

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 201, 606, and 610

[Docket No. 02N-0204]

RIN 0910-AC26

#### Bar Code Label Requirement For Human Drug Products and Blood

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing a new rule that would require certain human drug product labels and biological product labels to have bar codes. The bar code for human drug products and biological products (other than blood and blood components) would contain the National Drug Code (NDC) number in a linear bar code. The proposed rule would help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The proposed rule would also require the use of machine-readable information on blood and blood component container labels to help reduce medication errors.

**DATES:** Submit written or electronic comments on this proposed rule by June 12, 2003. Submit written comments on the information collection requirements by April 14, 2003.

**ADDRESSES:** Fax written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Fax electronic comments to <http://www.fda.gov/dockets/> ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Stuart Shapiro, Fax: (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

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#### I. Introduction

##### *A. What Actions Led to This Rulemaking?*

In 1999, the Institute of Medicine (IOM) issued a report entitled “To Err Is

Human: Building a Safer Health System” (Ref. 1). (The IOM is a private, nonprofit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences.) The IOM report cited studies and articles to estimate that between 44,000 and 98,000 Americans may die each year due to a range of medical mistakes made by health care professionals. The IOM report estimated that, in 1993 alone, an estimated 7,000 deaths were attributable to medication errors (Ref. 1 at p. 27) and that:

- Medication errors account for 1 out of every 131 outpatient deaths, and 1 out of every 854 inpatient deaths (Ref. 1 at p. 27); and

- The death rate attributable to medication errors may be increasing. The IOM report cited a study that examined death certificates from 1983 to 1993. The study found that, in 1983, 2,876 deaths were due to medication errors (which the authors defined as accidental poisoning by drugs, medicaments, and biological products resulting from acknowledged errors by patients or health care professionals) (Ref. 1 at p. 32, Ref. A-14 of the Appendix to this document). In 1993, 7,391 deaths were attributed to medication errors, a 2.57-fold increase in the death rate (Ref. 1 at p. 32). Moreover, a comparison of outpatient death rates suggested nearly an 8-fold increase in medication error death rates (Ref. 1 at pp. 32 and 33).

The IOM report stated that deaths due to medication errors are often preventable and cited bar codes as one way to prevent them (Ref. 1 at pp. 37, 175, 188, 189, 195-196).

The IOM report generated considerable controversy. Some felt that the IOM's figures were exaggerated (Ref. 2), while others felt the figures might have been too low (Ref. 3). Some felt that the term “medical errors” was, itself, misleading (Ref. 4). Others, including FDA, suggested that the IOM report's basic message—that medical errors are a serious public health problem—should not be lost regardless of whether the annual mortality was 10,000 or 100,000 (Ref. 5)

The IOM report led to new efforts to improve patient safety. For example:

- In December 1999, President Clinton directed the HealthCare Quality Task Force to analyze the IOM report and to report back on recommendations to