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HIBCC WEB UTILITY CREATES FDA COMPLIANT UDI’S

PHOENIX, AZ (October 1, 2013) - The Health Industry Business Communications Council (HIBCC) has released an on-line ‘UDI Generator’ that creates FDA compliant HIBC-UDIs. Beta version 2.3 is currently available and can be accessed from HIBCC’s home page at www.hibcc.org.

The FDA has identified the HIBC Supplier Labeling Standard (SLS) as an acceptable data format for UDI. The HIBCC ‘UDI Generator’ was developed in conformance with the final FDA regulation. The rule requires a product identifier, as well as a labeler identifier, such as the HIBC Labeler Identification Code (LIC). Additional production information including, lot, batch and serial number may also be included.

The ‘UDI Generator’ provides users an easy, on-line formatter to quickly enter the required data fields and create the resulting HIBC-UDI. Built-in help screens are available within the application to provide additional field definitions.

For additional information on FDA’s UDI initiative and the HIBCC ‘Utility’, or to register for a HIBC LIC, please contact the HIBCC office at: 602.381.1091 or visit www.hibcc.org.

HIBCC is an industry-sponsored, Standards Development Organization (SDO) founded in 1983 to develop a healthcare-specific standard for the unique identification of medical products. HIBCC is accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and is recognized by the International Organization for Standardization (ISO). Our efforts are supported worldwide by affiliate offices in Europe and Asia Pacific. The HIBC SLS has been recognized by the European Union in their developing regulation on device identification, as well as by the International Medical Device Regulators Forum. Additional information regarding the HIBCC organization can be accessed from the HIBCC website at: www.hibcc.org.

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