



**THE SALE OF FOOD AND DRUGS AMENDING
REGULATIONS 1945, NO. 3**

C. L. N. NEWALL, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington, this 19th day of
September, 1945

Present :

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to the Sale of Food and Drugs Act, 1908, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, doth hereby make the following regulations.

REGULATIONS

1. These regulations may be cited as the Sale of Food and Drugs Amending Regulations 1945, No. 3.
2. These regulations shall be read together with and form part of the regulations relating to the sale of food and drugs made on the 23rd day of June, 1924, and published in the *Gazette* on the 26th day of the same month at page 1505 (hereinafter referred to as the principal regulations).
3. These regulations shall come into force on the 21st day of September, 1945.

PENICILLIN

4. (1) Penicillin shall be an antibiotic substance produced during the growth of *Penicillium notatum*, and shall include salts of penicillin. Sodium penicillin or any other salt of penicillin shall be a dry sterile salt of penicillin. Any salt of penicillin shall contain not less than 150 Oxford units per milligram and shall not contain more than 2 per centum of moisture. It shall not contain any added preservative. When the penicillin salt is dissolved in water and diluted to contain 10,000 units per millilitre the solution shall be clear and shall not contain any visible particles or insoluble matter and shall have a hydrogen ion concentration within the range from pH 6.0 to pH 7.0.

SAFETY TEST

(2) No person shall sell any lot of any salt of penicillin unless a sample thereof has been tested for safety by the following method: Not less than five mice, each of about 20 gm. weight (limits 18 to 22 gm.) shall be injected in such a way as not to be a breach of section 7 of the Police Offences Act, 1927, with 1,000 units per mouse contained in 0.5 ml. of pyrogen-free distilled water. If more than 20 per centum of all mice so injected die within twenty-four hours, the lot shall not be offered for sale or sold.

PYROGENS

(3) Salts of penicillin shall not show the presence of pyrogenic substances when tested.

POTENCY

(4) The potency of any salt of penicillin shall be expressed in Oxford units per milligram in comparison with a reference standard salt of penicillin.

STERILITY

(5) No person shall sell or distribute any lot of any salt of penicillin intended for parenteral injection unless a sample thereof has been subjected to some suitable test for sterility and found to be sterile.

LABELLING

(6) No person shall sell any penicillin unless the label borne on every package of penicillin contains the following particulars:—

(a) The number of Oxford units in the package, or the number of milligrams of pure penicillin in the package:

(b) The date after which the penicillin should no longer be used.

(7) No person shall sell any preparation of which it is claimed that penicillin is an ingredient unless there is borne on every package containing such preparation a statement setting out the number of Oxford units of penicillin contained in a stated quantity of the preparation, and the date of manufacture.

PROHIBITION

(8) No person shall sell any penicillin, or any preparation of which it is claimed that penicillin is an ingredient, if the active penicillin present is less than the amount stated in the label to a degree exceeding one-tenth.

(9) If any test is made to determine whether the penicillin contained in any sample is active or inactive the test shall be commenced within a period of forty-eight hours after the time at which the sample was purchased or otherwise procured, and the sample shall have been kept in an ice-cooled box from the time of the completion of taking the sample until the commencement of the test.

ICE-CREAM

5. Notwithstanding anything to the contrary in Regulation 6 of the principal regulations, soluble saccharine may be added without declaration to ice-cream and ices in quantity not exceeding one and a half ounces to 100 gallons of ice-cream mix or ice mix.

C. A. JEFFERY,

Clerk of the Executive Council.

Issued under the authority of the Regulations Act, 1936.

Date of notification in *Gazette*: 29th day of September, 1945.

These regulations are administered in the Department of Health.