

We recognize that it is possible for a manufacturer to sell an OTC drug to a wholesaler or retailer who then re-sells the product, without making any changes to the product, directly to a hospital without the manufacturer's knowledge. We believe that, in most cases, the manufacturer would know that the product may be sold to a hospital (e.g., because of the product's labeling, packaging). However, there may be rare instances when the manufacturer may not have had reason to believe that its product would be sold to a hospital. Therefore, if the OTC drug is not packaged, labeled, marketed, promoted, or sold to a hospital as described above, we would not expect the OTC drug's manufacturer to comply with the bar code requirement.

Proposed § 201.25(b) would also include the phrase "dispensed pursuant to an order" with regard to OTC drugs. Some products in hospitals that are traditional types of OTC drugs, such as aspirin or acetaminophen, are dispensed pursuant to a physician's order. Other products that are regulated as OTC drugs are not dispensed pursuant to a physician's order. For example, a hospital might provide fluoride toothpaste or mouth rinses to a patient without a physician's order. Because these products are not likely to contribute to medication errors, the proposal would focus only on those OTC drugs used in hospitals that are dispensed pursuant to an order.

We recognize that there may be other ways to describe the types of OTC drugs that should have a bar code. For example, we considered requiring bar codes for OTC drugs "sold directly to hospitals." If the proposal pertained to OTC drugs sold directly to hospitals, most manufacturers, repackers, relabelers, and private label distributors who sold their products directly to hospitals would be subject to the rule, but the bar code requirement could be avoided by selling the OTC drugs to distributors or other third parties for resale to hospitals. We considered applying the bar code requirement to OTC drugs that are labeled for use in an institutional setting. This alternative is equally difficult to administer because it is easily circumvented by relabeling the drug. We considered requiring bar codes on OTC drugs commonly used in health care facilities (rather than hospitals), but could not determine whether clinics, nursing homes, and other facilities would invest in bar code scanning equipment.

We specifically invite comment on the terms we should use to describe OTC drugs that should be subject to the

bar code requirement. Comments should also consider the following issues:

- Who should be required to apply the bar code on the OTC drugs that are subject to a bar code requirement? If the proposal refers to OTC drugs "commonly used in hospitals," will manufacturers, repackers, and relabelers know which products require a bar code?

- Do the terms "dispensed pursuant to an order" sufficiently distinguish between those OTC drugs that are likely to be involved in medication errors from those that are not?

c. *Which Blood Products Are Covered?* Current FDA regulations state that the container label on blood and blood products "may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research" (see 21 CFR 606.121(c)(13)), but they do not require the use of such symbols nor do they specify a particular symbol. Correct identification of blood is essential because transfusion errors or use of contaminated blood can have serious adverse health consequences for a patient. For example, one comment submitted in response to the public meeting stated that transfusion errors cause as many as two dozen patient deaths annually and that the number may be under reported. Consequently, we propose to require that blood and blood component container labels bear "encoded information that is machine-readable" and approved for use by the Director of CBER. We address this specific requirement at proposed § 606.121(c)(13), which we discuss more fully in section II.H of this document.

d. *Why Did We Omit Medical Devices From the Rule?* At this time, we are omitting medical devices from this rulemaking. We recognize that different issues arise for devices than for drugs, so further consideration is needed regarding the need for putting bar codes on medical devices. We will continue to study whether to develop a proposed rule to require bar codes on medical devices to prevent or reduce medication errors.

#### C. *What Would the Bar Code Contain? (Proposed § 201.25(c)(1))*

##### 1. *What Is the National Drug Code Number, and Why Would It Be Helpful?*

Proposed § 201.25(c)(1) would require the bar code to contain, at a minimum, the drug's NDC number. The NDC number identifies each drug product that is listed under section 510 of the act. Most persons attending the public meeting agreed that a bar code should,

at a minimum, contain the drug's NDC number.

To complement this proposed requirement, we intend to revise our drug establishment registration and listing regulations to redefine the NDC number and to make the NDC number unique and more useful to informational databases, whether those databases are created for purposes of preventing medication errors, obtaining the latest information about a specific drug, or tracking drug use or distribution. We hope to publish a proposed drug establishment registration and listing rule in the **Federal Register** soon.

Please note that proposed § 201.25(c)(1) would require the bar code to contain, at a minimum, the NDC number. Several comments submitted in response to the public meeting indicated that some drug manufacturers already place bar codes on their products, but that the bar code contains a numerical identifier that contains, but is not identical to, the NDC number. For example, some comments suggested that the bar code contain the International Article Number (EAN) or the Global Trade Item Number (GTIN). We are aware that some drug companies already use a bar code containing the:

- Universal Product Code number (UPC). The UPC is usually a 12-digit number that may or may not contain the NDC number within it. For example, if the drug's NDC number were 1234567890, the UPC number might be 312345678906, where the first digit (3) signifies that the product is a drug, and the last digit is a "check digit" that helps confirm that the bar code was read correctly. However, some drugs, particularly OTC drugs, may have a UPC number that does not contain the NDC number;

- International Article Number (EAN). The EAN is a 13-digit number and also contains the NDC number within it; or

- Global Trade Item Number (GTIN). The GTIN is a 14-digit number that contains the NDC number in conjunction with a code that identifies the product's packing level. In the GTIN, the first digit signifies the packaging level.

Thus, under the proposal, the bar code could contain the NDC number alone or the UPC number, EAN number, or GTIN number, as long as the NDC number is present. By making the NDC number the minimum bar code information requirement, firms could continue using various numbering systems (such as the UPC, if the UPC number contains the NDC number, EAN, or GTIN numbers) in their bar codes, thus minimizing or eliminating the need for companies to redesign or generate new bar codes and