

## § 312.1

## 21 CFR Ch. I (4–1–08 Edition)

### Subpart C—Administrative Actions

- 312.40 General requirements for use of an investigational new drug in a clinical investigation.
- 312.41 Comment and advice on an IND.
- 312.42 Clinical holds and requests for modification.
- 312.44 Termination.
- 312.45 Inactive status.
- 312.47 Meetings.
- 312.48 Dispute resolution.

### Subpart D—Responsibilities of Sponsors and Investigators

- 312.50 General responsibilities of sponsors.
- 312.52 Transfer of obligations to a contract research organization.
- 312.53 Selecting investigators and monitors.
- 312.54 Emergency research under § 50.24 of this chapter.
- 312.55 Informing investigators.
- 312.56 Review of ongoing investigations.
- 312.57 Recordkeeping and record retention.
- 312.58 Inspection of sponsor's records and reports.
- 312.59 Disposition of unused supply of investigational drug.
- 312.60 General responsibilities of investigators.
- 312.61 Control of the investigational drug.
- 312.62 Investigator recordkeeping and record retention.
- 312.64 Investigator reports.
- 312.66 Assurance of IRB review.
- 312.68 Inspection of investigator's records and reports.
- 312.69 Handling of controlled substances.
- 312.70 Disqualification of a clinical investigator.

### Subpart E—Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses

- 312.80 Purpose.
- 312.81 Scope.
- 312.82 Early consultation.
- 312.83 Treatment protocols.
- 312.84 Risk-benefit analysis in review of marketing applications for drugs to treat life-threatening and severely-debilitating illnesses.
- 312.85 Phase 4 studies.
- 312.86 Focused FDA regulatory research.
- 312.87 Active monitoring of conduct and evaluation of clinical trials.
- 312.88 Safeguards for patient safety.

### Subpart F—Miscellaneous

- 312.110 Import and export requirements.
- 312.120 Foreign clinical studies not conducted under an IND.
- 312.130 Availability for public disclosure of data and information in an IND.

- 312.140 Address for correspondence.
- 312.145 Guidance documents.

### Subpart G—Drugs for Investigational Use in Laboratory Research Animals or in Vitro Tests

- 312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 371, 381, 382, 383, 393; 42 U.S.C. 262.

SOURCE: 52 FR 8831, Mar. 19, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 312 can be found at 69 FR 13717, Mar. 24, 2004.

### Subpart A—General Provisions

#### § 312.1 Scope.

(a) This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission to, and review by, the Food and Drug Administration of investigational new drug applications (IND's). An investigational new drug for which an IND is in effect in accordance with this part is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

(b) References in this part to regulations in the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

#### § 312.2 Applicability.

(a) *Applicability.* Except as provided in this section, this part applies to all clinical investigations of products that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to the licensing provisions of the Public Health Service Act (58 Stat. 632, as amended (42 U.S.C. 201 *et seq.*)).

(b) *Exemptions.* (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:

(i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used

to support any other significant change in the labeling for the drug;

(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and

(v) The investigation is conducted in compliance with the requirements of §312.7.

(2)(i) A clinical investigation involving an in vitro diagnostic biological product listed in paragraph (b)(2)(ii) of this section is exempt from the requirements of this part if (a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and (b) it is shipped in compliance with §312.160.

(ii) In accordance with paragraph (b)(2)(i) of this section, the following products are exempt from the requirements of this part: (a) blood grouping serum; (b) reagent red blood cells; and (c) anti-human globulin.

(3) A drug intended solely for tests in vitro or in laboratory research animals is exempt from the requirements of this part if shipped in accordance with §312.160.

(4) FDA will not accept an application for an investigation that is exempt under the provisions of paragraph (b)(1) of this section.

(5) A clinical investigation involving use of a placebo is exempt from the requirements of this part if the investigation does not otherwise require submission of an IND.

(6) A clinical investigation involving an exception from informed consent under §50.24 of this chapter is not exempt from the requirements of this part.

(c) *Bioavailability studies.* The applicability of this part to in vivo bioavailability studies in humans is subject to the provisions of §320.31.

(d) *Unlabeled indication.* This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 314 or of a licensed biological product.

(e) *Guidance.* FDA may, on its own initiative, issue guidance on the applicability of this part to particular investigational uses of drugs. On request, FDA will advise on the applicability of this part to a planned clinical investigation.

[52 FR 8831, Mar. 19, 1987, as amended at 61 FR 51529, Oct. 2, 1996; 64 FR 401, Jan. 5, 1999]

### §312.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Act apply to those terms when used in this part:

(b) The following definitions of terms also apply to this part:

*Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201-902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392)).

*Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

*Contract research organization* means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

*FDA* means the Food and Drug Administration.

*IND* means an investigational new drug application. For purposes of this part, "IND" is synonymous with "Notice of Claimed Investigational Exemption for a New Drug."

*Investigational new drug* means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is