



Happy Easter

PIC QUESTION OF THE WEEK: 4/10/06

Q: What are some of the major changes in the new guidelines for prescription package inserts?

A: The Food and Drug Administration (FDA) published a ruling on January 18, 2006 entitled *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*. It is an effort to make important aspects of the prescribing information (also known as the package insert) clearer and more accessible to healthcare professionals. This is the first time in more than 25 years the FDA has changed the format of the prescribing information. The new rule is part of FDA's initiative to manage the risks associated with prescription drug use as well as minimize adverse events involving the products it regulates. It applies to all new drugs. Products approved over the past five years are also included and will gradually be converted to the new format. Hopefully, the new format will make it easier for healthcare professionals to quickly read and use prescribing information in order to make clinical judgments. The FDA hopes this ultimately leads to better health outcomes for patients, more efficient delivery of healthcare, and improved doctor-patient interaction. These new labeling regulations will go into effect on June 30, 2006. Some of the most significant changes include:

- A new introductory section titled *Highlights* that provides immediate access to information healthcare professionals consider most important. It addresses indications, dosage and administration, contraindications, common adverse effects, and any major changes made to the existing prescribing information.
- A *Table of Contents* that lists the key areas of the insert including indications, drug interactions, use in specific populations, etc. The pharmacology and clinical studies supporting approval of the drug are now included near the end of the document.
- The date of initial product approval, which indicates how long a product has been on the market.
- A toll-free number and internet reporting information, that encourages more widespread reporting of suspected adverse events and side effects.

In a few weeks, the FDA is sponsoring a hands-on workshop for all individuals involved with prescription product labeling. The reader is encouraged to review the attached website to locate sample package inserts and additional information on the new regulations for package inserts.

References:

www.fda.gov/cder/regulatory.physLabel/default.htm

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