

(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 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.

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(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 for sale by its manufacturer, a person who wishes to submit an abbreviated new drug application for the drug shall comply with § 314.122.

(2) [Reserved]

(3) Drug products that have been declared suitable for an abbreviated new drug application submission by FDA through the petition procedures set forth under § 10.30 of this chapter and § 314.93.

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(b) FDA will publish in the list listed drugs for which abbreviated applications may be submitted. The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202-783-3238.

[57 FR 17983, Apr. 28, 1992, as amended at 64 FR 401, Jan. 5, 1999]

§ 314.93 Petition to request a change from a listed drug.

(a) The only changes from a listed drug for which the agency will accept a petition under this section are those changes described in paragraph (b) of this section. Petitions to submit abbreviated new drug applications for other changes from a listed drug will not be approved.

(b) A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

(c) To obtain permission to submit an abbreviated new drug application for a change described in paragraph (b) of this section, a person must submit and obtain approval of a petition requesting the change. A person seeking permission to request such a change from a reference listed drug shall submit a petition in accordance with § 10.20 of this chapter and in the format specified in § 10.30 of this chapter. The petition shall contain the information specified in § 10.30 of this chapter and any additional information required by this section. If any provision of § 10.20 or § 10.30 of this chapter is inconsistent with any provision of this section, the provisions of this section apply.

(d) The petitioner shall identify a listed drug and include a copy of the proposed labeling for the drug product that is the subject of the petition and a copy of the approved labeling for the listed drug. The petitioner may, under limited circumstances, identify more than one listed drug, for example, when the proposed drug product is a combination product that differs from the