

Corporate Regulatory and Quality Science

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Dockets Management Branch (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting [Docket 02N-0204]

Dear Sir or Madam:

Abbott Laboratories (Abbott) submits the following comments regarding FDA Notice "Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting" published in the Federal Register on June 18, 2002 at 67 FR 41360.

Thank you for the opportunity to provide these comments. In regards to bar coding drugs and biologics, Abbott endorses the position of PhRMA expressed at the July 26, 2002 public meeting. We supplement this position with our comments below. For medical devices, we endorse the position of AdvaMed expressed at the July 26, 2002 meeting and AdvaMed's corresponding comments submitted to the docket 02N-0204. We supplement this position with our comments below. Furthermore, we urge the Agency to hold a public meeting to discuss the complexities and unique issues associated with bar coding medical devices.

Part 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 (OTC) drugs be bar coded? Should blood products and vaccines carry a barcode?

All prescription medications and vaccines (except for clinical supplies and physician samples) supplied to hospitals should carry bar codes.

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,

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please provide it for the record. What information would be helpful but not necessarily critical, for reducing medication errors? Provide data.

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 Abbott Laboratories is aware, there are negligible data on whether encoding secondary identifiers such as lot number and expiration date will contribute to medication error reduction.

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? What are the pros and cons of each approach?

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 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).

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?

The greatest benefit is the use of bar coded NDC numbers 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.

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.

Where there is sufficient printing space, most pharmaceutical SKUs distributed within the USA carry a UPC symbology for the NDC numbers. This is currently used within the wholesale/retail supply chain.

Part B. Medical Device Questions

1a. Should medical devices carry a bar code?

Currently, many medical devices do carry bar codes. Medical device manufacturers have voluntarily employed bar codes for a variety of reasons from inventory control to shipping efficiencies. Market forces have and continue to drive the adoption of bar codes for medical devices. This has allowed the medical device industry to establish systems that work for a variety of different device types.

The use of bar codes on devices should be voluntary. Rather than mandate bar coding via FDA regulation, we recommend first assessing for which devices the addition of a bar code would result in enhanced safety. Second, it is important to consider to what extent industry has already incorporated bar codes for such devices, and the types of bar code technology currently implemented. Only after careful consideration of such items should FDA consider implementing bar code regulations for medical devices where safety benefits can be realized.

Furthermore, consideration of bar coding for medical devices must be done separately from coding of drugs and biologics. A regulation tailored to drugs and biologics would not recognize the unique issues posed by medical technologies, such as the diversity of products and the evolution of coding technology. Additionally, the physical bar coding of medical devices presents some unique issues, such as whether to label the device package or the device, itself. Depending on the medical device and the identified safety risk, the location of the bar code may differ. As such, FDA should not address medical devices in its pending regulation on bar coding for drugs and biologics.

1b. What information should be included in a bar code?

Should FDA move forward with bar coding for certain medical devices (i.e., devices for which bar coding would enhance safety), the information contained in the bar code should identify the manufacturer and the product and packaging level. FDA should not mandate a particular bar code standard or symbology. Rather FDA should allow industry to rely on existing standards such as HIBC or UCC without specifying a particular standard in a final rule. Such an approach would be the least disruptive to the end-user and the medical device industry.

2. If medical devices are bar coded, should all medical devices, or only certain devices carrying bar codes?

FDA should not require all medical devices to carry bar codes. Only after careful consideration of medical devices for which bar coding would enhance safety, should FDA explore required bar coding. Medical devices presenting similar issues as drugs (i.e., medication errors) may be candidates for bar coding. Devices, which are administered in a manner similar to drugs would be an area to explore. For example, pre-filled flush syringes are used in a manner similar to drugs. Therefore, bar coding on such devices may be appropriate.

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 bar codes be different from the original manufacturers bar code?



Reprocessed, repackaged, refurbished, or multiple-use medical devices should be treated no differently than other medical devices with respect to bar coding. In the event that original equipment manufacturers (OEMs) provide barcodes on their devices, refurbishers and reprocessors of those devices must be required to remove or permanently obliterate the OEM's bar code, just as they should remove or permanently obliterate human-readable OEM identifiers such as trademark and company name. If this is not done, products could be misidentified and failures could be mistakenly attributed to OEM devices rather than the reprocessed device and can severely compromise the OEM's proper application of its quality system regulations.

