

and effective use of the drug product in other identifiable patient populations.

(7) The heading, “What are the possible or reasonably likely side effects of (name of drug)?” followed by:

(i) A statement of the adverse reactions reasonably likely to be caused by the drug product that are serious or occur frequently.

(ii) A statement of the risk, if there is one, of patients’ developing dependence on the drug product.

(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.”

(8) General information about the safe and effective use of prescription drug products, including:

(i) The verbatim statement that “Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide” followed by a statement that patients should ask health professionals about any concerns, and a reference to the availability of professional labeling;

(ii) A statement that the drug product should not be used for a condition other than that for which it is prescribed, or given to other persons;

(iii) The name and place of business of the manufacturer, packer, or distributor of a drug product that is not also a biological product, or the name and place of business of the manufacturer or distributor of a drug product that is also a biological product, and in any case the name and place of business of the dispenser of the product may also be included; and

(iv) The date, identified as such, of the most recent revision of the Medication Guide placed immediately after the last section.

(9) Additional headings and sub-headings may be interspersed throughout the Medication Guide, if appropriate.

[63 FR 66396, Dec. 1, 1998, as amended at 73 FR 404, Jan. 3, 2008]

#### **§ 208.24 Distributing and dispensing a Medication Guide.**

(a) The manufacturer of a drug product for which a Medication Guide is required under this part shall obtain

FDA approval of the Medication Guide before the Medication Guide may be distributed.

(b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

(c) Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product.

(d) The label of each container or package, where the container label is too small, of drug product for which a Medication Guide is required under this part shall instruct the authorized dispenser to provide a Medication Guide to each patient to whom the drug product is dispensed, and shall state how the Medication Guide is provided. These statements shall appear on the label in a prominent and conspicuous manner.

(e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient’s agent), provide a Medication Guide directly to each patient (or to the patient’s agent) unless an exemption applies under § 208.26.

(f) An authorized dispenser or wholesaler is not subject to section 510 of the Federal Food, Drug, and Cosmetic Act, which requires the registration of producers of drugs and the listing of drugs

in commercial distribution, solely because of an act performed by the authorized dispenser or wholesaler under this part.

**§ 208.26 Exemptions and deferrals.**

(a) FDA on its own initiative, or in response to a written request from an applicant, may exempt or defer any Medication Guide content or format requirement, except those requirements in § 208.20 (a)(2) and (a)(6), on the basis that the requirement is inapplicable, unnecessary, or contrary to patients' best interests. Requests from applicants should be submitted to the director of the FDA division responsible for reviewing the marketing application for the drug product, or for a biological product, to the application division in the office with product responsibility.

(b) If the licensed practitioner who prescribes a drug product subject to this part determines that it is not in a particular patient's best interest to receive a Medication Guide because of significant concerns about the effect of a Medication Guide, the licensed practitioner may direct that the Medication Guide not be provided to the particular patient. However, the authorized dispenser of a prescription drug product subject to this part shall provide a Medication Guide to any patient who requests information when the drug product is dispensed regardless of any such direction by the licensed practitioner.

**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.

SOURCE: 73 FR 404, Jan. 3, 2008, unless otherwise noted.

**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.”