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NEWS RELEASE

FOR IMMEDIATE RELEASE
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FDA Press Office
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HHS Announces New Requirements for Bar Codes on Drugs and Blood to Reduce Risks of Medication Errors

HHS Secretary Tommy G. Thompson today announced that the Food and Drug Administration is issuing a final rule requiring bar codes on the labels of thousands of human drugs and biological products. The measure will help protect patients from preventable medication errors and reduce the cost of health care and represents a major step forward in the department's efforts to harness information technology to promote higher quality care.

"Bar codes can help doctors, nurses and hospital make sure that they give their patients the right drug at the appropriate dosage," Secretary Thompson said. "By giving health-care providers a way to check medications and dosages quickly, we create an opportunity to reduce the risks of medication errors that can seriously harm patients."

"We're encouraging widespread use of technologies that can help health care providers avoid hundreds of thousands of medication errors," FDA Commissioner Mark B. McClellan, M.D., Ph.D., said. "Bar coding systems have proved their dependability and effectiveness by ensuring the accuracy of a myriad of actions in commerce and industry. We're now advancing the adoption of these systems in settings where they can help save lives."

The FDA rule calls for the inclusion of linear bar codes -- such as are used on millions of packages of consumer goods -- on most prescription drugs and on certain over-the-counter drugs that are commonly used in hospitals and dispensed pursuant to an order. Each bar code for a drug will have to contain, at a minimum, the drug's National Drug Code number. This information will be encoded within the bar code on the label of the product. Companies also may include information about lot number and product expiration dates.

In addition, the rule requires the use of machine-readable information on container labels of blood and blood components intended for transfusion. These labels, which are already used by most blood establishments, contain FDA-approved, machine-readable symbols identifying the collecting facility, the lot number relating to the donor, the product code, and the donor's blood group and type.

The bar-code rule is designed to support and encourage widespread adoption of advanced information systems that, in some hospitals, have reduced medication error rates by as much as 85 percent. In these institutions, patients are provided with identification bracelets that bear a bar code, which identifies the patient. The health care professional then scans the patient's bar code and scans the drug's bar code. The information system then compares the patient's drug regimen information to the drug to verify that the right patient is getting the right drug, at the right time, and at the right dose and route of administration. In a study conducted at a Veterans Affairs Medical Center employing such a bar-code scanning system, 5.7 million doses of medication were administered to patients with no medication errors.

FDA estimates that the bar-code rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors over 20 years. The economic benefit of reducing health care costs, reducing patient pain and suffering, and reducing lost work time due to adverse events is estimated to be \$93 billion over the same period.

FDA first proposed bar-code requirements in March 2003. Comments from hospitals, health care professionals, trade and professional associations and others showed widespread support for the approach to improving patient safety and promoting higher quality care.

The final rule applies to most drug manufacturers, repackers, relabelers, private label distributors and blood establishments. New medications covered by the rule will have to include bar codes within 60 days of their approval; most previously approved medicines and all blood and blood products will have to comply with the new requirements within two years.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Email FDA](#)



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