



PIC QUESTION OF THE WEEK: 12/08/08

Q: Can you describe the new FDA regulation regarding prescription labeling and the reporting of adverse drug reactions?

A: In 2004, the Food and Drug Administration initially proposed a rule that encouraged patients to report suspected adverse drug reactions to the agency. The requirement was subsequently also included in sections of the Best Pharmaceuticals for Children Act (BPCA) and the FDA Amendments Act of 2007 (FDAAA). The rule is entitled “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products.” The final ruling on this proposal became effective November 28, 2008 while the *compliance date* for mandatory adherence is July 1, 2009. Based on this rule, the following statement must be included in the labeling of both new and refilled prescriptions: ***Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.*** It must be stressed that this FDA telephone number is for *reporting* purposes only and not to be used when seeking medical advice. Hospitals and other in-patient healthcare providers are excluded from this requirement. OTC drug products are also included in the ruling. Their original packaging must contain the phrase, ***Stop use and ask a doctor if side effects occur. You may report side effects to FDA at 1-800-FDA-1088.*** The following are the five options pharmacists may use to provide this information statement:

1. Place it on a sticker attached to the prescription vial, package, or container
2. Have it printed on the pharmacy vial cap
3. Put it on a separate sheet of paper that is distributed with all prescriptions
4. Include it in the consumer medication information leaflet
5. Distribute the appropriate FDA-approved Medication Guide that contains the statement

Pharmacies may voluntarily provide a sticker containing the side effect statement that can be attached by the consumer at home; however, this alone does not satisfy the requirements of the new rule. The basic goals of this FDA action are to promote patient safety and allow for better surveillance of significant adverse drug reactions. Please review the entire ruling included in the reference cited below.

Reference:

- US Department of Health and Human Services. Toll-free number for reporting adverse events on labeling for human drug products. Fed Regist 2008;73:63886-63897. <http://edocket.access.gpo.gov/2008/pdf/E8-25670.pdf> Accessed December 1, 2008.

Photo by: Mixmaster: used under Creative Commons License; <http://www.flickr.com/photos/audunbakkeandersen/387278546/> (Accessed November 12, 2008)

Jennifer E. Heasley and Renee T. Phelos, Pharm.D. Candidates

The PIC Question of the Week is a publication of the Pharmaceutical Information Center, Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA 15282 (412.396.4600).