inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.''

(k) *How Supplied.* This section of the labeling shall contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information shall ordinarily include:

(1) The strength of the dosage form, e.g., 10-milligram tablets, in metric system and, if the apothecary system is used, a statement of the strength is placed in parentheses after the metric designation;

(2) The units in which the dosage form is ordinarily available for prescribing by practitioners, e.g., bottles of 100;

(3) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, and National Drug Code; and

(4) Special handling and storage conditions.

(l) *Animal Pharmacology and/or Animal Toxicology.* In most cases, the labeling need not include this section. Significant animal data necessary for safe and effective use of the drug in humans shall ordinarily be included in one or more of the other sections of the labeling, as appropriate. Commonly for a drug that has been marketed for a long time, and in rare cases for a new drug, chronic animal toxicity studies have not been performed or completed for a drug that is administered over prolonged periods or is implanted in the body. The unavailability of such data shall be stated in the appropriate section of the labeling for the drug. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this section may be used.

(m) *''Clinical Studies'' and ''References''.* These sections may appear in labeling in the place of a detailed discussion of a subject that is of limited interest but nonetheless important. A reference to a specific important clinical study may be made in any section of the format required under §§ 201.56 and 201.57 if the study is essential to an understandable presentation of the available information. References may appear in sections of the labeling format, other than the ''Clinical Studies'' or ''References'' section, in rare circumstances only. A clinical study or reference may be cited in prescription drug labeling only under the following conditions:

(1) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning an indication for use of the drug, the reference shall be based upon, or the clinical study shall constitute, an adequate and well-controlled clinical investigation under § 314.126(b) of this chapter.

(2) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks shall also be identified or discussed in the appropriate section of the labeling for the drug.

[44 FR 37462, June 26, 1979, as amended at 55 FR 11576, Mar. 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under § 201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of § 314.126(b) of this chapter shall be submitted in writing as provided in § 314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20587, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990]

§ 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

(a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §§ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the

requirements set forth in the regulations, with the following exceptions:

(1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.

(2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

(3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

Effective	Revised labeling due	Drug class	Mail routing code
		BIOLOGICS	
Nov. 1, 1982	Nov. 1, 1980	Bacterial vaccines and antigens with no U.S. standard of potency.	HFB–240
Do	do	Skin test antigens	HFB–240
Nov. 1, 1982 [1]	Nov. 1,1980 [2]	Bacteral vaccines and toxoids with standards of potency.	HFB–240
Do	do	Viral and rickettsial vaccines	HFB–240
Do	do	Allergenic extracts	HFB–240
Do	do	Blood and blood derivatives	HFB–240
		NEW DRUGS AND ANTIBIOTIC DRUGS	
Nov. 1, 1982	Nov. 1, 1980	Antiarrhythmics	HFD–110
Do	do	Replenishers and regulators of electrolytes and water balance	HFD–110, HFD–510, and HFD–160
Do	do	Anticonvulsants	HFD–120
Do	do	Adrenal corticosteroids	HFD–510 and HFD–150
Do	do	Aminoglycosides	HFD–520
Do	do	Scabicides	Do.
Do	do	Pediculicides	Do.
Do	do	General anesthetics	HFD–160
Dec. 1, 1982	Dec. 1, 1980	Antivirals	HFD–520
Do	do	Dermatologics	Do.
Jan. 1, 1983	Jan. 1, 1981	Glaucoma ophthalmics	HFD–520
Do	do	Topical otics	Do.
Feb. 1, 1983	Feb. 1, 1981	Antispasmodics	HFD–110
Do	do	Anticholinergics	Do.
Do	do	Diuretics	Do.
Do	do	Narcotic antagonists	HFD–120
Do	do	Alcohol antagonists	Do.
Do	do	Antipsychotics/antimanics	Do.
Do	do	Androgens	HFD–510
Do	do	Anabolic steroids	Do.
Do	do	Hyperlipidemia	Do.
Do	do	Anthelmintics	HFD–520
Do	do	Antigout	HFD–150
Mar. 1, 1983	Mar. 1, 1981	Vaginal antibiotics	HFD–520
Apr. 1, 1983	Apr. 1, 1981	Cephalosporins	HFD–520
May 1, 1983	May 1, 1981	General analgesics	HFD–120
Do	do	Anterior pituitary hormones	HFD–510
Do	do	Hypothalamic hormones	Do.
Do	do	Progestins	Do.
Do	do	Mydriatic ophthalmics	HFD–520
Do	do	Cycloplegic ophthalmics	Do.
Do	do	Radiopharmaceuticals, diagnostic	HFD–150
Do	do	Radiopharmaceuticals, therapeutic	Do.
Do	do	Contrast agents diagnostic radiopaque	Do.
Do	do	Local anesthetics	HFD–160
Do	do	Antihistamines	Do.
June 1, 1983	June 1, 1981	Antifungals	HFD–520

