

§ 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 OTC drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to the bar code requirements in this section unless they are exempt from the registration and drug listing requirements in section 510 of the act.

(b) What drugs are subject to these bar code requirements? The following drug products are subject to the bar code label requirements: Prescription drug products (excluding samples), biological products, and over-the-counter drug products that are dispensed under an order and are commonly used in hospitals. For purposes of this section, an over-the-counter drug product is "commonly used in hospitals" if it is packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals.

(c) What does the bar code look like, and where does the bar code go?

(1) Each drug product described in paragraph (b) in 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 Uniform Code Council (UCC/EAN) 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 act.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

3. The authority citation for part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

4. Section 606.121 is amended by revising paragraph (c)(13) to read as follows:

§ 606.121 Container label.

* * * * *

(c) * * *

(13) The container label must bear encoded information that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research.

(i) Who is subject to this machine-readable requirement? All blood establishments that manufacture, process, repack, or relabel blood or blood components intended for transfusion and regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) What blood products are subject to this machine-readable requirement? All blood and blood components intended for transfusion are subject to the machine-readable information label requirement in this section.

(iii) What information must be machine-readable? Each label must have machine-readable information that contains, at a minimum:

- (A) A unique facility identifier,
- (B) Lot number relating to the donor,
- (C) Product code, and
- (D) ABO and Rh of the donor.

(iv) How must the machine-readable information appear? The machine-readable information must:

(A) Be unique to the blood or blood component;

(B) Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly; and

(C) Remain intact under normal conditions of use.

(v) Where does the machine-readable information go? The machine-readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

5. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

6. Section 610.67 is added to read as follows:

§ 610.67 Bar code label requirements.

Unless it is regulated as a device, a biological product must comply with the bar code requirements at § 201.25 of this chapter.

Dated: January 24, 2003.

Mark B. McClellan,
Commissioner of Food and Drugs.

Dated: February 6, 2003.

Tommy G. Thompson,
Secretary of Health and Human Services.
[FR Doc. 03-5205 Filed 3-13-03; 8:45 am]

BILLING CODE 4160-01-S