) In any proceedings under this Act the production by the prosecution of a certificate of analysis purporting to be signed by an analyst shall, without proof of the signature of the analyst, be sufficient evidence of the facts stated therein, unless the defendant requires that the analyst be called as a witness, in which case the defendant shall give notice thereof to the prosecution not less than three clear days before the date of the hearing.

(2) In any proceedings under this Act a copy of a record or an extract therefrom made by an officer pursuant to this Act and certified to be a true copy by the officer who made it pursuant to paragraph (d) of subsection (2) of section 21 of this Act or the person who was caused by the Medical Officer of Health to make it pursuant to subsection (2) of section 27 of this Act shall be deemed to be a true and correct copy until the contrary is proved.

Cf. 1947, No. 7, ss. 13 (2), 19; Food and Drugs Act (Canada), s. 29 (4)

37. Source of information or reports need not be disclosed—No prosecutor or witness in any prosecution under this Act shall be compelled to disclose the fact that he received any information, or the nature of such information, or the name of any person who gave such information; and no officer appearing as a prosecutor or witness shall be compelled to produce any confidential reports or documents made or received by him in his official capacity, or to make any statement in relation thereto.

Cf. 1947, No. 7, s. 25

38. Jurisdiction of Magistrates' Courts—(1) Every offence against this Act or against any regulations made under this Act shall be punishable on summary conviction.

(2) Notwithstanding anything in section 14 of the Summary Proceedings Act 1957 any information in respect of any offence against this Act or against any regulation made under this Act may be laid at any time within three years after the time when the matter of the information arose.

(3) The summons in any such proceedings shall not be made returnable in less than fourteen days from the day on which it is served.

(4) There shall be served with the summons in any such proceedings a copy of the analyst's certificate (if any) relating to the prosecution.

(5) In any such proceedings the Court shall on the request of either party to the proceedings, and may if it thinks fit without such request, order that the part of the sample retained by the officer under section 24 of this Act be submitted, for analysis and report, to some other analyst:

Provided that in any case the Court may, if it thinks fit, order that the said part be so submitted to two analysts together, of whom one shall be an analyst nominated by the defendant and the other shall be either the analyst whose certificate is before the Court or some other analyst appointed under this Act.

Cf. 1947, No. 7, ss. 20, 24

39. Penalties—(1) Every person who contravenes any provision of section 6 or section 7 of this Act commits an offence and is liable to a fine not exceeding two hundred dollars, or, if the offence is knowingly committed, to imprisonment for a term not exceeding three months or to a fine not exceeding five hundred dollars or to both:

Provided that in any proceedings which are taken against a person by virtue of subsection (2) of section 30 of this Act, knowledge shall not, for the purposes of this subsection, be imputed to that person by reason only of the knowledge of the agent or servant.

(2) Every person who contravenes any provision of section 9 of this Act commits an offence and is liable to a fine not exceeding one hundred dollars.

(3) Every person who contravenes any provision of section 10 of this Act commits an offence and is liable to imprisonment for a term not exceeding three months or to a fine not exceeding five hundred dollars or to both.

(4) Every person who contravenes subsection (2) of section 12 of this Act commits an offence and is liable to imprisonment for a term not exceeding six months or to a fine not exceeding five thousand dollars or to both.

(5) Every person who contravenes or fails to comply with subsection (2) or subsection (4) of section 14, or subsection (1) of section 17 or any condition imposed by subsection (2) of section 15, or any requirement under subsection (1) of section 47, of this Act commits an offence and is liable to a fine not exceeding one thousand dollars, and, if the offence is a continuing one, to a further fine not exceeding one hundred dollars for every day or part of a day during which the offence has continued.

(6) Every person who commits an offence against this Act for which no penalty is provided elsewhere than in this subsection is liable to a fine not exceeding two hundred dollars.

Cf. 1947, No. 7, ss. 6 (6), (7), 11G, 13 (4), 23; 1942, No. 11, s. 15; 1962, No. 50, s. 14

40. Forfeiture on conviction—(1) Where any person is convicted of an offence against this Act or any regulations made under this Act the Court may order that any food or drug or medical device to which the conviction relates, and any similar food or drug or medical device found on the premises of the defendant or in his possession at the time of the commission of the offence, together with all packages or vessels containing the food or drug or medical device, shall be forfeited to the Crown.

(2) Everything so forfeited to the Crown shall be disposed of as the Minister directs.

Cf. 1947, No. 7, s. 26

41. Payment of expenses of analysis on conviction—(1) Where any person is convicted of an offence against this Act or any regulations made under this Act, the Court may order that all fees and other expenses incidental to the analysis of any food or drug in respect of which the conviction is obtained (including any analysis under subsection (5) of section 38 of this Act) shall be paid by the defendant.

