(§ 130.3)

Amendment published in Federal Register:
* June 5, 1968; 33 F.R. 8338

(4) There is convincing evidence that the drug is ineffective for the purposes for which it is offered for investigational use; or

(5) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug; or

(6) The plan for clinical investigations of the drugs described under section 10 of the "Notice of claimed investigational exemption for a new drug" is not a reasonable plan in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe and effective for use; or

(7) The clinical investigations are not being conducted in accordance with the plan submitted in the "Notice of claimed investigational exemption for a new drug"; or

(8) The drug is not intended solely for investigational use, since it is being or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(9) The labeling or other informational material submitted for the drug as required by section 7 of the "Notice of claimed investigational exemption for a new drug" or any other labeling of the drug disseminated within the United States by or on behalf of the sponsor fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contraindications, side-effects, and precautions; or any promotional material disseminated within the United States by or on behalf of the sponsor contains any representation or suggestion that the drug is safe or that its usefulness has been established for the purposes for which it is offered for investigations; or

(10) The sponsor fails to submit accurate reports of the progress of the investigations with significant findings at intervals not exceeding 1 year; or

(11) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug;

* he shall notify the sponsor and invite his immediate correction or explanation. A conference will be arranged with the Bureau of Medicine if requested. If the Bureau of Medicine does not accept the explanation and/or the correction submitted by the sponsor, the Commissioner will provide the sponsor an opportunity for an informal hearing on the question of whether his exemption should be terminated, if the hearing is requested within 10 days after receipt of notification that the explanation or correction is not acceptable. After evaluating all the available information including any explanation and/or correction submitted by the sponsor, if the Commissioner determines that the exemption should be terminated he shall notify the sponsor of the termination of the exemption and the sponsor shall recall unused supplies of the drug. If at any time the Commissioner concludes that continuation of the investigation presents an imminent hazard to the public health, he shall terminate the exemption forthwith and notify the sponsor of the termination. The Commissioner will inform the sponsor that the exemption is subject to reinstatement on the basis of additional submissions that eliminate such hazard(s) and will afford the sponsor an opportunity for an informal hearing, on request, on the question of whether the exemption should be reinstated. The sponsor shall recall the unused supplies of the drug upon notification of the termination. *

(e) Where drugs were under clinical trial on man on or after August 10, 1962, the sponsor shall, within 30 days after these regulations become effective, submit a list of such investigational drugs, and within 120 days after such effective date shall submit to the Food and Drug Administration the completed "Notice of claimed investigational exemption for a new drug" or a new-drug application. Failure to do so shall automatically terminate the exemption. If any such clinical trials have been discontinued, the sponsor is requested to submit a statement of why the investigation was discontinued.

(f) [Reserved]

(g) A "Notice of claimed investigational exemption for a new drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), should be submitted initially to the Division of Biologics Standards, National Institutes of Health, Public Health Service, rather than to the Commissioner of Food and Drugs. Likewise, amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation, should be directed to the Division of Biologics Standards, which monitors the development of biological products subject to license under section 351 of the Public Health Service Act.

(h) Any requirement by this section for the submission of information or data that has been submitted previously may be incorporated by reference.

NOTE: Order of the Commissioner of Food and Drugs published at 28 F.R. 183, Jan. 3, 1963, provides as follows:

"That, § 130.3 (28 F.R. 179) shall not apply to radioactive new drugs, until further notice, provided the radioactive new drugs for investigational use are being shipped in complete conformity with the regulations issued by the Atomic Energy Commission."