DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fisher Lane, Room 1061 (HFA-305)
Rockville, MD 20857

RE: Docket # 00N-1269

Dear Sir or Madam:

I am a reviewer in the Center for Devices and Radiological Health, Office of Device Evaluation, Division of Clinical Laboratory Devices. My major review focus is devices for the determination of antimicrobial susceptibilities. I wish to comment on the Federal Register Notice "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Proposed Rule."

The Center for Drug Evaluation and Research (CDER) approved labeling for prescription drug products is used by reviewers in my branch for the selection of organisms to be tested, the Quality Control organisms selected and the interpretative criteria established by CDER. Our selection of organisms is always based on the "Indications and Usage" section of the approved label. We also review the "Microbiology" section for the performance of organisms on which "*in vitro* data are available but their clinical significance is unknown" in order to gather sufficient numbers of similar organisms to provide a statistical valid assessment of the performance of the device.

I strongly urge you to keep the "Microbiology" section in the labeling of anti-infective drugs. It contains information crucial to reviewers, manufacturers, and laboratories. It is referenced in various guidance documents to assist the *in vitro* Diagnostic (IVD) manufacturers in the selection of appropriate organisms for testing. The use of this list by the IVD manufacturers in establishing performance will benefit laboratories where IVD devices are used. When *in vitro* performance has been established, the information provided to the physician by the laboratory is helpful for patient management, especially when multiple organisms are recovered from the same patient. If performance has not been established, the physician may get inaccurate information.

The "Microbiology" section often contains warnings or contraindications about inaccurate test results with certain organisms. This information is very useful in the IVD device review process. With this information our reviewers can recommend to the IVD manufacturer that these results should not be reported and that they include a limitation

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statement in the IVD package insert contraindicating the testing and reporting of this organism group.

The removal from the "Microbiology" section of the *in vitro* data would be too restrictive to establish performance for IVD devices. Testing of organisms listed only in the "Indications and Usage" section may provide little evaluable data since these organisms are already known to be susceptible to the drug. With only a susceptible category to review, performance for laboratory testing cannot be established. If or when resistance develops in the select group of organisms, the IVD device may not be able to detect the resistance. The ability of an IVD device to detect resistance or even the trending toward the development of resistance is of high concern to the growing health threat of antimicrobial resistance.

Again, I strongly request that you keep the "Microbiology" section and include the information on *in vitro* testing. Moving this section to the end of the labeling may be a good compromise. It contains important information for laboratory testing and should be included.

Sincerely yours,

Sally T. Selepak

Sally T. Selepak
Microbiology Reviewer
CDRH/ODE/DCLD

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