



Unique Device Identification (UDI)

**FDA Small Business
Regulatory Education for Industry (REdI)
Silver Spring, Maryland
September 30, 2015**

Loretta E. Chi, JD

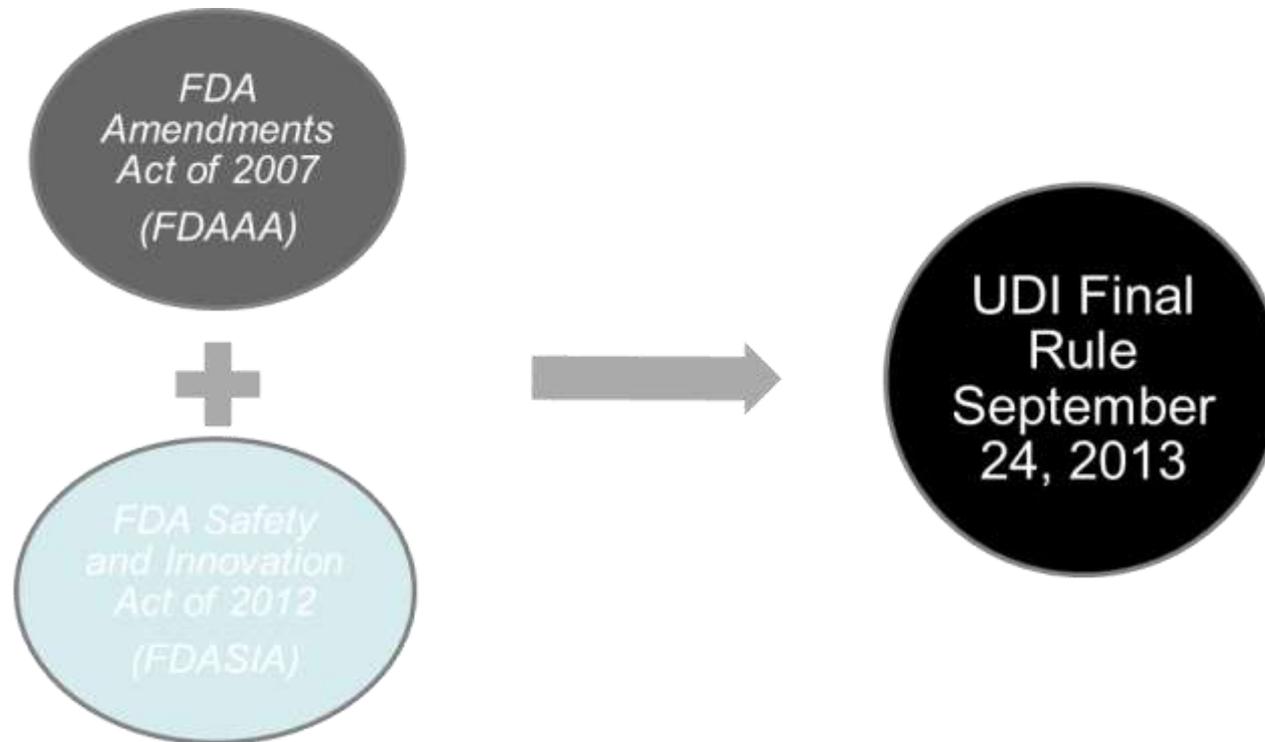
Regulatory Counsel
Office of Surveillance and Biometrics/Informatics
Center for Devices and Radiological Health
U.S. Food and Drug Administration



Presentation Overview

- UDI Program background including a summary of the program objectives and basic requirements
- UDI labeling requirements: what is a UDI, what is a labeler, the issuing agencies
- Data submission requirements and public access to this data through AccessGUDID
- UDI compliance dates and general and individual exceptions and alternatives to UDI labeling requirements
- Additional resources
- Questions and Answers

Statutes and Regulation



Unique Identification of Products is Not New

Example of a serialized National Drug Code (sNDC)

NDC

55555 666 77

+

SERIAL NUMBER

1111111111111111111111

labeler code + product code + package code

unique, up to 20 characters

The Unique Device Identification Program

Applies to devices placed in commercial distribution after the applicable compliance date

Devices
201(h) of FD&C Act

...instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory...

