FDA's Communication of Drug Safety Information
Summary of Public Hearing
December 7 and 8, 2005

Making FDA a reliable "trusted source" of healthcare provider and consumer information about medications emerged as the key theme at a public hearing on the Agency's risk communications. FDA was urged to engage health-care professional organizations, simplify its risk communications, improve provider and consumer access to its Internet site, develop consistent communication approaches and address those with limited health literacy and English skills.

The hearing, sponsored by FDA's Center for Drug Evaluation and Research, was held to:

- Gain insight into the strengths and weaknesses of its current tools
- Seek potential collaborators
- Assess timeliness, understandability and accessibility of its tools.
- Identify new tools
- Improve its risk communications.

Two panels of FDA officials heard testimony from 28 individuals and representatives. Among those testifying were researchers from academia and the private sector, consultants, private citizens, and practicing physicians. Representatives also testified on behalf of healthcare professional, consumer, and patient organizations. Organizations representing the pharmaceutical industry, retail pharmacies, and commercial preparers of consumer medical information dispensed with prescriptions also provided testimony.

Recommendations to FDA included:

Engage health-care professionals. Health-care professional associations and the National Council on Patient Information and Education urged FDA to concentrate on its traditional role of providing benefit-risk information to healthcare providers that would improve patient dialogue. The American Medical Association stressed the importance of targeting specific physician specialties and working closely with these groups to optimize education in risk communication.

Improve Internet access for patient information. FDA's current Web site is both product and process-oriented and difficult to navigate. Many recommended that FDA redesign the web site to make it more accessible and user-friendly as well as to address specific health concerns of patients, caregivers, and healthcare professionals.

Maintain benefit-risk balance in communications. Highlighting drug risk without mentioning a medicine's benefits may scare patients away from what is effective therapy for them. Research presented at the hearing highlighted differences between FDA's and health-care professionals' understanding of risks and the patient's understanding of risks. Understanding how patients, consumers and health care providers interpret and weigh information about the severity and frequency of side effects is essential in producing balanced messages about benefits and risks.

Standardize one-way communications. The large number of FDA communications tools, ranging from talk papers and press releases to health care advisories and patient information sheets, was seen as a barrier to effective risk communications. There are inconsistencies in content and format among the tools. One presenter recommended that FDA lead an effort to develop Good Risk Communication Practices for the Agency and industry.

Address needs of those with low health literacy and poor English skills. Recommendations ranged from improvements in the language and design of risk communications tools, and the development of population specific tools that would also allow use of foreign language communications tools approved by other nations' regulatory authorities.