The FDA Bar Code Rule Decoded

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The FDA Bar Code Rule Decoded

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Purpose

This document is a summary of the requirements contained in the FDA "Bar Code Label Requirements for Human Drug Products and Biological Products." It is designed to answer the most common questions about the Rule but is not intended to provide definitive answers to all possible questions. If there is any doubt about the applicability of the rule to a specific product or class of products, companies should contact the FDA for a clarification.

The discussion below focuses on prescription and over-the-counter (OTC) drugs and, except where specifically noted, does not apply to blood and blood products.

The FDA Rule was established to reduce the likelihood of errors dispensing medication. The use of bar codes is designed to ensure that the right medication in the right dosage is administered through the right route. The healthcare professional must ensure that it is administered to the right patient at the right time.

The Rule

A linear bar code containing the National Drug Code (NDC) must be applied to all unit-of-use levels of prescription drugs and over-the-counter (OTC) medications commonly used in hospitals and dispensed under an order.

Exempt from the Rule

- Samples
- Allergenic extracts
- Intrauterine devices regulated as drugs
- Medical gasses
- Radiopharmaceuticals
- Low-density polyethylene form fill and seal containers without over-wraps (i.e., nebules)
- Prescription drugs dispensed or shipped directly to patients (not administered in hospitals)
- Drugs compounded for patient use in hospitals or at home
- Drugs being tested (investigational drugs)

Blood and Blood Products

Blood and blood products must bear machine-readable information in a format approved by the CBER Director. The data shall be in conformance with existing FDA requirements and may also contain additional data required by ISBT.

Compliance Dates

- Drug products approved on or after April 26, 2004 must comply within 60 days of being approved.
- Drug products approved before April 26, 2004 must comply by April 26, 2006.
- Blood and blood products must comply by April 26, 2006.

Who Must Comply

Manufacturers, repackers, relabelers and private label distributors of human prescription and OTC drug products regulated under the Federal Food, Drug, and Cosmetic Act (the Act) or the Public Health Service Act (PHS Act).

Exempt from the Rule

Organizations that are exempt from the establishment registration and drug listing requirements in section 510(g)(1) of the Act are exempt from the bar code requirements of the Rule. Specifically:

Pharmacies "which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail are exempt.

Likewise, hospitals, clinics and public health agencies that formulate drugs solely to administer to patients under their professional care are also exempt under section 510(g)(1) of the Act.

The FDA recognizes that formulated or compounded drugs prepared for a specific patient will not have an NDC number and, therefore, cannot be bar coded in conformance with the Rule.

What Must Be Encoded

The National Drug Code (NDC) for the product assigned to the manufacturer, repacker, relabeler or private label distributor must be encoded in the bar code. Repackers and relabelers must use their own NDC number for the product.

LOT/BATCH AND EXPIRY:

The FDA does not require the inclusion of lot/batch and expiry in bar code format.

The FDA recognizes that there are many potential benefits not directly related to medication errors (which is the scope of the Rule) in encoding lot/batch and expiry. Therefore, the FDA does not object to its inclusion in bar code format. However, this information should be separate from the NDC number (e.g., in a Composite symbol). The NDC number must be in the "base" linear bar code portion of a composite symbol.

Data Structure

The NDC may only be presented in EAN.UCC or HIBCC data format.

Bar Code Symbologies

The NDC number may be encoded in any linear symbology that is compliant with EAN.UCC or HIBCC standards.

Companies using EAN.UCC data structures should use EAN.UCC symbologies. Likewise, companies using HIBCC data structures should use HIBCC symbologies.

The FDA considers RSS/Stacked a linear symbology.

The FCC also acknowledges current UCC Composite symbologies as "linear" but would require that the NDC number be encoded in the "base" linear portion of composite symbols.

At this time, the FDA does not approve the use of matrix symbologies for encoding the NDC. The FDA will revisit this topic in the future.

Bar Code Location

The bar code must be on the drug's label. If clarification of the definition of what constitutes the "label" is required, see Section 201.25(c)(2) of the Act.

Prescription Drug Labeling

All prescription drugs, except those noted below must be labeled at the unit-of-use level. Specific discussions on some of these exemptions are included below.

