Johnson & Johnson

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June 10, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: 21 CFR Parts 201, 606, and 610
Bar Code Label for Human Drug Products
And Blood; Proposed Rule

Dear Mr. Chao:

Johnson & Johnson is pleased to provide the attached comments for the consideration of the Food and Drug Administration ("FDA") in its development of regulations on bar code labeling for human drug products and blood. These comments respond to the agency's proposed rule in the Federal Register of March 14, 2003 (*68 Fed. Reg. 12500 (2003)*).

The Johnson & Johnson family of companies is the world's most comprehensive and broadly based group of manufacturers of healthcare products for the consumer, pharmaceutical, medical device, and diagnostics markets.

Johnson & Johnson belongs to several trade organizations that are also commenting on the Proposed Bar Code Label Rule. These organizations include the Advanced Medical Technology Association (AdvaMed), the trade association of the Automatic Identification and Data Capture Industry (AIM), the Consumer Health Products Association (CHPA), the Cosmetic, Toiletries and Fragrance Association (CTFA), the Health Industry Business Communications Council (HIBCC), the Healthcare Distribution Management Association (HDMA), HDMA's Industry Coalition on Patient Safety (ICPS), the National Alliance for Health Information Technology (NAHIT), and Pharmaceutical Research and Manufacturers America (PhRMA). Through our participation in these organizations Johnson & Johnson supports many of the positions taken by these organizations; these areas of agreement are highlighted in this correspondence.

Our companies have utilized bar coding in the healthcare industry for over ten years and have experience with customer usage throughout the consumer, medical device, and pharmaceutical sectors. Based on our experience, we recommend that FDA consider and incorporate modifications to the proposed rule in order to maximize the benefits of bar coding in patient safety systems.

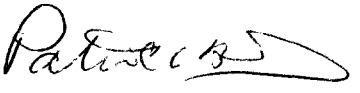
Johnson & Johnson's comments about the proposed rule encompass four issues:

- How the agency defines products that are subject to the bar code requirement;
- The necessity of the National Drug Code in all barcodes created pursuant to the rule;
- The technical standards that will be required under the rule; and
- The benefits of encouraging non-linear technology under the rule.

In addition to providing comments about these four issues, Johnson & Johnson responds to FDA's itemized questions.

Johnson & Johnson appreciates the opportunity to provide comments to the FDA on the development of bar code label regulations and would be pleased to address any questions that the agency may have on these comments.

Sincerely,



Patrick O'Brien
Senior Counsel
Johnson & Johnson Law Department

G /PCO/Letters/FS update Final FDA Response 6/10/03

Attachment

21 CFR Parts 201, 606, and 610
Bar Code Label for Human Drug Products and Blood; Proposed Rule
[Docket No. 02N–0204]

Johnson & Johnson Commentary
New Brunswick, New Jersey

June 10, 2003

Introduction

Johnson & Johnson strongly supports the agency's initiative to encourage bar coding for prescription drugs ordered and dispensed in hospitals.

With respect to medical devices, we agree with other public comments regarding medical devices that have recommended that the agency engage in "further study and a separate rulemaking for devices or the voluntary use of 'automatic identifiers'" 68 FR 12500 at 12504.

FDA should clarify the scope of OTC drugs subject to the proposed rule.

We are concerned that the proposed rule contains unnecessary ambiguities. Specifically, Johnson & Johnson recommends that the Agency clarify the terms "order" and "institution" as used in proposed 21 CFR 201.25(b), which states:

> The following drug products are subject to the bar code label requirements: Prescription drug products ... and over-the-counter drug products that are dispensed under an *order* and are commonly used in hospitals. For purposes of this section, an over-the-counter drug product is *commonly used in hospitals* if it is packaged for *institutional use*, labeled for institutional use, or marketed, promoted, or sold to hospitals.

The preamble of the rule should more clearly state the agency's intended meaning of the word "order," and should clarify that with respect to over-the-counter (OTC) drug products the rule applies only to products commonly used in hospitals (as opposed to other, non-hospital, institutions).

