Welcome to today’s FDA/CDRH Webinar

Thank you for your patience while we register all of today’s participants.

If you have not connected to the audio portion of the webinar, please do so now:
Dial: 1-800-369-3195
International Callers: 1-517-308-9090
Passcode: CDRH
Getting Ready for GUDID

January 14, 2015

Indira R. Konduri
GUDID Program Manager
FDA\CDRH\OSB\Informatics Staff
UDI = Unique Device Identifier

- Device Identifier (DI) + Production Identifier(s) (PI)

- DI = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device

- PI = a conditional, variable portion of a UDI that identifies one or more of the following when included on the label:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date
  - For an HCT/P regulated as a device, the distinct identification code
• Repository of key device identification information

• Contains ONLY the DI; PIs are not submitted to or stored in the GUDID
  - Contains only PI flags to indicate which PI attribute(s) are in the UDI
DI Record

DI Record = Device Identifier (DI) + GUDID attributes

CompuHyper GlobalMed®

Unique Medical Device

Brand Name

GMDN Description

Device Count

Production Identifier: Expiration Date

Production Identifier: Manufacturing Date

Storage & Handling Information

Qty: 1 each  Size: 20mm x 12.5mm  REF Z1234

2014-01-02  2010-01-02  LOT A1234  SN 1234

45°C  UPPER LIMIT OF TEMPERATURE  KEEP DRY

CompuHyper GlobalMed, LTD
101 Innovation Drive,
New Sales, MD 20999-0000

XXX-867-5309 (USA)
XXX-555-3226 (Outside USA)
http://www.compuhypergm.com

Labeler Name & Physical Address

Customer Contact Information

Size

Catalog Number

Unique Device Identifier (DI & PI)

Production Identifier: Serial Number

Production Identifier: Lot Number

Single Use
## Device Information

### Device Identifier (DI) Information

<table>
<thead>
<tr>
<th><strong>Issuing Agency:</strong></th>
<th><strong>Primary DI Number:</strong></th>
<th><strong>Device Count:</strong></th>
<th><strong>Unit of Use DI Number:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIBCC</td>
<td>wsDIOverview</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Labeler DUNS Number:</strong></th>
<th><strong>Company Name:</strong></th>
<th><strong>Company Physical Address:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>039169488</td>
<td>Safeway Grocery</td>
<td>4551 Forbes Blvd, Lanham, MD 207064389</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Brand Name:</strong></th>
<th><strong>Version or Model Number:</strong></th>
<th><strong>Catalog Number:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>DIOverview</td>
<td>123456</td>
<td>123456</td>
</tr>
</tbody>
</table>

**Device Description (max 2000 characters):**

DIOverviewRecord

### Commercial Distribution

<table>
<thead>
<tr>
<th><strong>DI Record Publish Date (yyyy-mm-dd):</strong></th>
<th><strong>Commercial Distribution End Date (yyyy-mm-dd):</strong></th>
<th><strong>Commercial Distribution Status:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-05-09</td>
<td></td>
<td>In Commercial Distribution</td>
</tr>
</tbody>
</table>
### Device Characteristics

**For Single-Use:** *Yes*

<table>
<thead>
<tr>
<th>Production Identifier(s) on Label</th>
<th>Latex Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot or Batch Number: <em>Yes</em></td>
<td>Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): <em>No</em></td>
</tr>
<tr>
<td>Serial Number: <em>No</em></td>
<td>Device labeled as &quot;Not made with natural rubber latex&quot;</td>
</tr>
<tr>
<td>Expiration Date: <em>Yes</em></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Date: <em>No</em></td>
<td></td>
</tr>
<tr>
<td>Donation Identification Number: <em>No</em></td>
<td></td>
</tr>
</tbody>
</table>

**Prescription Status**

- ✔️ Prescription Use (Rx)
- ✔️ Over the Counter (OTC)

