(§ 130.3)

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(b) A shipment or other delivery of a new drug that is being imported or is offered for importation into the United States shall be exempt from the requirements of section 505(a) of the act if the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use"; and

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has prior to such shipments and deliveries completed and submitted signed copies to the Food and Drug Administration of the "Notice of claimed investigational exemption for a new drug"; and acts as the sponsor of the clinical investigation to assure compliance with the conditions prescribed by paragraph (a) of this section; or

(3) The drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct clinical pharmacology and is intended solely for such use in such institutions and a "Notice of claimed investigational exemption for a new drug" covering this activity has been filed.

* (c) (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations outlined in Form FD–1572 or FD–1573 (set forth in paragraph (a) (12) and (13) of this section), or has submitted to the sponsor of the investigation false information in his Form FD–1572 or FD–1573 or in any required report, the Director of the Bureau of Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Medicine, the Commissioner will provide the investigator an opportunity for an informal hearing on the question of whether the investigator is entitled to receive investigational-use drugs, if the hearing is requested within 10 days after receipt of notification that the explanation is not acceptable.

(2) After evaluating all available information, including any explanation and assurance presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation and has failed to furnish adequate assurance that the conditions of the exemption will be met, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational-use drugs with a statement of the basis for such determination.

(3) Each "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571 set forth in paragraph (a) (2) of this section) and each approved new-drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use drugs will be examined to determine whether he has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new-drug application.

(4) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he will notify the sponsor and provide him with an opportunity for a conference and an informal hearing in accordance with paragraph (d) of this section. If an imminent hazard to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the Commissioner, on request, will afford the sponsor an opportunity for an informal hearing on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are such that a new-drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 505(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use drugs when the Commissioner determines that he has presented adequate assurance that he will employ such drugs solely in compliance with the exempting regulations in this section for investigational use drugs. *

(d) If the Commissioner of Food and Drugs finds that:

(1) The submitted "Notice of claimed investigational exemption for a new drug" contains an untrue statement of a material fact or omits material information required by said notice; or

(2) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(3) There is substantial evidence to show that the drug is unsafe for the purposes and in the manner for which it is offered for investigational use; or