Commercial Distribution
21 CFR 807.3(b)

...distribution of a device intended for human use which is held or offered for sale...

Objectives of the Unique Device Identification Program

“Establish a system to adequately identify devices through distribution and use”

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls

“Adequately Identify”



Point of
Distribution

Point of
Use

Summary of Basic UDI Requirements



Device label and device packages must bear a UDI



Key data for these devices must be submitted to GUDID

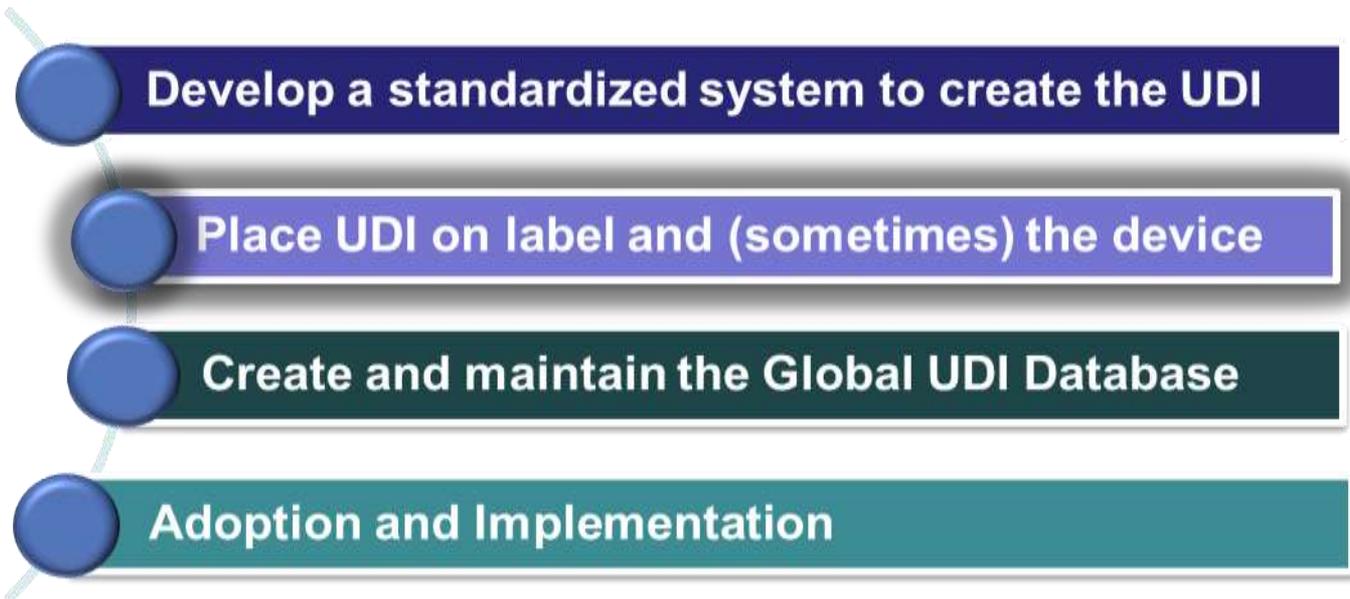


Four Steps to a Successful UDI Program



- 1. Develop a standardized system to create the UDI
- 2. Place UDI on label and (sometimes) the device
- 3. Create and maintain the Global UDI Database
- 4. Adoption and Implementation

Four Steps to a Successful UDI Program



Four Steps to a Successful UDI Program



- 1. Develop a standardized system to create the UDI
- 2. Place UDI on label and (sometimes) the device
- 3. Create and maintain the Global UDI Database
- 4. Adoption and Implementation

Four Steps to a Successful UDI Program



- 1. Develop a standardized system to create the UDI
- 2. Place UDI on label and (sometimes) the device
- 3. Create and maintain the Global UDI Database
- 4. Adoption and Implementation

