

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.

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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.”

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.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

Sec.

210.1 Status of current good manufacturing practice regulations.

210.2 Applicability of current good manufacturing practice regulations.

210.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

SOURCE: 43 FR 45076, Sept. 29, 1978, unless otherwise noted.

§ 210.1 Status of current good manufacturing practice regulations.

(a) The regulations set forth in this part and in parts 211, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

(c) Owners and operators of establishments engaged in the recovery, donor screening, testing (including donor testing), processing, storage, labeling, packaging, or distribution of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are drugs (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act), are subject to the donor-eligibility and applicable current good tissue practice