

Easy-to-Understand “Drug Facts” Label Now a Reality *Health Coalition Says Label Is Way to “Be MedWise”*

New York, NY; May 16, 2002 – On the day that a new government regulation goes into effect requiring a standardized “Drug Facts” label on the vast majority of over-the-counter (OTC) drugs, a broad-based coalition of health-related organizations is mobilizing a national “teach-in” to help Americans use this new label when buying and using nonprescription medicines.

At a news conference today, the National Council on Patient Information and Education (NCPPIE) joined forces with the U.S. Food and Drug Administration (FDA) to mark the date when most drug companies must begin manufacturing nonprescription medicines with this new label. Applying to over 100,000 OTC drug products, the new “Drug Facts” label is the result of an FDA regulation finalized in 1999. Because many manufacturers have already switched to the new format, FDA estimates that a large number of OTC products with the “Drug Facts” label are now on store shelves. Under the FDA rule, certain OTC products, such as sunscreens, do not have to use the new label until 2005.

“Today marks a major milestone for all Americans who have struggled trying to decipher the information on an OTC drug label,” said Jonca Bull, M.D., of FDA’s Center for Drug Evaluation and Research. “Through the changeover to a standardized ‘Drug Facts’ label, consumers will have an important new tool to help them select the most appropriate OTC medicine and to understand each drug’s risks and benefits more easily.”

Extensive Web Site, New Print Ads Will Teach How to Use the New Label

Because the label change represents what NCPPIE considers a “teachable moment” for the American public, the Council has developed a multi-media information campaign that will show consumers how the “Drug Facts” label can simplify selecting the most appropriate OTC product by increasing public understanding of each drug’s risks and benefits. Through its new OTC education campaign called *Be MedWise*, NCPPIE will be reaching consumers through a greatly expanded web site—www.bemedwise.org—where consumers, health professionals, educators, and the media can conduct individualized searches on any OTC drug by brand name or active ingredient. NCPPIE will also be running full-page ads in national magazines as a complement to the television advertising that began airing in January.

“The new ‘Drug Facts’ label has the potential to improve the way Americans choose and use OTC medicines but only if we teach consumers how to use it,” said Linda Bernstein, PharmD. of San Francisco, CA., a consumer advisor to the *Be MedWise* campaign.

“Investing in public education is essential if we are to make the new label immediately relevant and meaningful to people’s lives.”

New Survey Documents Need for OTC Label Education

The need for public education about the “Drug Facts” label was reinforced by the findings of a new survey that examined the self-medicating behaviors of the American public, including what information people seek when reading an OTC label. Conducted for NCPPIE by Harris Interactive, the survey of 1,011 adult Americans finds that label reading is very selective and incomplete. Although the vast majority of those who use nonprescription medicines (95%) read some portion of the OTC drug label, the survey finds that many consumers only seek partial information. When asked what information they look for when buying an OTC drug for the first time, only a third (34%) of those surveyed say they look for the active ingredient, while one in five (19%) say they seek out the usage directions (e.g. how to take the product) and one in six (16%) look at the dosage level.

Moreover, the survey provides a snapshot of what kind of information could help consumers be more “OTC literate.” Of special significance is the drug’s active ingredient, which must be stated at the top of the standardized “Drug Facts” panel. As the new label goes into effect, the survey finds that only 34 percent of Americans can identify the active ingredient in common brands of OTC pain relievers. Also, the poll found that because Americans do not recognize the potential risks of taking OTC medicines incorrectly, as many one in three adults – over 64 million consumers—say they have taken more than the recommended dose of a nonprescription medicine.

“These survey findings provide a solid foundation for designing a new and compelling public education campaign about the appropriate use of OTC medicines,” said W. Ray Bullman, executive vice president of NCPPIE. “By linking the new OTC label to this education effort, we can capture the public’s attention and promote real behavior change.”

OTC Label Was Years in the Making

FDA originally proposed its OTC labeling regulation in February 1997 and after considering almost 2,000 comments, issued a final rule in March 1999. Patterned after the Nutrition Facts food label, the new “Drug Facts” label uses plain-speaking terms to describe the facts about each drug in a type size large enough to be easily read. The new label also requires an easy-to-use, standardized format to help people compare and select OTC medicines and then follow dosage instructions.

Under FDA’s rule, the following information must appear on the “Drug Facts” label in this standardized order, usually on the package’s outside container or wrapper: 1) the product’s active ingredients; 2) the purpose of the medication; 3) uses and indications for the drug; 4) specific warnings; 5) dosage instructions; 6) other information, such as how to store the medication; and 7) the product’s inactive ingredients. In addition, the new label allows manufacturers to list a telephone number if consumers have questions. This

section is optional but must be added to the Drug Facts panel if the information is included on the label.

About NCPIE; *Be MedWise Campaign*

In January 2002, NCPIE launched the *BeMedWise* campaign with new information that many Americans do not recognize the potential risks of taking OTC drugs incorrectly. As part of this initiative, NCPIE has been airing television advertising donated by McNeil Consumer & Specialty Pharmaceuticals, which also provided an unrestricted educational grant to develop the program and to purchase airtime for the spot. Radio spots are also being planned.

Established in 1982, the National Council on Patient Information and Education is a diverse non-profit coalition that works to stimulate and improve the communication of information about the appropriate use of prescription and OTC medicines. The Council sponsors the national health observance, *Talk About Prescriptions Month*, every October. NCPIE's members include consumer organizations; patient advocacy groups; voluntary health agencies; schools of pharmacy and nursing; health-related trade associations; prescription and over-the-counter pharmaceutical manufacturers; the FDA and other government agencies. More information about NCPIE is available through its web site: www.talkaboutrx.org.

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