Backgrounder:
The "Drug Facts" Label As
A Consumer Education Tool

On May 16, 2002, a federal regulation went into effect requiring most over-the-counter (OTC) medicines to carry a standardized "Drug Facts" label that spells out each OTC product's active ingredients, the purpose of the medication, uses and specific warnings, dosage instructions and the medicine's inactive ingredients.

Developed by the U.S. Food and Drug Administration (FDA), the "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 changeover to a standardized OTC drug label provides a teachable moment for health care professionals to emphasize that OTC remedies are serious medicines that can cause harm if taken incorrectly. As such, the "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.

Behind Development of the "Drug Facts" Label

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 the 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 better-than-normal eyesight 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 on 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 "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 "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 or 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 label uses plain-speaking terms to describe the facts about each OTC medicine. For example, the term "uses" replaces "indications" while other technical words like "precautions" and "contraindications" have been eliminated. The label also requires a type size large enough to be read easily, and specific layout details – bullets, spacing between lines and clearly marked sections – to improve readability.

Ultimately, the "Drug Facts" label will appear on over 100,000 different OTC drug products, although certain OTC products are not required to use the new format until 2005. Dietary supplements are required to carry a separate "Supplement Facts" label.

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