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FDA Publishes Guidance on Communication of Drug Safety Information

The U.S. Food and Drug Administration (FDA) today issued final guidance that describes FDA's current approach to communicating drug safety information, including emerging safety information, to the public. The guidance also includes the factors that influence when such information is communicated. Important drug safety information has the potential to alter the benefit/risk analysis for a drug in a way that can affect decisions about prescribing or taking the drug. The guidance affirms the agency's commitment to communicate important drug safety information in a timely manner, including in some situations when the agency is still evaluating whether to take any regulatory action.

The information in the guidance, "Drug Safety Information-FDA's Communication to the Public," is intended to make emerging information on important drug safety issues available to the public and will facilitate patient and healthcare provider access to the most current information concerning the potential risks and benefits of a marketed drug.

"The guidance provides for timely communication of drug safety information, which has been, and continues to be, an extremely high priority for FDA," said Steven Galson MD, Director of FDA's Center for Drug Evaluation and Research (CDER). "Our goal is to make emerging drug safety information available in a balanced, impartial manner so that health care professionals and patients can consider the information when making decisions about medical treatments despite uncertainties in the data."

The guidance describes the various methods FDA currently uses to communicate established and emerging drug safety information to the public. FDA's drug safety communications are available through the FDA Web site. In addition to drug product labeling, FDA's methods of communicating important drug safety information includes:

- **Public Health Advisories** – provide information and advice regarding an emerging drug safety issue or other important public health information to the public, including patients and health care professionals.
- **Patient Information Sheets** – provide concise summaries in plain language, with the most important information about a particular drug.
- **Health care Professional Sheets** – provide a summary of important and often emerging drug safety issues, with information about the detection of the issue, and points to consider for clinical decision-making.
- **Alerts on Patient Information and Health Professional Sheets** – provide a summary of important, and often emerging, drug safety issues. Alerts may be placed on public health advisories, or patient and health care professional sheets. These may include:
    - newly observed serious adverse events that may be associated with a drug;
    - information about how such serious adverse events might be prevented by appropriate patient selection, monitoring of patients, or use or avoidance of the

therapy; and
- information regarding a serious adverse event that FDA believes may be associated with
use of a drug in populations in whom the drug was not previously studied.

The guidance describes the role of the Drug Safety Oversight Board and its staff in advising the Director of the Center for Drug Evaluation and Research on the management of and communication about emerging drug safety issues.

This guidance also achieves FDA's goal of issuing, in the first quarter of 2007, final guidance on communicating important drug safety information, including emerging drug safety information, as described in FDA's Response to the Institute of Medicine's (IOM) 2006 Report on the Future of Drug Safety.

FDA's risk communication efforts are part of a larger drug safety initiative that began in November 2004. In connection with FDA's drug safety initiative, FDA published a draft guidance in May 2005 that described a proposal to establish a new communication channel called the "Drug Watch" Web page to provide information to the public on emerging drug safety issues. FDA received and evaluated 30 comments from the public on this draft guidance and also has considered comments received in connection with a public hearing held in December 2005 regarding risk communication tools employed by FDA.

This final guidance (which supersedes the draft guidance on "FDA's 'Drug Watch' for Emerging Drug Safety Information") reflects FDA's consideration of these comments, as well as FDA's experience with posting emerging drug safety information. The guidance also describes the factors that influence when such information is communicated.

Due to potential confusion between the proposed "Drug Watch" and FDA's long-standing "MedWatch" program for alerting providers and the public to new information about medical products, FDA no longer plans to use the name "Drug Watch" to describe the Web page that contains links to drug safety information. The agency will continue to evaluate its communication efforts, and will modify them as appropriate to enhance their accessibility and effectiveness.

The public can access FDA's safety postings about specific drugs at http://www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm. The Index to the Drug-Specific Information Web page contains information about drugs that are the subject of a Public Health Advisory and/or an Alert regarding an important, and often emerging, drug safety issue, as well as established drug safety information. Drugs that have an active FDA safety alert are identified by an asterisk.

The guidance on "Drug Safety Information-FDA's Communication to the Public" is available at http://www.fda.gov/cder/guidance/index.htm.

For more information, visit: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01551.html.

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Guidance Document: Drug Safety Information-FDA's Communication to the Public

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