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§21–223.

(a) This section does not apply to any drug that:

(1) Was sold in this State or introduced into interstate commerce at any time before the enactment of the federal act, if its labeling contained the same representations concerning the conditions of its use; or

(2) Is licensed under the Public Health Service Act of July 1, 1944 or under the Animal Virus, Serum, Toxin, Antitoxin Act of March 4, 1913.

(b) A person may not sell, give away, or deliver any new drug:

(1) Unless an approved application for the drug is in effect under § 355 of the federal act; or

(2) Unless an application has been approved by the Secretary and is in effect under this section, if the drug is not subject to the federal act.

(c) To have an application approved by the Secretary, an applicant shall file with the Secretary an application that sets forth:

(1) Full reports of the investigations that have been made to show whether the drug is safe for use and whether the drug is effective in use;

(2) A full statement of the composition of the drug;

(3) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

(4) Any sample of the drug and of any article used as a component of the drug that the Secretary requires; and

(5) A specimen of the labeling that is proposed to be used for the drug.

(d) The Secretary may not approve an application filed under this section unless the drug has been tested and, under the conditions specified, recommended, or suggested in the proposed labeling of the drug, has been found to be safe for and effective in use.

(e) An application filed with the Secretary under this section shall be considered approved on the 180th day after it is filed, unless before that day and after giving the applicant notice and an opportunity for a hearing, the Secretary issues an order of disapproval under subsection (f) of this section on a finding that:

(1) The drug has not been tested properly, as required by subsection (d) of this section;

(2) Under the conditions specified, recommended, or suggested in the proposed labeling of the drug, it is not safe for or effective in use;

(3) The methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any way.

(f) If, before the date that the application otherwise would be considered approved the Secretary makes any of the findings that are enumerated in subsection (e) of this section concerning the drug, the Secretary shall issue an order that disapproves the application.

(g) (1) The Secretary may revoke an order that disapproved an application and the application then shall be considered approved.

(2) After providing an opportunity for a public hearing and judicial appeal, the Secretary may revoke an application that was approved under this section if, based on evidence that is acquired after approval, the Secretary finds that:

(i) The drug may not be safe for or effective in its intended use; or

(ii) The facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.

(h) In accordance with any rule or regulation that is adopted or any order that is issued by the Secretary under this section, the person who holds an application for a drug that is approved under this section shall:

(1) Keep records; and

(2) Submit reports to the Secretary.

(i) (1) The Secretary may adopt rules and regulations that apply generally to persons whose applications for drugs have been approved or, as to a particular person whose application has been approved, issue an order that requires an applicant:

(i) To keep records of information that relates to clinical experience with the drug and any other information that the applicant obtains about the drug; and

(ii) To submit reports to the Secretary concerning that information.

(2) When adopting a rule or regulation or issuing an order that requires

the submission of information under this subsection, the Secretary shall consider the professional ethics of the medical profession and the interests of patients.

(3) Any rule, regulation, or order under this section shall provide that if any person to whom the rule, regulation, or order applies requests it, and if the Secretary considers it to be appropriate, the person may examine similar information that is obtained by the Secretary concerning the drug.

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