(3) the establishment and maintenance of the records, and the making of the reports to the Secretary, by the manufacturer or the sponsor of the investigation of the drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (a).

Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs; provided, that the regulations adopted under Section ~~505~~ 355 (i) of the Federal Act shall be the regulations in this State; and provided further, that the Secretary may, in his discretion, promulgate regulations whether or not in accordance with regulations promulgated under the Federal Act.

(e) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to the drug, as the Secretary may by general regulation, or by order with respect to the application, prescribe: provided, however, that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom the regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof shall, upon request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify such records.

(f) The Secretary may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.

(g) This section shall not apply:

(1) to a drug sold in this State or introduced into interstate commerce at any time prior to the enactment of the Federal Act, if its labeling contained the same representations concerning the conditions of its use; or

(2) to any drug which is licensed under the Public Health Service Act of July 1, 1944 (58 stat. 682, as amended; 42 U. S. C. 201 et seq.) or under the animal Virus-Serum-Toxin Act of March 4, 1913 (13 stat. 832; 21 U. S. C. 151 et seq.), as either of said Acts have been or may be amended from time to time; or (3) to any drug which is subject to Section 189B (a)(1) of this subheading.