Risk Communication Advisory Committee
+ Members of the Drug Safety and Risk Management Advisory Committee
February 26-27, 2009 Discussion Topics

The goal as stated in Public Law 104-180 that 95 percent of patients should be receiving useful information by 2006 has not been met, according to the criteria of "useful" specified in the law and described in guidance provided by the long-range action plan and the FDA. In addition, some consumer groups have expressed concern that receiving multiple documents with their prescription drugs at the pharmacy can be confusing. Please comment on the following:

1. Does the existing scientific evidence recommend using multiple communication tools (CMI, PPI, Medication Guides) or a single tool to most effectively communicate prescription drug information to patients? Please describe.

2. In addition to published studies discussed above, what other types of scientific research should be conducted to ensure that FDA is effectively communicating prescription drug information to patients?

3. Based on what you've heard at this meeting and your knowledge of the literature, what is the best format for written patient information? For example, is there evidence supporting use of unstructured narrative, question and answer, tabular, listing of top ten risks, or another format?

4. How should FDA evaluate the effectiveness of different communication tools? Further, what are the most important parts of a complete assessment of a communication tool (for example, did the patient receive the tool, did the patient read the tool, did the patient understand the tool?)

5. Please prioritize the types of research relating to patient information. What projects are most important for moving forward expeditiously? Please include consideration of the following, plus other factors you think important.

- The amount of information patients receive from the pharmacy
- The appropriate balance of risk and benefit information
- The most effective order in which to present information (such as risks, benefits, instructions for use)
- Whether the information should be in a standard format or an "as appropriate for that product" format (An example of standard format is the "Drug Facts" label used on OTC products. Examples of product appropriate formats are a "top ten" most important things to know, or the question-and-answer format now used in Medication Guides)
- The most credible source for this information (i.e.: what source is most trusted by patients: government agency, manufacturers, healthcare professionals such as pharmacists, or other source?)
- How to effectively communicate with patients of differing literacy levels, primary language skills other than English, or underserved patient populations.