(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.