

Background: The “Drug Facts” Label as a Consumer Education Tool

Clear, simple and readable labels on nonprescription, over-the-counter (OTC) medicines are already beginning to appear on store shelves as a result of the changeover to a new “Drug Facts” label required by the U.S. Food and Drug Administration (FDA). This standardized label will make it easier for consumers to select the most appropriate OTC product and to understand each drug’s risks and benefits. Most OTC medicines manufactured after May 2002 must carry the new “Drug Facts” label.

Coming at a time when more consumers are using more types of OTC products than ever before, the new “Drug Facts” label has the potential to improve the way Americans choose and use OTC medicines, just as the simplified “Nutrition Facts” label has helped consumers choose healthier foods. Of equal significance, the advent of the new OTC drug label provides a teachable moment for healthcare professionals to emphasize that OTC remedies are serious medicines that can cause harm if taken incorrectly. As such, the new “Drug Facts” label offers an important framework around which educators can promote a better understanding about the appropriate dosing and safe use of OTC medicines.

Factors Contributing to Consumer Confusion

Before taking steps to simplify the OTC label, FDA first conducted extensive research on how consumers use OTC drug labels, finding a number of factors that contribute to consumer confusion. One major problem has been the readability of OTC drug labels, especially for older Americans, who purchase almost 30 percent of the nonprescription drugs sold in the United States. According to one survey cited by FDA, a significant number of people aged 60 and over could not read the print on some labels because the letter width was too compressed and the letter height too short. Another study showed that people had to have eyesight much better than normal to read most labels on 25 OTC drugs.

Beyond label readability, FDA also found that consumers find words like “indications,” “precautions” and “contraindications” too technical and confusing. Further, consumers have experienced difficulties finding important labeling information on OTC labels because the facts have not been presented in a standard format. Currently, FDA requires OTC drug labels to include all the information consumers need for safe and effective use. However, information about product directions, warnings and approved uses has appeared in different places on the label depending upon the OTC product and brand. For those Americans who may be allergic to an ingredient in a drug product, finding information about inactive ingredients has also been a challenge.

Because these factors can lead to the inappropriate use of OTC medicines—such as taking too much of an active ingredient—FDA has made public education about the new “Drug Facts” label part of its activities. This is especially important as potent prescription drugs increasingly switch to OTC status, requiring consumers to learn about how to take these drugs correctly. At the same time, expanded access to OTC medicines will require special care if consumers are taking more than one OTC product at the same time or if they take an OTC drug along with a prescription medicine.

A New Education Tool

Patterned after the “Nutrition Facts” food label, the new “Drug Facts” label uses simple language and an easy-to-read format to help people compare and select OTC medicines and then follow the dosage instructions. The following information must appear in this standardized order, usually on the package’s outside container or wrapper:

- The product’s active ingredients, including the amount in each dosage unit
- The purpose of the medication
- The uses/indications for the drug
- Specific warnings, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist.
- The warnings section also describes side effects that could occur and substances or activities to avoid
- Dosage instructions addressing when, how and how often to take the medication
- The product’s inactive ingredients, which is important information for those with specific allergies

Along with this standardized format, the new drug label uses plain-speaking terms to describe the facts about each OTC drug. For example, the term “uses” replaces “indications,” while other technical words like “precautions” and “contraindications” have been eliminated. The new label also requires a type size large enough to be easily read, as well as specific layout details—bullets, spacing between lines and clearly marked sections—to improve readability.

FDA’s new OTC labeling rule applies to over 100,000 OTC drug products. Most OTC medicines manufactured after May 2002 will carry the new “Drug Facts” label, although certain OTC products are not required to use the new format until 2005. However, FDA estimates that a large number of OTC medicines with the new labeling are already on store shelves.

#####