Questions to the Committee

We seek the advice of the committee on how we should implement the approach described in the guidance document *Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices*.

DISCUSSION QUESTION

Evaluation of a standard set by a nationally or internationally recognized standard development organization for possible recognition by FDA.

1. What characteristics or criteria should FDA consider when evaluating a standard (e.g., standards on susceptibility test interpretive criteria, quality control, and/or methods) and a nationally or internationally recognized standard development organization?
DISCUSSION QUESTION

2. Given the considerable number of products in need of updating, and the fact that a number of these products may have been out-of-date for a number of years, it may be difficult to identify all of the information that supported the Microbiology subsection in labeling or the standards set in past years. How should we approach the updating of the accumulated out-of-date microbiology information in product labeling for systemic antibacterial drug products to facilitate updating in a timely manner?

a. Given time and feasibility concerns, should the FDA evaluate each susceptibility test interpretive criterion, each set of quality control parameters, and the methods individually for each drug to see what information was used as the basis for the standard setting organization?

b. For updating the out-of-date microbiology labeling can we assume, in general, that the reference standard has more up-to-date information than the product labeling, unless we have specific information otherwise?

c. Other