

CFR – Code of Federal Regulations Title 21

TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER D--DRUGS FOR HUMAN USE

PART 317 -- QUALIFYING PATHOGENS

Sec. 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*.

Source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=317.2>