Exempt from the Rule

- Samples
- Allergenic extracts
- Intrauterine devices regulated as drugs
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- Radiopharmaceuticals
- Low-density polyethylene form fill and seal containers without overwraps (e.g. nebules)
- Prescription drugs dispensed or shipped directly to patients (not administered in hospitals)
- Drugs compounded for patient use in hospitals or at home
- Drugs being tested (investigational drugs)

PRESCRIPTION DRUG SAMPLES

The FDA does not object to bar code labeling of prescription drug samples.

ALLERGENIC EXTRACTS

Because allergenic extracts are compounded for a specific patient, they will not have an NDC number and cannot be bar code labeled in compliance with the Rule.

RADIOPHARMACEUTICALS

Radiopharmaceuticals are regulated by existing Nuclear Regulatory Commission (NRC) procedures. These procedures are stringent enough to prevent misapplication.

NEBULES

Because nebules are most commonly packaged in low-density polyethylene (LDPE) form fill and seal containers, there is concern about migration of any chemical used to mark directly on the nebule through the packaging. However, nebules that are packaged with an over-wrap must be bar code labeled.

DRUGS BEING TESTED (INVESTIGATIONAL DRUGS)

Because drugs being tested have not received FDA approval, they cannot be assigned an NDC number and thus cannot be bar code labeled in compliance with the Rule.

OTC Product Labeling

OTC products that "are commonly used in hospitals and are dispensed under an order" must be labeled. There are two criteria for determining if OTC products must be labeled.

First, the product must be "commonly used in hospitals." While this criterion is open to some interpretation, the second criterion clarifies this significantly.

The product must be "dispensed under an order." That means that the medication or treatment must be ordered by a physician, nurse or other qualified healthcare professional to be dispensed to the patient. This does not mean that a prescription is required to dispense the product; it does mean that a qualified healthcare professional must authorize or approve dispensing.

Exempt from the Rule

OTC products such as mouth rinses, soaps, cosmetic-like products and other products that may be dispensed to a patient but do not require approval or authorization by a healthcare professional.

Products not intended for sale to hospitals are not required to be bar code labeled at the unit-of-use level. Companies may package a product for retail purposes without bar codes but would be required to provide the bar code for packaging designated for "hospital," "industrial," or "not for retail" use. This provision does not prevent companies from bar code labeling both retail and non-retail packaging of the product.

Limited General Exemption

The FDA deemed it prudent to add a general exemption provision to the rule. Section 201.25(d) states that the FDA may, on its initiative or in response to a written request, exempt a drug from the bar code label requirement. The request must state why the exemption is necessary, why problems cannot be feasibly solved by packaging, or cite other, existing regulatory procedures that will satisfy the goal of reducing medication errors.

For more information on the general exemption request, see Section 201.25(d)(1)(1) of the FDA Rule.

Other FAQs

Q: MUST ALL DRUGS NOW BE PACKAGED AS UNIT-DOSE OR UNIT-OF-USE?

A: No, the FDA has declined to require unit-dose or unit-of-use packaging.

Q: WHAT ABOUT "KITS" THAT CONTAIN MULTIPLE ITEMS (CO-PACKAGED ITEMS)?

A: Each component in the kit that requires an NDC number should be individually labeled. The kit itself would have an NDC number and that must be included on the kit itself.

Q: WHAT ABOUT EXTREMELY SMALL VIALS?

A: Extremely small vials (as small as 1 ml) have been bar code labeled using Reduced Space Symbology (RSS). It is recognized that labeling directly on the vial may be difficult but the Rule only requires the bar code to be on the product's label. Labeling the vial's immediate container can satisfy the Rule although it may require some modification to packaging to accommodate a bar code.

Q: CAN OTHER INFORMATION BE OMITTED TO INCLUDE THE BAR CODE?

A: Information that is currently required by Federal law to be on the label in human readable form cannot be omitted. Other items, such as company logos (but not company name), could be omitted.

Q: WHAT ARE THE PRINT QUALITY GUIDELINES?

A: The FDA cites existing bar code quality guidelines and standards bodies such as EAN.UCC and HIBCC believing their requirements adequately address the issue.

The FDA expects that bar code data problems as well as scanning problems will be reported as any other packaging problem and reported through established channels.

Additionally, the FDA believes its GMP (Good Manufacturing Practices) requirements and the Drug Quality Reporting System provide additional safeguards to ensure bar code quality.

GMP provides a level of "readability" inspection that requires suppliers to "comply with written specifications." Thus, hospitals can specify an existing quality level or establish their own bar code quality standards.

Q: CAN MATRIX SYMBOLOGIES BE USED?

