§ 6817. New drugs. 1. Except as otherwise provided in the Federal Food, Drug and Cosmetic Act, no person shall sell, deliver, offer for sale, hold for sale, or give away any new drug, unless:

a. an application with respect thereto has become effective, or in the case of an investigational drug the sponsor has complied with the applicable requirements, under the Federal Food, Drug, and Cosmetic Act, or

b. when not subject to such act, such drug has been tested and has not been found to be unsafe or ineffective for use under the conditions prescribed, recommended or suggested in the labeling thereof, and, prior to selling or offering for sale such drug, there has been filed with the department an application setting forth

(1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;

(2) a full list of the ingredients used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drugs;

(5) such samples of such drug and of the ingredients used as components thereof as the board or secretary may require; and

(6) specimens of the labeling proposed to be used for such drug.

2. An application provided for in paragraph b of subdivision one shall become effective on the one hundred eightieth day after the filing thereof, except that if the secretary or board finds, after due notice to applicant and giving him an opportunity for a hearing, that the drug is not safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

3. A drug dispensed on a written or oral prescription of a physician, dentist, podiatrist or veterinarian (except a controlled substance), shall be exempt from the requirements of this section if such drug bears

a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription and the name of the physician, dentist, podiatrist or veterinarian issuing the prescription and the name of the patient. In addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

4. The board shall promulgate regulations for exempting from the operation of this section drugs (and with the concurrence of the commissioner of health, pursuant to article thirty-three of the public health law, controlled substances) intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs and labeled "For Investigational Use Only". Such regulations may, within the discretion of the board, among other conditions relating to the protection of the public health, provide for conditioning such exemptions upon:

a. The submission to the secretary before any clinical testing of a new drug is undertaken of reports by the manufacturer or sponsor of the investigation of such drug, of preclinical tests, including tests on animals of such drug adequate to justify the proposed clincial testing.

b. The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator or to clinics for administration to human beings; and

c. The establishment and maintenance of such records and the making of such reports to the board by the manufacturer or the sponsor of the investigation of such drugs of data including, but not limited to, analytical reports by investigators obtained as the result of such

investigational use of such drug as the board finds will enable it to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subdivision one of this section.

5. This section shall not apply to any drug which was licensed under the federal virus, serum, and toxin act of July first, nineteen hundred two (32 Stat. 728) or is licensed under section two hundred sixty-two of the public health service act of July first, nineteen hundred forty-four (58 Stat. 682), or under the federal virus, serums, toxins, antitoxins and analogous products act of March fourth, nineteen hundred thirteen (37 Stat. 832).