

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 211, and 601

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Certifier R. LEDESMA

Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments for the development of a regulation on bar code labeling for human drug products, including biologic products. We (FDA) will also explore issues surrounding bar codes on medical devices. We are holding this meeting to support the initiative of the Secretary of Health and Human Services to reduce medication errors.

DATES: The public meeting will be held on July 26, 2002, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by July 12, 2002. Submit written or electronic comments for consideration during the meeting by July 12, 2002.

ADDRESSES: The meeting will be held at the Natcher Auditorium, Building 45, National Institutes of Health (NIH), Bethesda, MD. Parking will be limited and there may be delays entering the NIH campus due to increased security. We recommend arriving by Metro if possible. NIH is accessible from the Metro's red line at the Medical Center/NIH stop.

FOR FURTHER INFORMATION CONTACT:

Registration for Speaking Attendees: If you wish to speak at the public meeting, please contact Mary C. Gross, Office of Drug Safety, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, rm. 15B-32, Rockville, MD 20857, 301-827-3193, FAX 301-443-9664, e-mail: grossm@cder.fda.gov. Speakers must register and submit a short summary of

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your presentation by July 12, 2002, to Mary C. Gross; faxed copies of presentations are permissible. We encourage consolidation of like-minded presentations to enable a broad range of views to be presented.

Registration for General Attendees: If you wish to attend the public meeting, register with Elizabeth French, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, Rockville, MD 20857, 301-827-3360, FAX 301-827-6777, e-mail: efrench@oc.fda.gov. General attendees should register no later than July 12, 2002. As time permits, we will accept oral comments from the audience. More information is available on the Internet at <http://internet-dev.fda.gov/oc/meetings/barcodemtg.html>.

SUPPLEMENTARY INFORMATION:

I. Background

In 1999, the Institute of Medicine (IOM) report entitled "To Err is Human: Building a Safer Health System" cited research stating that there are an estimated 100,000 deaths in the United States every year from preventable medical errors in hospitals alone.¹ The range of deaths reported, between 44,000 and 98,000 deaths, was based on the 1984 Harvard Medical Practice Study and confirmatory studies done in Colorado and Utah. These numbers reflect the entire area of medical errors, including, for example, surgical errors, iatrogenic infections, medication errors, and incorrect use of medical products. Of the projected 100,000 deaths, we believe that approximately 30 to 50 percent are associated with errors involving FDA regulated medical products (e.g., drugs, devices, blood and blood products, or vaccines). In addition to the human cost of errors involving drugs, there are also significant economic costs. An article published in 1995 estimated the direct cost of preventable drug related mortality and morbidity to be \$76.6 billion, with drug related

¹ Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, editors; "To Err Is Human: Building a Safer Health System," Committee on Quality of Health Care in America, Institute of Medicine, November 29, 1999.

hospital admissions accounting for much of the cost.² Another article, published in 2001, used updated cost estimates derived from current medical and pharmaceutical literature to revise the \$76.6 billion estimate to exceed \$177.4 billion; of which hospital admissions accounted for \$121.5 billion in costs, and long-term care admissions accounted for another \$32.8 billion.³

Medication errors are a subset of the wider category of medical errors. Medication errors are defined by the National Coordinating Council for Medication Error Reporting and Prevention as:

* * * any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.⁴

Medication errors can lead to adverse drug events. It is estimated that 770,000 adverse drug events leading to injury or death occur yearly in U.S. hospitals alone, and that between 28 to 95 percent of these are preventable, i.e., can be defined as errors. Computerized hospital medication use and monitoring systems could prevent many of these medication errors.⁵

In response to the IOM report, the Secretary of Health and Human Services directed FDA to explore possible regulatory approaches to reduce these preventable errors. Errors related to

² Johnson, J. A. and J. L. Bootman, "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," *Archives of Internal Medicine*, pp. 1949–1956 (1995).

³ Ernst, F. R. and A. J. Grizzle, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," *Journal of the American Pharmaceutical Association*, vol. 41, pp. 192–199, March/April 2001.

⁴ National Coordinating Council for Medication Error Reporting and Prevention, "What is a Medication Error?" (Undated).

⁵ Agency for Health Care Quality and Research, "Research in Action: Reducing and Preventing Adverse Drug Events (ADEs) to Decrease Hospital Costs," April 11, 2001. (<http://www.ahrq.gov/qual/aderia/aderia.htm>)

dispensing and administration can be minimized through the use of bar codes. For example, if a health professional could use a bar code scanner to compare the bar code on a human drug product to a specific patient's drug regimen, the health professional would be able to verify that the right patient is receiving the right drug, at the right dose, and at the right time. Bar code advocates have recommended that the bar code contain a unique numerical code that is dose specific to identify the manufacturer, product, and package size or type, lot number, and expiration date.

The availability of bar codes for pharmaceuticals would also facilitate other patient safety initiatives, for example, automated drug prescribing or ordering, automated monitoring for drug toxicities in hospitals, and as a component of the automated medical record. Automation of the drug prescribing and ordering system, if linked to a bar coding system, has the potential not only to minimize drug mixups, but also to make sure prescribers have access to crucial information at the point of prescribing.

We are considering whether to require bar codes on human drug products, including certain biologic products. The bar code would contain certain information about the product, such as a dose-specific individual identifying number. We are considering whether to require the bar code to contain other information, such as the drug product's expiration date and lot number, to make it easier to identify expired drugs and recalled drugs that may not be safe and effective for use. We are also exploring issues surrounding bar codes on medical devices.

II. Scope of Discussion

We will hold a public meeting on June 13, 2002, from 9 a.m. to 5 p.m., to discuss bar code labeling. We will give careful consideration to technical issues regarding the development and implementation of a possible bar code label. We anticipate that discussions will include presentations from invited speakers as well as from members of the public.

We invite public comment on this issue, and we intend to focus on the following questions:

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?

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.

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?

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?

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. Medical Device Questions

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.

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.

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?

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

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?

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

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.)?

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?

III. Comments

Interested persons, who wish their comments to be considered during the meeting, may submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments by July 12, 2002. Comments will be accepted after the meeting until August 9, 2002. Submit electronic comments to fdadockets@oc.fda.gov or <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857. The transcript of the public meeting will be available approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after June 28, 2002, at the Dockets Management Branch (see *Comments*) between 9 a.m. and 4 p.m., Monday through Friday and on the Internet at <http://www.fda.gov>.

V. Electronic Access

Persons with access to the Internet may obtain additional information on the public meeting at <http://internet-dev.fda.gov/oc/meetings/barcodemtg.html>.

Dated: 6/11/02
June 11, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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