

minimizing any disruptions to the companies' international markets.

We recognize that some comments supported the use of a unique identifying number rather than the NDC number. One comment explained that the UPC code that goes on the product label does not always use the NDC number, so if we required the bar code to contain the NDC number, important label changes could go unnoticed if health care professionals relied on the bar codes instead of product labels. The comment suggested that if distributors establish the unique identifying codes and revise those codes when they make label changes, the revised code could then trigger a need for a health care professional administering the drug to read the label and to update its database accordingly. Another comment described the NDC number as a "dumb number" in OTC drugs and suggested following UCC/EAN guidelines instead to identify the product. Another comment stated that OTC drugs should use the UPC number instead of the NDC number because changing UPC bar codes to include the NDC number would result in great expense without a discernable benefit. Additionally, during a meeting with CHPA and others, the industry representatives stated that UPC codes do not always contain NDC numbers, and retailers rely on the UPC codes, so requiring the use of NDC numbers would be disruptive to the industry and retailers. The industry representatives suggested using a unique identifier other than the NDC number.

We decline to require the use of unique identifying numbers other than the NDC number. Through the proposed drug establishment registration and listing rule, the NDC number would become a unique identifying number for listed drugs and correspond to a particular listed drug. If we allowed distributors to assign unique identifying numbers and did not coordinate the assignment of such numbers to drugs, the result could be extremely confusing as distributors could use different identification schemes (such as a mixture of letters, numbers, or other characters). Moreover, creating and maintaining databases on drug products for medication error purposes would become more difficult because identifying information would have to come from multiple sources. For example, the Federal Government might be the source for NDC number information, but firms who created unique, non-NDC identifying numbers would have to provide information on those numbers to the databases themselves if the databases are to be

complete and useful. Multiple information sources would increase the likelihood that some information and databases might not be updated as frequently as others, that some information might be unavailable, or that the information would be presented in different or incompatible ways. While we understand the OTC drug industry's reservations about changing UPC codes to include NDC numbers because of a possible impact on retailers, proposed § 201.25(b) would only require bar codes on OTC drugs that are dispensed pursuant to an order and are commonly used in hospitals, so most OTC drugs should not be affected.

2. Would the Bar Code Be Required to Contain the Lot Number and Expiration Date?

Many organizations and individuals have recommended that the bar code contain information regarding the drug's lot number and expiration date, and others have recommended phasing-in a requirement to have the bar code contain the lot number and expiration date.

We decline to require lot number and expiration date information in the bar code at this time. In general, while lot number and expiration date information would make it easier to identify drugs that had been recalled or were expired, we neither found nor received data to show that the benefits of bar coding lot number and expiration date information would exceed the costs of putting that information in the bar code. There is, however, limited information on the extent to which patient safety is affected by and medication errors occur as a result of taking expired or recalled drugs. We reviewed data from our adverse event reporting system (containing 71,546 cases) and found 90 cases where patients received an expired drug and 21 cases where patients received a recalled drug. Expired drugs may become subpotent and might not have the intended therapeutic effect. They also may contain degradation products associated with aging. Products may be recalled for a variety of reasons including no active ingredient present in the product or contamination of the product that could lead to infection.

We also tabulated data from the Office of Compliance, Center for Drug Evaluation and Research, on the reasons for and the extent to which drug products have been recalled from the market. From fiscal year 1997 through fiscal year 2002, there were 1,230 recalls, of which 97 were Class I (reasonable probability that the use or exposure to the violative product will

cause serious adverse health consequences or death) and 1,133 were Class II (use or exposure of the violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote). Despite this number of recalls for safety and health reasons, we received few reports of adverse events associated with the administration of a recalled drug, and we do not have reliable data that show how often these products were administered to patients.

Thus, based on the data available to us, we cannot determine the magnitude of the public health problem associated with administering expired or recalled products, and we cannot quantify the patient safety benefit associated with requiring lot number and expiration date information in a bar code.

Some comments suggested that requiring lot number and expiration date information in a bar code could have benefits outside the medication error context by making it easier to track or trace products and to identify counterfeit products.

We agree that bar codes may be useful outside the medication error context, but our rule focuses on the use of bar codes to prevent medication errors.

Industry comments indicated that adding lot number and expiration date information to the bar code would adversely affect production line speed. One comment from a drug company predicted that encoding lot number and expiration date information would reduce packaging line speed by 40 percent and cost more than \$4.8 million for its product lines. Another drug industry comment indicated that a requirement to encode lot number and expiration date information could cause companies to reconsider their packaging choices, or require companies to alter their printing methods.

We also note that inclusion of lot number and expiration date information might require the use of a different machine-readable format, such as a two-dimensional symbology, in addition to or as a substitute for a linear bar code, and that could affect a hospital's equipment purchasing decision. Use of nonlinear bar code formats could require the purchase of a different scanning or reading device and also increase a hospital's equipment costs.

Based on the evidence we had and our obligation under Executive Order 12866 to choose regulatory approaches that maximize net benefits, the potential burden of encoding lot number and expiration date information appeared to outweigh the potential benefit at this time. Consequently, the proposed rule