The agency should clearly explain that the word "order" is intended to mean "a prescription of a practitioner licensed by law to administer drugs." FDA should further clarify its intended scope of the rule by providing clear guidance on product categories for which FDA does *not* intend the rule to apply, even though such products might occasionally be "dispensed pursuant to an order." The use of specific examples of products would help the agency convey the intended scope of the rule.

An excellent example of a category of products that should be excluded from the rule consists of all OTC products that do not presently have dosage limitation. These products have low risk potential as demonstrated by having no dosage limitation. Requiring bar coding on such products would not appear to advance any of the goals that FDA has articulated for the proposed rule.

Johnson & Johnson is concerned with the shift in language from "hospitals" to "institutions" within the proposed rule. The agency should unambiguously limit the scope of the proposed rule regarding OTC drugs to the hospital setting. Additionally, the final rule should expressly state the rule does not apply to OTC products that find their way into hospital inventories through indirect means.

Use of the term "institution" unnecessarily widens the scope of the proposed rule to potentially include long-term care institutions such as drug treatment facilities. In these setting, "orders" are routinely written for all expenditures purely for reimbursement reasons. In such institutions, orders are written, for example, to provide sunscreen to patients or residents in the program. Though the FDA may not have considered OTC sunscreen drug products subject to the bar code rule, use of the term "institution" might make a topical sunscreen dispensed in a long-term care facility subject to the bar code requirement.

FDA should refrain from requiring the inclusion of the National Drug Code as the exclusive identifying code in mandatory bar codes for OTC drugs.

The proposed rule requires the inclusion of the National Drug Code (NDC) within all mandatory bar codes, including OTC drugs. Johnson & Johnson is concerned that the exclusive use of the NDC as the identifying code will disrupt pre-existing systems. Today, firms have flexibility in assigning UPC numbers, including among packaging levels, such as blister packs, finish product packages, cartons and pallets. Many of UPC numbers for OTC products do not contain NDC codes. Prohibiting such UPC numbers in barcodes would be unnecessarily restrictive and burdensome.

Johnson & Johnson is also concerned that implementation of NDC encoded barcodes will disrupt the processes that have been established specifically for the purpose of retail distribution and sales. Under the proposed rule, any NDC-related change would affect the entire retail customer base. Requiring exclusive use of NDC codes on OTC products in place of the existing UPC numbers may drive creation of sole use packages for hospitals in order to eliminate disruption to the retail system.

FDA should revise the proposed rule to permit the use of either the UCC/EAN or the HIBCC standard, where appropriate.

The agency's proposed rule requires a bar code that "meets the Uniform Code Council (UCC/EAN) standard." 68 FR 12500 at 12534 (proposed 21 CFR 201.25(c)(1)). The proposed rule should be revised to permit either the UCC/EAN standard or the Health Industry Business Communications (HIBCC) standard.

Johnson & Johnson agrees that the UCC/EAN standard may be an appropriate standard for certain manufacturers in certain settings. However, limiting the bar code format exclusively to the UCC/EAN standard restricts manufacturers and end users from utilizing other ISO-approved industry standards currently used widely in the health care industry such as HIBCC. As presently drafted, the rule would also appear to prohibit standards such as ISBT.

The agency's intent to provide the NDC number in a bar code for prescription drugs can be met by including the Health Industry Business Communications Council (HIBCC) Standard. If a manufacturer follows the existing HIBCC Supplier Labeler Standard and encodes the NDC in a code 128 symbol, the manufacturer will meet the intent of proposed 201.25(c)(1).

We understand that market research underway by HDMA shows there are at least eight drug manufacturers who follow the HIBCC standard. HIBCC is a global standard and contains a single data format that is accepted throughout the world. Although UCC/EAN claims to be global, the Global Trade Identification Number (GTIN) consists of a collection of formats, which vary by geographic region. Indeed, some EAN bar code formats, for example EAN 13, are not even used in the United States.

It is also noteworthy that the HIBCC standard is widely used for medical devices and diagnostics products on a global basis. If, in the future, FDA considers a similar bar code rule for medical devices, limiting the drug-specific rule to the UCC/EAN standard would likely impede the implementation of automatic identification coding and scanning for medical devices.

The linear HIBCC code can be read by any scanner that reads UCC/EAN linear code. Excluding the HIBCC standard penalizes drug manufacturers that use the HIBCC standard, and potentially, device manufacturers that use the HIBCC standard.

