

**PhRMA STATEMENT REGARDING BAR CODE LABEL REQUIREMENTS  
FOR HUMAN DRUG AND BIOLOGIC PRODUCTS**

**FOOD AND DRUG ADMINISTRATION PUBLIC MEETING  
JULY 26, 2002**

**DOCKET NUMBER 02N-0204; 67 FEDERAL REGISTER 41360**

**PhRMA continues to be supportive of efforts to utilize standardized bar codes down to the unit of use level on drug and biologic products as part of the initiative to reduce medication errors.**

**Current printing and scanning technology allows for the application and reading of a bar code on the label for all but the smallest primary containers.**

**PhRMA encourages the use of a standard bar code and data structure for encoding the National Drug Code (NDC) number in these applications. The NDC number is a unique identifier for the manufacturer (or distributor), the drug formulation, and package size and type. In addition to the currently used Uniform Product Code (UPC) and Code 128 symbologies, PhRMA also endorses the Reduced Space Symbology (RSS) and the 2-D code DataMatrix.**

**Based upon the current state-of-the-art technology available for incorporating bar codes on small container labels, it may be necessary to amend current FDA text requirements so that certain human readable information now required to be on all primary drug or biologic container labels be exempted. This will provide sufficient space to print a high quality, machine-readable bar code and more prominent human readable text to help to reduce medication errors.**

**If there were agreement on the above conditions, it would be possible for pharmaceutical manufacturers to extend the use of machine-readable bar codes on container labels where there is available space and to have those bar codes on such**

**container labels within two to three years. For container labels where the necessary space is not readily available, the feasibility of incorporating the NDC number into a machine-readable bar code, and the timing for its implementation would require further discussion with the Food and Drug Administration regarding its requirements and procedures for handling exemptions and supplements for label changes.**

**The present technology is limited in its ability to support the application of machine-readable bar codes incorporating additional information beyond that contained within the NDC number, such as product lot number and expiration date. The material benefit of a bar coded lot number and expiration date to achieve a reduction in medication errors warrants further discussion among stakeholders.**

**As a recent paper from the National Coordinating Council for Medication Error Reporting and Prevention cites:**

**“Further research is needed to quantify the safety and cost-effectiveness of bar coding in the medication-use process and should be undertaken before their universal incorporation into these processes. The use of bar coding technology as a mechanism to improve medication safety should be implemented incrementally with careful planning and given thoughtful deliberation for cost, cultural, and implementation issues.”<sup>1</sup>**

**PhRMA is prepared to convene a group of interested stakeholders for the purpose of conducting the recommended needs assessment and evaluation of this further application of bar code technology for human drug and biologic products.**

---

<sup>1</sup> “Promoting and Standardizing Bar Coding on Medication Packaging: Reducing Errors and Improving Care,” a position paper prepared by the National Coordinating Council for Medication Error Reporting and Prevention; June 27, 2001

**We look forward to working with the Agency and other health care stakeholders in efforts to improve patient safety.**

**PhRMA RESPONSE TO FDA QUESTIONS  
REGARDING BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG AND  
BIOLOGIC PRODUCTS**

Questions Cited in Federal Register / Vol. 67, No. 117 / Tuesday, June 18, 2002 / Proposed Rules / Docket No. 02N-0204

<b>A. General Questions Related to Drugs and Biologics</b>		<b>PhRMA Response</b>
1.	Which medical products should carry a bar code? For example, should all prescription and over-the-counter (OTC) drugs be bar coded? Should blood products and vaccines carry a barcode?	<b>All prescription medications and vaccines (except for clinical supplies and physician samples) supplied to hospitals should carry bar codes.</b>
2.	What information should be contained in the bar code? What do you consider to be critical bar code information that will reduce medical product errors? If data exists, please provide it for the record. What information would be helpful but not necessarily critical, for reducing medication errors? Provide data	<b>The NDC number should be the primary information contained within the bar code. This number is already required by FDA regulation and is a unique identifier for the product. Use of appropriate scanners, data base systems, and nurse and physician practices can lead to a reduction in medication errors. As far as PhRMA is aware, there is negligible data on whether encoding secondary identifiers such as lot number and expiration date will markedly contribute to medication error reduction.</b>
3.	Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific bar code symbology (e.g., reduced space symbology (RSS) and 2-dimensional symbology)? Should we adopt one symbology over another, or should we allow for "machine readable" formats?	<b>The rule should not specify a single symbology. Current new scanners are capable of reading different symbologies. The symbologies that are widely used are UPC and Code 128. To comply with this potential regulation, RSS and 2-D DataMatrix are also recommended because of their</b>