**MRI Safety**

What MRI safety information does the labeling contain?: *

- Labeling does not contain MRI Safety Information
- MR Safe
- MR Unsafe
- MR Conditional
- Labeling does not contain MRI Safety Information
• Secure Web Application

• Submission of device information one record at a time by Labelers
GUDID HL7 SPL Submission Option

- HL7 = Health Level 7
- SPL = Structured Product Labeling
- Submission of device information as xml files – one record per file
- Technical specifications available on the UDI website
- Uses the FDA Electronic Submissions Gateway (ESG) to transmit the file [www.fda.gov/esg](http://www.fda.gov/esg)
- **Testing required** prior to production submission
GUDID Search and Retrieval

• Working with the National Library of Medicine (NLM) to provide:
  - Public Search
  - Database Download
  - Web Services (future)

• Releasable attributes of Published DI records will be available

• Targeting Spring 2015 for availability
GUDID and Data Quality

• Key component of the UDI program
  - Ready to provide assistance and work collaboratively with labelers
  - Use lessons learned for program and database improvements; refine instructions

• “Bake-in” Data Quality as you work on GUDID
Preparing for GUDID

1) Review resources on the UDI Website
2) Select Issuing Agency and label your devices with UDI
3) Determine primary submission option
4) Gather your data
5) Understand the GUDID Account Structure
6) Identify/Obtain DUNS numbers
7) GUDID Web Interface Submitters - TO DO
8) GUDID HL7 SPL Submitters - TO DO
9) Subscribe to get notified about GUDID System Status
1) Review Resources on our website: www.fda.gov/udi

Unique Device Identification - UDI

FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). The public will be able to search and download information from the GUDID.
Start with **UDI Basics** section – what is a UDI, who is a Labeler

**Unique Device Identification - UDI**

FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to FDA’s Global Unique Device Identification Database (GUDID). The public will be able to search and download information from the GUDID.
Look at UDI Resources for Final Rule, GUDID Guidance, FAQs, training

UDI Resources

This page contains links to more information on Unique Device Identification System-related rules, guidances, training, and communications.

UDI Rule and Guidelines

- Final Rule - Unique Device Identification System: September 24, 2013
- Amendment to the UDI Proposed Rule: November 19, 2012
- Unique Device Identifier Proposed Rule: July 10, 2012
- Global Unique Device Identification Database (GUDID) - Guidance for Industry and Food and Drug Administration Staff: June 27, 2014 (PDF - 2.8MB)
Review the **GUDID** section

The Global Unique Device Identification Database (GUDID) is a publicly searchable database administered by the FDA that will serve as a reference catalog for every device with an identifier. Under the UDI final rule, the labeler of each medical device labeled with a unique device identifier (UDI) must submit information concerning that device to the GUDID, unless subject to an exception or alternative.

According to the UDI final rule, “The **labeler** is the person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; in most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.”

The GUDID contains ONLY the device identifier (DI), which serves as the primary key to obtain device information in the database. Production Identifiers (PI) are not submitted to or stored in the GUDID, but the GUDID will contain production identifier flags to indicate which PI attribute(s) are on the device label.
Review the GUDID section

- Must read!
- What you should do now
- How to request a GUDID Account
- GUDID User Manual
- GUDID HL7 SPL Technical Specification Files
- GUDID System Status Information
- GUDID Enhancements & Fixes Info
Review the GUDID Resources section

- CDRH Learn with GUDID Overview
- Guidance - Global Unique Device Identification Database (GUDID) - June 27, 2014 (PDF - 2.8MB)
- HL7 SPL Implementation Files (ZIP - 1.5MB)
- FDA Webinar: Global Unique Device Identification Database (GUDID) Account Set Up
- GUDID Data Elements Reference Table - May 7, 2014 (XLS - 91KB)
- UDI Formats by FDA-Accredited Issuing Agency May 7, 2014 (DOC - 132KB)
- GUDID User Manual -- May 2014 (PDF - 2.2MB)
## GUDID Data Elements Reference Table

