HIBC UDI IMPLEMENTATION

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INTERNATIONAL STANDARDS DEVELOPMENT

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).

The **HIBC Supplier Labeling Standard (SLS)** will likely be a recognized standard under FDA’s UDI program and has been identified by the European Union (EU) in their developing regulation on device identification, as well as by the International Medical Device Regulators Forum (IMDRF).

Our standards efforts are supported worldwide by a network of affiliate offices in Europe and Asia Pacific.
HIBC UDI allows you to directly use your exact product identifiers. No cross-referencing to other codes is necessary.

**ALPHANUMERIC (0 – 9), (A-Z)**
Provides a larger set of possible identifiers and the ability for literal incorporation of product identifiers, eliminating risky cross-referencing of data.

**VARIABLE LENGTH PRODUCT DATA (1-18 CHARACTERS)**
Enables manufacturers to incorporate their exact product identifiers within the data structure, eliminating need to truncate or add digits.
BENEFITS OF HIBC UDI –
ONE LIC COVERS ALL YOUR PRODUCTS

HIBC UDI encompasses multi-levels of packaging in a format standardized for domestic and international markets. Your LIC registration covers its use throughout the world.

PACKAGE LEVEL CONSISTENCY
HIBC symbols are consistent on all levels of packaging – i.e. SKU, carton, case. This allows for easier identification within various packaging configurations.

GLOBAL MARKET CONSISTENCY
HIBC format is globally consistent so identifiers are the same everywhere in the world.
THE HIBC UDI FORMAT

FDA UDI REQUIREMENTS

A device identifier that identifies the specific version or model of a device and the labeler of that device; and

HIBC UDI FORMAT - Device Identifier

Flag Character
Labeler Identification Code (LIC)
Product/Catalog ID
Unit of Measure
Check Character

FDA UDI REQUIREMENTS

A production identifier that identifies one or more of the following, when present on the label of the device:

The lot or batch within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured."

HIBC UDI FORMAT - Production Identifier

Flag Characters
Date/Lot/Batch/Serial Number
Expiration Date
Link Character
Check Character
LIC REGISTRATION FEES

The FDA has emphasized in its proposal that the cost of UDI should not cause an undue financial burden on manufacturers and other labelers.

LIC REGISTRATION IS:

- A one time fee - there are no reoccurring annual costs to maintain the registration.
- Modestly priced, and registrations begin at $500.
- Based on an organization’s gross annual sales, not by individual packaging configurations.
- Applicable at every level and variation of packaging with no additional fees.
- Globally compatible and can be used throughout the world with no additional fees.
USING HIBCC’S ONLINE UDI FORMATTER

1. If you do not already have a registered LIC, apply to HIBCC by submitting an application online, by mail or by fax.

2. After HIBCC assigns your LIC, you can then begin creating UDIs using the HIBC Supplier Labeling Standard (SLS).

3. Then you can confirm your UDI’s using the HIBC UDI Formatter available online.
HIBCC & GUDID

The FDA is proposing that UDI data be submitted to a public database to encourage broad integration within various healthcare delivery support systems.

HIBCC will apply it’s extensive database resources currently deployed for administration of systems such as the Health Industry Number (HIN) to develop processes in support of GUDID standardization and submission to FDA.

Additional information on HIBCC GUDID resources will be available as the FDA specifications are further identified.
HIBCC UDI RESOURCES

The HIBC UDI Resource page can be found at www.HIBCC.org/UDI-Resources and includes the following informational materials:

- HIBCC UDI GUIDELINES
- LIC APPLICATION FORM
- HIBC SUPPLIER LABELING STANDARD (SLS)
- UDI DATA FORMATTER – BETA VERSION
- CURRENT HIBC REGISTRANTS BY COUNTRY
- DEVELOPING GUDID SPECIFICATIONS
- THIS SLIDE SET

Questions can be addressed to the HIBCC Resource Desk @ 1.855.HIBC.UDI (1.855.442.2834);
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