Four Steps to a Successful UDI Program



- 1. Develop a standardized system to create the UDI
- 2. Place UDI on label and (sometimes) the device
- 3. Create and maintain the Global UDI Database
- 4. Adoption and Implementation **by all stakeholders**

Summary of Basic UDI Requirements



Device label and device packages must bear a UDI



Key data for these devices must be submitted to GUDID



Device label and device packages must bear a UDI



Label

“Label” means a “display of written, printed, or graphic matter upon the immediate container of any article...” 21 USC 321(k)

Qty: 1 each

Size: 20mm x 12.5mm

REF Z1234



(01)12345678901234(17)140102(11)100102(10)A1234(21)1234



2014-01-02



2010-01-02

LOT A1234

SN 1234



45°C
UPPER
LIMIT OF
TEMPERATURE



KEEP DRY



Manufacturer

CompuHyper GlobalMed, LTD

101 Innovation Drive,
New Sales, MD 20999-0000

XXX-867-5309 (USA)

XXX-555-3226 (Outside USA)

<http://www.compuhypergm.com>

What is a Unique Device Identifier (UDI)?

Is a unique numeric or alphanumeric code;



Displayed in both human readable (plain text) and machine readable (AIDC) form;



that consists of two parts:

Device Identifier (**DI**)

Production Identifier(s) (**PI**)

UDI Example

Required on the device label, packaging or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI

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



(01)12345678901234(17)140102(11)100102(10)A1234(21)1234

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

 45°C
UPPER LIMIT OF TEMPERATURE

 KEEP DRY



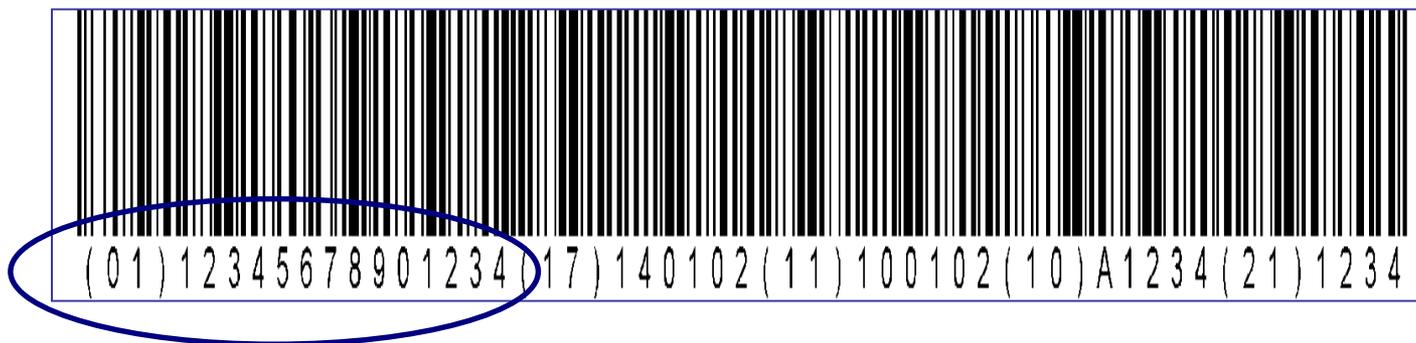
 **Manufacturer** **CompuHyper GlobalMed, LTD**
101 Innovation Drive,
New Sales, MD 20999-0000

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



Device Identifier (DI)

- Mandatory, fixed portion of a UDI that identifies the specific **version or model** of a device and the **labeler** of that device
- Entered in GUDID



Production Identifier (PI)

Production Identifier(s) (PI) is a conditional, variable portion of a UDI

- Not required for class I devices



Includes (when on the device label):

- lot, batch or serial number,
- expiration date or date of manufacture
- HCT/P's regulated as devices: the required distinct identification code.