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Description</th>
<th>Data Entry Notes</th>
<th>Edit Rules After Grace Period</th>
<th>Required in Database</th>
<th>Data Type &amp; Length</th>
<th>Entry List of Values (LOV)</th>
<th>New DI Trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Device Identifier (DI) Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Issuing Agency</strong></td>
<td>Organization accredited by FDA to operate a system for the issuance of UDs.</td>
<td>Choose a value from the drop down LOV.</td>
<td>None</td>
<td>Required</td>
<td>NA</td>
<td>GS1; HIBCC; ICCBBA</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Primary DI Number</strong></td>
<td>An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.</td>
<td>Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanumeric.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters</td>
<td>None</td>
<td>Required</td>
<td>Type: Num. or Alphanumeric. Length: min-6, max-23*</td>
<td>NA</td>
<td>YES</td>
</tr>
</tbody>
</table>

When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.
2) Select Issuing Agency for your UDIs and label your device with UDI

• Presently three FDA Accredited Issuing Agencies to choose from
  – GS1
  – HIBCC
  – ICCBBA

• Place the UDI in human readable (Plain Text) and machine readable (AIDC) on label and packaging, and for certain devices, on the device itself.
3) Determine GUDID Submission Option

• Primary submission option - GUDID Web Interface or HL7 SPL?
  - Ability to submit records via one option and edit via another after-DI-record-grace-period
  - Develop SOPs for record keeping

• If necessary, identify a third-party submitter -- company/individual authorized to submit to GUDID on behalf of the labeler
4) Gather Device Identification Data

- Attribute list in Data Elements Reference Table
- Global Medical Device Nomenclature (GMDN) Preferred Terms - *Required
  - Identify/obtain active GMDN preferred terms for your devices, www.gmdnagency.org
- FDA Listing Number - *Required
  - Identify/obtain correct Listing Number for your devices
- “Bake-in” data quality processes
5) GUDID Account – TO DO

- GUDID Account is needed for submission of device information to GUDID
- Understand GUDID Account structure and User Roles
- Identify individuals for the different GUDID User Roles
- Ensure they understand GUDID functionality and responsibility for their user role

Note: You need a GUDID Account regardless of the submission option you choose.
GUDID Account Structure

GUDID Account: Identified by Company DUNS Number — headquarters or parent DUNS for the Labelers in the GUDID Account

Labeler Organization

GUDID Account: has one and only one

Labelers

Labeler DUNS 1

Labeler DUNS 2

Labeler DUNS 3

...................

Labeler DUNS n

Coordinator User:
Responsible for management of the GUDID account for assigned Labeler DUNS

GUDID Coordinator 1

GUDID Coordinator 2

Labeler Data Entry User:
Responsible for day to day entry, submission and management of DI records for assigned Labeler DUNS

GUDID Labeler Data Entry User 1

GUDID Labeler Data Entry User 2

GUDID Labeler Data Entry User n

Regulatory Contact:
Has one and only one
Responsible for ensuring labeler organization meets GUDID submission requirements

Third Party Submitters

Third Party DUNS 1

Third Party DUNS n

Third Party Submitter:
Company/individual authorized to submit GUDID information on behalf of the Labeler.
6) Identify/Obtain DUNS Numbers

• DUNS = Data Universal Numbering System
• 9 digit number assigned by Dun & Bradstreet
• DUNS Numbers are used to identify labeler organizations in GUDID
• Labeler name and address pulled from DUNS database
• [Link](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm)
DUNS Numbers in GUDID

Organization DUNS - identifies the labeler organization for a GUDID Account

Labeler DUNS - identifies the Labeler as shown on the medical device label

Third-Party DUNS - identifies the individual/company authorized to submit information to GUDID on behalf of labeler
DI Record

