

on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.

We intend to make a machine-readable information requirement effective for blood and blood components 3 years after we publish a final rule in the **Federal Register**. Changes to existing blood and blood component labels would require the submission of an annual report as described in 21 CFR 601.12(f)(3).

I. What Bar Code Requirement Would Apply to Biological Products? (Proposed § 610.67)

The proposal would create a new § 610.67 that describes a new labeling requirement for biological products (other than blood and blood products, which would be covered by proposed § 606.121(c)(13)). Proposed § 610.67 would simply state that biological products must be labeled in accordance with the bar code requirements at § 201.25. In addition to the separate authority provided by section 351(j) of the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act also applies to a biological product that is regulated under section 351 of the Public Health Service Act.

The proposal would not apply to biological products that are regulated as devices for the reasons we stated earlier in section II.B.2.d of this document.

III. Legal Authority

We believe we have the authority to impose a bar coding requirement for the efficient enforcement of various sections of the act. These include sections 201(n), 201(p), 501, 502, 503, 505, and 701(a)) (21 U.S.C. 321(n), 321(p), 351, 352, 353, 355, and 371(a)) of the act, and sections 351 and 361 of the Public Health Services Act.

A bar coding requirement for drugs would permit the efficient enforcement of the misbranding provisions in section 502(a) and (f) of the act, as well as the safety and effectiveness provisions of sections 201(p) and 505 of the act. Bar coding is expected to significantly advance: (1) The provision of adequate directions for use to persons prescribing, dispensing, and administering the drug; (2) the provision of adequate warnings against use by patients where a drug's use may be dangerous to health; and (3) the prevention of unsafe use of prescription drugs.

Section 502(a) of the act prohibits false or misleading labeling of drugs. This prohibition includes, under section 201(n) of the act, failure to reveal material facts relating to potential consequences under customary

conditions of use. Information in a database that could be readily accessed through the use of a bar code, such as the drug strength, dosage form, route of administration, and active ingredient and drug interactions is material with respect to consequences which might result from use of the drug under such conditions of use. Because all the drugs (prescription drugs and the subset of covered OTC drugs) covered by this proposal may be used in the hospital setting, such use in hospitals can be considered the "conditions of use as are customary or usual." As is made clear in section I of this document, bar coding can be expected to reduce the incidence of the following types of medication errors:

- Administering the wrong dose to a patient;
- Administering a drug to a patient who is known to be allergic;
- Administering the wrong drug to a patient or administering a drug to the wrong patient;
- Administering the drug incorrectly;
- Administering the drug at the wrong time; and
- Missing or duplicating doses.

Because information accessed through use of the bar code will reveal material facts relating to potential consequences under customary conditions of use, the bar code requirements are justified under section 502(a) of the act.

Section 502(f) of the act requires drug labeling to have adequate directions for use, adequate warnings against use by patients where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration, in such manner and form, as necessary to protect users. The bar code would make it easier for the person administering the drug to have full access to all of the drug's labeling information, including directions for use, warnings and contraindications. Moreover, because the bar code's information would go to the computer where it could be compared against the patient's drug regimen and medical record, the person administering the drug will be able to determine whether the right patient is receiving the right drug (including the right dose of that drug in the right route of administration) at the right time. The person administering the drug will also be able to avoid giving products to a patient who might be allergic to, or otherwise unable to take, a particular drug. Because the bar code will facilitate access to information including adequate directions for use and adequate warnings, the bar code requirements are justified under section 502(f) of the act.

In addition to the misbranding provisions, the premarket approval provisions of the act authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act, we will approve a new drug application (NDA) only if the drug is shown to be safe and effective for its intended use under the conditions set forth in the drug's labeling. Bar coding will ensure the safe and effective use of drugs by reducing the number of medication errors in hospitals and other health care settings. Such coding would allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is given to the right patient at the right time.

Section 505(b)(1)(D) of the act requires a new drug application to contain a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. The same requirement exists for abbreviated new drug applications (see section 505(j)(2)(A)(vi) of the act) and for biological products (see section 351(a)(2)(B)(i)(II) of the Public Health Service Act). Information in the bar code would reflect the facilities and controls used to manufacture the product. As described in section II.C.1 of this document, the NDC number would identify the manufacturer, product, and package.

A bar coding requirement also would permit the efficient enforcement of the adulteration provisions of the act. A regulation requiring the bar coding of products should avert unintentional mix up and mislabeling of drugs during labeling, packaging, relabeling, and repackaging. A bar coding requirement therefore prevents adulteration under section 501(a)(2)(B) of the act. It is a manufacturing method or control necessary to ensure that a drug product has the identity and strength its labeling represents it to have, and meets the quality and purity characteristics which the drug purports or is represented to possess.

Requiring that the bar code be surrounded by sufficient blank space, and remain intact under normal conditions of use, would also further the efficient enforcement of section 502(c) of the act. Section 502(c) of the act provides that a drug product is misbranded if: Any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with