	What are the pros and cons of each approach?	<b>reduced size. If a single symbology is used, it will significantly reduce the ability to comply quickly since more artwork will require revisions for the industry as a whole (especially since different companies have already adapted to either UPC or Code 128).</b>
4.	Assuming that we require bar codes on all human drug products, where on the package should the bar codes be placed? 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? Is there a way to distinguish whether certain containers with a bar code will have a more significant effect on preventing errors than others?	<b>The greatest benefit is the use of bar coded NDC # on all levels of packaging. There is relatively no technical issue in printing an NDC barcode down to the unit of use level as it is preprinted. If space constraints can be overcome through either providing relief of other repetitive label copy (e.g., container label with outer carton) or allowing various symbologies to be used there should be NO issue whatsoever. The location of the bar code should generally be left to the discretion of the manufacturer.</b>
5.	What products already contain bar codes? Who (i.e., hospitals, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these bar codes and how? As with all comments, if data exists, please provide it for the record.	<b>Where there is sufficient printing space, most pharmaceutical SKUs distributed within the USA carry a UPC symbology for the NDC #. This is currently used within the wholesale/retail supply chain.</b>

**PhRMA RESPONSE TO FDA QUESTIONS  
REGARDING BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG AND  
BIOLOGIC PRODUCTS**

Questions Cited in Federal Register / Vol. 67, No. 117 / Tuesday, June 18, 2002 / Proposed Rules / Docket No. 02N-0204

<b>B. Medical Device Questions</b>		<b>PhRMA Response</b>
1.	Should medical devices carry a bar code? What information should be included in the bar code? For example, unlike drug products, medical devices do not have unique identifier numbers.	<b>Stakeholders other than PhRMA are better positioned to address the questions in this Section.</b>
2.	If medical devices are bar coded, should all medical devices, or only certain devices be bar coded? For example, tongue depressors, syringes, and crutches are medical devices, but perhaps do not need a bar code.	
3.	Should reprocessed, repackaged, refurbished, or multiple-use medical devices be bar coded? Who should be responsible for generating and applying the new bar codes and how should these barcodes be different from the original manufacturers' bar codes?	
4.	What public health/patient safety benefits can be derived from bar coding medical devices? If data exists, please provide it for the record.	

**PhRMA RESPONSE TO FDA QUESTIONS  
REGARDING BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG AND  
BIOLOGIC PRODUCTS**

Questions Cited in Federal Register / Vol. 67, No. 117 / Tuesday, June 18, 2002 / Proposed Rules / Docket No. 02N-0204

C. General Questions and Economic Impact Questions		PhRMA Response
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?	<b>PhRMA believes that if the regulation proposes only the NDC number, few modifications will be necessary. If the regulation includes other information such as Lot Number and Exp. Date, companies may reconsider the packaging choices due to space and feasibility of the package to encode all the information specified.</b>
2.	Have you implemented bar code technology in your product line? If so, what elements and symbology are included in the bar code?	<b>PhRMA member companies have incorporated bar code technology on many current packages. Symbologies used include UPC and Code 128. On many products where there is sufficient space, an NDC number bar code is present.</b>
3.	If you manufacture and bar code products, how do verification requirements for bar codes affect your ability to add bar codes? How much barcode verification is appropriate as part of the quality system?	<b>If companies preprint a barcode, good prepress, printing and incoming inspection practices can be used to ensure a high degree of scan-ability and that it is correct. However, all variable information printed on line requires a high level of on line verification that the information is legible and correct. If the barcode is printed on-line, companies will need to verify correctness of each barcode printing (as they do with the variable human readable). Companies will have to validate the system to ensure these barcodes afford a high degree of</b>

		<b>scan-ability and verify routinely with in-process inspection.</b>
4.	Can bar codes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?	<b>No, there are limitations with current technology such that it is not likely that all three identifiers can be printed on line at current production line speeds.</b>
5.	What equipment solutions are vendors offering to manufacturers for bar coding or scanning? How quickly can such systems run? What type of packaging line is equipment used for?	<b>Presentations of on-line printing and scanning systems for variable barcode information have not adequately demonstrated their ability to print labels at the current highest line speeds.</b>
6.	What is the expected rate of technology acceptance in all health care sectors of machine-readable technologies? What are the major inhibiting factors to the current use of machine-readable technologies? What would be the expected benefit of using machine-readable technology in the delivery of health care services (including drug products)? What would be the expected benefit of machine-readable technology for other potential uses (e.g., reports, recordkeeping, inventory control, formulary setting, etc.)?	<b>This question is more relevant to stakeholders other than PhRMA.</b>
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 coding requirement? Would a certain compliance time sharply reduce costs of relabeling?	<b>If the requirement is a unique number like the NDC #, it may be implemented in two to three years for labels that have space available.</b> <b>If variable information such as lot number and expiration date are required then about five years would be required and significant equipment changes are anticipated.</b>