



Health Industry Business Communications Council

FOR IMMEDIATE RELEASE

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FDA'S FINAL RULE ADVOCATES HIBC STANDARDS Regulation to Mandate Bar Code Labeling for Medical Error Reduction

PHOENIX, ARIZONA (February 27, 2004)— The Food and Drug Administration (FDA) released yesterday their final rule on Bar Code Label Requirements for Human Drug Products and Biological Products. The ruling calls for the inclusion of linear bar codes on most prescription drugs and advocates the use of HIBC labeling Standards to aid in the reduction of medical error.

The ruling incorporates changes to the FDA's originally proposed language that required exclusive use of retail-based standards. The changes are based upon review of numerous comments from the industry that raised concerns regarding the exclusion of HIBC Standards. In the final rule the FDA explained their decision stating, "We decided to give firms the option of using HIBCC data formats because HIBCC is a widely-recognized non-profit standards development organization...we also cannot preclude the possibility that some firms may prefer using alphanumeric code formats, which HIBCC uses."

Health Industry Bar Code (HIBC) Standards were developed by the healthcare industry when leading associations determined that the existing retail-based bar code standards were inadequate for the specific applications and needs of a health care environment. The all-numeric retail standards, developed for the point-of-sale, "cash register" needs of retailers, did not adequately address patient and consumer safety concerns. The HIBC Standards employ an alphanumeric data structure considered by many industries to be an inherently safer method of encoding data.

"We welcome the FDA's action to support the implementation of bar code technology as a means of reducing medical error," states Robert A Hankin, Ph.D., HIBCC President and CEO. "Their inclusion of HIBC Standards provides added assurance to healthcare institutions and HIBC labelers that their processes are correct for patient care and the industry at large."

The FDA's bar code rule, anticipated to prevent nearly 500,000 adverse events when fully implemented, becomes effective April 26, 2004. Excerpts of the ruling, as well as additional information regarding the HIBC Standards and the HIBCC organization can be accessed from the HIBCC web site at: www.hibcc.org.

HIBCC is an industry-sponsored, non-profit standards development organization (SDO), established in 1983 by major national healthcare associations to develop and maintain information technology standards for healthcare applications. Its mission is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners. HIBCC extends its mission globally via IHIBCC, an international network of HIBCC offices.

HIBCC and the HIBC Standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN).

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