

§ 316.40

order will embody the Director's findings and conclusions and will constitute final agency action. An order withdrawing the sponsor's exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Once withdrawn under this section, exclusive approval may not be reinstated for that drug.

Subpart E—Open Protocols for Investigations

§ 316.40 Treatment use of a designated orphan drug.

Prospective investigators seeking to obtain treatment use of designated orphan drugs may do so as provided in § 312.34 of this chapter.

Subpart F—Availability of Information

§ 316.50 Guidance documents.

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the FEDERAL REGISTER. A request for a copy of the list should be directed to the Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

[65 FR 56480, Sept. 19, 2000]

§ 316.52 Availability for public disclosure of data and information in requests and applications.

(a) FDA will not publicly disclose the existence of a request for orphan-drug designation under section 526 of the act prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Upon final FDA action on a request for designation, FDA will deter-

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mine the public availability of data and information in the request in accordance with part 20 and § 314.430 of this chapter and other applicable statutes and regulations.

(d) In accordance with § 316.28, FDA will make a cumulative list of all orphan drug designations available to the public and update such list monthly.

(e) FDA will not publicly disclose the existence of a pending marketing application for a designated orphan drug for the use for which the drug was designated unless the existence of the application has been previously publicly disclosed or acknowledged.

(f) FDA will determine the public availability of data and information contained in pending and approved marketing applications for a designated orphan drug for the use for which the drug was designated in accordance with part 20 and § 314.430 of this chapter and other applicable statutes and regulations.

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Subpart A—General Provisions

Sec.

320.1 Definitions.

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.

320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.

320.23 Basis for measuring in vivo bioavailability or demonstrating bioequivalence.

320.24 Types of evidence to measure bioavailability or establish bioequivalence.

320.25 Guidelines for the conduct of an in vivo bioavailability study.

320.26 Guidelines on the design of a single-dose in vivo bioavailability or bioequivalence study.

320.27 Guidelines on the design of a multiple-dose in vivo bioavailability study.

320.28 Correlation of bioavailability with an acute pharmacological effect or clinical evidence.

320.29 Analytical methods for an in vivo bioavailability or bioequivalence study.