4. What public health/patient safety benefits can be derived from bar coding medical devices?

For pharmaceuticals the bar code regulation is being proposed to address medication errors (administering the wrong drug and/or dose). Unlike pharmaceuticals, use of the wrong device has not been reported as a prevailing issue. With the exception of medical devices that are administered similarly to drugs, it is unlikely that bar coding medical devices would address medication errors.

Part 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?

Drugs and Biologics:

Abbott Laboratories 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 expiration date, companies may reconsider the packaging choices due to space and feasibility of the package to encode all the information specified.

Medical Devices:

Yes, bar coding would require modification of packaging choices, especially for device packages that are too small to accommodate a bar code.

2. Have you implemented bar code technology in your product line? If so, what elements and symbology are included in the bar code?

Drugs and Biologics:

Abbott Laboratories has incorporated bar code technology on many current packages. Symbologies used include UPC, Code 128, and RSS. On many products where there is sufficient space, an NDC number bar code is present.

Medical Devices:

In response to customer requests, some of our product lines, but not all, use the HIBC or UCC bar code standard. Data format is encoded in Code 128 or UPC symbology depending on the product line.

3. If you manufacture and bar code products, how do verification requirements for bar codes affect your ability to add bar codes? How much bar code verification is appropriate as part of the quality system?

Drugs, Biologics, and Medical Devices:

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 scan-ability and verify routinely with in-process inspection.

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

Drugs, Biologics, and Medical Devices:

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.

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?

Drugs and Biologics:

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.

Medical Devices:

We are unable to respond to this question given the variety of medical devices.

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.)?

Drugs, Biologics, and Medical Devices:

This question is more relevant to stakeholders other than Abbott Laboratories.

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?



Drugs and Biologics:

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. If variable information such as lot number and expiration date are required then about five years would be required and significant costs due to equipment changes are anticipated.

Medical Devices:

Any final rule should be phased in related to the risk to the patient and the complexity of the task to convert to a bar coding system.

Should you have any questions regarding drugs and biologics, please contact Richard Johnson at (847) 938-1750 or by facsimile at (847) 938-4422. For questions regarding medical devices, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in cursive script that reads 'Doug Sporn /jis'.

Douglas L. Sporn
Divisional Vice President
Corporate Regulatory Affairs, Abbott Laboratories

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FedEx USA Airbill
Form Tracking Number
832546009630

1 From This portion can be returned for Recipient's records
FedEx Tracking Number 832546009630
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Company ABBOTT LABS

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2 Your Internal Billing Reference *CHAMP 587*

3 To Recipient's Name *DOCKETS INTERNATIONAL BLDG 301-877-3380*

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City *KNOXVILLE* State *MA* ZIP *01052*



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4a Express Package Service Packages up to 150 lbs. Earliest next business morning. Delivery commitment may be later in some areas.

FedEx Priority Overnight Next business morning

FedEx Standard Overnight Next business afternoon

NEW FedEx Extra Hours Later drop-off with next business afternoon delivery in select locations.

4b Express Freight Service Packages over 150 lbs. Delivery commitment may be later in some areas.

FedEx 2Day Second business day

FedEx 2Day Freight Second business day

FedEx 3Day Freight Third business day

5 Packaging Declared value limit \$500

FedEx Envelope* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak

Other Pkg Includes FedEx box, tube, and customer tag

6 Special Handling Include FedEx address in Section 3

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

No As per attached Shipper's Declaration

Yes Dry Ice, UN 1845 x kg

Yes Shipper's Declaration not required

No Dangerous Goods (Level Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours Service

7 Payment Bill to

Sender (if No in Section 8) Bill to be billed

Recipient

Third Party

Credit Card

Cash/Check

Other Pkg Art. No.

Fedex Card

8 Release Signature Sign to authorize delivery without obtaining signature

Your liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

Total Packages [redacted] Total Weight [redacted] Total Charges [redacted]

Credit Card Auth [redacted]

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