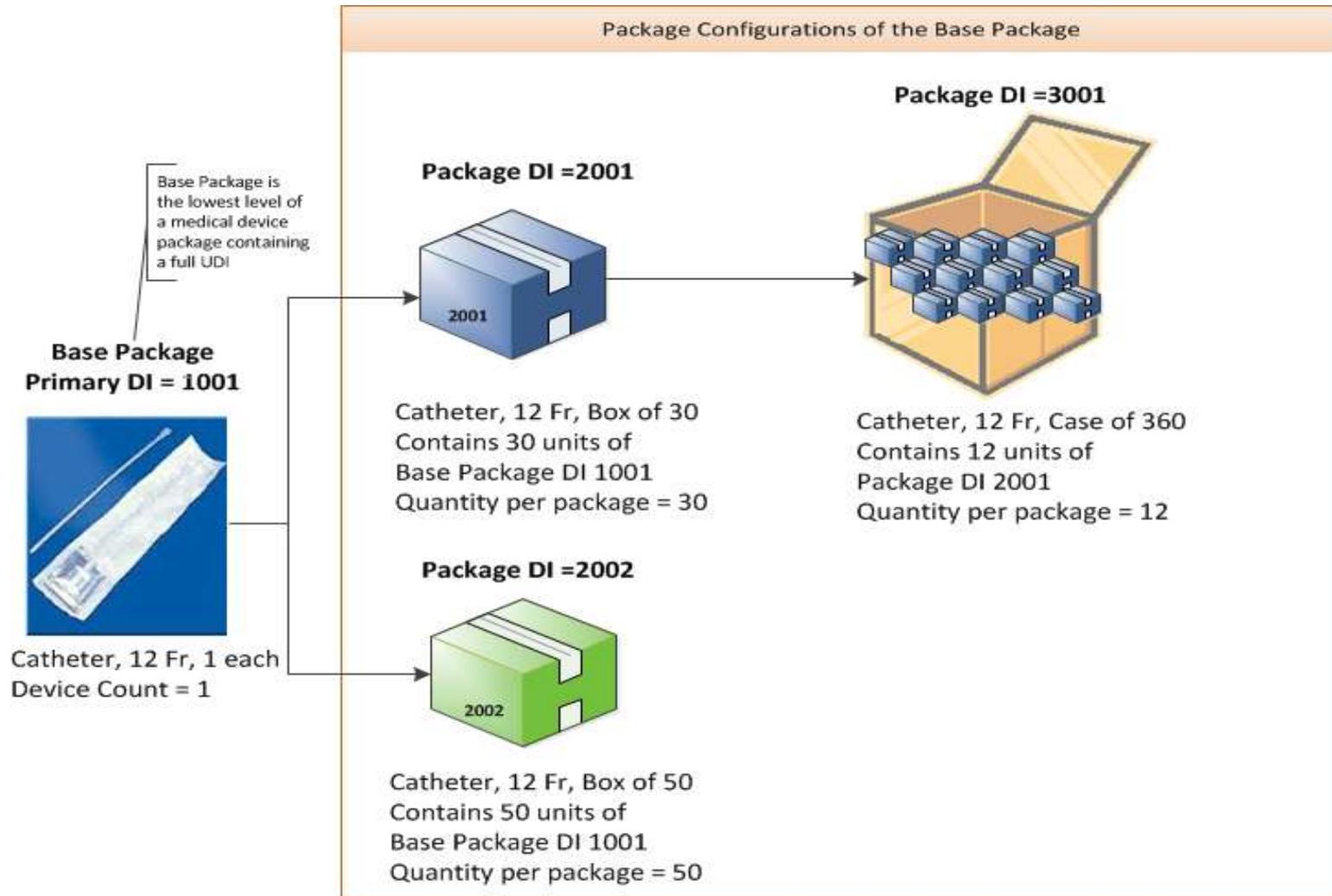
Device Package

A device package contains a fixed quantity of a particular version or model of a device

Each level of packaging requires a different UDI



Levels of Packaging



Shipping Containers are Not Device Packages and Do Not Require a UDI



Direct Marking

In addition to its label, the device itself must also bear a permanent marking UDI if the device is:

- intended to be used more than once, and
- intended to be reprocessed before each use.

