

[Docket No. 02N-0204]

FDA BAR CODE LABEL REQUIREMENTS FOR
HUMAN DRUG PRODUCTS

July 26, 2002

A. *General Questions Related to Drugs and Biologics:*

1. Which medical products should carry a bar code? For example: should all prescription and over-the-counter drugs be bar coded?

All prescription and over-the-counter drugs should be bar coded down to the single unit dose or unit of use level. Bar coding includes benefits such as:

- 1) **Ensuring the accuracy of medication identification and administration.**
- 2) **Improving efficiencies within the medication-use process.**
- 3) **Improving overall public health and patient safety by reducing the number of errors such as the administration of incorrect doses and wrong drug products.**
- 4) **Improving overall efficiencies in the supply system, including purchasing, storage and distribution of drug products.**

The most important benefit is the improvement of patient safety. However, the bar code technologies will show benefits only if utilized in the healthcare facility at the point of patient care level. The addition of bar codes by manufacturers and packagers alone will not reduce medication errors.

In the hospital pharmacy, bar codes assist in drug distribution and monitoring of dose administration. In retail pharmacy, advances are possible with point of sale checkout scanning systems.

2. What information should be contained in the bar code?

The information that should be contained in the bar code is the National Drug Code (NDC) to indicate drug name, strength, unit of measure corresponding to strength and the package level (the unit or number of units which make up a package).



UDL currently places a label on the side of the unit cartons which includes two C128 bar codes. The top bar code contains the NDC and the bottom bar code contains the expiration date and lot number. This can be used at point of receipt of the unit carton by the wholesaler/hospital pharmacy customer to scan in the NDC, lot number and expiration date. (Examples of the labels are provided in Attachment A.)

What do you consider to be critical bar code information that will reduce medical product errors?

The critical bar code information that will reduce dispensing errors is the NDC that identifies the product. The information such as lot number and expiration date is of no value with respect to reducing dispensing errors. The lot number and expiration date information is useful for commercial issues such as improved inventory control, supply chain management and recall management.

3. Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific bar code symbology (e.g. RSS (reduced space symbology) and composite (2-dimensional) symbology)?

The rule should adopt a specific bar code symbology. An industry standard should be established to be compatible with existing technology and affordable for implementation at the user level.

Should we adopt one symbology over another, or should we allow for "machine readable" formats?

We should allow some flexibility for "machine readable formats" based on the current approved symbologies in the marketplace.

What are the pros and cons of each approach?

In order to promote standardization, UDL is recommending that the FDA adopt a specific numbering system for the bar-coding of all drug product packaging (rationale is provided in answer C. 1.). However, if the rule is to be all inclusive, covering even the smallest unit of use container (i.e., 2 ml vial), then an effort should be made to provide some flexibility for the use of other approved symbologies currently being used in the market place.



The UCC (Uniform Code Council) numbering system, based on the Global Trade Identification Number, is compatible with the existing National Drug Code (NDC) and allows for the differentiation between levels of packaging through the use of "Packaging Indicator" digits. The adoption of this numbering system will eliminate the need for assigning new NDC's for each level of packaging. The standardization of the coding technology will be the easiest, most cost-effective way to implement a system to provide the needed controls. The rule should provide clear and concise direction to the manufacturer / packager and dispensing institutions alike.

The UCC numbering system facilitates modification to readily adopt new symbologies. It currently is compatible with most common bar codes including UPC, UCC/EAN, RSS and Data Matrix.

4. Assuming that we require bar codes on all human drug products, where on the package should the bar codes be placed?

UDL Laboratories has been bar coding product with the NDC to the unit dose level since approximately 1991. Examples of the placement of our bar codes throughout the different levels of packaging are provided in Attachment A. The bar code for our unit dose blister package is placed on the lidding material. The NDC bar code should be placed above or below the human readable NDC.

Are there benefits to placing bar codes on immediate containers, such as the bottles, tubes, foiled-wrapped tablets, and capsules, found inside prescription or OTC product cartons?

Yes, there are benefits to placing bar codes on immediate containers, such as the bottles, tubes, foil-wrapped tablets and capsules, found inside prescription or over-the-counter product cartons. The primary benefit is patient safety. The prescription or OTC product carton is not always dispensed to the patient; therefore, the bar codes on the product carton alone will not have as much of an impact on patient safety. The bar code should be placed on the FDA approved selling unit (e.g., bottles of 100 tablet/capsules). There are also various commercial benefits such as improved traceability (i.e., tracking lot numbers and expiration dates for commercially available packages).

Is there a way to distinguish whether certain containers with a bar code will have a more significant effect on preventing errors than others?

Published literature supports that there is a reduction in medication errors when bar codes are used on product containers in conjunction with bar code scanners and computer equipment. It is believed that this would be demonstrated in all containers.



5. What products already contain bar codes?

As previously mentioned in question A. 4, UDL Laboratories has been bar coding the NDC on its unit dose generic tablet and capsule packages since approximately 1991. All marketed solid oral dosage form products, except for those private labeled by outside vendors for UDL, contain a bar code which includes the NDC. UDL Laboratories has 337 bar coded stock keeping units in its current generic oral solid dosage product line. In addition, Mylan Pharmaceuticals and Bertek Pharmaceuticals, like UDL wholly owned subsidiaries of Mylan Laboratories, bar code the NDC number on their sellable packages.