(2) All such fees and expenses shall be deemed to be part of the costs attending the conviction, and shall be recoverable accordingly.

Cf. 1947, No. 7, s. 27

Miscellaneous Provisions

42. Statements by Director-General—(1) Notwithstanding anything in this Act, the Director-General may from time to time, for the purpose of protecting the public, publish statements in respect of any food or drug or medical device, or in respect of any matter contained or implied in advertisements (either generally or in any particular advertisement or any class or classes of advertisements) relating to any food or drug or medical device.

(2) Every statement published under this section shall be privileged unless the publication is proved to be made with malice.

Cf. 1947, No. 7, s. 28A; 1962, No. 50, s. 11

43. Examination of Customs entries—For the purposes of this Act, any officer shall have the right at all times, subject to the convenience of the Collector or other responsible officer of Customs, to inspect any Customs entry relating to any goods imported or proposed to be imported into New Zealand, or to inspect any certificate or invoice relating to those goods, if and so long as any such document is in the possession or control of the Collector or other responsible officer as aforesaid.

Cf. 1947, No. 7, s. 14

44. Protection of persons acting under authority of Act—A person who does any act in pursuance or intended pursuance of any of the provisions of this Act shall not be under any civil or criminal liability in respect thereof, whether on the grounds of want of jurisdiction, or mistake of law or fact, or on any other ground, unless he has acted in bad faith or without reasonable care.

Cf. 1947, No. 7, s. 28B; 1962, No. 50, s. 12

45. Amendment of First Schedule—The Governor-General may from time to time, by Order in Council published in the *Gazette*, add to or omit from Part I or Part II of the First Schedule to this Act any disease or disorder or class of disease or disorder or otherwise amend that Schedule, and every such Order in Council shall have effect according to its tenor.

46. Regulations—(1) The Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:

(a) Prescribing standards of composition, including standards of strength, weight, quality, purity, or quantity for any food or drug or for anything contained in or added to or intended to be contained in or added to any food or drug:

(b) Permitting the addition of a specified thing, or a specified thing in a specified quantity or proportion, to any food or drug for which a standard is prescribed:

(c) Prohibiting the sale of any food or drug for which a standard is not prescribed and to which a specified thing has been added or has been added in a quantity or proportion in excess of a specified quantity or proportion:

(d) Prohibiting the sale of any medical device:

(e) Prohibiting, regulating, or restricting the importation, manufacture, preparation, packing, or preservation of any food or drug or medical device, controlling the quality of any drug or medical device manufactured or packed in New Zealand and requiring the manufacturer or packer thereof to keep such records as may be prescribed, providing for the inspection of any such records, and providing for the licensing of manufacturers or packers of therapeutic drugs and for the registration of manufacturers or packers of any drugs:

(f) Securing the cleanliness and freedom from infection, deterioration, or contamination of any food or drug or medical device in the course of its manufacture, preparation, storage, packing, carriage, delivery, or exposure for sale, securing the cleanliness of places, packages, receptacles, appliances, and vehicles used for the sale of any food or drug or medical device or in such manufacture, preparation, storage, packing, carriage, or delivery, preventing the use of any such place, receptacle, appliance, or vehicle contrary to any such regulation, and conferring powers and imposing duties on local authorities in relation to the administration and enforcement of any regulations made under this paragraph:

(g) Prohibiting, restricting, or regulating the sale or supply for human consumption of any food which is infected or contaminated or which is reasonably suspected by any Medical Officer of Health, within the meaning of the Health Act 1956, of being infected or contaminated:

(h) Prescribing the mode of labelling, branding, printing, or marking of appliances, containers, or instruments used or intended for use in or in connection with the preparation or storage of any food or drug or medical device, and prohibiting the sale of any such appliance, container, or instrument which is not labelled, branded, printed, or marked in accordance with any such regulations:

(i) Prescribing the mode of labelling of packages containing any substance or preparation used or intended for use or held or kept for use in the manufacture or preparation of, or as an ingredient of, any food or drug or medical device:

(j) Prescribing the mode of labelling of any food or drug or medical device sold in a package, and requiring any matter to be printed, embossed, impressed, branded, stamped, or otherwise marked on any food or drug or medical device (whether sold in a package or otherwise) in such manner as may be prescribed:

(k) Prescribing the matter to be contained or not to be contained in any label for any of the aforesaid purposes and the nature and appearance of any package containing a particular kind of food or drug or medical device:

