Prescribing Information – Commonly Called the "Package Insert" – is Getting a NEW LOOK!

FDA has revised its rules for the content and format of prescribing information for prescription drug and biological products. The new look will make prescribing information easier to read and help health-care professionals find the information they need more easily and quickly. Importantly, FDA's electronic health initiative also will make updated prescribing information available on the Internet, creating an even faster and more efficient way for health professionals to have current prescribing information.

Products Affected

The new prescribing information requirements apply to:

- prescription drugs, including those that were approved on or after the effective date of the final rule
- drugs that had been approved in the 5 years before the effective date of the final rule
- older drugs for which there is a major change in the prescribing information (e.g., approval of a new use).

For more information on FDA's new prescribing information, visit our web site at **www.fda.gov** or call

1-888-INFO-FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

(FDA) CDER 06-1901

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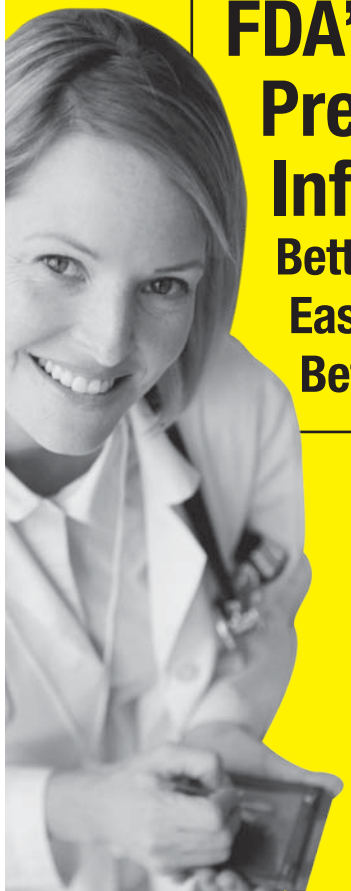


FDA's New Prescribing Information:

Better Organized. Easier to Read. Better Healthcare.

Benefits to Health-care Professionals and Patients

The changes to drug prescribing information are intended to improve patient safety by making it easier for health-care professionals to access, read, and use prescribing information, thereby increasing the extent to which health-care professionals rely on it. FDA made these changes because, in recent years, there has been an increase in the length, detail, and complexity of the prescribing information, making it more difficult to find the right information at the right time.

How does this change affect prescribers and health-care professionals? In the new format, which will be phased in gradually, some prescribing information will be located in newly created or different sections or subsections. Also, some individual sections in the old format have been combined in the new format and some new information (e.g., a drug's approval date) that was not mandatory under the old requirements is now required.

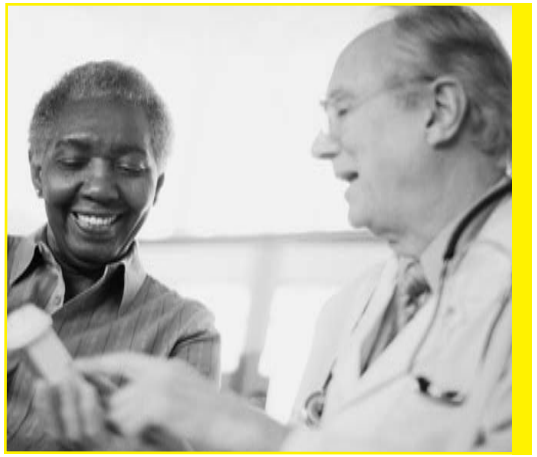
The New Look

Under the new rules, introductory information called *Highlights of Prescribing Information* (*Highlights*), will be added to the beginning of the prescribing information. *Highlights* will provide a concise summary of information most important to prescribers and will refer them to the appropriate section or sections in the *Full Prescribing Information* (*FPI*) where additional, more detailed information is located. *Highlights* will typically be half a page in length and will include:

- **Recent Major Changes**. A list of all substantive changes made to the following sections of the *FPI* within the past year: *Boxed Warning, Indication and Usage, Dosage and Administration, Contraindications,* and *Warnings and Precautions*. The corresponding new or revised text in the *FPI* will be identified by a vertical line in the left margin. This will help health-care professionals quickly identify new information that has been added to the prescribing information.
- **Drug Approval Date.** The date of FDA approval of the original drug to allow for easy identification of new products
- **Adverse Event Reporting.** A toll-free number and Internet site to report suspected adverse reactions
- **Table of Contents (Contents).** A list of all the sections and subsections in the FPI.

Additionally, much of the information contained in the FPI will be reorganized and reordered to make it easier to find and use. Frequently used sections, such as the *Indications and Usage*, and *Dosage and Administration* sections, have been moved to the front of the prescribing information. By creating a *Patient Counseling Information* section, information that health-care professionals can use when counseling patients has been made more prominent. If the drug also has FDA-approved patient information, it will be reprinted in or accompany the prescribing information.

Sections containing risk information are now all located together. For example, risk information that had been listed separately in either the *Warnings Section* or in the *Precautions Section* is combined into a new *Warnings and Precautions Section*. In addition, new sections have been created that address specific safety issues (e.g., *Drug Interactions*, *Use in Specific Populations*).



Certain graphical features including minimum type size and standardized bolding are now required, so that the prescribing information is easier to read.

DailyMed

The new format is important to the success of other initiatives aimed at improving patient care and decreasing the likelihood of medication errors. For example, the recently launched DailyMed, a health information clearinghouse created by FDA and the National Library of Medicine, has begun to electronically disseminate up-to-date and comprehensive medication information for use with information systems that support patient care via http://dailymed.nlm.nih.gov. The DailyMed will make current information about FDA-regulated products readily available, free of charge, to physicians, other health-care professionals, and patients. This is an important step toward creating electronic access to drug safety and effectiveness information so that prescribers can get up-to-date information at the point of care.