UDI may be provided through either or both of the following:

- Easily readable plain text
- AIDC technology or any alternative technology, that will provide UDI on demand

The direct mark UDI may be:

- identical to the UDI that appears on the label of the device, or
- different UDI used to distinguish the unpackaged device from any device package containing the device

Labeler

Labeler is responsible for UDI requirements

Defined under 21 CFR 801.3 as any person who causes a label to be:

Applied to a device with the intent that the device will be commercially distributed; or

Replaced or modified with the intent that the device will be commercially distributed

Labeler Examples

Manufacturer

Contract Manufacturer

Private label distributor

Convenience Kit Assembler

Standards



UDI regulations require UDIs:

- Be issued under a system operated by an FDA-accredited issuing agency
- Conform to each of the following international standards:
 - ISO/IEC 15459-2
 - ISO/IEC 15459-4
 - ISO/IEC 15459-6
- Use only characters and numbers from the invariant character set of ISO/IEC 646

Issuing Agency (IA)

FDA accreditation requires that the issuing agency's system conforms to the ISO standards incorporated into the UDI Rule.

Accreditation is granted for an initial term of 3 years; may be renewed upon submission and FDA approval of a renewal application; may be revoked by the FDA.

Creating DIs

The UDI rule requires all UDIs to be issued under a system operated by an FDA-accredited issuing agency.

An issuing agency operates a system for issuing UDIs to labelers.

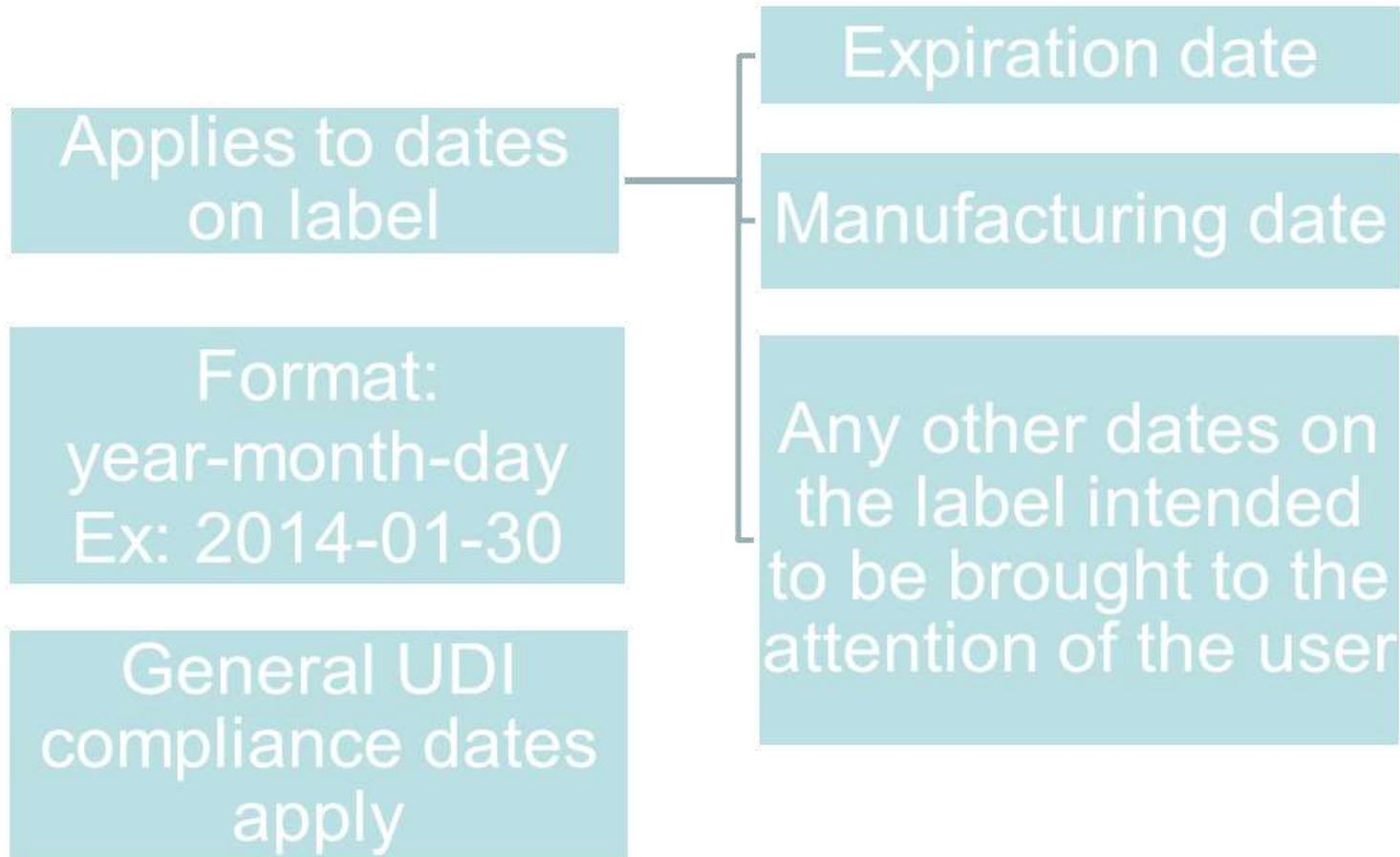
Each labeler receives unique labeler identifier from issuing agencies

