



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

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Passcode: CDRH



Getting Ready for GUDID

January 14, 2015

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GUDID Program Manager

FDA\CDRH\OSB\Informatics Staff

UDI = Unique Device Identifier

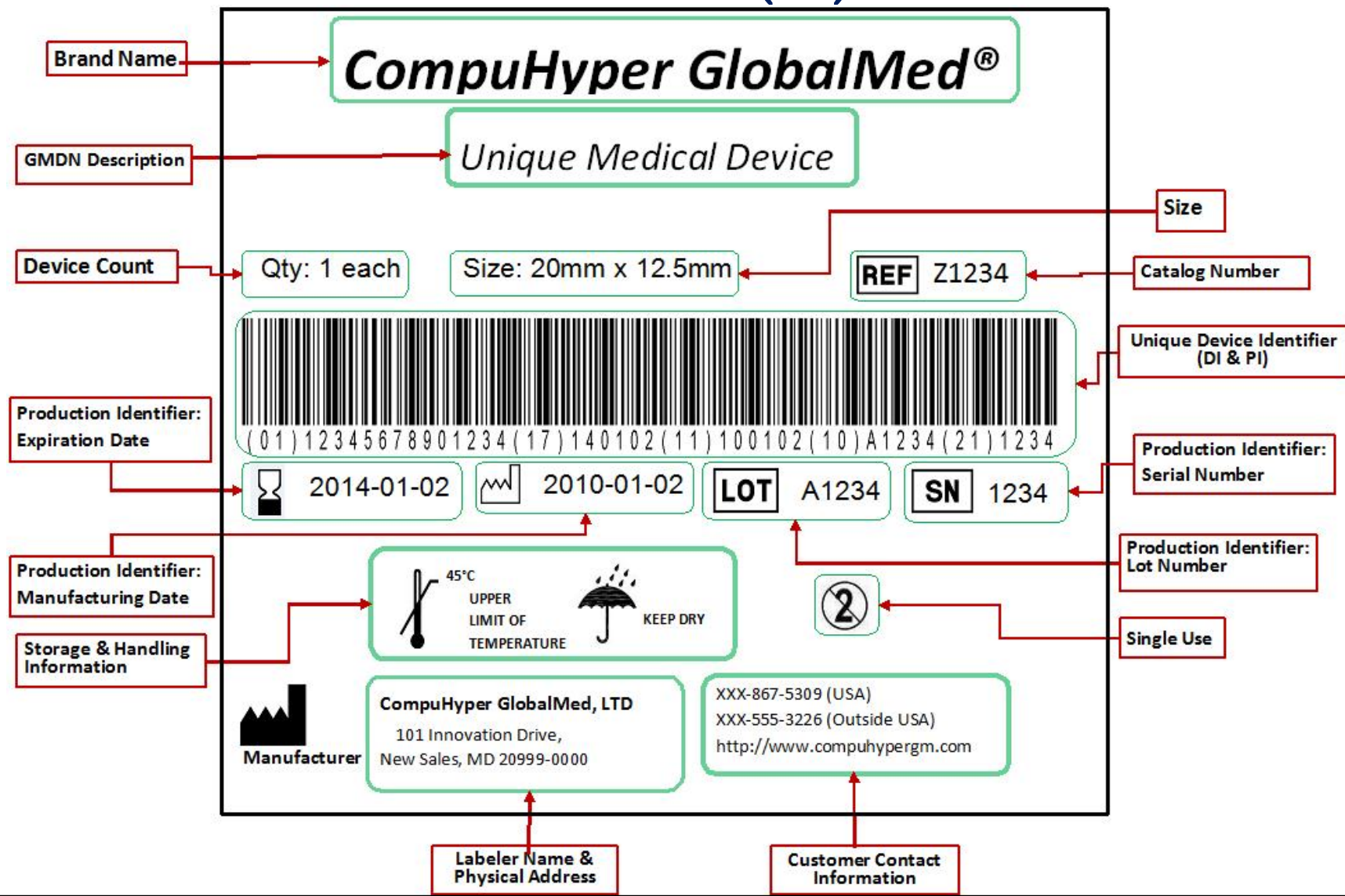
- **Device Identifier(DI) + Production Identifier(s)(PI)**
- **DI= mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device**
- **PI= a conditional, variable portion of a UDI that identifies one or more of the following when included on 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



Device Information

Administration
Public Health

www.hhs.gov



Device Identifier (DI) Information

Issuing Agency: *

HIBCC

Primary DI Number: *

wsDIOverview

Device Count: *

1

Unit of Use DI Number:

