New Prescription Drug Information Format to Improve Patient Safety

The U.S. Food and Drug Administration (FDA) today (January 18, 2006) unveiled a major revision to the format of prescription drug information, including drugs to treat HIV/AIDS, commonly called the package insert or drug label, to make information for healthcare professionals clear and concise to help ensure safe and optimal use of drugs. Part of an effort to manage the risks of medication use and reduce medical errors, the newly designed package insert will provide the most up-to-date information in an easy-to-read format that draws attention to the most important pieces of drug information, thus reducing the complexity of information on prescription drug labels. The new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

The new drug labeling requirements will be phased in gradually, and initially will apply to newly and recently approved prescription drugs and drugs that receive approval for new uses. The agency is encouraging drug makers to consider complying with the new labeling requirements earlier on a voluntary basis. All drugs approved within the past five years are included, and they will gradually be converted to the new prescribing information format.

The new format requires that the prescription information for newly approved products and those approved within the last five years, meet specific graphical requirements, including the reorganization of critical information so physicians can find the information they need quickly. Some of the most significant changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A *Table of Contents* for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

The most notable change is the addition of a summary, outlining the most important information about a product, prominently displayed at the top of the page to help healthcare professionals find the information they need quickly. This summary, called *Highlights,* will typically be half a page in length and will provide a concise summary of information about specific areas including: *Boxed Warning, Indications and Usage,* and *Dosage and Administration;* and will refer the healthcare professional to the appropriate section of the *Full Prescribing Information*. In addition, drug makers will be required to include a list of all substantive recent changes made within the year, to ensure healthcare professionals have immediate access to the most up-to-date information about the product before prescribing it.

A new *Table of Contents* will refer readers to detailed information located in the label. The *Full Prescribing Information* is reorganized to give greater prominence to the most important and most commonly referenced information. As a result of feedback from two national physician surveys, the *Indications and Usage* and the *Dosage and Administration* sections are moved to the beginning of *the Full Prescribing Information.*

The addition, a new *Patient Counseling Information* section places greater emphasis on the importance of communication between professionals and patients. This new section is designed to help doctors advise their patients about important uses and limitations of medications. It will also serve as a guide for discussions about the potential risks involved in taking a specific treatment and steps for managing those risks. If FDA has approved patient information for a prescription drug, it will be printed at the end of the label immediately following the *Patient Counseling Information* section or will accompany the label so it can be easily shared.

As prescription information is updated in this new format it will be added to a new online health information clearinghouse called *DailyMed* that will provide up-to-date medication information free to consumers, healthcare professionals and healthcare information providers. This information can be accessed through the National Library of Medicine at http://dailymed.nlm.nih.gov. Only one example is available at this time.

In the future, this new information will also be provided through a website called facts@fda, a comprehensive Internet resource designed to give one-stop access for information about all FDA-regulated products.

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