Using the issuing agency system, the labeler then establishes DIs for each version or model of its devices.

2014-01-02

**Dates on the device label must
be in specified format**

Date Format



Summary of Basic UDI Requirements



Device label and device packages must bear a UDI



Key data for these devices must be submitted to GUDID



Key data must be submitted to GUDID

The GUDID logo, consisting of the acronym 'GUDID' in large, bold, white letters with a slight shadow effect, followed by the full name 'Global Unique Device Identification Database' in a smaller, white, sans-serif font, all set against a dark blue rectangular background.

GUDID Global Unique Device
Identification Database

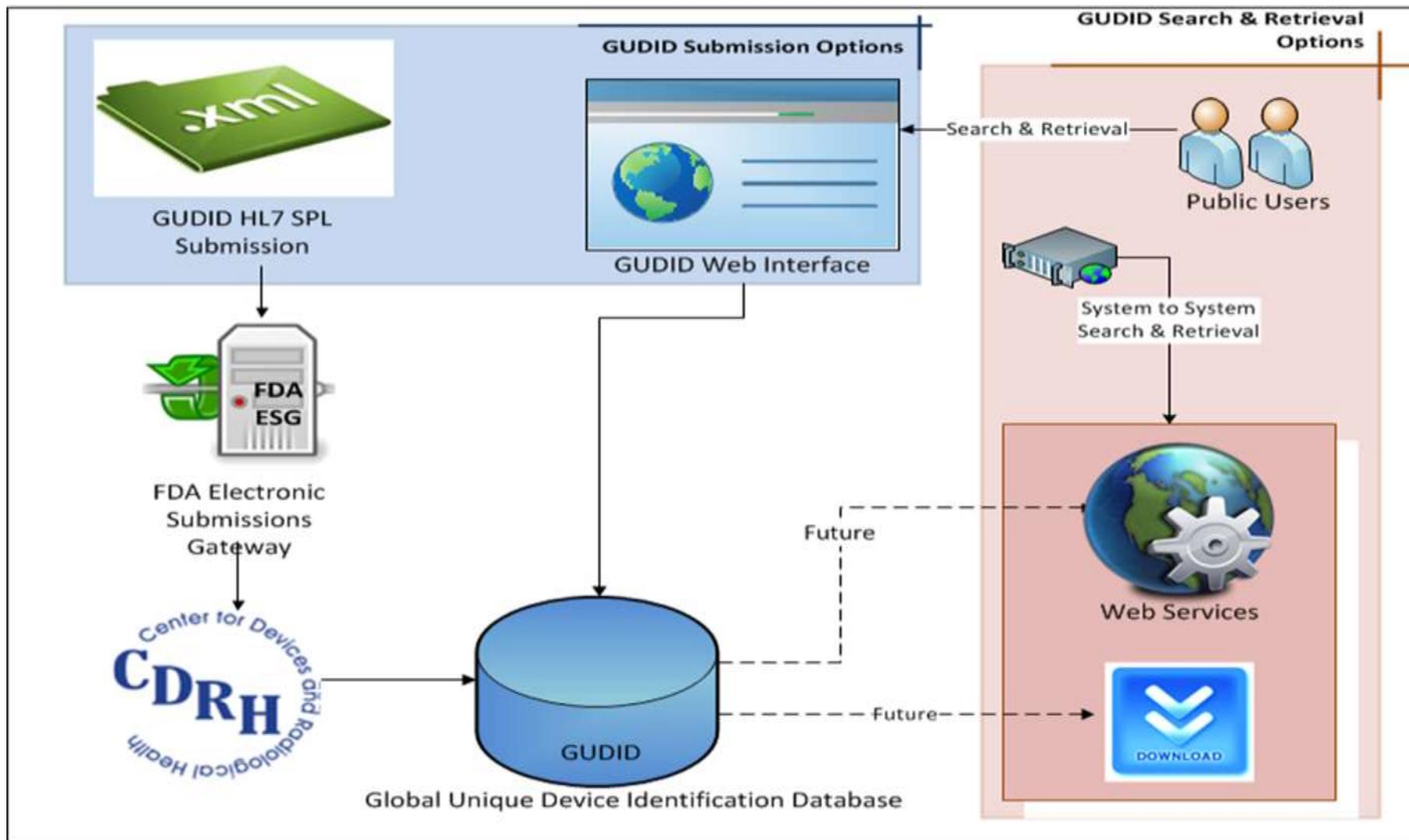
GUDID

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 PIs are on the device UDI

GUDID Overview



GUDID Data Elements

General

- Company Name
- Device Identifier
- Brand Name
- Model Number
- FDA Premarket #

Categorization

- Global Medical Device Nomenclature (GMDN)
- SNOMED (NLM)
- FDA Product Code

Flags: (Yes or No)

- Rx
- OTC
- HCT/P
- Combination Product
- Requires Sterilization Prior to Use
- Kit
- For Single Use

GUDID Data Elements Cont.

Patient Safety

- Labeled as containing Latex
- Packaged as Sterile
- What MRI safety information does the labeling contain?

Production Identifier Flags:

- Lot or Batch Number
- Serial Number
- Expiration Date
- Manufacture Date
- Donation Identification Number



GUDID DI Screen (First of Five)

Device Information

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): <input type="text"/>	Commercial Distribution Status: In Commercial Distribution
--	--	---

GUDID Submissions

The labeler should submit data to GUDID no later than 15 calendar days after the date the label of the device must bear a UDI

GUDID Data Elements Table

Submit to FDA an update to the information required by 21 CFR 830.310

AccessGUDID

NIH U.S. NATIONAL LIBRARY OF MEDICINE
FDA TOOLS AND RESOURCES



IDENTIFY YOUR MEDICAL DEVICE



Enter Device Identifier, Name, or Company



ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

Unique device identification is a system being established by the FDA to adequately identify devices sold in the U.S. from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once.

[MORE INFO](#)
[ABOUT UDI](#)
[ABOUT GUDID](#)

DOWNLOAD

[Download Data](#)

 Download the latest full releases and update files provided to the NLM by the FDA.

