

(d) In the "Precautions" section, under the "Information for Patients" subsection, the labeling must state:

Patients should be counseled that antibacterial drugs including (*insert name of antibacterial drug product*) should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When (*insert name of antibacterial drug product*) is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by (*insert name of antibacterial drug product*) or other antibacterial drugs in the future.

[68 FR 6081, Feb. 6, 2003]

§ 201.25 Bar code label requirements.

(a) *Who is subject to these bar code requirements?* Manufacturers, repackers, relabelers, and private label distributors of a human prescription drug product or an over-the-counter (OTC) drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to these bar code requirements unless they are exempt from the registration and drug listing requirements in section 510 of the Federal Food, Drug, and Cosmetic Act.

(b) *What drugs are subject to these bar code requirements?* The following drug products are subject to the bar code label requirements:

(1) Prescription drug products, however:

(i) The bar code requirement does not apply to the following entities:

- (A) Prescription drug samples;
- (B) Allergenic extracts;
- (C) Intrauterine contraceptive devices regulated as drugs;
- (D) Medical gases;
- (E) Radiopharmaceuticals; and
- (F) Low-density polyethylene form fill and seal containers that are not packaged with an overwrap.

(ii) The bar code requirement does not apply to prescription drugs sold by a manufacturer, repacker, relabeler, or private label distributor directly to patients, but versions of the same drug product that are sold to or used in hos-

pitals are subject to the bar code requirements.

(2) Biological products; and

(3) OTC drug products that are dispensed pursuant to an order and are commonly used in hospitals. For purposes of this section, an OTC drug product is "commonly used in hospitals" if it is packaged for hospital use, labeled for hospital use (or uses similar terms), or marketed, promoted, or sold to hospitals.

(c) *What does the bar code look like? Where does the bar code go?*

(1) Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN.UCC) or Health Industry Business Communications Council (HIBCC) standards. Additionally, the bar code must:

(i) Be surrounded by sufficient blank space so that the bar code can be scanned correctly; and

(ii) Remain intact under normal conditions of use.

(2) The bar code must appear on the drug's label as defined by section 201(k) of the Federal Food, Drug, and Cosmetic Act.

(d) *Can a drug be exempted from the bar code requirement?*

(1) On our own initiative, or in response to a written request from a manufacturer, repacker, relabeler or private label distributor, we may exempt a drug product from the bar code label requirements set forth in this section. The exemption request must document why:

(i) compliance with the bar code requirement would adversely affect the safety, effectiveness, purity or potency of the drug or not be technologically feasible, and the concerns underlying the request could not reasonably be addressed by measures such as package redesign or use of overwraps; or

(ii) an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.

(2) Requests for an exemption should be sent to the Office of New Drugs (HFD-020), Center for Drug Evaluation

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and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (requests involving a drug product) or to the Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 (requests involving a biological product).

[69 FR 9170, Feb. 26, 2004]

EFFECTIVE DATE NOTE: At 69 FR 9170, Feb. 26, 2004, §201.25 was added, effective Apr. 26, 2004.

Subpart B—Labeling Requirements for Prescription Drugs and/or Insulin

§ 201.50 Statement of identity.

(a) The label of prescription and insulin-containing drugs in package form shall bear as one of its principal features a statement of the identity of the drug.

(b) Such statement of identity shall be in terms of the established name of the drug. In the case of a prescription drug that is a mixture and that has no established name, the requirement for statement of identity shall be deemed to be satisfied by a listing of the quantitative ingredient information as prescribed by §201.10.

(c) The statement of identity of a prescription drug shall also comply with the placement, size and prominence requirements of §201.10.

[40 FR 13998, Mar. 27, 1975, as amended at 63 FR 26698, May 13, 1998]

§ 201.51 Declaration of net quantity of contents.

(a) The label of a prescription or insulin-containing drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement of quantity of drugs in tablet, capsule, ampule, or other unit dosage form shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in terms of fluid measure

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if the drug is liquid. When the drug quantity statement is in terms of the numerical count of the drug units, it shall be augmented to give the weight or measure of the drug units or the quantity of each active ingredient in each drug unit or, when quantity does not accurately reflect drug potency, a statement of the drug potency.

(b) Statements of weight of the contents shall in the case of prescription drugs be expressed in terms of avoirdupois pound, ounce, and grain or of kilogram, gram, and subdivisions thereof. A statement of liquid measure of the contents shall in the case of prescription drugs be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, fluid-ounce, and fluid-dram subdivisions thereof, or of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.). A statement of the liquid measure of the contents in the case of insulin-containing drugs shall be expressed in terms of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.).

(c) The declaration shall contain only such fractions as are generally used in expressing the quantity of the drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(d) The declaration shall appear as a distinct item on the label and, in the case of large volume parenterals, may be embossed on the glass.

(e) The declaration shall accurately reveal the quantity of drug in the package exclusive of wrappers and other material packed therewith.

(f) A statement of the quantity of a prescription or insulin-containing drug in terms of weight or measure applicable to such drug, under the provisions of paragraph (a) of this section, shall express with prominence and conspicuousness the number of the largest whole unit, as specified in paragraph (b) of this section, that are contained in the package. Any remainder shall be expressed in terms of common or decimal fractions of such unit or in terms of the next smaller whole unit and common or decimal fractions thereof.