Labeler DUNS
Number: *

039169488

Company Name:

Safeway Grocery

Company Physical Address:

4551 Forbes Blvd, Lanham, MD 207064389

Brand Name: *

DIOverview

Version or Model Number: *

123456

Catalog Number:

123456

Device Description (max 2000 characters):

DIOverviewRecord

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): *

2014-05-09

Commercial Distribution End Date (yyyy-mm-dd):



Commercial Distribution Status:

In Commercial Distribution



Device Characteristics

For Single-Use: *

Yes

Production Identifier(s) on Label

Lot or Batch Number: *

Yes

Serial Number: *

No

Expiration Date: *

Yes

Manufacturing Date: *

No

Donation Identification Number: *

No

Prescription Status

☒ Prescription Use (Rx)

☒ Over the Counter (OTC)

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): *

No

☐ Device labeled as "Not made with natural rubber latex"

MRI Safety

What MRI safety information does the labeling contain?: *

Labeling does not contain MRI Safety Information

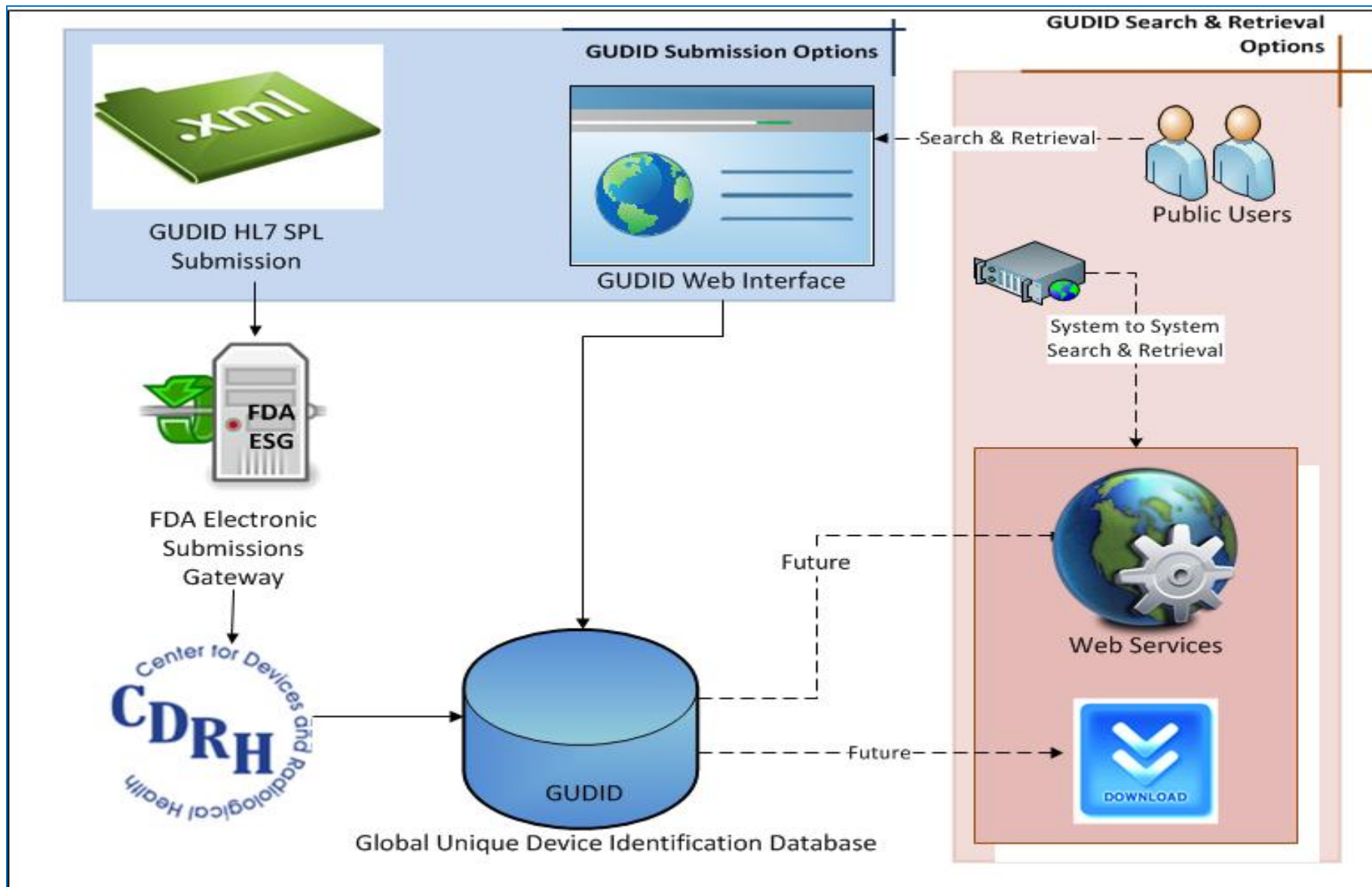
MR Safe

MR Unsafe

MR Conditional

Labeling does not contain MRI Safety Information

GUDID Overview



GUDID Web Interface

- **Secure Web Application**
- **Submission of device information one record at a time by Labelers**



GUDID Web Interface

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
- **Testing required** prior to production submission



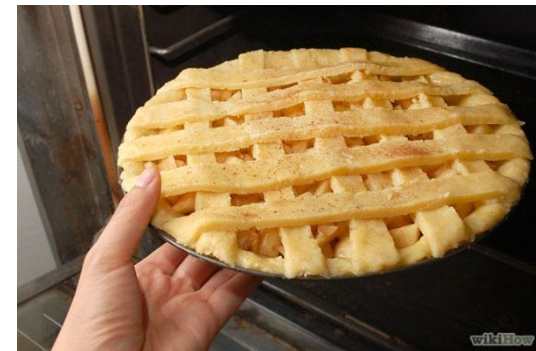
GUDID Search and Retrieval

- **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

**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

[Home](#) | [Food](#) | [Drugs](#) | [Medical Devices](#) | [Radiation-Emitting Products](#) | [Vaccines, Blood & Biologics](#) | [Animal & Veterinary](#) | [Cosmetics](#) | [Tobacco Products](#)

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Unique Device Identification

Device Advice: Comprehensive Regulatory Assistance

- ▶ Unique Device Identification
- UDI Basics
- Benefits of a UDI system
- Global UDI Database (GUDID)
- Compliance Dates for UDI Requirements

Unique Device Identification - UDI

Unique Device Identification: Get e-mail updates 

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.

Spotlight

- Global UDI Database (GUDID) - Guidance for Industry and FDA Staff (PDF - 2.8MB)
- UDI System: Small Entity Compliance Guide - Guidance for Industry and FDA Staff (PDF - 671KB)
- UDI System: Frequently Asked Questions, Vol. 1 - Guidance for Industry and FDA Staff (PDF - 726KB)



Start with **UDI Basics** section – what is a UDI, who is a Labeler

