Subpart A—General Provisions

§ 314.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration of applications and abbreviated applications to market a new drug under section 505 of the Federal Food, Drug, and Cosmetic Act, as well as amendments, supplements, and postmarketing reports to them.

(b) This part does not apply to drug products subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 et seq.)) and subchapter F of chapter I of title 21 of the Code of Federal Regulations.

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


Subpart B—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.10 Scope.

§ 314.11 Approval based on evidence of effectiveness from studies in animals.

§ 314.15 Withdrawal procedures.

§ 314.16 Postmarketing safety reporting.

§ 314.17 Promotional materials.

§ 314.18 Termination of requirements.

Subpart C—Approval of New Drugs Under Section 505(b)(2) of the Act

§ 314.20 Scope.

§ 314.21 Approval based on evidence of effectiveness from studies in animals.

§ 314.22 Withdrawal procedures.

§ 314.23 Postmarketing safety reporting.

§ 314.24 Promotional materials.

§ 314.25 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart D—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.30 Approval based on evidence of effectiveness from studies in animals.

§ 314.35 Withdrawal procedures.

§ 314.36 Postmarketing safety reporting.

§ 314.37 Promotional materials.

§ 314.38 Termination of requirements.

Subpart E—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.40 Scope.

§ 314.45 Approval based on evidence of effectiveness from studies in animals.

§ 314.46 Withdrawal procedures.

§ 314.47 Postmarketing safety reporting.

§ 314.48 Promotional materials.

§ 314.49 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart F—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.50 Approval based on evidence of effectiveness from studies in animals.

§ 314.55 Withdrawal procedures.

§ 314.60 Postmarketing safety reporting.

§ 314.65 Promotional materials.

§ 314.70 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart G—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.60 Approval based on evidence of effectiveness from studies in animals.

§ 314.65 Withdrawal procedures.

§ 314.70 Postmarketing safety reporting.

§ 314.75 Promotional materials.

§ 314.80 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

§ 314.50 Scope.

§ 314.55 Approval based on evidence of effectiveness from studies in animals.

§ 314.60 Withdrawal procedures.

§ 314.65 Postmarketing safety reporting.

§ 314.70 Promotional materials.

§ 314.75 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.

Subpart I—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

§ 314.60 Approval based on evidence of effectiveness from studies in animals.

§ 314.65 Withdrawal procedures.

§ 314.70 Postmarketing safety reporting.

§ 314.75 Promotional materials.

§ 314.80 Termination of requirements.


Source: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

Editorial Note: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.