189D.

(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and approval has not been withdrawn under Section ~~505~~ 355 of the Federal Act, or (2) when not subject to the Federal Act, unless the drug has been tested and has been found to be safe for use and effective in 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 Secretary an application setting forth (i) full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use; (ii) a full list of the articles used as components of the drug; (iii) a full statement of the composition of such drug; (iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug; (v) such samples of the drug and of the articles used as components thereof as the Secretary may require; and (vi) specimens of the labeling proposed to be used for the drug.

(b) An application provided for in subsection (a) (2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, (1) that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or (2) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drugs are inadequate to preserve its identity, strength, quality, and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any partciular, then he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the Secretary.

(d) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, and in addition to other conditions which may be imposed relating to the protection of the public health, provide for such exemption to be conditioned upon:

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of the drug adequate to justify the proposed clinical testing;

(2) 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 the 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 the drug to any other investigator, or to clinics, for administration to human beings; and