The screenshot shows the FDA's Medical Devices webpage. The top navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The 'Medical Devices' section is active, and the breadcrumb trail reads: Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Unique Device Identification. On the left sidebar, under 'Device Advice: Comprehensive Regulatory Assistance', the 'Unique Device Identification' link is expanded, and the 'UDI Basics' link is circled in red. The main content area is titled 'Unique Device Identification - UDI' and includes a sub-header 'Unique Device Identification: Get e-mail updates' with an email icon. The text below explains that FDA is establishing a unique device identification system to identify medical devices through their distribution and use. A 'Spotlight' section on the right lists several resources, including the Global UDI Database (GUDID) and UDI System: Small Entity Compliance Guide.

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Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Unique Device Identification

Device Advice: Comprehensive Regulatory Assistance

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 - UDI Basics**
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Look at **UDI Resources** for Final Rule, GUDID Guidance, FAQs, training

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Unique Device Identification > UDI Resources

Device Advice: Comprehensive Regulatory Assistance

- Unique Device Identification
- ▶ UDI Resources

Resources for You

- FDA UDI Help Desk

UDI Resources

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

UDI Rule and Guidances

- [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 \(PDF - 2.8MB\)](#)
- [Unique Device Identification System: Small Entity Compliance Guide - Guidance for Industry and Food and Drug Administration Staff: August 13, 2014 \(PDF - 420KB\)](#)



Review the GUDID section

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Medical Devices

Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Unique Device Identification > Global UDI Database (GUDID)

Device Advice: Comprehensive Regulatory Assistance

Unique Device Identification

▶ Global UDI Database (GUDID)

GUDID Guidance

Prepare for GUDID

Request a GUDID Account

GUDID Web Interface

GUDID Health Level 7 (HL7) Structured Product Labeling (SPL)

Global UDI Database (GUDID)

GUDID: Get e-mail notification on database updates and system status

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

Global UDI Database (GUDID)

GUDID Guidance

Must read!

