

# FDA REGULATION – TOLL FREE NUMBER DISTRIBUTION/RX LABELING

Effective Date: 11/28/2008

Compliance Date: 07/01/09

Federal Register Notice – Proposed Rule: <http://edocket.access.gpo.gov/2008/pdf/E7-25426.pdf>

Federal Register Notice – Final Rule: <http://edocket.access.gpo.gov/2008/pdf/E8-25670.pdf>

## § 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling. \* \* \* \* \*

(c) \* \* \*

(5) \* \* \*

(vii) \* \* \* For all OTC drug products under an approved drug application whose packaging does not include a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug product, the following text shall immediately follow the subheading: “[Bullet] side effects occur. You may report side effects to FDA at 1–800–FDA–1088.” The telephone number must appear in a minimum 6–point bold letter height or type size.

## § 208.20 Content and format of a Medication Guide.

\* \* \* \* \*

(b) \* \* \*

(7) \* \* \*

(iii) For drug products approved under section 505 of the act, the following verbatim statement: “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.”

\* \* \* \* \*

\_ 5. Add part 209 to read as follows:

## **PART 209—REQUIREMENT FOR AUTHORIZED DISPENSERS AND PHARMACIES TO DISTRIBUTE A SIDE EFFECTS STATEMENT**

### **Subpart A—General Provisions**

Sec.

209.1 Scope and purpose.

209.2 Definitions.

### **Subpart B—Requirements**

209.10 Content and format of the side effects statement.

209.11 Dispensing and distributing the side effects statement.

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371; 42 U.S.C. 241.

### **Subpart A—General Provisions**

#### **§ 209.1 Scope and purpose.**

(a) This part sets forth requirements for human prescription drug products approved under section 505 of the Federal Food, Drug, and Cosmetic Act and dispensed by authorized dispensers and pharmacies to consumers. This part requires distribution of a side effects statement and applies to new and refill prescriptions. This part is not intended to apply to authorized dispensers dispensing or administering prescription drug products to inpatients in a hospital or health care facility under an order of a licensed practitioner, or as part of supervised home health care.

(b) The purpose of providing the side effects statement is to enable consumers to report side effects of prescription drug products to FDA.

## **§ 209.2 Definitions.**

For the purposes of this part, the following definitions apply: *Act* means the Federal Food, Drug, and Cosmetic Act (sections 201–907 (21 U.S.C. 301–397)).

*Authorized dispenser* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice. *Consumer medication information* means written information voluntarily provided to consumers by dispensing pharmacists as part of patient medication counseling activities.

*Medication Guide* means FDA approved patient labeling conforming to the specifications set forth in part 208 of this chapter and other applicable regulations.

*Pharmacy* includes, but is not limited to, a retail, mail order, Internet, hospital, university, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs.

*Side effects statement* means the following verbatim statement: “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.”

## **Subpart B—Requirements**

### **§ 209.10 Content and format of the side effects statement.**

(a) *Content.* The side effects statement provided with each prescription drug product approved under section 505 of the act must read: “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.”

(b) *Format.* The side effects statement must be in a single, clear, easy-to-read type style. The letter height or type size used for the side effects statement in accordance with paragraphs (b)(1) and (b)(2) of § 209.11 must be no smaller than 6 points (1 point = 0.0138 inch). The letter height or type size for the side effects statement under paragraphs (b)(3), (b)(4), and (b)(5) of § 209.11 must be no smaller than 10 points.

### **§ 209.11 Dispensing and distributing the side effects statement.**

(a) Each authorized dispenser or pharmacy must distribute the side effects statement with each prescription drug product approved under section 505 of the act and dispensed. The side effects statement must be distributed with new and refill prescriptions.

(b) An authorized dispenser or pharmacy must choose one or more of the following options to distribute the side effects statement:

(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.