(l) Requiring, where the label on any package that contains food bears any statement to the effect that the package contains any number of portions or servings of food, that the label shall also bear a statement giving particulars of the quantity of each purported portion or serving, by weight or volume, when ready for consumption:

(m) Prescribing in the case of any specified class or classes of food or drugs or medical devices imported into New Zealand that all articles belonging to any such class, or the packages containing such articles, shall be branded, stamped, or marked so as to indicate the fact of their importation and the country of origin:

(n) Prohibiting or restricting the sale of any food or drug or medical device which is not marked or labelled, in accordance with any regulations made under this Act, and the sale of specified articles of food otherwise than in a package or otherwise than by weight or volume:

(o) Requiring with respect to any specified article of food that, when it is sold otherwise than in packages, there shall be conspicuously displayed in the place of sale, so as to be easily read by the purchaser, the same particulars (if any), but subject to such necessary modifications as may be expressed or indicated in the regulations, as are required by any regulations made under this Act to be contained in the labels when the article is sold in packages:

(p) Requiring that any specified food or drug, or foods or drugs of any specified class or classes, shall be artificially coloured by the addition thereto of such colouring substance or substances as may be prescribed, in such proportion or proportions as may be prescribed, and prohibiting the sale of any such food or drug not so coloured:

(q) Prohibiting or restricting the sale of any vessel or utensil intended for use in the storage, preparation, or cooking of food and made of any material containing any substance capable of imparting any poisonous or injurious property to any food that might be stored, prepared, or cooked therein:

(r) Requiring, subject to subsection (2) of this section, the insertion in any medical advertisement, or a particular class of medical advertisement, of such information or warning, or kind of information or warning, concerning any unwanted, incidental, or untoward effects of the drug or medical device or method of treatment advertised or the class or kind of drug or medical device or method of treatment to which the article or method advertised belongs, and such statement or kind of statement of the precautions to be taken by any user of that drug or medical device or method of treatment, as may be prescribed:

(s) Prohibiting the advertising of any specified therapeutic drug or class of therapeutic drug in any medical advertisement, or a particular class of medical advertisement, other than a label or an advertisement to

which section 11 of this Act applies, and prohibiting or requiring the mention in any such advertisement or class of advertisement, other than an advertisement to which section 11 of this Act applies, of such matters relating to the composition, properties, nomenclature, origin, and use of the drug or medical device or method of treatment advertised as may be prescribed:

(t) Prescribing the method of analysis of any food or drug and prescribing the form of the certificate of an analyst and any other forms that may be required for the purposes of this Act or of any regulations made under this Act:

(u) Exempting or providing for exemptions from any specified provision of any regulations made under this Act:

(v) Permitting the sale of therapeutic drugs or specified therapeutic drugs or specified classes of therapeutic drugs generally or by such classes of persons and subject to such conditions as may be prescribed:

(w) Prohibiting the use of any package of a kind specified or described in the regulations for any purpose other than the storage or sale of food or drugs for internal use:

(x) Prescribing fees in respect of the analysis by an analyst of any food or drug and in respect of any licence issued or registration effected or renewed pursuant to any regulations made under this Act:

(y) Prescribing offences in respect of the contravention of or non-compliance with any regulations made under this Act, and the amount of the fines that may be imposed in respect of any such offences, which fines shall be an amount not exceeding two hundred dollars and, where the offence is a continuing one, a further amount not exceeding ten dollars for every day or part of a day during which the offence has continued:

(z) Providing for such matters as are contemplated by or necessary for giving full effect to this Act and for its due administration.

(2) Any regulations made under paragraph (r) of subsection (1) of this section—

(a) Shall be made only on the recommendation of the Minister after consultation with such organisations

as appear to him to represent any class or classes of persons whose interests might be affected by the regulations; and

(b) Shall be designed to achieve a fair and balanced indication of the potential effects of the drug or medical device or method of treatment advertised; and

(c) Shall not require the disclosure of information which may reasonably be regarded as confidential or which cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published or the inclusion of which in the advertisement is otherwise impracticable.

(3) The Minister may, by notice in the *Gazette,* vary for such period (not exceeding twelve months) as may be specified in the notice, any limit imposed by any such regulations on the quantity or proportion of any specified thing that may be contained in any food or drug or medical device or may, in like manner, permit the addition of a specified thing, or of a specified thing in any quantity or proportion to a food or drug or medical device for which a standard is prescribed.

(4) Any regulation under this section may be made applicable either to foods or drugs or medical devices generally or to specified foods or drugs or medical devices only.