Prepare for GUDID

What you should do now

Request a GUDID Account

How to request a GUDID Account

GUDID Web Interface

GUDID User Manual

GUDID Health Level 7 (HL7)
Structured Product Labeling
(SPL)

GUDID HL7 SPL Technical
Specification Files

GUDID System Status

GUDID System Status Information

GUDID Enhancements and Fixes

GUDID Enhancements & Fixes Info

Review the **GUDID Resources** section

GUDID Resources

- [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

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period ¹	Required in Database? ²	Data Type & Length ³	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Information							
<u>Device Identifier (DI) Information</u>							
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down LOV.	None	Required	NA	GS1; HIBCC; ICCBBA	YES
Primary DI Number	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.	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 (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None	Required	<u>Type:</u> Num. or Alphanum. <u>Length:</u> min-6, max-23* *defined by Issuing Agency structure.	NA	YES

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

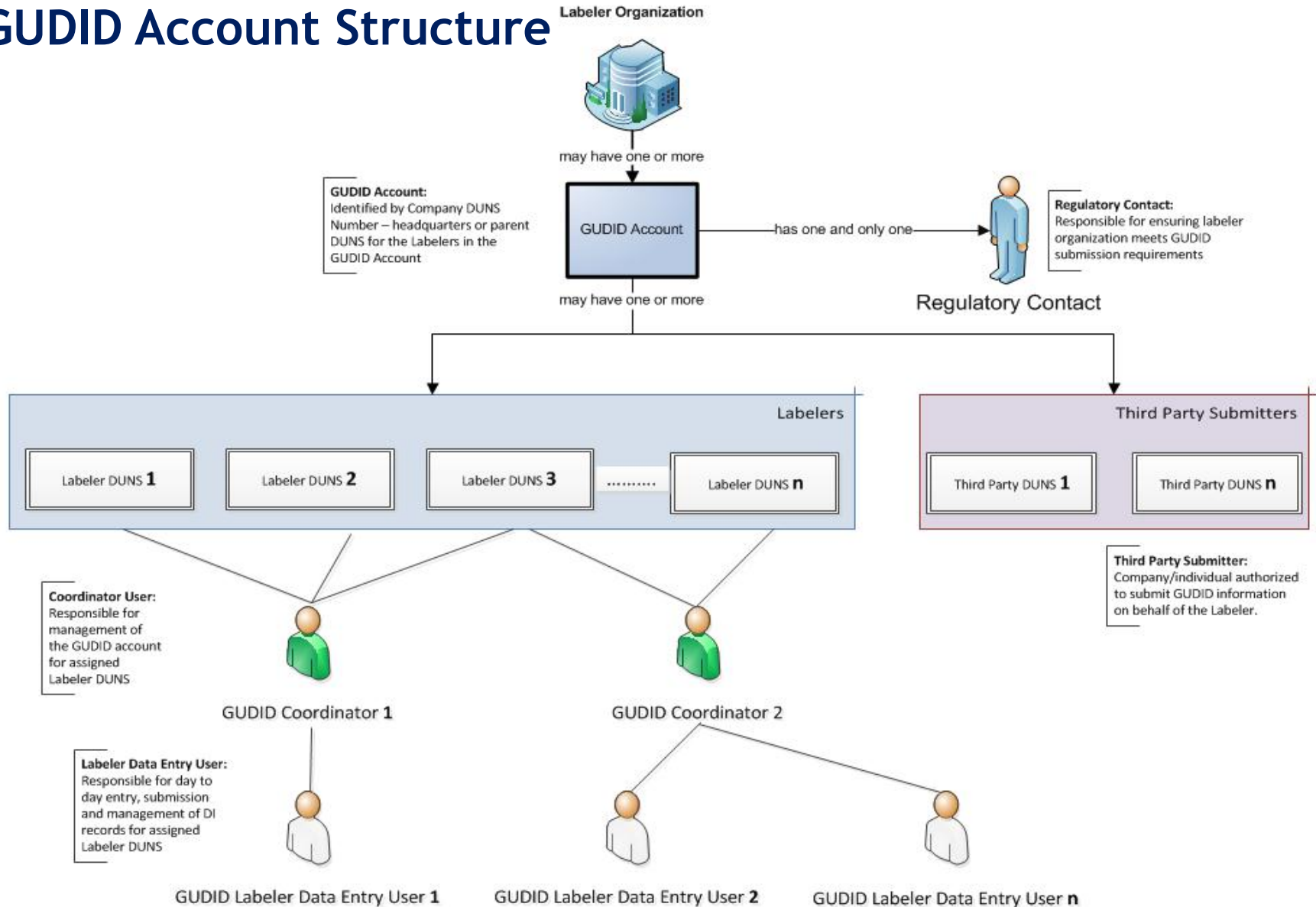
- Attribute list in Data Elements Reference Table
- Global Medical Device Nomenclature (GMDN)
Preferred Terms - ***Required**
 - Identify/obtain active GMDN preferred terms for your devices, www.gmdnagency.org
- FDA Listing Number - ***Required**
 - Identify/obtain correct Listing Number for your devices
- “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.

