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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 Once withdrawn under this section, exclusive approval may not be reinstated for that drug.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 subpart I of this chapter.

[74 FR 40945, Aug. 13, 2009]

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, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

[78 FR 35135, June 12, 2013]

§ 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 determine 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 317—QUALIFYING PATHOGENS

Sec.
317.1 [Reserved]
317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

AUTHORITY: 21 U.S.C. 355f, 371.

SOURCE: 79 FR 32480, June 5, 2014, unless otherwise noted.

§ 317.1 [Reserved]

§ 317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

The term ''qualifying pathogen'' in section 505E(f) of the Federal Food, Drug, and Cosmetic Act is defined to mean any of the following:

(a) *Acinetobacter* species.
(b) *Aspergillus* species.
(c) *Burkholderia cepacia* complex.
(d) *Campylobacter* species.
(e) *Candida* species.
(f) *Clostridium difficile*.
(g) *Coccidioides* species.
(h) *Cryptococcus* species.
(i) Enterobacteriaceae.
(j) *Enterococcus* species.
(k) *Helicobacter pylori*.
(l) *Mycobacterium tuberculosis* complex.
(m) *Neisseria gonorrhoeae*.
(n) *Neisseria meningitidis*.

(o) Non-tuberculous mycobacteria species.
(p) *Pseudomonas* species.
(q) *Staphylococcus aureus*.
(r) *Streptococcus agalactiae*.
(s) *Streptococcus pneumoniae*.
(t) *Streptococcus pyogenes*.
(u) *Vibrio cholerae*.

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

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 371.

Subpart A—General Provisions

§ 320.1 Definitions.

The definitions contained in § 314.3 of this chapter apply to those terms when used in this part.

[81 FR 69658, Oct. 6, 2016]

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

SOURCE: 42 FR 1648, Jan. 7, 1977, unless otherwise noted.

§ 320.21 Requirements for submission of bioavailability and bioequivalence data.

(a) Any person submitting a full new drug application to the Food and Drug Administration (FDA) shall include in the application either:

(1) Evidence measuring the in vivo bioavailability of the drug product that is the subject of the application; or

(2) Information to permit FDA to waive the submission of evidence measuring in vivo bioavailability.

(b) Any person submitting an abbreviated new drug application to FDA shall include in the application either:

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b) of this chapter). A complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation, the applicant must submit either a complete or summary report. If a summary report of a bioequivalence study is submitted and FDA determines that there may be bioequivalence issues or concerns with the product, FDA may require that the applicant submit a complete report of the bioequivalence study to FDA; or

(2) Information to show that the drug product is bioequivalent to the reference listed drug which would permit FDA to waive the submission of evidence demonstrating in vivo bioequivalence as provided in paragraph (f) of this section.