

the Freedom of Information Act to exempt from public disclosure specific information identified in paragraph (a) of this section.

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

Subpart A—General Provisions

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Subpart A—General Provisions

§ 208.1 Scope and purpose.

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products, that the Food and Drug Administration (FDA) determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information. It applies primarily to human prescription drug products used on an out-patient basis without direct supervision by a health professional. This part shall apply to new prescriptions and refill prescriptions.

(b) The purpose of patient labeling for human prescription drug products required under this part is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

(c) Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

§ 208.3 Definitions.

For the purposes of this part, the following definitions shall apply:

(a) *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.

(b) *Dispense to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) *Distribute* means the act of delivering, other than by dispensing, a drug product to any person.

(d) *Distributor* means a person who distributes a drug product.

(e) *Drug product* means a finished dosage form, e.g., tablet, capsule, or solution, that contains an active drug ingredient, generally, but not necessarily, in association with inactive ingredients. For purposes of this part, drug product also means biological product within the meaning of section 351(a) of the Public Health Service Act.

(f) *Licensed practitioner* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to prescribe drug products in the course of professional practice.

(g) *Manufacturer* means for a drug product that is not also a biological product, both the manufacturer as described in § 201.1 and the applicant as

described in § 314.3(b) of this chapter, and for a drug product that is also a biological product, the manufacturer as described in § 600.3(t) of this chapter.

(h) *Medication Guide* means FDA-approved patient labeling conforming to the specifications set forth in this part and other applicable regulations.

(i) *Packer* means a person who packages a drug product.

(j) *Patient* means any individual with respect to whom a drug product is intended to be, or has been, used.

(k) *Serious risk or serious adverse effect* means an adverse drug experience, or the risk of such an experience, as that term is defined in §§ 310.305, 312.32, 314.80, and 600.80 of this chapter.

Subpart B—General Requirements for a Medication Guide

§ 208.20 Content and format of a Medication Guide.

(a) A Medication Guide shall meet all of the following conditions:

(1) The Medication Guide shall be written in English, in nontechnical, understandable language, and shall not be promotional in tone or content.

(2) The Medication Guide shall be scientifically accurate and shall be based on, and shall not conflict with, the approved professional labeling for the drug product under § 201.57 of this chapter, but the language of the Medication Guide need not be identical to the sections of approved labeling to which it corresponds.

(3) The Medication Guide shall be specific and comprehensive.

(4) The letter height or type size shall be no smaller than 10 points (1 point = 0.0138 inches) for all sections of the Medication Guide, except the manufacturer's name and address and the revision date.

(5) The Medication Guide shall be legible and clearly presented. Where appropriate, the Medication Guide shall also use boxes, bold or underlined print, or other highlighting techniques to emphasize specific portions of the text.

(6) The words “Medication Guide” shall appear prominently at the top of the first page of a Medication Guide. The verbatim statement “This Medication Guide has been approved by the

U.S. Food and Drug Administration” shall appear at the bottom of a Medication Guide.

(7) The brand and established or proper name of the drug product shall appear immediately below the words “Medication Guide.” The established or proper name shall be no less than one-half the height of the brand name.

(b) A Medication Guide shall contain those of the following headings relevant to the drug product and to the need for the Medication Guide in the specified order. Each heading shall contain the specific information as follows:

(1) The brand name (e.g., the trademark or proprietary name), if any, and established or proper name. Those products not having an established or proper name shall be designated by their active ingredients. The Medication Guide shall include the phonetic spelling of either the brand name or the established name, whichever is used throughout the Medication Guide.

(2) The heading, “What is the most important information I should know about (name of drug)?” followed by a statement describing the particular serious and significant public health concern that has created the need for the Medication Guide. The statement should describe specifically what the patient should do or consider because of that concern, such as, weighing particular risks against the benefits of the drug, avoiding particular behaviors (e.g., activities, drugs), observing certain events (e.g., symptoms, signs) that could prevent or mitigate a serious adverse effect, or engaging in particular behaviors (e.g., adhering to the dosing regimen).

(3) The heading, “What is (name of drug)?” followed by a section that identifies a drug product's indications for use. The Medication Guide may not identify an indication unless the indication is identified in the indications and usage section of the professional labeling for the product required under § 201.57 of this chapter. In appropriate circumstances, this section may also explain the nature of the disease or condition the drug product is intended to treat, as well as the benefit(s) of treating the condition.

(4) The heading, “Who should not take (name of drug)?” followed by information on circumstances under which the drug product should not be used for its labeled indication (its contraindications). The Medication Guide shall contain directions regarding what to do if any of the contraindications apply to a patient, such as contacting the licensed practitioner or discontinuing use of the drug product.

(5) The heading, “How should I take (name of drug)?” followed by information on the proper use of the drug product, such as:

(i) A statement stressing the importance of adhering to the dosing instructions, if this is particularly important;

(ii) A statement describing any special instructions on how to administer the drug product, if they are important to the drug’s safety or effectiveness;

(iii) A statement of what patients should do in case of overdose of the drug product; and

(iv) A statement of what patients should do if they miss taking a scheduled dose(s) of the drug product, where there are data to support the advice, and where the wrong behavior could cause harm or lack of effect.

(6) The heading “What should I avoid while taking (name of drug)?” followed by a statement or statements of specific, important precautions patients should take to ensure proper use of the drug, including:

(i) A statement that identifies activities (such as driving or sunbathing), and drugs, foods, or other substances (such as tobacco or alcohol) that patients should avoid when using the medication;

(ii) A statement of the risks to mothers and fetuses from the use of the drug during pregnancy, if specific, important risks are known;

(iii) A statement of the risks of the drug product to nursing infants, if specific, important risks are known;

(iv) A statement about pediatric risks, if the drug product has specific hazards associated with its use in pediatric patients;

(v) A statement about geriatric risks, if the drug product has specific hazards associated with its use in geriatric patients; and

(vi) A statement of special precautions, if any, that apply to the safe 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

§ 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.

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(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

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