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

§ 314.500 Scope.
§ 314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.
§ 314.520 Approval with restrictions to assure safe use.
§ 314.530 Withdrawal procedures.
§ 314.540 Postmarketing safety reporting.
§ 314.550 Promotional materials.
§ 314.560 Termination of requirements.

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

§ 314.600 Scope.
§ 314.610 Approval based on evidence of effectiveness from studies in animals.
§ 314.620 Withdrawal procedures.
§ 314.630 Postmarketing safety reporting.
§ 314.640 Promotional materials.
§ 314.650 Termination of requirements.


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

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 (38 Stat. 632 as amended (2 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.

application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application.

Approval letter means a written communication to an applicant from FDA approving an application or an abbreviated application.

Drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

FDA means the Food and Drug Administration.

Listed drug means a new drug product that has an effective approval under section 505(c) of the act for safety and effectiveness or under section 505(j) of the act, which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product’s identification as a drug with an effective approval in the current edition of FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (the list) or any current supplement thereto, as a drug with an effective approval. A drug product is deemed to be a listed drug on the date of effective approval of the application or abbreviated application for that drug product.

Not approvable letter means a written communication to an applicant from FDA stating that the agency does not consider the application or abbreviated application approvable because one or more deficiencies in the application or abbreviated application preclude the agency from approving it.

Reference listed drug means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

Right of reference or use means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

The list means the list of drug products with effective approvals published in the current edition of FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations” and any current supplement to the publication.

[50 FR 7493, Feb. 22, 1985, as amended at 57 FR 17981, Apr. 28, 1992]