

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 the FDA at 10800-FDA-1088."**

The statement can be given to the patient in one of five 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, contact 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.