Food and Drug Administration Requirements Concerning Toll-Free (1-800) Number for Reporting Adverse Events on Labeling of Drug Products

On October 28, 2008, FDA published a final rule implementing the provisions relating to the toll-free number for reporting adverse events and the required side effects statement. **The final rule delays the compliance date from January 1, 2009 to July 1, 2009.**

The final rule sets forth the requirements for the addition of a statement on the labeling for drug products which includes: 1) a toll-free number maintained by the FDA that is to be used for reporting side effects, and 2) a statement that the number is to be used for reporting purposes only, not to receive medical advice. Pharmacists are required to distribute the side effects statement with prescription medications and over-the-counter products which do not already include a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug product. The side effects statement can be distributed to patients in an outpatient setting as follows:

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 (CMI); or
5. In the appropriate FDA-approved Medication Guide that contains the side effects statement.

For prescription medications, the prescription must include: **"Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088."** If not included in the printed prescription label, then the statement must be provided by one of the options previously listed.