FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Drug Safety and Risk Management Advisory Committee (DSaRM)

Holiday Inn
8777 Georgia Avenue
Silver Spring, Maryland
May 18 & 19, 2005

QUESTIONS

Today, an overview of both passive and active surveillance methods currently used by FDA to detect safety signals has been presented.

DAY 1 WEDNESDAY MAY 18, 2005

Please comment on the following topics and questions:

1. The Adverse Event Reporting System (AERS)

   a. What types of safety problems are most effectively addressed by using a "passive" surveillance system such as AERS that depends on voluntary reporting?

   b. Are there safety problems where use of this system is less effective?

   c. If so, please specify the type or nature of these safety issues where passive surveillance is ineffective.

   d. How can the FDA passive surveillance system be improved?

2. Active Surveillance

   a. How can active surveillance systems be used to augment the currently available FDA systems for safety signal detection and risk characterization?
   b. What types of drug products or safety problems are best suited to active surveillance methods?
   c. How might active surveillance systems for drug safety problems be used most efficiently, that is, with greater specificity and sensitivity?

3. Drug Utilization

   a. Based upon the presentations today, what are the priority areas for FDA to expand or improve its use of drug use data?

4. Surveillance Gaps

   a. In light of the surveillance methods described today and the answers to the above questions, what are the priority data gaps and how might they be filled?