Hospital clinical staff use medical devices and dispense prescription drugs in the same settings. Though this proposed rule will not require medical device manufacturers to implement bar coding, if the FDA were to include the HIBCC standard in this rule the rule would encourage hospitals to select scanning technologies and inventory software systems that will read and accept the HIBCC bar codes that are widely used on medical devices.

FDA should remove the requirement of linear bar coding from the proposed rule.

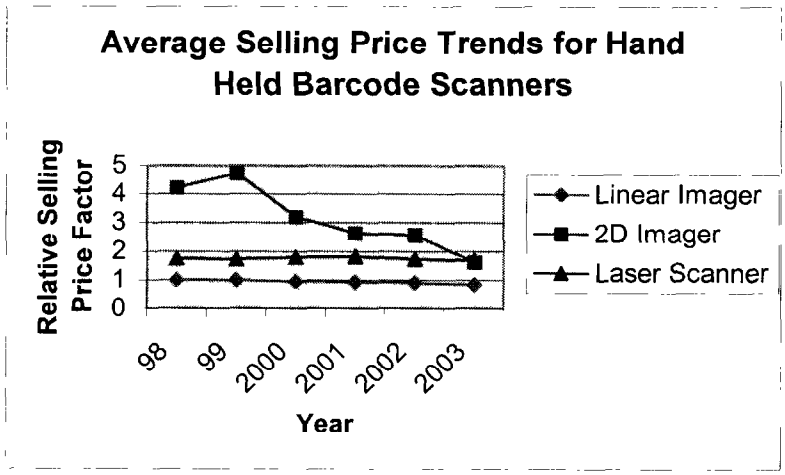
The rule should specify data required (such as the NDC) and industry standards (such as UCC/EAN and HIBCC), but the rule should not restrict symbologies to linear symbols. Rather, the rule should be written to enable the adoption of appropriate non-linear symbologies such as two-dimensional symbols and Radio Frequency Identification (RFID) tags. The rule should rely on the international standards development organizations of UCC, HIBCC and the International Society for Blood Transfusion

(ISBT) to govern and promote the introduction of automatic identification technologies into healthcare. Linear symbols require more space on packaging, which will increase the number of requested exemptions and limit the amount of information barcodes might contain, such as lot number and expiration data.

Johnson & Johnson acknowledges the argument that permitting nonlinear symbology under the rule will cause a slight increase in the cost of scanner implementation in hospitals. However, the cost of image scanners to hospitals will in no measure be prohibitive. The cost of scanners is a small percentage of the costs hospitals will pay in the implementation of electronic medication administration recording and scanning systems. It has been reported that hospitals now believe the cost of image scanners are within reach and will certainly be acceptable by the end of the FDA's three-year implementation period.

Johnson & Johnson is not alone in its support of non-linear bar coding technology. As an end-user member of AIM, Johnson & Johnson is aware that AIM is forwarding comments to FDA that advocate that the proposed rule be expanded to include two-dimensional symbols.

AIM members have shared the following graph and commentary with Johnson & Johnson. The graph demonstrates that while linear imager and laser price points have remained relatively flat over the past several years, the average selling price of two-dimensional imager hand held scanners have fallen sharply and are now price competitive.



