FDA's Bar Code Label Requirements for Human Drug Products

General Questions Related to Drugs and Biologics

FDA Question	HDMA Response
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?	**All prescription drugs and vaccines administered in in-patient settings should carry an NDC bar code. OTC drugs can continue to use the current UPC coding.**
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.	**An initial phase of implementation can utilize the NDC bar code to the unit-dose level. The NDC code contains critical information specific to medication name and dose, which are the most important data to convey for elimination of medication errors. In a later phase, the lot number and expiration date may be added in order to address the remaining small percentage of errors occurring due to these factors, and supply other useful healthcare supply chain information.**
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?	**The rule should not stipulate a specific symbology, unless a substantial phase-in period is allowed. There are numerous symbologies in use now, and a mandated single one would result in great expense and delay in complying with the rule. A machine-readable barcode containing the NDC, at minimum, would be preferable. Even here, however, the implementation could result in confusion, delay and increased costs, as patient care facilities and other healthcare partners may have to deal with symbologies that are not compliant with their current scanners, databases and other technologies and processes. This obviously is an issue that requires careful planning with significant ongoing input and cooperation from industry participants.**

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?	**Any bar coding requirement should allow for flexibility in bar code placement, in order to facilitate compliance with labeling regulations while maintaining productivity and scanning rates. The NDC bar code should be placed on the immediate container at the unit dose level, in order to achieve desired results in reducing medication errors.**
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.	**Most products in the healthcare arena currently contain a bar code. In a number of cases, however, the NDC bar code is not originally printed at the unit dose level from the manufacturer. Repackagers must perform this duty, shortening the shelf life of the product. As the FDA develops a position on bar coding for medication errors, they must be cognizant of the significant increase in costs that will result for either manufacturers or repackagers as a result of bar coding to the unit-dose level.** **Existing bar codes are used for a variety of applications: inventory control and management functions, and on a lesser scale but increasingly in hospitals for medication error purposes. In all cases where bar codes are in use for medication error prevention, the NDC number alone is being used to reduce dispensing errors.**

General Questions & Economic Impact Questions

FDA Question	HDMA 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?	**If the regulation calls for bar coding to the unit dose level with the NDC only, then there should be little cause for package modification. If the initial recommendation requires more data presentation than the NDC, then both current and future packaging and processes may be affected. Manufacturers in particular will find it difficult to create unit-dose packaging, as label space will become restrictive and cost issues prohibitive.**
2. Have you implemented bar code technology in your product line? If so, what elements and symbology are included in the bar code?	**HDMA member companies are utilizing bar codes on most packaging. Many repackagers are bar coding to the unit-dose level, using NDC as the identifier. Many manufacturers are encoding NDC on products as label space allows. UPC and Code 128 symbologies are in wide use.**
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?	**If a bar code is not readable at the point of dispensing, then the medication can not be administered until it is verified, which essentially results in a 100% verification at the point of use. This should not, however, be the standard for in-line verification, as it would be cost prohibitive to comply at a point prior to drug administration. It is recommended that the bar code accuracy standard be set at the same current high standard as human readable information.**
4. Can bar codes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?	**While our membership perform varying functions with varying capabilities throughout the healthcare supply chain, generally speaking, an attempt to include all three of the identifiers mentioned at left at the highest production line speeds is not currently possible. This is increasingly true for members were lot number and expiration date to be attempted to the unit-dose level on all products.**

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?	**Currently, the greater the complexity of the bar code, the less available are systems and equipment capable of rapid scanning and particularly printing. Also, and perhaps as a result, the more complex the symbology, the less is the installed base capable of processing the bar code.**
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.)?	**Machine-readable technologies are beginning to gain appreciation and usage at the point of patient interface. While there are numerous potential benefits from bar coding and other technologies for the entire healthcare supply chain, some not yet realized, it is best to allow market forces to continue to drive those changes. The short-term problem of medication errors can be best solved by a current solution that utilizes an NDC bar code at the unit-dose level. The other benefits of this technology for use in reducing healthcare costs, increasing drug availability and reducing wait times, tracking healthcare products, and the like, are best achieved in a later phase of implementation and/or by market forces.**
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?	**There may need to be staggered compliance dates due to the varying readiness of certain portions of the industry and of certain products or types of products. If the regulation calls for bar coding only NDC to the unit-dose level, then a relatively shorter time frame possible. The greater the complexity of the proposed plan, the greater the time required to adapt and comply. There seems to be some consensus around a 2-year compliance period if the final rule is for NDC only.**

Medical Device Questions

FDA Question	HDMA Response
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.	**Not applicable to HDMA members.**
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.	**Not applicable to HDMA members.**
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?	**Not applicable to HDMA members.**
4. What public health/patient safety benefits can be derived from bar coding medical devices? If data exists, please provide it for the record.	**Not applicable to HDMA members.**