

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subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.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 |
| Do |do | Skin test antigens | HFB-240 |
| Nov. 1, 1982 ¹ | Nov. 1, 1980 ² | Bacterial 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. |