(5) Notwithstanding anything contained in any regulation made under this section, it shall be lawful for any person, at any time within twelve months after the date of the commencement of the regulation, to sell any food or drug or medical device of which the sale is otherwise lawful, if he proves that at the said date the food or drug or medical device was part of the existing stock in trade in New Zealand of any person carrying on business there, and that since the said date no act has been done whereby the food or drug or medical device fails to conform to the regulation. For the purposes of this subsection any goods purchased before the said date for importation into New Zealand shall be deemed to be part of the purchaser's stock in trade in New Zealand.

Cf. 1947, No. 7, s. 29; 1957, No. 27, s. 2; 1962, No. 50, s. 13; 1942, No. 11, s. 14

47. Power to obtain information for purposes of regulations—(1) For the purpose of enabling the making of regulations under this Act, the Director-General may from time to time, by notice in writing to the manufacturer in New Zealand of any compounded food or drug which is sold under a trade

name, or to the importer into New Zealand of any such food or drug, require such manufacturer or importer to state correctly in writing to the Director-General the nature of the ingredients of the food or drug and the proportions in which those ingredients are contained in it. For the purposes of this subsection, the term "manufacturer", in relation to a food or drug, means the person who, as owner, packs the food or drug for sale or causes it to be so packed.

(2) The disclosure of any information pursuant to subsection (1) of this section shall not prejudice any application subsequently made for a patent.

Cf. 1947, No. 7, s. 13 (2A) and (2B); 1962, No. 50, s. 7

48. Repeals—The enactments specified in the Second Schedule to this Act are hereby repealed.

49. Revocations—The regulations specified in the Third Schedule to this Act are hereby revoked.

SCHEDULES

Section 10 (1) (d) and (e)

FIRST SCHEDULE

PART I

Alcoholism.
Appendicitis.
Arteriosclerosis.
Arthritis.
Blood poisoning.
Blood pressure disorders.
Bright's disease.
Cancer.
Cataract.
Diabetes.
Diphtheria.
Dropsy.
Epilepsy.
Erysipelas.
Gallstones, kidney stones, bladder stones.
Gangrene.
Glaucoma.
Goitre.
Heart disease.
Influenza.
Leukaemia.
Lockjaw.
Locomotor Ataxia.
Menstrual flow, disorders of.
Pleurisy.
Pneumonia.
Poliomyelitis.
Prostatic gland, disorders of.
Ruptures.
Scarlet Fever.
Sexual impotence.
Smallpox.
Spinal Meningitis.
Tetanus.
Thrombosis.
Trachoma.
Tuberculosis.
Tumours.
Typhoid Fever.
Ulcers of the gastro-intestinal tract.
Venereal diseases.

PART II

Asthma.
Common cold.
Dental decay.
Disorders arising from the ingestion of alcohol.
Gout.

FIRST SCHEDULE—*continued*

PART II—*continued*

Haemorrhoids.
Impaired hearing.
Obesity.
Pyorrhoea.
Piles.
Rheumatism.
Varicose veins.

SECOND SCHEDULE

Section 48

ENACTMENTS REPEALED

1942, No. 11—The Medical Advertisements Act 1942. (1957 Reprint, Vol. 9, p. 529.)
1945, No. 40—The Statutes Amendment Act 1945: Section 46. (1957 Reprint, Vol. 9, p. 537.)
1947, No. 7—The Food and Drugs Act 1947. (1957 Reprint, Vol. 5, p. 327.)
1948, No. 77—The Statutes Amendment Act 1948: Section 19. (1957 Reprint, Vol. 5, p. 345.)
1949, No. 51—The Statutes Amendment Act 1949: Sections 16 and 17. (1957 Reprint, Vol. 5, p. 345.)
1951, No. 79—The Fees and Travelling Allowances Act 1951: So much of the First Schedule as relates to the Medical Advertisements Board, and so much of the Second Schedule as relates to the Medical Advertisements Act 1942. (1957 Reprint, Vol. 9, p. 532.)
1951, No. 81—The Statutes Amendment Act 1951: Section 12. (1957 Reprint, Vol. 5, p. 346.)
1956, No. 37—The Food and Drugs Amendment Act 1956. (1957 Reprint, Vol. 5, p. 346.)
1957, No. 27—The Food and Drugs Amendment Act 1957. (1957 Reprint, Vol. 5, p. 347.)
1962, No. 50—The Food and Drugs Amendment Act 1962.

THIRD SCHEDULE

Section 49

REGULATIONS REVOKED

S.R. 1943/63—The Medical Advertisements Regulations 1943: Regulations 4, 5, 7, 8, 10, 12, 13, 14, and 17, and the Schedule to the regulations.
S.R. 1944/47—The Medical Advertisements Procedure Rules 1943.

This Act is administered in the Department of Health.