

## § 314.440

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in § 20.117 are available for public disclosure.

[50 FR 7493, Feb. 22, 1985, as amended at 50 FR 21238, May 23, 1985; 55 FR 11580, Mar. 29, 1990; 57 FR 17996, Apr. 28, 1992; 61 FR 51530, Oct. 2, 1996; 64 FR 26698, May 13, 1998; 64 FR 402, Jan. 5, 1999; 66 FR 1832, Jan. 10, 2001; 68 FR 24879, May 9, 2003; 69 FR 18766, Apr. 8, 2004; 73 FR 39610, July 10, 2008]

### § 314.440 Addresses for applications and abbreviated applications.

(a) Applicants shall send applications, abbreviated applications, and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the appropriate office identified below:

(1) Except as provided in paragraph (a)(4) of this section, an application under § 314.50 or § 314.54 submitted for filing should be directed to the Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. Applicants may obtain information about folders for binding applications on the Internet at <http://www.fda.gov/cder/ddms/binders.htm>. After FDA has filed the application, the agency will inform the applicant which division is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be addressed to 5901-B Ammendale Rd., Beltsville, MD 20705-1266, to the attention of the appropriate division.

(2) Except as provided in paragraph (a)(4) of this section, an abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Office of Generic Drugs (HFD-600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Place, rm. 150, Rockville, MD 20855. This includes items sent by parcel post or overnight courier service. Correspondence not associated with an abbreviated application should be addressed specifically to the intended office or division and to the person as follows: Office of Generic

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Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Attn: [insert name of person], Metro Park North II, HFD-[insert mail code of office or division], 7500 Standish Place, rm. 150, Rockville, MD 20855. The mail code for the Office of Generic Drugs is HFD-600, the mail codes for the Divisions of Chemistry I, II, and III are HFD-620, HFD-640, and HFD-630, respectively, and the mail code for the Division of Bioequivalence is HFD-650.

(3) A request for an opportunity for a hearing under § 314.110 on the question of whether there are grounds for denying approval of an application, except an application under paragraph (b) of this section, should be directed to the Associate Director for Policy (HFD-5).

(4) The field copy of an application, an abbreviated application, amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application and an abbreviated application shall be sent to the applicant's home FDA district office, except that a foreign applicant shall send the field copy to the appropriate address identified in paragraphs (a)(1) and (a)(2) of this section.

(b) Applicants shall send applications and other correspondence relating to matters covered by this part for the drug products listed below to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, except applicants shall send a request for an opportunity for a hearing under § 314.110 on the question of whether there are grounds for denying approval of an application to the Director, Center for Biologics Evaluation and Research (HFM-1), at the same address.

(1) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components;

(2) Plasma volume expanders and hydroxyethyl starch for leukapheresis;

(3) Blood component processing solutions and shelf life extenders; and

## (4) Oxygen carriers.

[50 FR 7493, Feb. 22, 1985, as amended at 50 FR 21238, May 23, 1985; 55 FR 11581, Mar. 29, 1990; 57 FR 17997, Apr. 28, 1992; 58 FR 47352, Sept. 8, 1993; 62 FR 43639, Aug. 15, 1997; 69 FR 13473, Mar. 23, 2004; 70 FR 14981, Mar. 24, 2005; 73 FR 39610, July 10, 2008; 74 FR 13113, Mar. 26, 2009]

**§ 314.445 Guidance documents.**

(a) FDA has made available guidance documents under § 10.115 of this chapter to help you to comply with certain requirements of this part.

(b) The Center for Drug Evaluation and Research (CDER) maintains a list of guidance documents that apply to CDER's regulations. The list is maintained on the Internet and is published annually in the FEDERAL REGISTER. A request for a copy of the CDER list should be directed to the Office of Training and Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

[65 FR 56480, Sept. 19, 2000, as amended at 74 FR 13113, Mar. 26, 2009]

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

SOURCE: 57 FR 58958, Dec. 11, 1992, unless otherwise noted.

**§ 314.500 Scope.**

This subpart applies to certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

[57 FR 58958, Dec. 11, 1992, as amended at 64 FR 402, Jan. 5, 1999]

**§ 314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.**

FDA may grant marketing approval for a new drug product on the basis of

adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval under this section will be subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome. Post-marketing studies would usually be studies already underway. When required to be conducted, such studies must also be adequate and well-controlled. The applicant shall carry out any such studies with due diligence.

**§ 314.520 Approval with restrictions to assure safe use.**

(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:

- (1) Distribution restricted to certain facilities or physicians with special training or experience; or
- (2) Distribution conditioned on the performance of specified medical procedures.

(b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

**§ 314.530 Withdrawal procedures.**

(a) For new drugs approved under §§ 314.510 and 314.520, FDA may withdraw approval, following a hearing as provided in part 15 of this chapter, as modified by this section, if:

- (1) A postmarketing clinical study fails to verify clinical benefit;
- (2) The applicant fails to perform the required postmarketing study with due diligence;
- (3) Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the drug product;