FDA Announces Final Rule on the Requirements for Prescribing Information for Drug and Biological Products

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Today's Action

The Food and Drug Administration (FDA) today published a final rule, titled Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, in an effort to better manage the risks of medical product use and reduce medical errors associated with the use of prescription drug products.

Final Rule

FDA is revising the regulations governing the content and format of prescribing information for human prescription drug and biological products (21 CFR 201.56 and 201.57). The final rule requires that the prescribing information of new and recently approved products include (1) highlights of the prescribing information (*Highlights*), (2) a table of contents (*Contents*), (3) reordering and minor content changes, and (4) minimum graphical requirements.

Benefits of the Revisions to the Prescribing Information

The final rule is part of FDA's strategic initiative to manage the risks of medical product use and reduce adverse events involving the products it regulates. The revisions will make it easier for healthcare professionals to access and use information contained in the prescribing information, thereby increasing the extent to which they rely on it to obtain information. FDA believes the revisions to content and format of the prescribing information will enhance the safe and effective use of prescription drug products and, in turn, reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

Revisions to the Prescribing Information

The *Highlights* section will provide immediate access to the information that healthcare professionals most commonly refer to and view as most important. This summary typically will be 1/2 page in length.

Additional innovations provided in *Highlights* include:

- The date of approval of the original drug product.

- *Recent Major Changes*, a list of all substantive changes made within the past year to the following sections of the prescribing information: *Boxed Warning*, *Indications* and *Usage, Dosage and Administration*, *Contraindications*, and *Warnings and Precautions*. These changes will be identified in the full prescribing information as well.

- Adverse drug reaction reporting contact information.

The *Contents* section will serve as a navigational tool to reference all the sections and subsections in the full prescribing information, some of which will not be referenced in *Highlights*.

Reorganization and format changes to the prescribing information include:

- The information practitioners refer to most frequently and consider most important (e.g. *Boxed Warning*, *Indications* and *Usage, Dosage and Administration*, and Dosage Forms and Strengths (separated from Storage and Handling)) will be located at the front of the prescribing information.

- Risk information will be consolidated. The *Adverse Reactions* section will follow after the *Warnings and Precautions* section, consolidating risk information in one location and helping to put in context the relative seriousness of the adverse reactions discussed.

- Other information formerly found in the *Precautions* section will be located in sections devoted to *Use in Specific Populations*, *Drug Interactions*, and *Patient Counseling Information*.

- A separate *Patient Counseling Information* section will be added to the requirement that all FDA-approved patient information be reprinted in or accompany the drug product's prescribing information. The purpose of this change is to increase the prominence of patient information. The rule regarding the inclusion of all FDA-approved patient information applies also to older products not otherwise subject to the new content and format requirements.

- There will be standardized bolding, white space, and established minimum font sizes to enhance communication of important information.

Implementation Initiative

In coordination with the publication of the final rule, FDA today published 4 guidance documents.

- Labeling for Human Prescription Drug and Biological Products -- Implementing the New Content and Format Requirements. This draft guidance focuses on, among other things, how to determine what information should be presented in *Highlights*.

- Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products - Content and Format. This final guidance focuses on how to organize the large body of complex information that is typically contained in the *Adverse Reactions* section and discusses how to determine whether a reported adverse event should be included in the *Adverse Reactions* section.

- Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products - Content and Format. This final guidance focuses on how to select the studies that are appropriate for inclusion in the *Clinical Studies* section and what information should be provided for those studies.

- Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products - Content and Format. This draft guidance focuses on how to determine whether an adverse reaction should be discussed in the *Warnings and Precautions*, *Contraindications*, or *Boxed Warning* sections and what information should be provided for the adverse reaction.

FDA also has developed several prototypes (or examples) of prescribing information that illustrate approaches to complying with the content and format requirements. These and other educational materials will be posted in a dedicated area on the FDA Web site. Furthermore, FDA plans to engage in external outreach and training for industry, physicians, and interested consumers, in addition to internal training programs for FDA reviewers.

The content and format revisions to the prescribing information are a key component of FDA's initiatives designed to make prescribing more error-free and better informed by using new information technology. For example, on November 2, 2005, the FDA began requiring drug manufacturers to submit prescription drug labeling information to the FDA in a new electronic format. Using embedded computer tags and standardized medical terminology, the new format will enable physicians to quickly search and access specific prescribing information and thereby help reduce medication errors.

The new electronic product labels will be the key element and primary sources of medication information for "DailyMed", a new interagency online health information clearing house created cooperatively by the FDA and the National Library of Medicine (NLM) for the benefit of patients and healthcare professionals. "DailyMed" can be accessed for free at http://dailymed.nlm.nih.gov.