

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