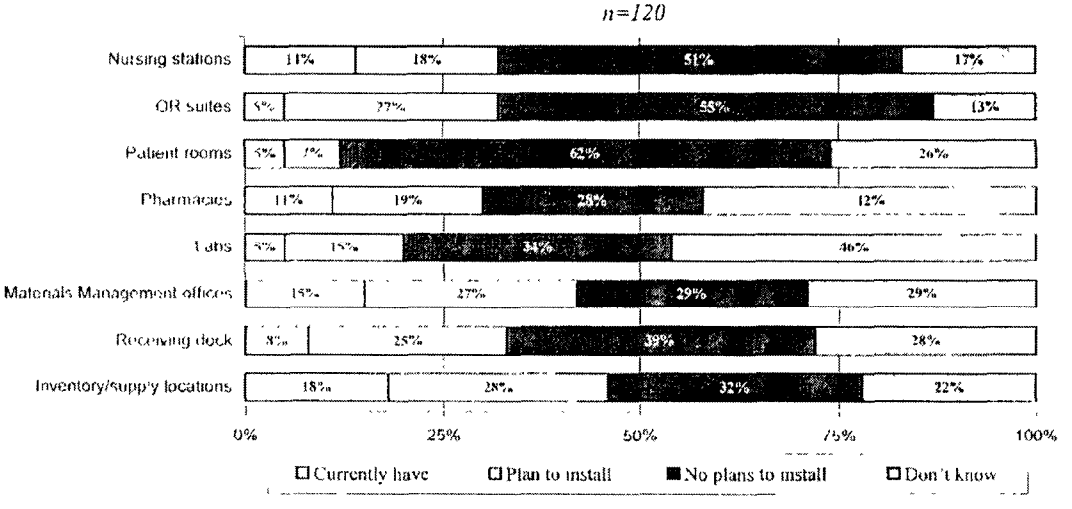
The Relative Average Selling Price factor represents all price data normalized to the linear imager price in 1998. The data for the graph comes from AIM member financial data and Venture Development Corporation, a market research firm.

The increased rate of adoption of two-dimensional image readers can be attributed to the improved performance and versatility the technology delivers and the dramatic cost basis reduction of the technology. Two-dimensional readers are commonly used for traditional

linear barcode reading. The cost of two-dimensional image readers has been reduced considerably due to the cost reduction of key product components like the imager chip, microprocessor and memory.

From a qualitative market research study conducted by a third party for Johnson & Johnson in December 2002, only a small percentage of hospitals have purchased scanners for bedside systems. Allowing manufacturers to use nonlinear symbols will provide future benefits to those hospitals that are currently scanning at the bedside.

The figure below depicts that 5% of the study respondents are actively scanning at the bedside. In the commentary of the March 14, 2003 proposed rule, FDA identified the installed base at bedside to be 2%. While it is true that the majority of these installed systems employ laser scanners to read linear codes, there is ample opportunity to migrate these scanners to areas in the hospital where small two-dimensional symbols will not be present. Manufacturers who follow either the UCC/EAN or HIBCC standard will continue to use linear codes on cases, shippers and pallets. Twenty-five percent of the respondents indicated that they intend to scan bar codes on inventory at the receiving dock, in materials management supply rooms and warehouses.



If FDA were to include two-dimensional symbols in the scope of this proposed rule, the five percent of U.S. hospitals that are actively scanning at the bedside would have the option to buy new image scanners for the bedside and migrate their existing scanners to supply chain uses. Alternatively, hospitals could continue to print linear bar codes and apply labels as they do now for medications that are not bar coded. Accepting either option means that those hospitals that are now scanning will not be forced into image scanning until they see the merits of the superior technology.

Use of smaller, square-shaped symbols such as DataMatrix would enable hospitals to identify and scan challenging applications such as those associated with infant care. The limb circumference of infants makes a linear bar coded wristband unreadable. Image scanners also have the ability to capture digital images of patients. To meet JCAHO's

National Safety Patient Goal for improving patient identification hospitals have begun the practice of identifying patients via digital images attached to patient records[1]. This is especially true where patients routinely remove their wristbands.

There are two key components to medication administration systems: ordering and dispensing. By limiting the bar codes to be used to linear codes, the proposed rule would impede technology for computerized physician order entry (CPOE) as well. The image capture feature of image scanners is commonly being used to capture signatures for many "proof of delivery" applications. This same inherent technology could be used to capture and submit images of written prescriptions. Image scanners integrated into portable data terminals and palm computing devices can serve dual purposes; (1) allow CPOE prescription entry and, (2) scan nurse/patient/drug administration once the prescription is filled.

The inclusion of two-dimension codes will create a technological pathway to provide future customer needs for lot numbering and expiration data in the bar code. The DataMatrix symbology has already been incorporated into the HIBCC Supplier Labeler Standard. A Johnson & Johnson company currently prints DataMatrix symbols encoding the UPN, lot number, and expiration date on suture packages. Over 250,000 sutures are packaged and bar-coded with DataMatrix symbols each day. This production rate could not be considered with the use of the UCC standard's RSS symbols.

