

Toll-Free Reporting Number FAQs

What is the “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” rule?

This final federal rule issued on October 28, 2008 requires the addition of a statement on the labeling of certain human drug products for which an application is approved under the Federal Food, Drug, and Cosmetic Act. The added statement includes a toll free number for reporting adverse effects and advises that the number is to be used only for reporting side effects and is not intended for medical advice (the side effects statement).

When is the deadline for implementing the rule in pharmacies?

The FDA recognizes that affected entities, including manufacturers of drug products, authorized dispensers, and pharmacies, will need time to update labeling and systems to comply with the new requirements. Therefore, the agency has extended the original January 1, 2009 compliance date by six months, to fall on July 1, 2009.

What information is required on the new labeling?

The side effects statement should include the following verbatim statement: “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1800FDA1088.”

How must the new information be distributed?

Each authorized dispenser or pharmacy must distribute the side effects statement with each new or refill prescription drug product and dispensed. One or more of the following options to distribute the side effects statement may be used:

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

What are the formatting requirements for the new labeling?

The side effects statement must be in a single, clear, and easy to read type style. The letter height or type size used for the side effects statement as mandated in options 1 and 2 (see previous question) must be no smaller than 6 points (1 point = 0.0138 inch). The letter height or type size for the side effects statement as mandated in options 3, 4, and 5 (see previous question) must be no smaller than 10 points.

Additional questions?

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