# Prescription Drug Leaflets Need Improvement

Improvement is needed for the printed consumer medication information (CMI) that accompanies new prescriptions, according to a new study released by the Food and Drug Administration (FDA).

The study found that this information does not consistently provide easy-to-understand information about the use and risks of the prescription product.

"The current voluntary system has failed to provide consumers with the quality information they need in order to use medicines effectively and safely," says Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research.

## What is CMI?

After a pharmacy dispenses a prescription, the pharmacy personnel usually staple CMI to the bag or put it inside the bag with your medicine. CMI provides information on how to use your prescription medicine safely and effectively and should be given with all new prescriptions.

Usually, CMI information is purchased by pharmacies from outside companies that use the FDA-approved information for health care professionals (professional labeling) as the basis for the CMI.

## Study Results

The study, *Expert and Consumer Evaluation of Consumer Medication Information*, was conducted by the National Association of Boards of Pharmacy through a subcontract with researchers at the University of Florida, College of Pharmacy.

Shoppers trained to simulate patients visited pharmacies throughout the United States, purchased prescription medications, and collected the CMI provided.

The study showed that:

- Ninety-four percent of shoppers received CMI with new prescriptions.
- About 75 percent of this information met the minimum criteria for usefulness.

These results fall short of a Congressionally-mandated goal that called for 95 percent of all prescriptions to be accompanied by useful CMI by 2006.

## FDA's Role

FDA regulates prescription drug labels written for health care professionals and Medication Guides and Patient Package Inserts written for consumers. But the agency does not regulate the CMI leaflets or other materials that may be given to consumers when they pick up prescriptions.

FDA's role has been:

- to encourage the private sector to provide CMI
- to supply the companies that write CMI with the necessary guidance
- to evaluate pharmacies' progress in providing useful CMI

As part of this effort, FDA published *Guidance: Useful Written Consumer Medication Information* to help the private sector meet goals regarding the usefulness of CMI information.

## FDA Seeks Public Comments

If the Congressional goals aren't met, the law requires FDA to seek public comments on initiatives that can be used to meet the goals. "We need to work with pharmacy operators, manufacturers, health care professionals, and consumers to come up with a sensible, comprehensive, and more effective solution," says Woodcock.

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The study also recommended that the amount of redundant information in CMI, as well as the presentation of irrelevant information, be examined. In early 2009, the FDA Risk Communication Advisory Committee will hold a public meeting to discuss the study's findings.

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