

21 U.S. Code § 360a-1

Clinical trials

(a) Review and revision of guidance documents

(1) In general

The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

- (A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and
- (B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

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