



FDA 1-800 Phone Number for Reporting Side Effects Mandatory for July 1, 2009

Effective July 1, 2009, as mandated by the FDA Amendments Act of 2007, pharmacies must provide the patient with the 1-800 FDA phone number for reporting adverse events each time a new prescription and REFILL is dispensed. The statement should include the following: **“Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.”**

The statement can be given to the patient in 1 of 5 ways:

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

If you want to add this to your labels, please call your vendor as soon as possible. McKesson recommends to do all your labeling changes at once if needed, since there is a small fee involved per hour of time.

The FDA Delayed Implementation of Toll Free Adverse Event Reporting Labeling Requirement Until July 1, 2009 On October 28, the Food and Drug Administration (FDA) issued a final rule delaying by six months a compliance deadline for including FDA's toll-free number for adverse event reporting on prescription drug labeling that was scheduled to go into effect on January 1, 2009.

Please view the Federal Register document for additional guidance on font size and other prerequisites: www.mtpharmacist.org/documents/FR04-9069_FDA_phone#.pdf