The proposed bar code rule creates a competition for package label space between the "Drug Facts" labeling rule for OTC medications and the rule on bar coding. Use of two-dimension codes may lessen the white space demand and thereby eliminate the need for significant package redesigns in many cases. At a minimum, FDA should provide guidance for manufacturers trying to meet both rules if non-linear bar coding is prohibited under the final rule.

At the Institute for International Research (IIR) Symposium held in Washington on March 24-25, 2003, many of the drug companies on the panel expressed concern that there is not sufficient space for a bar code even with RSS symbology. Companies fear they are faced with two alternatives: provide drugs exclusively in bulk package, or increase the size of the unit dose package. The first shifts the burden of unit dose packaging to hospitals. The second unnecessarily increases costs to the manufacturer and costs to the hospital (by increasing the need for storage space and medical solid waste disposal).

There is widespread industry acceptance of the two-dimensional DataMatrix symbology. In February 2003, Baxter Healthcare submitted a Global Standards Management Process Change Request to UCC/EAN to allow DataMatrix to be used with UCC/EAN application identifiers[2]. In March 2003, the Industry Forum subcommittee of the Vaccine Identification Standards Initiative (VISI) working group made a similar request to

[1] Correspondence from National Patient safety Foundation (NPSF) List-serv
[2] Uniform Code Council website

UCC/EAN[3]. Subcommittee members include Aventis, Chiron, Glaxo Smith Kline, Merck, Novartis, and Wyeth.

If the pharmaceutical manufacturers present at the IIR Symposium are having trouble fitting the RSS base component, then the stacked portion that would carry lot and expiration data would be even more of a burden. The solution is use of 2-dimensional symbols such as DataMatrix. With instances of drug dilution and piracy, the ability to trace by lot numbers is becoming even more critical. By deleting the word "linear", the proposed rule will allow Johnson & Johnson companies and other manufacturers to use DataMatrix symbols for this important industry initiative.

Johnson& Johnson is actively involved with the AUTO ID Center at MIT and the ePC alliance. We believe there is significant potential in RFID technology especially as a deterrent to product piracy and adulteration. The use of RFID tags can also enable increased nursing staff productivity in the capturing of product and patient information. Johnson & Johnson recommends that the FDA, together with industry, monitor the advances in RFID application and standardization. As this technology evolves, it can then be effectively used in patient safety systems.

FDA Itemized Questions

In the proposed rule, the FDA itemized 13 questions for comment. Following are responses to those questions.

1) Should the rule require bar codes on prescription drug samples and if so what are the costs/benefits of their inclusion?

   Johnson & Johnson supports addition of bar codes to drug samples. We are studying the cost of adding bar codes to unit dose sample packaging. Physicians dispense samples to their patients and these samples sometimes wind up in hospitals, especially when the physician's office is close to the hospital. The goal of bar coding unit dose packaging is to monitor drug usage in hospitals, and whether the drug is sold or sampled should not matter as long as samples are recorded as no-charge products for reimbursement purposes. Even if hospital protocol does not allow the use of samples, an accurate scan of a drug not on formulary would indicate and record the attempted use.

2) What are the risks and benefits of including vaccines in the rule?

   Although Johnson & Johnson companies do not currently manufacture vaccines, we believe that the answer for small containers, such as vaccines, is the use of non-linear symbologies such as Data Matrix. Linear bar codes will be difficult to read on small vials due to the size of the code and small space available.

[3] Uniform Code Council website

3) Are the terms used to describe the OTCs covered by the rule sufficient?

No. FDA should clarify several terms in the proposed ruling regarding OTC's. The use of the terms "hospital" and "institution" within the proposed rule create ambiguity because the term "institution" could be broadly interpreted. Additionally, the agency should clarify the meaning of the phrase, "pursuant to an order". There is widespread confusion over this term, some industry groups have interpreted an "order" as a "sales order" while other have defined an "order" as a "clinician's order."

4) Should the lot number and expiration date be included in the rule and if so what is the data on the costs and benefits that would justify their inclusion.

The rule should not require inclusion of lot and expiration date at this time. If lot number and expiration date are included in the rule, the implementation date must be extended beyond three years.

5) Should the rule refer to linear bar codes without mentioning any particular standard?

