515(I) REGULATORY CLASSIFICATION OF AUTOMATED EXTERNAL DEFIBRILLATORS

Panel Questions

1. In determining whether AEDs should be regulated as Class II or as Class III, FDA focused its review on the ability of these devices to appropriately detect ventricular arrhythmias and deliver therapy. A malfunctioning device compromises the ability to rescue a patient.

    a. Do you agree that this is the most significant safety and effectiveness issue for AEDs?

    b. Should other significant safety and effectiveness issues be included in this consideration? If so, please identify and discuss.

2. The primary sources of information that FDA reviewed to identify the risks associated with AEDS were device recalls and adverse events reported through the Medical Device Reporting (MDR) system. Are there other sources of safety and effectiveness information that need to be included in FDA's identification and evaluation of AED risks? If so, please identify and discuss.

3. As part of its preliminary recommendation concerning the regulatory classification of AEDs, FDA identified several regulatory controls (e.g., preapproval inspection) as resources for consideration. Are you aware of any other regulatory measures that would be useful to FDA in mitigating the risks associated with AEDs? If so, please identify and discuss.

4. Please provide your overall recommendation for the classification for AEDs from the options listed below:

    - Class I
    - Class II
    - Class III