A: The FDA has ruled against matrix symbologies for encoding the NDC. The FDA does recognizes the potential of matrix symbologies, RFID and other technologies to combat counterfeit drugs and recognizes other benefits not associated with medication errors but, insofar as these applications are outside the scope of the Rule, can make no recommendation on the use of these technologies. The FDA has stated, however, that it has no objection to other technologies being used for track-and-trace or even lot/batch information since neither application is covered by the Rule.

Q: WHAT ABOUT VACCINES?

A: Vaccines must be labeled. The FDA does not require inclusion of lot/batch and expiry but does not object to such voluntary labeling. Again, inclusion of additional data must not interfere with reading of the NDC number.

Q: WHAT ABOUT ORAL CONTRACEPTIVES?

A: Oral contraceptives must be labeled. However, since oral contraceptives are packaged in a single blister pack that is packaged with a single label, the bar code would go on the label, not individual blisters.

Q: WHAT ABOUT DILUENTS?

A: Diluents must be labeled since they can have an impact on drug strength and administration. Diluents that do not currently have an NDC number must be assigned one. Diluents co-packaged with a drug must be individually labeled (as noted above).

Q: WHAT ABOUT PRESCRIPTION DENTAL DRUGS?

A: Prescription dental drugs that will be administered in hospitals must be labeled.

Q: CAN BAR CODES BE PRINTED DIRECTLY ON PILLS OR TABLETS?

A: No, the FDA has prohibited printing directly on pills or tablets. The bar code must go on the drug's label.

Q: ARE INTRAVENOUS IMMUNE GLOBULIN (IGIV) AND ALBUMIN INCLUDED?

A: Yes, IGIV and albumin are covered by the Rule and must have an NDC. They are not considered blood or blood products.

Q: WHAT ABOUT BIOLOGICAL PRODUCTS?

A: Biological products are covered by the Rule and must be bar code labeled.

Q: WILL ADDING A BAR CODE REQUIRE PRIOR FDA APPROVAL FOR LABEL CHANGES?

A: Most packaging changes to include a bar code will not require prior FDA approval. Most packaging changes can be reported to the FDA through supplemental or annual reports. For drugs already approved by the FDA, the 2 year compliance timeframe will provide ample time to notify the FDA of any label changes.

Q: WHAT ABOUT EXISTING DRUGS WITH AN EXPIRATION DATE GREATER THAN 2 YEARS?

A: Drugs that were manufactured or marketed prior to April 26, 2004 that have an expiration date of greater than 2 years will be allowed to remain on the market without a bar code.

Q: IS THE FDA CHANGING THE NDC?

A: Under separate rulemaking, the FDA will change the NDC number to ensure that it is a unique identifying number for listed drugs. The FDA admits a

shortcoming in assignment in the past and vows to rectify this. It also insists that any changes will be backwardly compatible with existing NDC numbers. Thus, companies can proceed with bar code labeling of the NDC number with confidence. Questions concerning the NDC should be directed to the FDA.

System Considerations

WLANs

The FDA has expressed concern about the use of wireless LANs in the healthcare environment and the possible effects of RF on electronic monitoring equipment.

> "We recommend that interested parties gather information and conduct research about wireless bar code scanners (or other scanning or reading equipment) and their EMI potential on other medical devices. We also encourage voluntary standards development organizations, such as the Association for the Advancement of Medical Instrumentation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American National Standards Institute (ANSI), and the International Electrotechnical Commission (IEC) to work with us toward the goal of coordinated policies, research, and standards development to ensure a base level of EMC in all health care facilities. This would include recommendations for safely deploying wireless technology in hospitals and health care facilities."

The FDA has not prohibited the use of WLANs and wireless bar code scanning in hospitals but system designers are encouraged to determine possible EMI effects in each application and location.

NDC Limitations

The FDA recognizes that the NDC number has some limitations, particularly when used on packaging that does not contain a single dose of medication or where partial dosage is required because of the patient's age, weight, condition, etc.

The FDA cites the example of a bottle of 20 tablets identified with an NDC. If dosage is 1 tablet, scanning the NDC only provides strength and route of administration verification. It will be unable to automatically provide correct dosage information.

The FDA agrees that it would be helpful if a computerized database could alert health care professionals to check dosages given to patients. The FDA encourages hospitals and systems designers to consider this when designing computerized systems.

FURTHER INFORMATION

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