

would not require lot number and expiration date information in the bar code. We will continue to study the issue and invite comments and, more importantly, data on costs and benefits associated with requiring lot number and expiration date information in the bar code. If comments provide information and data to support requiring lot number and expiration date information, we may consider requiring that information with the bar coded NDC number as part of a final rule.

Although the proposed rule would not require the drug's lot number and expiration date to appear in the bar code, the proposed rule would not prohibit the inclusion of such information. In other words, FDA will not object if a manufacturer, repacker, relabeler, or private label distributor were to add the lot number and expiration date to its bar code or add such information in a machine-readable format provided that the lot number and expiration date information is accurate. In a meeting with PhRMA on August 19, 2002, the industry representatives suggested to us that they might add machine-readable lot number and expiration date information if a demand existed for it. (We have placed a memorandum of this meeting in the docket for this rule, along with memoranda of meeting for other meetings we attended.) We do not know how much more such drugs would cost (compared to drugs that only had the NDC number encoded in the bar code) or whether hospitals and other health care facilities would be willing to pay more for drugs that have the NDC number, lot number, and expiration date in a bar code or machine-readable code, but the meeting raises the possibility that market forces could lead to the inclusion of lot numbers and expiration dates in bar codes or other machine-readable formats.

D. Would the Rule Require a Specific Type of Bar Code? (Proposed § 201.25(c)(1))

1. What Did We Hear from the Public Meeting?

In the public meeting notice, we asked whether we should require the use of a specific bar code symbology, such as reduced space symbology (RSS), adopt one symbology over another, or allow for "machine readable" formats (67 FR 41360 at 41361). We also asked for the "pros and cons" of each approach (id.). We had identified RSS as a possible symbology because we knew about industry-conducted pilot studies that used RSS bar codes on small vials

(Ref. 35). Our reasoning was that if RSS symbology could be used on small containers, it could be used on larger containers, too.

The comments we received reflected an array of differing opinions, ranging from the adoption of a specific, non-bar code technology to prescribing no specific symbology or standard at all in order to promote innovation. Two principal, yet contradictory, themes emerged. One view advocated requiring a specific symbology or standard to promote uniformity and to create the conditions whereby hospitals could invest confidently in bar code scanning equipment, without having to buy different pieces of equipment to read different bar codes or other machine readable formats or without having to fear that any equipment purchases would soon become obsolete. Another comment declared that the bar code symbology adopted by FDA should be compatible with current scanning devices used by health care organizations. However, if the rule adopted a single symbology or standard, the rule could affect future innovation in this field, and we would have to engage in new rulemaking to adopt any newer symbology or standard.

The other view stated that we should not select any specific symbology or even require linear bar codes at all; instead, these comments said the rule should require the use of machine-readable or automatic identifier technology, thus creating the conditions under which newer, and perhaps better, technologies could be used in the future. However, the comments and our own analysis suggested that if the rule allowed for multiple symbol types or technologies, hospitals might be confronted with incompatible technologies and decide against buying multiple pieces of equipment. For example, if one drug used an RSS bar code, another used a radio frequency identification format, and a third used a unique, patented, automatic identification technology, a hospital would have to decide whether to buy a bar code scanner, a device to detect the radio frequency information, and a device to detect the patented identifier, or some combination of the three devices. If those costs were too great, the hospital could decide against making any equipment investments altogether, and the benefits from bar coding would not be realized.

Other comments suggested that we require the use of machine-readable codes capable of being read by "machines currently deployed" and "economically available" or use

symbology that is "compatible" with "current scanners."

Some comments suggested that we conduct research to develop time lines for adopting specific bar code symbologies, that we have USP provide bar code standards, or adopt a standard or family of symbologies. Other comments said we should form a group involving various interests to study issues further or create an "automatic identification coordinating council" to ensure that minimum information requirements are met and that the best technology is used.

Deciding whether to require a specific symbology, standard, or an unspecified "machine-readable" symbol was a very difficult decision because of the comments' competing and sometimes incompatible positions. For guidance, we examined how another Federal agency reached a decision when confronted with an analogous problem of whether to require a particular action to accomplish a specific goal or to let market forces decide the outcome. We examined how the Federal Communications Commission (FCC) decided to adopt an order to require all television receivers to include digital television (DTV) reception capability in order to move towards a 2006 target date for a transition to digital television. Congress had imposed a December 31, 2006, target date for the return of the spectrum used by broadcasters for analog channels unless 85 percent of homes in a market could not receive local digital broadcast television signals. The FCC faced a problem; the public was reluctant to buy DTV receivers until there were DTV stations offering attractive DTV programs, but broadcasters lacked the incentive to provide such DTV programming in the absence of an audience that would attract advertisers (Ref. 36 at p. 13). Moreover, because analog televisions were still being sold, each sale of an analog television set put the FCC farther from reaching the 85 percent DTV reception goal (Refs. 37 and 38). The FCC ultimately decided to adopt a plan to require DTV tuners on almost all new television sets by 2007 and established a 5-year rollout schedule to minimize costs to television manufacturers and consumers. It recognized that requiring the manufacture of DTV receivers would address "the root cause of the problem, namely the lack of television receivers capable of receiving DTV signals" (Ref. 36 at p. 13). The FCC also recognized that, without its intervention, the transition to DTV might remain stalled. The FCC's decision to require all television receivers to include digital television (DTV) reception capability is