DI Record = Device Identifier (DI) + GUDID attributes

CompuHyper GlobalMed®

Unique Medical Device

Brand Name

GMDN Description

Device Count

Production Identifier: Expiration Date

Production Identifier: Manufacturing Date

Storage & Handling Information

Manufacturer

Labeler Name & Physical Address

CompuHyper GlobalMed, LTD
101 Innovation Drive,
New Sales, MD 20999-0000

XXX-867 5309 (USA)
XXX-555-3226 (Outside USA)
http://www.compuhypergm.com

Qty: 1 each
Size: 20mm x 12.5mm

REF Z1234

2014-01-02
2010-01-02
LOT A1234
SN 1234
7) Web Interface Submitters – TO DO

- Request and obtain a GUDID Account
  - No required testing
  - Request a GUDID Account, [www.fda.gov/udi](http://www.fda.gov/udi)

- Get familiar with the system
  - Create Draft DI records
  - May submit DI records with a “future” publish date, i.e., Unpublished DI records - not available via public search

- Submit and publish DI Records
8) HL7 SPL Submitters – TO DO

- Register with the FDA ESG and complete ESG testing
  - Existing test accounts can be used
- Request a GUDID Test Account, [www.fda.gov/udi](http://www.fda.gov/udi)
- Complete HL7 SPL testing
  - Test thoroughly, listed test scenarios are the bare minimum
- Request and obtain a GUDID Account for production submission
- Submit DI records
  - Note: "Draft" DI Record state is not available via HL7 SPL
Third-Party Submitters – TO DO

• Verify information in the DUNS database is correct; update if needed
• May test HL7 SPL submission option independently of Labelers
  - Request a GUDID Account, www.fda.gov/udi - indicate it is for HL7 SPL testing
  - Dummy data for certain required attributes will be provided for testing purposes ONLY, upon request
9) Subscribe for GUDID System Status

• Subscribe to GUDID Email Alerts

• Scheduled downtimes -- email alerts sent and posted on www.fda.gov/udi, GUDID System Status

• Unscheduled downtimes
  - Visit www.fda.gov/udi for information
  - If no information, report issue via Help Desk
GUDID Status

• Accepting submissions from Labelers of:
  - Class III medical devices
  - Devices licensed under the PHS Act
  - Life Supporting/Life Sustaining/Implant devices - open Monday, Jan 26, 2015

• GUDID Search and Retrieval targeting Spring 2015 for availability
How to Contact Us

• HL7 SPL submitters with FDA ESG questions
  -- ESGHelpDesk@fda.hhs.gov

• All other inquiries via FDA UDI Help Desk
  - Regulatory questions
  - Technical questions
FDA UDI Help Desk

• Submit question via the web, www.fda.gov/udi
• Please complete all fields on the web form!

The FDA UDI Help Desk is the primary way to obtain information and assistance on the UDI program and the GUDID. Labelers and GUDID users are encouraged to use the help desk to submit all questions related to UDI and the GUDID. Please complete the information below to submit a UDI support question/comment. Once the question is received, an FDA UDI Help Desk analyst will respond to you as soon as possible.

First Name:* 
Last Name:* 
Organization:* 
Email:* 
Phone:* 
Subject:* 
Question:* 
Type:*

Fields marked with * are REQUIRED

Submit Question
Reset
FDA UDI Help Desk

- Question becomes a “case” in help desk tool
- Response will be sent to the email you provide
  - Ask follow-up questions by responding to the email, will append to the “case”

- Please ensure you can receive emails from help desk - check your spam folder
We are here to help!

- Please submit complete and correct information
  - Help Desk questions
  - Account Requests
  - DI Records
- Build data quality into all tenets of your process as you get organized for GUDID submission
Questions?

FDA UDI Help Desk: www.fda.gov/udi

Slide Presentation, Transcript and Webinar Recording will be available at: www.fda.gov/CDRHWWebinar

Under Heading: Unique Device Identification (UDI) System