Who (i.e., hospitals, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these bar codes and how?

The bar codes are utilized on a limited basis. We are not aware of anyone outside of the in-patient environment who is using these bar codes. A limited number of hospitals are utilizing the bar codes to verify the product. It should be noted that in 1995, UDL Laboratories introduced to the institutional marketplace a new industry standard package design for ROBOT-Rx™, the automated pharmacy dispensing station developed by McKesson HBOC Automated Healthcare Inc. of Pittsburgh. The automated station incorporates UDL's fully integrated bar coding program at every level of hospital unit dose handling - from shipping cases to unit dose blisters. The bar codes allow the ROBOT-Rx™ to robotically dispense single doses of medication. The bar code which includes the NDC and expiration date also allows the ROBOT-Rx™, to automatically check, credit, restock and control inventory for over 95% of current hospital formularies without significant changes in departmental operating procedures. An example of UDL's Robot-Ready package bar code is provided in Attachment B.

B. *Medical Device Questions*

Not applicable to UDL.

C. *General Questions and Economic Impact Questions*

1. Will bar code printing costs cause you to modify your packaging choices, such as reconsidering the use of blister packages or influencing future package choices? If so, how?

Bar code printing costs will not modify our packaging choices, such as reconsidering the use of blister packages. Repackaging generic solid oral



dosage forms into unit dose blister packages is our core business; therefore, we would not change our packaging choices. UDL Laboratories' unit dose blister packages are currently bar coded with the NDC to the single unit dose or unit of use. However, our future packaging choices will be influenced by a requirement to add lot number and expiration date to our bar code. The potential exists for bar code printing costs to increase significantly if the rule were to adopt a specific symbology requiring more space than our current Code 128C. For most unit dose suppliers, increasing the size of their packaging configurations to accept a larger code would require the complete re-tooling for the entire unit dose product line. It is UDL's belief that the implementation of the RSS with Composite is the most cost-effective method to increase the amount of machine-readable information at the unit of use level. This would require the purchasing of additional bar code printing equipment, bar code creation program, scanners and verifiers. It must also be understood, that even with RSS with Composite there is a limit to the amount of information that can be contained in the bar code for most unit dose packaging configurations. Based on our current studies of RSS with Composite, we recommend machine readable information be limited to: NDC, lot number, expiration date and unit of use (package level).

2. Have you implemented bar code technology in your product line?

Yes, as previously mentioned in questions A. 4 and A. 5, UDL Laboratories has been bar coding the NDC on its unit dose generic tablet and capsule packages since approximately 1991. All marketed solid oral dosage form products, except for a few private labeled by outside vendors for UDL, contain a bar code which includes the NDC. UDL Laboratories has 337 bar coded stock keeping units in its current generic oral solid dosage product line. In addition, Mylan Pharmaceuticals and Bertek Pharmaceuticals, like UDL wholly owned subsidiaries of Mylan Laboratories, bar code the NDC number on their sellable packages. Examples of UDL's current barcodes are provided for reference in Attachment A.

If so, what elements and symbology are included in the bar code?

Our unit carton label bar code is a UPC-A which represents the NDC with package code indicating the amount of product contained within the unit carton (i.e., pkg code "20" = 100 tablets/capsules, "22" = 200 tablets/capsules)

Our blister card bar code is a Code 128C which represents the NDC with package code indicating the number of tablets/capsules contained within the blister (i.e., pkg code "01" = 1 tablet/capsule, "02" = 2 tablets/capsules).



Our unit cartons also have an additional bar coded 2"x 2" label placed on the left side panel. This label bears a UPC-A bar code of the NDC and a separate Code 128 bar code of the lot number and expiration date (mmyy).

In addition, UDL is currently taking steps to evaluate the possibility of providing its customer base with bar codes that will contain the NDC, lot number and expiration date at the unit of use level. The symbology under evaluation is RSS Limited Composite. To date, UDL has been successful in the development of the printing plate (laser engraved rubber) and has printed readable codes at maximum line speeds with current printing technology. These manufactured RSS symbols received overall ANSI print quality verification grades of B and C. The equipment used to verify the ANSI print quality grades is referenced in question C. 5. Examples are provided for reference in Attachment C.

3. If you manufacture and bar code products, how do verification requirements for bar codes affect your ability to add bar codes?

Verification requirements do impact the ability to add bar codes. The limited amount of space available on unit dose packages affects the size of the bar code and therefore impacts the speed of scanning and verifying.

How much bar code verification is appropriate as part of the quality system?

The optimal situation is 100% on-line bar code verification; however, this potentially will be cost prohibitive and will impact production speeds. Extensive on-line testing should be performed to establish bar code scan parameters prior to the onset of bar code applications during production. The sampling plan for inspection should be established based on production quantities and a known standard (i.e., ANSI). A representative sample of units should be collected at set-up, in-process and at the completion of the bar coding operation to verify the accuracy of the bar code. The plan may be modified over time based on performance of the equipment and a collection of historical data during in-process testing. All bar coded labeling generated by UDL is tested for compliance with symbology, readability and data content specifications. Each manufacturer or packager should establish their own acceptable quality levels based on their equipment, processes and their ability to produce a consistent quality bar code application.



