

The FDA's Final Rule on Bar Coding

by Susan M. Zordan

On 24 February 2004, the US Food and Drug Administration (FDA) issued a final rule that requires certain human drug and biological product labels to have bar codes. The rule also requires the use of machine-readable information on container labels for blood and blood components. A section, 21 CFR 201.25, has been added to the *Code of Federal Regulations* for drugs, and section 21 CFR 610.67 has been added for biological products other than blood and blood components. The preexisting voluntary provision for machine-readable symbols on blood and blood-component labels has been amended into a requirement in revised section 21 CFR 606.121(c)(13).

PATIENT SAFETY IS THE GOAL

The intent of the rule is to help hospitals and healthcare institutions use technological solutions to reduce the number of preventable adverse drug events (ADEs) and acute hemolytic transfusion reactions (AHTRs) associated with medication errors. Such errors can result in serious injury or death for patients, and they represent a significant economic cost. When the bar-code rule is implemented, healthcare professionals can use bar-code



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scanning equipment along with computerized databases to verify that the right drug, dose, and route of administration are given to the right patient at the right time and to help prevent transfusion errors for blood and blood components.

Hospitals are not required to use or adopt bar-code technology and can decide whether to take advantage of bar codes on human drugs and biological products. However, in its preamble to the final rule, the FDA stated that regulatory intervention to establish a standardized system of bar codes was needed to motivate hospital administrators to adopt an important health-saving technology that could reduce the number of ADEs and AHTRs.

TECHNICAL REQUIREMENTS

Bar codes will provide unique identifying information about drugs to be administered. Each must be a linear bar code that meets standards of the European Article Number-Uniform Code Council (EAN.UCC, www.uc-council.org/ean_ucc_system) or the Health Industry Business Communications Council (HIBCC, www.hibcc.org/barcode1.htm). Minimally, a bar code must contain the National Drug Code (NDC) number that identifies the dosage, strength, nature, and form of each product. The FDA maintains a computerized database of NDC numbers and makes it available for

use in commercial computerized systems that can provide bedside bar-code identification.

Under current FDA regulations for labeling of blood and blood products, 21 CFR 606.121(c)(13), encoding information in machine-readable symbols is voluntary.

Under the new final rule, the following information is required in a machine-readable format approved for use by the director of the Center for Biologics Evaluation and Research (CBER): a unique facility identifier, a lot number relating to the donor, a product code, and the ABO and Rh of the donor. That information must be unique to the blood or blood component.

Both the bar coding for drug products and the machine-readable information for blood and blood products must have sufficient blank space around them to allow for accurate scanning. The bar code must remain intact under normal use conditions and appear on the product's label.

AFFECTED PRODUCTS

The final rule applies to most prescription drugs, biological products, and over-the-counter (OTC) drugs commonly used in hospitals and dispensed under an order. Prescription drugs sold directly to patients by a manufacturer, repacker, relabeler, or private-label distributor are not covered by the requirements, but versions of the same drugs sold to or used in hospitals are subject to them.

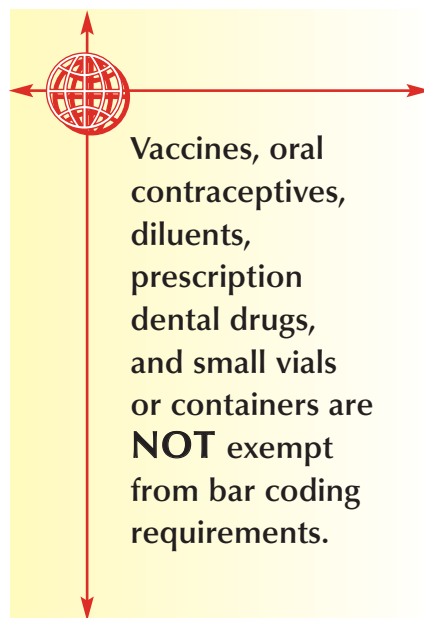
The following OTC drug products must have bar codes on their labels: those packaged for hospital use; labeled for hospital use; or marketed, promoted, or sold to hospitals and dispensed under an order. However, OTC manufacturers may make other packages of the same product for retail sale that do not require bar codes.

All blood and blood components intended for transfusion are covered by the machine-readable information requirement in the final rule. 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 are subject to the machine-readable requirement.

EXEMPTIONS FROM THE FINAL RULE

In response to comments on the 14 March 2003 proposed rule, the FDA evaluated requests for several types of exemptions. Prescription



drug samples, allergenic extracts, intrauterine contraceptive devices regulated as drugs, medical gases, radiopharmaceuticals, low-density polyethylene form-fill-and-seal containers packaged without an overwrap, and medical devices regulated by CBER are exempted from the bar coding requirements. Investigational new drugs and devices are not covered by the bar code requirements. Blood and blood components intended for transfusion do not require bar codes on the labels, but they do require machine-readable information as described above.

Vaccines, oral contraceptives, diluents, prescription dental drugs, and small vials or containers are *not* exempt from bar coding requirements.

The FDA also clarified what entities are exempt from the bar code requirement. For example, repackers, relabelers, and private-label distributors exempt from FDA establishment registration and drug listing requirements are also exempt from the bar-code requirements. Pharmacies that compound drugs in accordance with section 510(g) of the Food, Drug and Cosmetic Act and are therefore not required to have establishment registrations do not have to include bar codes on their labels either.

The final rule contains a limited, general exemption provision that allows the FDA to grant specific drug product exemptions on its own initiative or in response to a written request from a manufacturer, repacker, relabeler, or private-label distributor under two circumstances: if compliance with the bar-code requirement would adversely affect the safety, effectiveness, purity, or potency of the drug or not be technologically feasible or if an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.

IMPLEMENTATION

The final rule became effective 26 April 2004. Drugs approved on or after that date must comply within 60 days of their approval date. Drugs approved before that date must comply with the bar code requirement within two years of the final rule's effective date: 26 April 2006. Companies should notify the FDA that bar codes have been added to the product's labeling in annual reports as minor label changes.

Blood and blood components must comply within two years of the effective date of the final rule. 🌐

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