U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting Your Health
U.S. Food & Drug Administration

Drugs

New Requirements for Prescribing Information

The U.S. Food and Drug Administration (FDA) is issuing final regulations amending the content and format of prescribing information for human drug and biologic products. The final rule

- Revises the current regulations to require that the prescribing information of new and recently approved products includes highlights of the prescribing information (Highlights) and a table of contents (Contents) for the full prescribing information (FPI)
- Reorders currently required information and makes minor changes in its content
- Establishes minimum graphical requirements

The goal is to provide more informative and accessible prescribing information, resulting in a better risk communication and management tool. These revisions will make it easier for healthcare professionals to access, read, and use prescribing information, and will enhance the safe and effective use of prescription drug products.

- FDA Online Continuing Accredited Educational Module: An Introduction to the Improved FDA Prescription Drug Labeling [1]. The primary audience for the course is physicians, nurses, and pharmacists. Continuing education credit is offered free for those groups. The course is also available at no charge for individuals not seeking continuing education credit.
- CDER Teleconference: "An Introduction to the Improved FDA Prescription Drug Labeling", November 7, 2006. Handouts and an audio download of this teleconference are available on the ISMP website [2]. To receive an audio CD and handouts by mail, please email dpapubs@fda.hhs.gov.
- FDA Announces New Prescription Drug Information Format to Improve Patient Safety [3]
- Summary of the Final Rule on the Requirements for Prescribing Information for Drug and Biological Products [4]
- Questions and Answers About the New Content and Format Requirements for Prescribing Information [5]
- Final Rule: Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products, January 24, 2006. Effective June 30, 2006. [PDF - 780KB [6]]
- Guidance for Industry
  - Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products - Content and Format - (Draft guidance)(PDF - 144KB) [7] Federal Register notice [8]
- Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products [9] (***Draft***)
  - Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format [10]
  - Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format [11]
  - Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements [12] (***Draft***)
  - Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format [13]
- Fictitious Examples of Revised Prescribing Information (These fictitious examples illustrate approaches for complying with the new requirements and do not represent the prescribing information for any FDA-approved prescription drug.)
  - Imdicon (cholinasol) [14]
  - Fantom (motnaf) [15]
  - Pretend Inhalizer (notrealatol inhalation powder) [16]
  - FriendChip (smilealot) [17]
- Sample Tool Illustrating the Format for Highlights and Contents [18]. Please see § 201.57 for detailed information

on specific requirements. (5/15/2006)

- Information for Healthcare Professionals
  - FDA's New Prescribing Information for Drugs [19]
  - "FDA's New Prescribing Information: Better organized. Easier to read. Better healthcare [20]." [Brochure]
- Information for Consumers
  - New Requirements for Prescribing Information [21]
  - FDA Consumer magazine article, March-April, 2006: The FDA Announces New Prescription Drug Information Format [22]
- Public Service Announcement
  - "Prescribing Information – Commonly Called the "Package Insert" – is Getting a New Look! [23]" [Print PSA]

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