(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

320.21 Requirements for submission of 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.
320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.
320.31 Applicability of requirements regarding an ''Investigational New Drug Application.''
320.32 Procedures for establishing or amending a bioequivalence requirement.
320.33 Criteria and evidence to assess actual or potential bioequivalence problems.
320.34 Requirements for batch testing and certification by the Food and Drug Administration.
320.35 Requirements for in vitro testing of each batch.
320.36 Requirements for maintenance of records of bioequivalence testing.
320.38 Retention of bioavailability samples.
320.63 Retention of bioequivalence samples.

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