4. Can bar codes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?

Yes, bar codes can be produced with a dose specific unique identifying number, lot number and expiration date with modifications to printing, decoding and bar code verification equipment. The cost and impact on production speed is dependent upon the type of equipment.

5. What equipment solutions are vendors offering to manufacturers for bar coding or scanning?

Equipment and bar code development software solutions appear to be readily available from numerous automatic identification and data capture device manufacturers. During our study of the RSS Limited with Composite, UDL evaluated the Symbol Technologies Cyclone M-2000 -I200 hand held visible laser diode scanner for decoding. The Cyclone readily decoded both the RSS symbols and Composite components. The Cyclone M-2000 -I200 was selected for use because it delivered optimum flexibility with existing, new and emerging bar code symbologies.

To verify the RSS symbol the 101/201 Webscan TruCheck Laser Verifier was used. The laser is equipped with a 6 mil aperture as specified by the UCC for RSS verification on symbols with a nominal "X"- dimension of 10 mils. The UDL manufactured RSS symbols produced at maximum line speeds with current printing technology received ANSI print quality verification grades of B and C. The 101/201 Webscan TruCheck Laser Verifier was selected because it possessed the following features:

- 1. Laser movement is automatic for multiple scan grading.**
- 2. It provides very rapid, repeatable results and detailed reporting.**
- 3. It is calibrated to traceable standards.**

UDL has not yet researched Automatic Identification systems for on - line 100% bar code inspection.

How quickly can such systems run?

Symbol Technologies Cyclone M-2000-I200 required approximately 1.5 seconds of scan time per code. The throughput of the 101/201 Webscan TruCheck Laser Verifier per scan including the printing of the detailed report is approximately 15 seconds.

What type of packaging line is equipment used for?

Hospital Unit Dose Blister Packaging



6. What is the expected rate of technology acceptance in all health care sectors of machine-readable technologies?

The expected rate of technology acceptance by practitioners is 100 percent. We believe that the end user will philosophically embrace the concept of this technology. However, the actual adoption rate depends on the ability of the manufacturers and packagers to provide scannable bar codes for the end users and the capital funding available to the end user to purchase the machine readable technology.

What are the major inhibiting factors to the current use of machine readable technologies?

The major inhibiting factors to the current use of machine readable technologies are the cost of systems and the technology issues (i.e., the ability of the end users' legacy systems to interface with the new technology). All levels of health care need affordable patient safety technology.

What would be the expected benefit of using machine readable technology in the delivery of health care services (including drug products)?

The primary benefit of using machine readable technology in the delivery of health care services (including drug products) is improved patient safety by the reduction of medication errors. Additional benefits include increased efficiencies, a reduction of paperwork, improved audit trails and improved accuracy of medication identification.

What would be the expected benefit of machine readable technology for other potential uses (e.g., reports, record keeping, inventory control, formulary setting, etc.)?

The other expected benefits of machine readable technology for other potential uses are improvement of overall efficiencies in the supply system, including purchasing, storage, inventory control, record keeping, and distribution of drug products. The health care industry will realize the same benefits that are realized today by virtually every other industry (i.e., general merchandise retail and apparel, grocery and food service, hardware and office products, publishing, distribution and transportation, etc.).



7. Assuming a final rule is issued requiring bar coding, when should it become effective? For example, would some industries or products require more time than others to comply with a bar code requirement?

UDL supports the comprehensive use of standardized bar code labeling for human drug products, and the use of associated standardized databases to aid in the reduction of medication errors. There are current users of the machine readable bar code technology today and different sectors of the health care industry are at various stages of technology evaluation, development and implementation. There are clearly some issues which need to be addressed which include the various space limitations for different dosage forms, packaging configurations and products, some FDA regulations concerning the specifications of label text, and the advancement of the on-line bar coding application technology to assure high quality and machine readable bar codes. Other issues include what information should be required in standardized bar code labeling and which of the various symbologies and technologies should be standardized.

UDL believes that a task force or committee should be formed to address these issues to aid the agency in developing new bar code regulations. The task force should include representatives from the end user (hospital staff, pharmacists), drug manufacturers and packagers, FDA and bar code technology companies.

The final rule should become effective as soon as possible in order to introduce bar coding at an elementary level and to allow the system to evolve as technological advancements occur. The time required to comply with a final rule will depend on the resolution of the issues previously mentioned. However, it is UDL's opinion that all products should require the same amount of time to comply with a bar code requirement. More importantly, if in fact the end user at the facility level is unable to purchase or implement the machine readable technology, the benefits of bar codes will not be realized.

Would a certain compliance time sharply reduce costs of relabeling?

The final rule should not require relabeling. The regulation should require bar codes on drug products initially introduced or initially delivered for introduction into interstate commerce after the effective date of the rule.