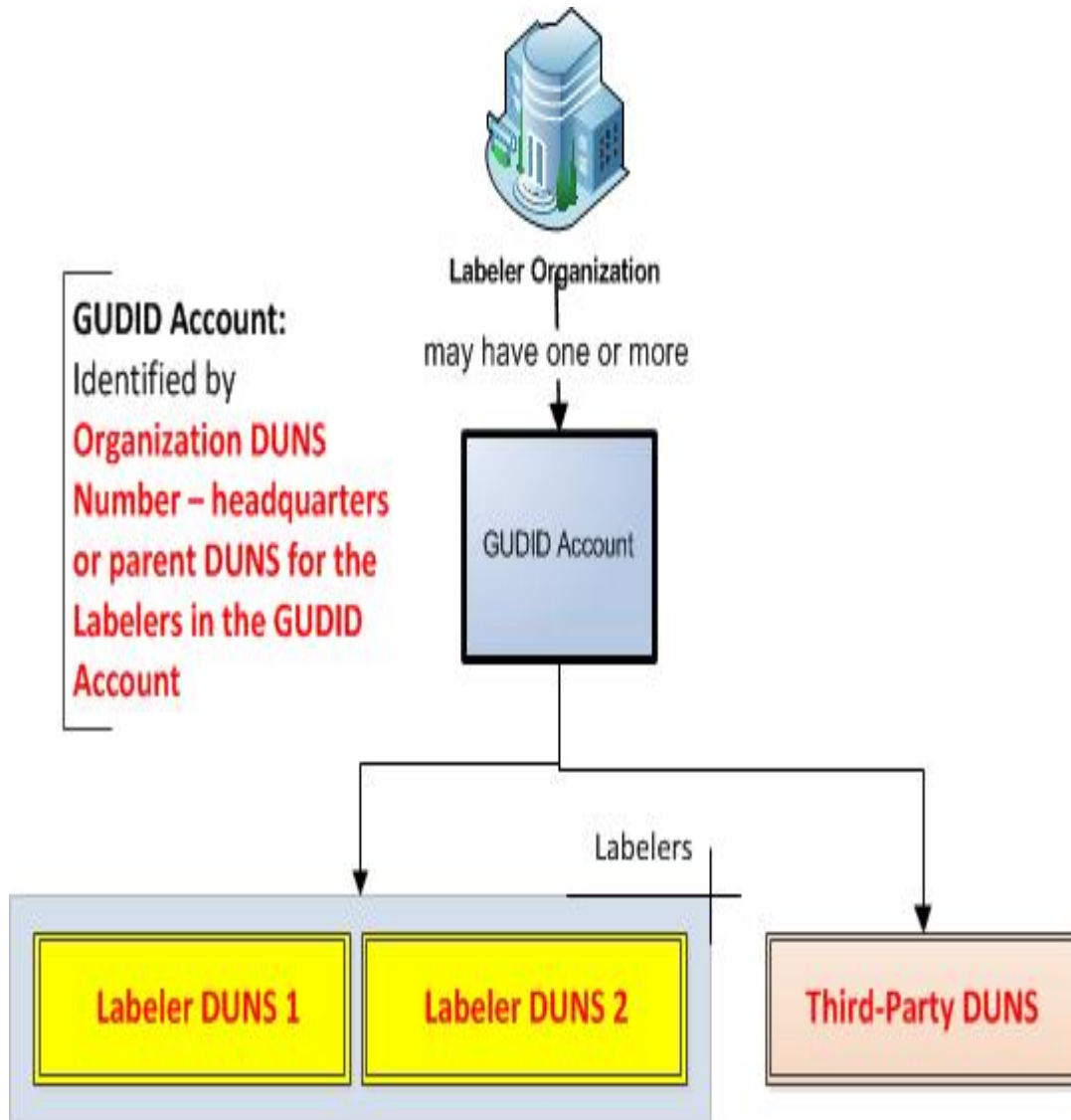
GUDID Account Structure



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
- <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm>