Effective	Revised labeling due	Drug class	Mail routing code
July 1, 1983 ..	July 1, 1981 ..	Antidiarrheals	HFD–110
Do	.....do	Cardiac glycosides	Do.
Do	.....do	Sedatives	HFD–120
Do	.....do	Hypnotics	Do.
Do	.....do	Tetracyclines	HFD–520
Aug. 1, 1983	Aug. 1, 1981	Calcium metabolism	HFD–510
Do	.....do	Vitamins and minerals	Do.
Do	.....do	Antiinfective ophthalmics	HFD–520
Do	.....do	Antiinflammatory ophthalmics	Do.
Sept. 1, 1983	Sept. 1, 1981	Antihypertensives	HFD–110
Do	.....do	Drugs indicated for extrapyramidal movement disorders	HFD–120
Do	.....do	Antiprotozoals	HFD–520
Oct. 1, 1983 ..	Oct. 1, 1981	Penicillins	HFD–520
Nov. 1, 1983	Nov. 1, 1981	Blood glucose regulators (except sulfonylureas)	HFD–510
Oct. 9, 1984 ..	July 10, 1984	Sulfonylurea blood glucose regulators	HFN–130
Nov. 1, 1983	Nov. 1, 1981	Drugs indicated for parenteral nutrition	HFD–510 and HFD–160
Do	.....do	Drugs indicated for enteral nutrition	Do.
Do	.....do	Miscellaneous ophthalmics	HFD–520
Do	.....do	Immunomodulators	HFD–150
Dec. 1, 1983	Dec. 1, 1981	Anticoagulants	HFD–110
Do	.....do	Thrombolytics	Do.
Do	.....do	Drugs indicated for acid peptic disorders	Do.
Do	.....do	Antidepressants	HFD–120
Do	.....do	Drugs indicated for skeletal muscle hyperactivity	Do.
Do	.....do	Sulfonamides and related sulfa compounds	HFD–520
Do	.....do	Dental preparations	HFD–160
Jan. 1, 1984 ..	Jan. 1, 1982	Miscellaneous antibacterials	HFD–520
Feb. 1, 1984	Feb. 1, 1982	Drugs indicated for infertility	HFD–510
Do	.....do	Thyroids	Do.
Do	.....do	Antithyroids	Do.
Do	.....do	Polymyxins	HFD–520
Do	.....do	Antineoplastics	HFD–150
Mar. 1, 1984	Mar. 1, 1982	Urinary tract stimulants	HFD–110
Do	.....do	Urinary tract relaxants	Do.
Do	.....do	Antimigraine	HFD–120
		Antimycobacterials (including antileprosy)	HFD–520
Do	.....do	Adjuncts to anethesia	HFD–160
Apr. 1, 1984 ..	Apr. 1, 1982	Antianginals	HFD–110
Do	.....do	Laxatives	Do.
Do	.....do	CNS stimulants	HFD–120
Do	.....do	Anorexiants	Do.
Do	.....do	Chloramphenicol and derivatives	HFD–520
May 1, 1984 ..	May 1, 1982	Drugs indicated for vertigo/motion sickness/vomiting	HFD–120
Do	.....do	Antidiuretics	HFD–510
Do	.....do	Contraceptives	Do.
Do	.....do	Macrolides	HFD–520
Do	.....do	Lincosamides	Do.
Do	.....do	Antiarthritics	HFD–150
Do	.....do	Antitussives	HFD–160
Do	.....do	Expectorants	Do.
Do	.....do	Inhalants	Do.
June 1, 1984	June 1, 1982	Urinary tract antiseptics	HFD–520
July 1, 1984 ..	July 1, 1982 ..	Chelating agents/heavy metal antagonists	HFD–110
Do	.....do	All other gastrointestinal drugs	HFD–110
Do	.....do	Antianxiety	HFD–120
Do	.....do	Drugs indicated for myasthenia gravis	HFD–120
Do	.....do	All other antiinfective drugs	HFD–520
Do	.....do	Bronchodilators/antiasthmatics	HFD–160
Aug. 1, 1984	Aug. 1, 1982	Estrogens	HFD–510
Do	.....do	Uterine stimulants	HFD–510
Do	.....do	Uterine relaxants	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock	HFD–110
Oct. 1, 1984 ..	Oct. 1, 1982	All other cardiac drugs	HFD–110
Do	.....do	Nasal decongestants	HFD–160
Nov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	

[1] Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).
[2] Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]