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

You have seen the FDA portfolio of post-market drug surveillance approaches and observational study methods. Please discuss the best use of these methods and approaches to assess risks of marketed drugs.

DAY 2 THURSDAY MAY 19, 2005

Please comment on the following topics and questions:

1. Under what circumstances are each of the following types of studies best suited to detect or quantify a risk in the post-marketing setting:

   a. An epidemiological study?
   b. A clinical trial?
   c. A registry?

2. In light of the time and effort entailed in conducting population-based studies:

   a. What kinds of safety problems are best studied by these methods?

   b. What criteria should be used to prioritize drug safety signals for quantification in population-based studies?

3. What are the best avenues for FDA to strategically expand its access to data needed to conduct population-based studies to evaluate the safety of marketed drugs? Examples include, but are not limited to, Federal organizations (VA, DoD, CMS, others), health care benefits programs (such as Medicaid, managed care organizations, and FFS programs), and foreign sources (GPRD, Saskatchewan.)

4. Based on the discussions over the past two days, please offer strategic advice on how our data systems could be strengthened in the following timeframes:

   a. Short-term (6 months - 18 months)
   b. Long-term (18 months – 5 years)