DUNS Numbers in GUDID



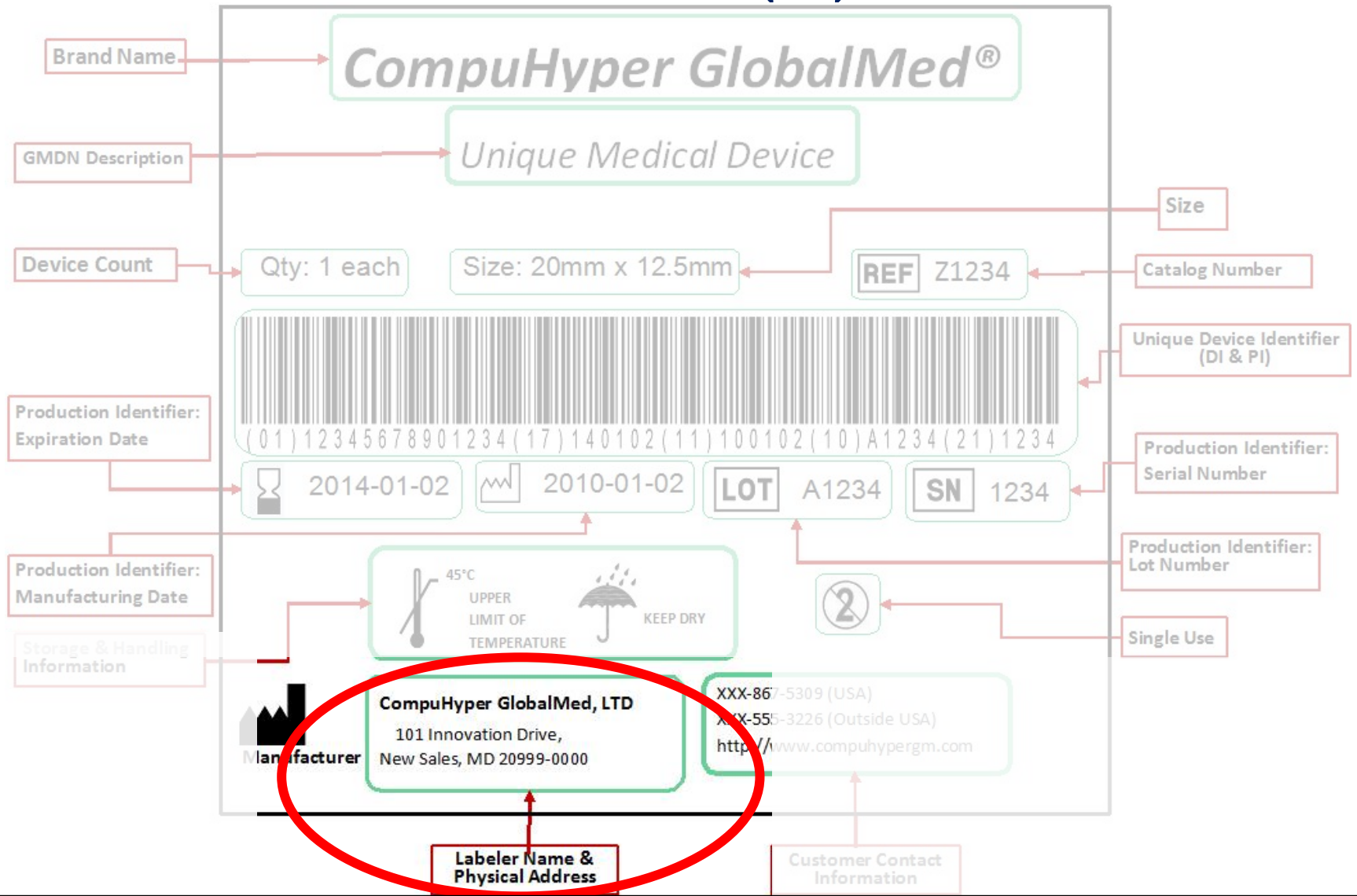
Organization DUNS -
identifies the labeler
organization for a GUDID
Account

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



7) Web Interface Submitters – TO DO

- **Request and obtain a GUDID Account**
 - No required testing
 - Request a GUDID Account, 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
- 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!

FDA UDI Help Desk

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

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
Under He



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



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医疗器械任职培训
WEB TRAINING
CENTER



器械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
器械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE

nar
DI) System