FDA FACT SHEET - 6/15/2010

Media Contacts: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov

FDAAA 2007 Section 915: Enhancing FDA's Safety Reporting on Recently Approved Therapies

The U.S. Food and Drug Administration will now provide a new source of information for patients and health care professionals on the safety of recently approved drugs and biologics. Summaries of FDA safety analyses on recently approved products will now be periodically prepared and posted on FDA's website along with a brief discussion of the steps FDA is taking to address any identified safety issues.
FDA approves drugs for marketing after reviewing how patients respond to a product during clinical trials. Approval is based on determining whether a product's benefits outweigh its risks.

History of Safety Reporting

Some previously unknown adverse effects will not become apparent until the medicine is available to a larger, more demographically and medically diverse population than the population enrolled in a clinical trial. In addition, adverse events already identified in clinical studies may increase in frequency once the product is marketed.

FDA uses a variety of tools to identify post-approval adverse effects. Much of this information is gathered from mandatory reports filed by drug and biologic companies, and supplemented by reports voluntarily submitted to the FDA's MedWatch program from health care professionals and patients. Taken together, these sources generate more than 500,000 unique reports each year. Information is also collected from the medical literature and ongoing drug studies.

FDA also works with drug companies to reduce the potential for medication errors that may be caused by confusing labels, similar sounding drug names or drugs that treat similar information.

Once new safety information is assessed, FDA may determine either that the current product label satisfactorily conveys safety information to ensure safe use or that the label should be changed to communicate significant new safety information. For significant new safety information, FDA may also determine that it is important to develop a plan for communicating specific safety risks to health care professionals and patients. Rarely, FDA may restrict access to a product due to specific safety concerns.

Changes in Law Require Enhanced Safety Monitoring for Recently Approved Products

In 2007, the U.S. Congress passed the Food and Drug Administration Amendments Act (FDAAA), which authorized FDA to enhance the methods currently used to assess, and summarize the safety of recently approved products and to communicate the Agency's ongoing

safety monitoring activities to the public in a timely manner. FDAAA requires FDA to prepare comprehensive safety summaries of recently approved drug and biologic products. These summaries are intended to share what the FDA has learned about the safety of products 18 months after approval or after the medicine was used in 10,000 patients, whichever occurs later. The requirement applies to certain prescription drugs. The website will also post safety data for certain biologic products.

Summaries of FDA safety analyses on recently approved products will be periodically prepared and posted on the new Postmarketing Drug Safety Evaluation website at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm

The summaries will include all potentially important new safety information since each drug was first marketed. FDA will also specify if safety evaluations *did not* show evidence of a new safety concern. In instances where evaluations indicate potentially important new safety information, the summaries will specify the steps FDA is taking to address the safety issue.

On the website, patients and health care professionals can expect to find information on several drugs and biologic products used to treat a wide range of medical conditions, including infections, hypertension, depression, and asthma. New summaries will be posted quarterly.

Design Features Make Reviewing Summary Safety Reports Easier for Consumers

Consumers and health care professionals **should** expect the summaries to include:

- The name of the drug or biologic product
- The number of the new drug or biologic licensing marketing application
- The date the product was approved
- The product's indications
- The summary of FDA's findings, including newly identified serious side effects and any pending actions

Consumers and health care professionals **should not** expect the summaries to include:

- Safety summaries on drugs or biologics approved before September 27, 2007
- Premarket safety information

The new safety information available in these reports will help health care professionals and consumers understand any new and potentially serious side effects that may be associated with a medicine, and make them aware of the steps FDA is taking to communicate the potential side effects.

These new safety summaries complement other important drug safety information already included in the product label or issued in an FDA Drug Safety Communication.

Members of the public are encouraged to contact FDA at 1-888-INFO-FDA (1-888-463-6332) with any questions about the summaries or the medications they are using.

#