NEWS

[AccessGUDID News](#)

Posted: September 1, 2014

HELP

[Help using AccessGUDID](#)

 [Searching AccessGUDID](#)
[Downloading Release Files](#)
[NLM Web Guidelines](#)
[Still Need Help?](#)

FDA TOOLS AND RESOURCES

 [FDA UDI Home](#)
[FDA Medical Devices Home](#)
[Report a Device Problem \(MedWatch\)](#)
[Device Recalls](#)
[Device Safety Communications](#)

AccessGUDID

The screenshot shows the AccessGUDID website interface. At the top, there are logos for NIH (U.S. National Library of Medicine) and FDA (Tools and Resources). The main heading is "ACCESS GUDID" with the tagline "IDENTIFY YOUR MEDICAL DEVICE". A search bar contains the text "pump" and a magnifying glass icon. A dropdown menu displays search results for "pump":

- pump**
- pump**, blood, cardiopulmonary bypass, non-roller type
- ambulatory insulin infusion **pump**
- pump**, infusion, implanted, programmable
- general-purpose implantable infusion **pump**, programmable
- intrathecal implantable infusion **pump**, nonprogrammable
- centrifugal circulatory assist **pump**, electric
- cardiopulmonary bypass system centrifugal **pump**

On the left side, there is an "ABOUT" section with links for "MORE INFO", "ABOUT UDI", and "ABOUT GUDID". Below that is a "NEWS" section with a link for "AccessGUDID News" and a post date of "September 1, 2014". On the right side, there is a "FDA TOOLS AND RESOURCES" section with links for "FDA UDI Home", "FDA Medical Devices Home", "Report a Device Problem (MedWatch)", "Device Recalls", and "Device Safety Communications". A search history or status bar at the top right shows "Searching AccessGUDID" and other related links.

Compliance Dates for UDI Requirements

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	<ul style="list-style-type: none"> • Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	<ul style="list-style-type: none"> • Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	<ul style="list-style-type: none"> • Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	<ul style="list-style-type: none"> • Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	<ul style="list-style-type: none"> • Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Exceptions and Alternatives

General exceptions under 21 CFR 801.30

FDA may grant an individual exception or alternative.

FDA will post individual exception/alternative grants on the UDI website.

Key General Exceptions

General exceptions from UDI labeling and data submission requirements include*

Class I cGMP exempted devices

Individual single-use devices sold and stored in a single package until removed for use

IDEs or devices used solely for nonclinical use

Devices intended solely for export from the US

Individual devices in convenience kits

Three year "grandfather"

*See [21 CFR 801.30](#) for full list of exceptions

Objectives of the UDI Program

“Establish a system to adequately identify devices through distribution and use”

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls



UDI Labeled Device to Care Provider



Company submits data to GUDID

Vision for UDI Adoption

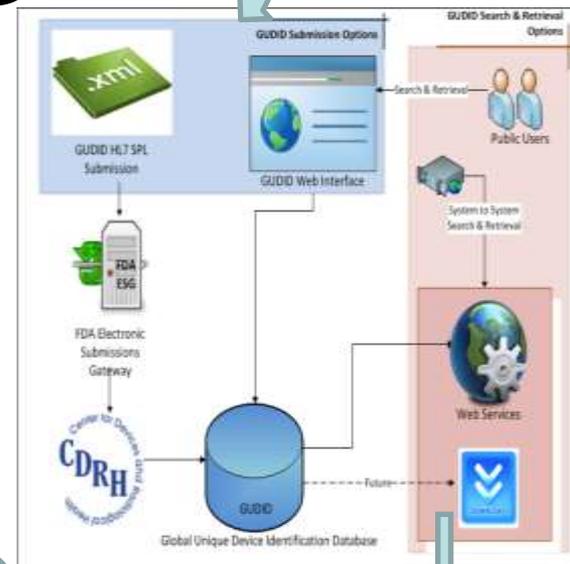


Device used on patient

Document Device Use



Inventory Management & Replenishment
Patient Charge
Electronic Health Record (EHR)



GUDID as source of standard device information



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

Additional Resources

www.fda.gov/udi

FDA Webinar: The Unique Device Identification Program (UDI 101)

FDA Webinar: Getting Ready for GUDID

FDA Webinar: Device Identifier Record

FDA Webinar: GUDID HP7 SPL Submission Option Overview

GUDID Database Elements Reference Table

UDI Issuing Agencies

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D2S6

Final Thoughts



- **Develop a standardized system to create the UDI**
- **Place UDI on label and (sometimes) the device**
- **Create and maintain the Global UDI Database**
- **Adoption and Implementation by all stakeholders**