

through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

[40 FR 14016, Mar. 27, 1975, as amended at 40 FR 58799, Dec. 18, 1975; 41 FR 48266, Nov. 2, 1976; 42 FR 15674, Mar. 22, 1977; 60 FR 38480, July 27, 1995; 72 FR 69119, Dec. 6, 2007]

EFFECTIVE DATE NOTE: At 44 FR 37467, June 26, 1979, §202.1(e)(6) (ii) and (vii) were revised. At 44 FR 74817, Dec. 18, 1979, paragraphs (e)(6) (ii) and (vii) were stayed indefinitely. At 64 FR 400, Jan. 5, 1999, these paragraphs were amended. For the convenience of the user, paragraphs (e)(6) (ii) and (vii), published at 44 FR 37467, are set forth below:

**§ 202.1 Prescription-drug advertisements.**

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(e) \* \* \*  
(6) \* \* \*

(ii) Represents or suggests that a prescription drug is safer or more effective than another drug in some particular when the difference has not been demonstrated by substantial evidence. An advertisement for a prescription drug may not, either directly or by implication, e.g., by use of comparative test data or reference to published reports, represent that the drug is safer or more effective than another drug, nor may an advertisement contain a quantitative statement of safety or effectiveness (a) unless the representation has been approved as part of the labeling in a new drug application or biologic license, or (b) if the drug is not a new drug or biologic, unless the representation of safety or effectiveness is supported by substantial evidence derived from adequate and well-controlled studies as defined in §314.111(a)(5)(ii) of this chapter, or unless the requirement for adequate and well-con-

trolled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

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(vii) Suggests, on the basis of favorable data or conclusions from nonclinical studies of a prescription drug, such as studies in laboratory animals or in vitro, that the studies have clinical significance, if clinical significance has not been demonstrated. Data that demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and have not been shown by adequate and well-controlled clinical studies to pertain to clinical use may be used in advertising except that (a), in the case of anti-infective drugs, in vitro data may be included in the advertisement, if data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown" and (b), in the case of other drug classes, in vitro and animal data that have not been shown to pertain to clinical use by adequate and well-controlled clinical studies as defined in §314.111(a)(5)(ii) of this chapter may not be used unless the requirement for adequate and well-controlled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

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**PART 203—PRESCRIPTION DRUG MARKETING**

**Subpart A—General Provisions**

- Sec.
- 203.1 Scope.
- 203.2 Purpose.
- 203.3 Definitions.

**Subpart B—Reimportation**

- 203.10 Restrictions on reimportation.
- 203.11 Applications for reimportation to provide emergency medical care.
- 203.12 An appeal from an adverse decision by the district office.

**Subpart C—Sales Restrictions**

- 203.20 Sales restrictions.
- 203.22 Exclusions.
- 203.23 Returns.

**Subpart D—Samples**

- 203.30 Sample distribution by mail or common carrier.
- 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).
- 203.32 Drug sample storage and handling requirements.