A medication’s professional product label, commonly called the package insert, contains the legal basis for prescribing a medication based on scientific data reviewed and approved by the FDA. A medication’s label describes the conditions under which the medication can be prescribed safely and effectively.

**Why is the label so technical?**
The package insert is written by the medication’s manufacturer, and the final language of the label is negotiated between the company and the FDA. The FDA must approve the final language in all package inserts. The information contained in the package insert is written in dense technical jargon and assumes the reader is a health professional.

There is another element that may explain why labels can be so difficult for consumers to read. According to some FDA and pharmaceutical industry observers, labels are written with input from company attorneys in such a way as to limit the liability of the manufacturer in the event that an adverse drug reaction injures a consumer. Overall, package inserts are very difficult to understand due to the professional jargon and legal language.

Also, because package inserts are written for health professionals, the benefits of the drug may be not fully described, another limitation for consumers. As a result, the information may be viewed negatively by consumers and lead to adherence problems (see Chapter 41). Reading the long list of potential adverse reactions and events may be discouraging to some patients.

**How can the label be made more user-friendly?**
Over the years, consumer organizations and others have urged the FDA to mandate the use of a “consumer version” of the package insert for all prescription medications they approve. These attempts have been met with stiff opposition from groups representing pharmacy, medicine, and the pharmaceutical industry.

The written medication information that most consumers receive in the pharmacy are published by unregulated commercial information vendors and is of questionable quality. In two large surveys, the medication information distributed by pharmacists failed to meet voluntary minimal content quality
Chapter 35 - Why are drug labels so difficult to understand?
The closest thing to FDA-approved package inserts written specifically for consumers are called Medication Guides, or Med Guides for short. The FDA has the regulatory authority to require the distribution of Medication Guides for medications that present serious public health concerns. For example, this would be done if the medication is one that has serious risks relative to benefits. In this case, consumers should be made aware of these risks because this information could affect the consumer’s decision to use, or to continue to use, the medication.

There are now over 100 drugs that require a pharmacist to dispense a Medication Guide with each new and refill prescription. A list of these medications can be found on the FDA’s Web site, at www.fda.gov/drugs/drugsafety/ucm085729. This list includes all antidepressants, medications for attention deficient hyperactivity disorder, and the popular non-steroidal anti-inflammatory drugs (NSAIDs) widely used for pain and arthritis.

**Are there efforts to simplify the label?**

There are several programs underway to improve consumer access to professional product labels and to make them easier to read and understand. The first source is called Drugs@FDA, which can be found on the FDA Web site. This is a comprehensive catalog, and it provides consumers with access to professional product labels for prescription medications. This FDA page also contains FDA-approved consumer information on medications approved since 1998. It is easy to use and can be found at www.accessdata.fda.gov/scripts/cder/drugsatfda/

The FDA and the National Library of Medicine (NLM), a part of the NIH, are working together to provide consumers with free access to professional product labels for all medications approved in the U.S. on the NLM’s Web site. These labels are continually updated to provide access to the most current label information, and almost 10,000 labels are available to the public. This Web site, called DailyMed, can be accessed online at www.dailymed.nlm.nih.gov/dailymed/about.cfm. One of DailyMed’s best features is that the font size is large enough that the labels can be easily read by almost everyone.

The FDA issued regulations effective June 30, 2006, that changed the format for professional product labels with the goal of providing more informative and accessible information for health professionals. The regulation applies to drugs approved after June 30, 2006, and to drugs approved in the five years prior to that date.

There are several aspects of the new format that may be very useful to consumers. The most important of these is a “Highlights Section”
that will appear at the beginning of the label and contain the date of the medication’s approval. There is a “Recent Major Changes” section that will list all important changes made within the past year to these label sections: Boxed Warning, Indications and Usage, Dosage and Administration, Contraindications, and Warnings and Precautions.

A “Table of Contents” for each professional product label will provide quick access to the most commonly used information.

An important initiative for consumer access to professional product labels and medication risk information was included in the Food and Drug Administration Amendments Act (FDAAA) of 2007. The law requires the development and maintenance of an accessible, consolidated Internet site that is easily searchable for medication safety information. In October 2008, the FDA announced the creation of a new Web page that consolidates drug safety information for consumers and health care professionals in one Internet access point. The drug safety Web page can be accessed at www.fda.gov/drugs/drugsafety/default.htm Some of the categories of information available are professional product labels, product recalls, and safety alerts.

We recommend that you consult this Web page before having a new prescription filled and check it periodically for new safety information on medications you are already taking.

**How do patients value the package inserts?**
Most patients do not find the inserts very useful. Some of them leave decisions to their doctors, while others find the inserts lacking information. Also, some insert information can be out-of-date, though the development of new, up-to-date sources of information is a step in the right direction.

**Key messages**

- Package inserts (medication labels) are written for health professionals, not for consumers and are available at the pharmacy upon request.
- Its language can be technical and difficult for the average consumer to understand.
- There is a general dissatisfaction with drug labels.
- Efforts are being made to make drug labels more user-friendly, up-to-date and accessible to consumers.
- Initiatives are underway to provide consumers with easily accessible drug information on the Internet.