

C.F.R. = CODE OF FEDERAL REGULATIONS

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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: Secs. 301, 301, 601, 502, 503, 506, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 361, 362, 363, 365, 366, 367, 371); sec. 361 of the Public Health Service Act (42 U.S.C. 262).

Source: 53 FR 8831, Mar. 19, 1987, unless otherwise noted.

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 requirement 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

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

(6) 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.

(b) **Bioavailability studies.** The applicability of this part to in vivo bioavailability studies in humans is subject to the provision 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 or antibiotic 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.

§ 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.

IND 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, antibiotic drug, or biologic drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sponsor-investigator" includes any other individual member of that team.

Marketing application means an application for a new drug submitted under section 505(b) of the Act, a request to provide for certification of an antibiotic submitted under section 507 of the Act, or a product license application for a biological product submitted under the Public Health Service Act.

Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are in investigators.

Sponsor-investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirement applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

Subject means a human who participates in an investigation, either as a recipient of the investigational new