

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 ini-

tially 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subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.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
Dodo	Skin test antigens	HFB-240
Nov. 1, 1982 ¹	Nov. 1, 1980 ²	Bacterial vaccines and toxoids with standards of potency.	HFB-240
Dodo	Viral and rickettsial vaccines	HFB-240
Dodo	Allergenic extracts	HFB-240
Dodo	Blood and blood derivatives	HFB-240
NEW DRUGS AND ANTIBIOTIC DRUGS			
Nov. 1, 1982	Nov. 1, 1980	Antiarrhythmics	HFD-110
Dodo	Replenishers and regulators of electrolytes and water balance ...	HFD-110, HFD-510, and HFD-160
Dodo	Anticonvulsants	HFD-120
Dodo	Adrenal corticosteroids	HFD-510 and HFD-150
Dodo	Aminoglycosides	HFD-520
Dodo	Scabicides	Do.
Dodo	Pediculicides	Do.

Effective	Revised labeling due	Drug class	Mail routing code
Dodo	General anesthetics	HFD-160
Dec. 1, 1982 ..	Dec. 1, 1980 ..	Antivirals	HFD-520
Dodo	Dermatologics	Do.
Jan. 1, 1983 ..	Jan. 1, 1981 ..	Glaucoma ophthalmics	HFD-520
Dodo	Topical otics	Do.
Feb. 1, 1983 ..	Feb. 1, 1981 ..	Antispasmodics	HFD-110
Dodo	Anticholinergics	Do.
Dodo	Diuretics	Do.
Dodo	Narcotic antagonists	HFD-120
Dodo	Alcohol antagonists	Do.
Dodo	Antipsychotics/antimanics	Do.
Dodo	Androgens	HFD-510
Dodo	Anabolic steroids	Do.
Dodo	Hyperlipidemia	Do.
Dodo	Anthelmintics	HFD-520
Dodo	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
Dodo	Anterior pituitary hormones	HFD-510
Dodo	Hypothalamic hormones	Do.
Dodo	Progestins	Do.
Dodo	Mydriatic ophthalmics	HFD-520
Dodo	Cycloplegic ophthalmics	Do.
Dodo	Radiopharmaceuticals, diagnostic	HFD-150
Dodo	Radiopharmaceuticals, therapeutic	Do.
Dodo	Contrast agents diagnostic radiopaque	Do.
Dodo	Local anesthetics	HFD-160
Dodo	Antihistamines	Do.
June 1, 1983 ..	June 1, 1981 ..	Antifungals	HFD-520
July 1, 1983 ..	July 1, 1981 ..	Antidiarrheals	HFD-110
Dodo	Cardiac glycosides	Do.
Dodo	Sedatives	HFD-120
Dodo	Hypnotics	Do.
Dodo	Tetracyclines	HFD-520
Aug. 1, 1983 ..	Aug. 1, 1981 ..	Calcium metabolism	HFD-510
Dodo	Vitamins and minerals	Do.
Dodo	Antiinfective ophthalmics	HFD-520
Dodo	Antiinflammatory ophthalmics	Do.
Sept. 1, 1983 ..	Sept. 1, 1981 ..	Antihypertensives	HFD-110
Dodo	Drugs indicated for extrapyramidal movement disorders	HFD-120
Dodo	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
Dodo	Drugs indicated for enteral nutrition	Do.
Dodo	Miscellaneous ophthalmics	HFD-520
Dodo	Immunomodulators	HFD-150
Dec. 1, 1983 ..	Dec. 1, 1981 ..	Anticoagulants	HFD-110
Dodo	Thrombolytics	Do.
Dodo	Drugs indicated for acid peptic disorders	Do.
Dodo	Antidepressants	HFD-120
Dodo	Drugs indicated for skeletal muscle hyperactivity	Do.
Dodo	Sulfonamides and related sulfa compounds	HFD-520
Dodo	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
Dodo	Thyroids	Do.
Dodo	Antithyroids	Do.
Dodo	Polymyxins	HFD-520
Dodo	Antineoplastics	HFD-150
Mar. 1, 1984 ..	Mar. 1, 1982 ..	Urinary tract stimulants	HFD-110
Dodo	Urinary tract relaxants	Do.
Dodo	Antimigraine	HFD-120
Dodo	Antimycobacterials (including antileprosy)	HFD-520
Dodo	Adjuncts to anesthesia	HFD-160
Apr. 1, 1984 ..	Apr. 1, 1982 ..	Antianginals	HFD-110
Dodo	Laxatives	Do.
Dodo	CNS stimulants	HFD-120
Dodo	Anorexiant	Do.
Dodo	Chloramphenicol and derivatives	HFD-520
May 1, 1984 ..	May 1, 1982 ..	Drugs indicated for vertigo/motion sickness/vomiting	HFD-120

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Effective	Revised labeling due	Drug class	Mail routing code
Dodo	Antidiuretics	HFD-510
Dodo	Contraceptives	Do.
Dodo	Macrolides	HFD-520
Dodo	Lincosamides	Do.
Dodo	Antiarthritics	HFD-150
Dodo	Antitussives	HFD-160
Dodo	Expectorants	Do.
Dodo	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
Dodo	All other gastrointestinal drugs	HFD-110
Dodo	Antianxiety	HFD-120
Dodo	Drugs indicated for myasthenia gravis	HFD-120
Dodo	All other antiinfective drugs	HFD-520
Dodo	Bronchodilators/antiasthmatics	HFD-160
Aug. 1, 1984	Aug. 1, 1982	Estrogens	HFD-510
Dodo	Uterine stimulants	HFD-510
Dodo	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
Dodo	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]

EFFECTIVE DATE NOTE: At 69 FR 266, Jan. 5, 2004, §201.59 was amended in the BIOLOGICS section of the table, under "Mail Routing Code" by removing "HFB-240" everywhere it appears and adding in its place "HFM-99"; in the BIOLOGICS section of the table, under the headings "Effective" and "Revised labeling due" by revising the entries for the drug classes "Bacterial vaccines and toxoids with standards of potency" and "Viral and rick-

ettsial vaccines" and in the NEW DRUG AND ANTIBIOTIC DRUGS section of the table for the drug class "Sulfonylurea blood glucose regulators", under "Mail routing code," by removing "HFN-130" and adding in its place "HFM-99", effective Jan. 4, 2003. In a document filed in the Office of the Federal Register on Jan. 6, 2004, the effective date was corrected to read Jan. 4, 2005. At 69 FR 1320, Jan. 8, 2004, the effective date was corrected to read Jan. 4, 2005. For the convenience of the user, the revised text follows:

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

- (a) * * *
- (3) * * *

Effective	Revised labeling due	Drug class	Mail routing code
Biologics			
July 5, 2006	See footnote ³	Bacterial vaccines and toxoids with standards of potency	HFM-99
*	*	*	*
Nov. 1, 1982 ¹	Nov. 1, 1980 ²	Viral and rickettsial vaccines	HFM-99
*	*	*	*
New Drugs and Antibiotic Drugs			
Oct. 9, 1984	July 10, 1984	Sulfonylurea blood glucose regulators	HFM-99
*	*	*	*

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 § 601.25(g) of this chapter.
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 § 601.25(g) of this chapter.
³ FDA has determined that a review of product labeling under this section is unnecessary.