

Testing and Materials has a standard procedure for bar code verification (Ref. 41). The International Organization for Standardization has various standards for automatic identification and data capture techniques, and several deal with bar code quality and symbologies. The UCC has guidelines on bar code placement and other documents on specific symbologies or quality matters. Given these standards and other documents, as well as the comparatively greater expertise of standards organizations in this area, we do not intend to develop our own guidance documents regarding bar code details such as quality, verification, or testing.

The bar code can also be used to access the medication information found in the professional labeling of a specific drug product. We are currently working on a collaborative initiative with the National Library of Medicine and the Department of Veterans Affairs to create a collection of up to date, computer readable electronic labels for marketed drug products called the "DailyMed." By linking the NDC to the appropriate label in the DailyMed, people will be able to use computer systems to access important medication information simply by scanning the bar code found on the drug package. This could help locate proper dosage instructions, identify drug interactions, and find other information necessary for the safe use of medications.

E. Where on the Label Would the Bar Code Appear? (Proposed § 201.25(c)(2))

In the public meeting notice, we asked where the bar code should be placed. We asked if there were benefits to placing bar codes on immediate containers and if there was a way to distinguish whether certain containers with a bar code would have a more significant effect on preventing medication errors than other containers (67 FR 41360 at 41361).

Some comments suggested that the bar code go on every package level down to the unit-of-use or unit dose. Other comments recommended placing the bar code on the "immediate container" or unit dose or unit-of-use package only.

In contrast, one comment expressed surprise that we would even consider putting bar codes on unit dose or unit-of-use packages because of the potential impact on manufacturers.

Several comments also disagreed as to whether we should specify where a bar code should appear on a particular package. For example, one comment recommended that we draft guidelines for bar code placement; the guidelines would consider ergonomics, scanner

types, symbologies, and packaging. Another comment would require the bar code to be placed where "the typical user of the scanning device can reliably and consistently scan it."

In contrast, other comments stated that we should not restrict the bar code's placement on a package because differences relating to package size, shape, and material demand flexibility as to the bar code's placement.

Proposed § 201.25(c)(2) would require the bar code to appear on the drug's label. Section 201(k) of the act defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper." Thus, by requiring the bar code to be on the drug's label, proposed § 201.25(c)(2) would result in bar codes on the drug's immediate container label as well as the outside container or wrapper, unless the bar code is easily legible and machine-readable through the outside container or wrapper.

We decline to adopt the comments' positions to require bar codes on all packages or only on immediate containers because that would either result in too many products being bar coded or too few. For example, if we required every package to bear a bar code, then arguably a shipping container of drugs would have a bar code, even though no hospital would dispense a drug directly from a shipping container to a patient, and a bar code on the shipping container would have no impact on medication errors. (The bar code could help with inventory control and tracking, but such matters are outside the scope of this proposed rule.) If we required only the immediate container (which is the container that is in direct contact with the drug at all times) to have a bar code, then patients receiving multiple-unit containers (such as a box holding blister packed tablets) would be vulnerable to medication errors because the multiple-unit container would not have a bar code.

As the previous paragraph suggests, there may be more than one bar code on a product depending on the package and whether it has a unique NDC number. For example, assume that you make drug tablets that are individually packaged in a plastic blister pack and then boxed in a cardboard container. If

the individually packaged tablets have a unique NDC number, then each individual blister pack would have a bar code. The cardboard container holding the blister pack would have to have a bar code, too, because the cardboard container would be an "outer container" within the statutory definition of "label."

Although proposed § 201.25(c)(2) would not require the bar code to appear at a specific location on a product, proposed § 201.25(c)(1)(ii) would require the bar code to remain intact under normal conditions of use. The latter requirement may influence the bar code's location.

F. What Would Happen if a Bar Code Could Not Be Put on a Product?

The proposed rule would not contain an exemption provision. We are aware of industry-conducted pilot studies that have placed RSS bar codes on small vials (Ref. 35). These pilot studies suggest that almost all products are capable of bearing a bar code. However, some comments from the public meeting suggested that small products might not be capable of bearing a bar code and recommended that we allow for exemptions.

We decline to create an exemption provision because we believe that almost all products are capable of bearing a bar code. In addition, exemption provisions sometimes create unintended administrative problems and consume agency resources as some individuals or firms may be tempted to submit exemption requests notwithstanding their ability to comply with a particular regulatory requirement. For example, if we were to create a general exemption provision, a firm whose drug product was packaged in a small vial might seek an exemption even though it could use a RSS linear bar code on that vial. If we tried to impose a limitation on the exemption, such as allowing for possible exemptions if it would not be technologically feasible to affix a bar code on the label, a firm might argue over whether economic or other considerations determined whether a bar code was technologically feasible. In the end, we could be obliged to devote resources to reviewing, deciding, and perhaps re-examining exemption requests, and we can avoid that potential drain on FDA resources by not creating an exemption provision. We invite comment as to whether any specific product or class of products should be exempt from a bar code requirement and the reasons why such an exemption is considered to be necessary. We also invite comment on