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(7) If the investigations adduce facts showing that there is substantial doubt that they may be continued safely in relation to the drug's potential therapeutic effects, the sponsor shall promptly discontinue the investigation, notify all investigators and the Food and Drug Administration, recall all stocks of the drug outstanding, and furnish the Food and Drug Administration with a full report of the reason for discontinuing the investigation. The Food and Drug Administration will be prepared to confer with the sponsor on the need to discontinue the investigation.

(8) The sponsor shall discontinue shipments or deliveries of the new drug to any investigator who has repeatedly or deliberately failed to maintain or make available his records or reports of his investigations.

(9) The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505(b) of the act (or give reasons for not submitting such application, or a statement that the investigation has been discontinued and the reasons therefor):

(i) With reasonable promptness after finding that the results of such investigation appear to establish the safety and effectiveness of the drug; or

(ii) Within 60 days after receipt of a written request for such an application from the Commissioner.

(10) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the drug being distributed interstate for investigational use is safe or useful for the purposes for which it is under investigation. This regulation is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay communications media; its sole intent is to restrict promotional claims of safety or effectiveness by the sponsor while the drug is under investigation to establish its safety or effectiveness.

(11) The sponsor shall not commercially distribute nor test-market the drug until a new-drug application is approved pursuant to section 505(b) of the the act.

(12) The sponsor shall obtain from each investigator involved in clinical pharmacology a signed statement in the following form:

Form FD 1572

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator (Clinical Pharmacology)

Name of investigator _____
Date _____
Name of drug _____
To supplier of the drug:
Name _____
Address _____

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of Title 21 of Code of Federal Regulations as a condition for receiving and conducting clinical pharmacology with a new drug limited by Federal (or United States) law to investigational use.

1. A statement of the education and training that qualifies me for clinical pharmacology.

2. The name and address of the medical school, hospital, or other research facility where the clinical pharmacology will be conducted.

3. The expert committees or panels responsible for approving the experimental project.

4. The estimated duration of the project, and the maximum number of subjects that will be involved.

5. A general outline of the project to be undertaken. (Modification is permitted on the basis of experience gained without advance submission of amendments to the general outline.)

6. The undersigned understands that the following conditions generally applicable to new drugs for investigational use govern his receipt and use of this investigational drug: