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# 21 U.S. Code § 360a-2

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## Susceptibility test interpretive criteria for microorganisms

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### **(a) Purpose; identification of criteria**

#### **(1) Purpose**

The purpose of this section is to clarify the Secretary's authority to—

- (A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;
- (B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and
- (C) clear under section 360(k) of this title, classify under section 360c(f)(2) of this title, or approve under section 360e of this title, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

#### **(2) Identification of criteria**

The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

- (A) if such criteria are available on the date of approval of the drug under section 355 of this title or licensure of the drug under section 262 of title 42 (as applicable), upon such approval or licensure; or
- (B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

#### **(3) Bases for initial identification**

The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

- (A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;
- (B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and
- (C) such other evidence and information as the Secretary considers appropriate.

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