

applications to which the report applies.

(2) *Patient identification.* Applicants should not include in reports under this section the names and addresses of individual patients; instead, the applicant should code the patient names whenever possible and retain the code in the applicant's files. The applicant shall maintain sufficient patient identification information to permit FDA, by using that information alone or along with records maintained by the investigator of a study, to identify the name and address of individual patients; this will ordinarily occur only when the agency needs to investigate the reports further or when there is reason to believe that the reports do not represent actual results obtained.

(d) *Withdrawal of approval.* If an applicant fails to make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(Collection of information requirements approved by the Office of Management and Budget under control number 0910-0001)

[50 FR 7493, Feb. 22, 1985; 50 FR 14212, Apr. 11, 1985, as amended at 50 FR 21238, May 23, 1985; 55 FR 11580, Mar. 29, 1990; 57 FR 17983, Apr. 28, 1992; 63 FR 66670, Dec. 2, 1998; 64 FR 401, Jan. 5, 1999; 65 FR 64617, Oct. 30, 2000; 66 FR 10815, Feb. 20, 2001; 68 FR 69019, Dec. 11, 2003; 69 FR 18766, Apr. 8, 2004; 69 FR 48775, Aug. 11, 2004; 72 FR 58999, Oct. 18, 2007]

#### § 314.90 Waivers.

(a) An applicant may ask the Food and Drug Administration to waive under this section any requirement that applies to the applicant under §§ 314.50 through 314.81. An applicant may ask FDA to waive under § 314.126(c) any criteria of an adequate and well-controlled study described in § 314.126(b). A waiver request under this section is required to be submitted with supporting documentation in an application, or in an amendment or supplement to an application. The waiver request is required to contain one of the following:

(1) An explanation why the applicant's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The applicant's compliance with the requirement is unnecessary for the agency to evaluate the application or compliance cannot be achieved;

(2) The applicant's alternative submission satisfies the requirement; or

(3) The applicant's submission otherwise justifies a waiver.

[50 FR 7493, Feb. 22, 1985, as amended at 50 FR 21238, May 23, 1985; 67 FR 9586, Mar. 4, 2002]

#### § 314.91 Obtaining a reduction in the discontinuance notification period.

(a) *What is the discontinuance notification period?* The discontinuance notification period is the 6-month period required under § 314.81(b)(3)(iii)(a). The discontinuance notification period begins when an applicant who is the sole manufacturer of certain products notifies FDA that it will discontinue manufacturing the product. The discontinuance notification period ends when manufacturing ceases.

(b) *When can FDA reduce the discontinuance notification period?* FDA can reduce the 6-month discontinuance notification period when it finds good cause exists for the reduction. FDA may find good cause exists based on information certified by an applicant in a request for a reduction of the discontinuance notification period. In limited circumstances, FDA may find good cause exists based on information already known to the agency. These circumstances can include the withdrawal of the drug from the market based upon formal FDA regulatory action (e.g., under the procedures described in § 314.150 for the publication of a notice of opportunity for a hearing describing the basis for the proposed withdrawal of a drug from the market) or resulting from the applicant's consultations with the agency.

(c) *How can an applicant request a reduction in the discontinuance notification period?* (1) The applicant must certify in a written request that, in its opinion and to the best of its knowledge, good

## § 314.92

## 21 CFR Ch. I (4–1–08 Edition)

cause exists for the reduction. The applicant must submit the following certification:

The undersigned certifies that good cause exists for a reduction in the 6-month notification period required in § 314.81(b)(3)(iii)(a) for discontinuing the manufacture of (*name of the drug product*). The following circumstances establish good cause (*one or more of the circumstances in paragraph (d) of this section*).

(2) The certification must be signed by the applicant or the applicant's attorney, agent (representative), or other authorized official. If the person signing the certification does not reside or have a place of business within the United States, the certification must contain the name and address of, and must also be signed by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(3) For drugs regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), one copy of the certification must be submitted to the Drug Shortage Coordinator at the address of the Director of CDER, one copy to the CDER Drug Registration and Listing Team, Division of Compliance Risk Management and Surveillance in CDER, and one copy to either the director of the review division in CDER responsible for reviewing the application, or the director of the office in CBER responsible for reviewing the application.

(d) *What circumstances and information can establish good cause for a reduction in the discontinuance notification period?*

(1) A public health problem may result from continuation of manufacturing for the 6-month period. This certification must include a detailed description of the potential threat to the public health.

(2) A biomaterials shortage prevents the continuation of the manufacturing for the 6-month period. This certification must include a detailed description of the steps taken by the applicant in an attempt to secure an adequate supply of biomaterials to enable manufacturing to continue for the 6-month period and an explanation of why the biomaterials could not be secured.

(3) A liability problem may exist for the manufacturer if the manufacturing

is continued for the 6-month period. This certification must include a detailed description of the potential liability problem.

(4) Continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer. This certification must include a detailed description of the financial impact of continuing to manufacture the drug product over the 6-month period.

(5) The manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code (11 U.S.C. 701 *et seq.* and 1101 *et seq.*). This certification must be accompanied by documentation of the filing or proof that the filing occurred.

(6) The manufacturer can continue distribution of the drug product to satisfy existing market need for 6 months. This certification must include a detailed description of the manufacturer's processes to ensure such distribution for the 6-month period.

(7) Other good cause exists for the reduction. This certification must include a detailed description of the need for a reduction.

[72 FR 58999, Oct. 18, 2007]

### Subpart C—Abbreviated Applications

SOURCE: 57 FR 17983, Apr. 28, 1992, unless otherwise noted.

#### § 314.92 Drug products for which abbreviated applications may be submitted.

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A "listed drug" is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term "same as" means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered