

**EXCERPTS OF FDA FINAL RULE:
BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS
 AND BIOLOGICAL PRODUCTS**

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I. Introduction

In the Federal Register of March 14, 2003, FDA (we) published a proposed rule that would require certain human drug and biological product labels to have a linear bar code.

After reviewing the comments, FDA made several changes to the rule. The principal changes between the proposed and final rule are as follows:

Proposed Rule	Final Rule
Would apply to prescription drugs (except for samples) and to over-the-counter drugs commonly used in hospitals and dispensed pursuant to an order	Applies to most prescription drugs (except for samples, allergenic extracts, intrauterine contraceptive devices that are regulated as drugs, medical gases, radiopharmaceuticals, low-density polyethylene form fill and seal containers, and prescription drugs sold directly to patients) and to over-the-counter drugs commonly used in hospitals and dispensed under an order. We explain the reasons for exempting certain prescription drugs in section II.B.4 of this document.
Did not contain a general exemption provision	Contains a limited, general exemption provision. We explain the reasons for creating a general exemption provision in section II.B.4.c of this document.
Would require a linear bar code that meets Uniform Code Council standards	Requires a linear bar code that meets Uniform Code Council standards or Health Industry Business Communications Council standards. We explain the reasons for this change at section II.D.1 of this document.
Would create a 3-year implementation period	Establishes different compliance dates depending on when a drug was approved. In general, the rule is effective 60 days after date of publication in the Federal Register . If a drug receives approval on or after the effective date, it must comply with the bar code requirement within 60 days of the drug's approval date. If the drug received approval before the rule's effective date, it must comply with the bar code requirement within 2 years of the final rule's effective date. For blood and blood components, a 2 year compliance date exists. We explain the implementation of this rule at section II.I of this document.

II. Comments on the Proposed Rule and FDA's Response

B. What Products Must Have a Bar Code? (Sec. 201.25 (b))

5. Should Medical Devices Be Excluded From the Rule?

Proposal

The preamble to the March 2003 proposal explained that we did not intend to issue any bar code requirement for medical devices at this time (see 68 FR 12500 at 12506). The preamble to the March 2003 proposal stated that devices present different issues compared to human drug and biological products and that we would continue to study whether to develop a proposed rule to require bar codes on medical devices to prevent or reduce medication errors (id.).

Ruling

We decline to include devices in the final rule. Unlike drugs, medical devices do not have a standardized, unique identifying system comparable to the NDC number. (There is a National Health Related Items Code (NHRIC) system for identifying and numbering marketed medical device packages, but participation in the NHRIC system is voluntary, and the database may contain out-of-date information due to industry acquisitions and mergers.) The absence of a standard, numerical identification system comparable to the NDC number is one of several issues that complicate efforts to put bar codes on medical devices for purposes of preventing or reducing medication errors.

As for voluntary use of UPNs on medical devices and the use of EAN.UCC or HIBCC standards, we recognize that some devices already bear a bar code for reasons relating to purchasing or inventory control, and we have not objected to their use nor to the bar code standards used.

D. Does the Rule Require a Specific Type of Bar Code? (Sec. 201.25(c)(1))

1. Should the Rule Require Linear Bar Codes?

Proposal

Proposed § 201.25(c)(1)'s would require the bar code to be a linear bar code that meets EAN/UCC Standards. The preamble to the March 2003 proposal discussed, in some detail, how we decided to propose the use of linear bar codes and described the tension between trying to create a bar code requirement that would enable hospitals to buy scanning equipment with the confidence that their purchased equipment would not be rendered obsolete by new technology and trying to create a bar code requirement that offered some room for technological innovation (see 68 FR 12500 at 12508 through 12510). We also invited comment on whether we should consider the use of another symbol, standard, or technology, either with or in place of a linear bar code, the acceptance of that other symbol, standard, or technology among parties that would be subject to the rule, and the ability of hospitals to read or use other symbols, standards, or technologies (id. at 12510 and 12529).

Ruling

Linear Bar Code Requirement

Comments

- Many comments addressed the subject of linear bar codes. Several comments indicated the rule should require the use of linear bar codes because of their widespread use and because hospitals that are currently printing and scanning bar codes might be unable to upgrade their technology to support nonlinear technologies.
- Most comments, however, argued against the use of linear bar codes or asked us to encompass other technologies or to eliminate any reference to linear bar codes in the final rule. Many comments claimed that the rule would discourage or inhibit technological innovation, although they differed as to their preferred alternatives to a linear bar code.

Response

After reviewing the comments, we have decided to retain the linear bar code requirement, but will consider revising the rule to accommodate newer technologies as they become more mature and established. Our decision to retain the linear bar code requirement rests largely on the following considerations:

- Linear bar codes are an established and proven technology.
- Linear bar codes are easily recognized and easily used or applied. Most individuals can identify a linear bar code quickly and can scan it without much training.
- Although most comments opposed the proposed linear bar code requirement, they failed to agree on alternative technologies. For example, some comments supported two-dimensional codes, particularly DataMatrix, but others supported radio frequency identification chips.

We believe that if the rule is to result in any significant benefits, it must specify a technology so that hospitals and other interested parties can purchase the correct scanning or reading equipment. We also disagree that the rule prevents or otherwise hinders innovation. Automatic identification technologies are useful in other contexts, such as retail environments, and are used on many different consumer goods. In other words, the fact that the final rule requires the use of linear bar codes does not mean that all progress on other automatic identification technologies must stop, nor does it mean that innovative automatic identification technologies cannot be used on other products.

Nevertheless, we reiterate that we will consider revising the rule to accommodate new technologies. As we explain in more detail in section II.I of this document, we expect compliance with the bar code requirement within 2 years after the final rule's effective date. At that time, we will begin examining other automatic identification technologies to determine whether we should amend the rule to allow the use of such technologies.

EAN/UCC – HIBCC Standards

Regarding the EAN/UCC system, the final rule allows the use of either EAN/ UCC or HIBCC standards. We discuss the reasons behind this change at comment 41 of this document.

Comment 41

Some comments questioned or criticized the proposed rule's reference to UCC standards.

- One comment said that “standards” refers to the data structure and not to symbologies. The comment asked if we meant that the linear bar code had to be one used by the UCC and that the NDC number had to be in a UCC data format.
- One comment, submitted by a medical device trade association, supported use of either the EAN.UCC or HIBCC standards. The comment explained that most medical device manufacturers who are voluntarily labeling their products use the UPN system, and the EAN.UCC and HIBCC standards comprise the UPN system.
- HIBCC also recommended that the final rule not rely solely on EAN.UCC standards; it acknowledged that EAN.UCC standards are “by far the most prevalent in pharmaceutical labeling,” but suggested that alphanumeric coding (which HIBCC standards use) “allows for literally-encoded information that is inherently safer” (than numeric coding alone).
- HIBCC, as well as another comment, also stated that requiring EAN.UCC standards would create a monopolistic environment that might inhibit the development and implementation of technologies outside the EAN.UCC's purview.
- The other comment claimed that the UCC is not a standards body, has proprietary interests, provides sponsored bar codes to members as part of a variable annual fee, and that the linear bar codes that would be used on hospital patient identification bands are not EAN.UCC codes, so that there would be no benefit in selecting EAN.UCC standards. The comment protested that the EAN.UCC standard requirement would compel manufacturers to join the UCC even though adequate bar codes are available in the public domain, and declared that the rule would violate unnamed Federal laws by referring to EAN.UCC standards.
- Another comment advocated use of both EAN.UCC and HIBCC standards. It suggested that this would encourage the adoption of automatic identification technologies as they develop, although the comment also recommended that linear bar codes be the initial technological requirement so that hospitals that have bar code systems are not disadvantaged.

Response

Proposed § 201.25(c)(1)'s reference to UCC.EAN “standards” was intended to mean that the linear bar code had to be one that the UCC recognized and the data standard had to be in a UCC.EAN format (see 68 FR 12500 at 12509). However, after considering the comments, we will interpret § 201.25(c)(1) as meaning that the linear bar code can be in any format, and the final rule gives firms the option of using EAN.UCC or HIBCC data standards.

In other words, the manner in which the NDC number is encoded may be in an EAN.UCC or HIBCC format, and the manner in which the NDC number is visually presented must be a linear bar code.

We have decided to give firms the option of using HIBCC data formats because HIBCC is a widely-recognized, nonprofit standards development organization whose standards, like EAN.UCC standards, are accredited by ANSI, and, as the comments suggested, allowing the use of either EAN.UCC or HIBCC standards may encourage further development and adoption of other automatic identification technologies.

We also cannot preclude the possibility that some firms may prefer using alphanumeric code formats, which HIBCC uses, although we do not express any opinion as to whether alphanumeric codes are “safer” than numeric ones.

Allowing the use of HIBCC standards will also prevent the creation of the “monopolistic” environment that some comments feared.

The Full Text of the Final Ruling can be accessed through the Federal Register at:
<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.pdf>

Contact the HIBCC Office with any questions or comments regarding the ruling at:



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