



## FDA REQUIRES SIDE EFFECTS STATEMENT ON LABELING

### Pharmacies Must be Compliant by July 1, 2009

On November 28, 2008, the FDA's final rule requiring the addition of a statement and toll-free number to the labeling of certain human drug products became effective. However, the FDA has stated that it will begin enforcing compliance on July 1, 2009.

The rule entitled, **TOLL-FREE NUMBER for REPORTING ADVERSE EVENTS on LABELING for HUMAN DRUG PRODUCTS** applies to drug products approved under Section 505 of the Food, Drug and Cosmetic Act.

**For prescription drug products, the side effects statement provided must read:  
"CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS.  
YOU MAY REPORT SIDE EFFECTS TO FDA AT 1-800-FDA-1088."**

This statement must be in a single, clear, easy-to-read type style and must be distributed via one or more of the following options:

1. On a sticker attached to the unit package, vial or container of the drug product
2. On a preprinted pharmacy prescription vial cap
3. On a separate sheet of paper
4. In consumer medication information
5. In the appropriate FDA-approved Medication Guide that contains the side effects statement

For options 1 and 2 above, the letter height or type size used for the side effects statement must be no smaller than 6 points.

For options 3, 4, and 5 above, the letter height or type size for the side effects statement must be no smaller than 10 points.

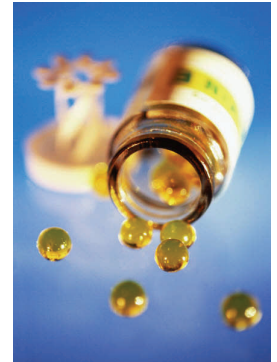
The requirement also applies to labeling of approved over-the-counter (OTC) drug products, unless the package label includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug. Most national brand OTC drug products already conform to the requirements. However, most private label OTC drug products currently in the market do not meet the requirements and would need to be modified to comply with the final rule. The side effect statement for OTC drug products is to be included in the package after the subheading:

**"STOP USE AND ASK A DOCTOR IF SIDE EFFECTS OCCUR"**

The statement must then read:

**You may report side effects to FDA at 1-800-FDA-1088**

Exempt from the rule are pharmacies that dispense or administer prescription drugs to inpatients in a hospital or healthcare facility under an order of a licensed practitioner, or as part of a supervised home healthcare.



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