

how we might create a waiver provision that would minimize the potential for misuse of the waiver. We will consider whether to incorporate specific exemptions into the rule.

#### *G. What Is the Proposed Implementation Plan?*

If we issue a final rule to require bar coding, we would require bar codes on human prescription drugs and OTC drugs dispensed under an order and commonly used in hospitals within three years after we publish the final rule in the **Federal Register**. The 3-year period would give affected parties time to obtain NDC numbers, if necessary, exhaust supplies of existing labels, and make new labels that contain the bar code or machine-readable information.

Additionally, because the bar code's addition to a label would be a ministerial act that would not require us to exercise any judgment as to the information being presented, we intend to have firms whose drug products are already approved or marketed notify us about the addition of the bar code to their product labels through an annual report (see § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii) and 601.12(d)). For marketed OTC drugs, there is no comparable, routine reporting requirement if the drug is not the subject of an approved new drug application, and we do not intend to impose any reporting obligation relating to bar codes on OTC drugs.

We recognize that the bar codes' ability to prevent medication errors depends on many external factors outside this rule, such as the availability of bar code scanners, computer software that can process the bar code information and compare it against patient information, training health care professionals to use scanning equipment, and the willingness of hospitals to invest in bar code scanning equipment. However, requiring bar coding on human drugs is a necessary "first step" for promoting the use of technology to combat medication errors (Ref. 42).

We also acknowledge the various comments from the public meeting suggested different implementation periods for this rule. In general, some comments suggested short implementation dates measured in months whereas other comments suggested implementation dates measured in years. A few comments suggested different implementation dates for different products or would have the implementation date depend on the product's potential for harm. Several comments recommended requiring bar codes to contain the NDC

number first, and require the lot number and expiration date at some future date.

We decided on the 3-year implementation date to give affected firms time to redesign their labels and exhaust pre-existing label stocks and to give hospitals time to decide which scanning devices or systems to develop or purchase. Additionally, as we suggested earlier, we want to give hospitals more time to decide whether they would be willing to work with pharmaceutical firms to have other information (such as lot number and expiration date) encoded. While we believe the 3-year implementation date is appropriate, we invite comment on whether the implementation period can and should be shortened.

We decline to create a "phased-in" implementation system whereby we would require the NDC number first, and then require inclusion of lot numbers and expiration dates at a future time. As we explained earlier in section II.C.2 of this document, we lack data that would support requiring lot numbers and expiration dates on bar codes at this time. While we will not object if firms volunteer to encode such information (assuming that they encode the correct information), we will not require or specify any implementation period for the encoding of lot number and expiration date information.

#### *H. How Does This Rule Apply to Blood and Blood Components? (Proposed § 606.121(c)(13))*

Like medication errors, errors involving blood transfusions can result in serious injury or death. For example, one study examined reported transfusion errors occurring between January 1, 1990, and December 31, 1999, from approximately 256 transfusion services in New York (Ref. 43). The study focused on reports involving the administration of a unit of blood to someone other than the intended patient or the issuance of incorrect blood because of a blood bank or phlebotomy error. During the study period, nine million red blood cell and whole-blood units were transfused, and 659 cases of erroneous administration were observed, for a frequency of 1 error per 14,000 transfusions. Five cases resulted in fatalities, at a rate of 1 per 1,800,000 units. In cases where the patient received an incompatible unit, nearly half (47 percent) suffered no ill effects, but 41 percent of the cases resulted in an acute hemolytic reaction, and 2 percent resulted in fatalities (id.) The most common error outside blood banks was administering properly labeled blood to a patient other than the one for whom the unit was intended (37

percent). In blood banks, the study identified issuance of the wrong unit (4 percent) and testing errors (7 percent) as some common errors (id.).

Current FDA regulations, at 21 CFR 606.121(c)(13), state that the container label for blood and blood components "may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research." The reference to "machine-readable symbols" in § 606.121(c)(13) was intended to be flexible and accommodate changes in machine-readable technologies. For example, FDA recognized the use of Codabar (a specific bar code symbology) in 1985, and, in 2000, approved the use of ISBT 128, version 1.2.0 (Ref. 44).

Unlike the situation for other prescription drugs, there is already substantial use of bar codes for blood and blood products. Most blood establishments currently use machine-readable symbols or "ABC Codabar" on their blood and blood component labels. In August, 1989, the International Society for Blood Transfusion (ISBT), an organization established to promote and maintain a high level of ethical, medical, and scientific standards in blood transfusion medicine and science throughout the world, recognized that ABC Codabar, the first bar coding system adopted by the health care industry, was becoming outdated and initiated the design of a new system using the bar code symbology which eventually became known as ISBT 128.

In December, 1996, the International Council for Commonality in Blood Bank Automation (ICCBBA) held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although there was a consensus for use of ISBT 128, some participants expressed concerns regarding implementation time frames and costs of implementation to hospital transfusion services. However, ISBT 128 has numerous advantages over the ABC Codabar. For example, ISBT 128 is more secure, allows more flexibility in coding highly variable information, uses double-density coding to allow more information to be encoded in a limited space, and can be interpreted by the same bar code readers used with ABC Codabar.

The ISBT 128 bar code system established by ISBT is similar, but not identical to, Code 128. ISBT 128 is a copyrighted symbology. The ability to read, store, interpret, transfer, print, or otherwise manipulate ISBT 128 data structures requires registration with the ICCBBA and payment of an annual