The word "linear" is too restrictive because it locks all stakeholders into current, older technologies, limits the amount of information contained in the bar code, and is space inefficient compared to newer technologies such as two-dimensional Data Matrix.

Johnson & Johnson supports FDA's desire not to become a standards organization. We recommend that multiple standards organizations such as UCC/EAN and HIBCC be identified in the rule.

6) What is the current state of bar code scanners and their ability to read various symbologies?

The current technology for laser scanners limits their utility in the healthcare environment. Manufacturers of scanners have driven their research and development efforts in the area of image scanners rather than laser scanners due to the greater versatility of this newer technology. Image scanners are immediately adaptable to new technologies with software downloads and not hardware replacement. With their versatility and flexibility for upgrades to accommodate new standards, image scanners give the ability to read linear bar codes, two-dimensional codes such as Data Matrix, and even taking electronic pictures of objects such as patient faces. Image scanners are superior in their design as they turn objects into data allowing for decoding of all standards, being limited only by software storage size.

Johnson & Johnson, as an end user of Automatic Identification and Data Capture technology, has seen a significant drop in the cost of image scanners and recognizes merit in their application in healthcare. Comments to the FDA from

AIM contain market data suggesting that the acceptance of image scanners is widespread and that costs are becoming competitive. Within the three-year implementation period of the ruling, image scanning of non-linear symbologies is a viable technology for patient safety.

7) Should the rule adopt a different format for the machine readable code, what should that format be, how widely is it accepted by the industry and will hospitals be able to read it with existing equipment or equipment under development?

Yes, the rule should include other machine-readable codes such as, two-dimensional Data Matrix Symbology. We support inclusion of UCC/EAN and HIBCC standards that specify these types of machine-readable codes. These formats are widely accepted in industries such as delivery companies, aerospace, electronics, grocery, banking, and the auto industry.

If hospitals install laser-style readers now, they will be limited to reading "linear" bar codes. The final rule should encourage conversion to image style scanners, which would allow hospitals to read both "linear" and two-dimensional codes.

8) Should there be specific product exemptions from the rule and how should they be defined?

Exemptions should be considered and granted for small packages on an extremely limited basis in consideration of special and unique requirements.

Linear bar codes, unfortunately, will not fit on many packages thus creating a desire for small package exemptions. However if the rule permits nonlinear bar coding, the desire for exemptions based upon space constraints could be significantly reduced.

The amount of printable space on unit dose packaging is limited. This proposed rule for bar coding competes with the FDA labeling rule for print space. Changes to 21 CFR Part 201.1 as suggested by PhRMA may enable manufacturers to print a two-dimensional bar code, NDC number for prescription drugs, product name and dosage. Johnson & Johnson agrees with PhRMA's recommendation to eliminate the manufacturer name and address on solid dose blister packaging.

We suggest FDA create an advisory board made up of industry representatives to review and advise on the exemption process. Johnson & Johnson would be willing to participate on such an advisory board.

9) Is the implementation time frame of three years appropriate or can it be shortened? Should there be a different time frame for new drug products?

The three-year period is appropriate for the NDC requirement for drugs currently on the market. New drugs should enter the market in compliance with the rule.

The rule should, however, acknowledge that there will be un-expired inventory in the supply chain at the time the rule becomes effective.

10) Should the ISBT 128 standard be adopted for blood or should an UCC/EAN standard be required?

Because Johnson & Johnson does not use ISBT 128, we have no comment on this question.

11) How will the rule for blood affect hospitals purchasing decisions for bar code technology given the requirements in the rest of the rule for drug products?

Because Johnson & Johnson does not use ISBT 128, we have no comment on this question.

12) Are any of the alternatives discussed by the FDA in the economic impact section of the rule, of issuing no rule or requiring additional information in the code, viable?

To the extent the rule provides NDC bar coding for prescription drugs it is timely and appropriate.

13) Are there concerns about the economic assumptions made by the FDA in the proposed rule and how might they be addressed?

FDA has significantly underestimated the economic impact of the rule. Without clear guidance for OTC products, relief of data requirements on packages lacking room for codes, and by requiring 'linear' bar codes, a clear economic impact cannot be accurately predicted.