

# **FOOD** Food and Drug Administration



**Center for Devices and Radiological Health** 

## **Global Unique Device Identification Database (GUDID) User Manual**

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#### **DOCUMENT HISTORY**

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2.0	FDA UDI Staff	April 2019	Updated to include technical GUDID changes as of revision date
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# **1.** Introduction

The Unique Device Identification System will offer a range of benefits to industry, FDA, consumers, health care providers and health care systems, such as, ability to accurately identify a device through distribution and use; allowing more accurate reporting of adverse event data and identification of device problems; ability to document device use in electronic health records and other benefits. 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 the FDA's Global Unique Device Identification Database (GUDID). The public can search and download information from the GUDID at <u>AccessGUDID</u>.

This document is intended primarily to provide labelers with information about submitting data to the Global Unique Device Identification Database (GUDID)<sup>1,2</sup>. Please note the FDA will continue to enhance the system to improve user experience, build in better validation rules, and make other necessary changes as we "learn" from the initial roll-out and implementation of GUDID. The FDA intends to periodically update this document to reflect system changes and enhancements.

FDA technical documents, including this technical document, do not establish legally enforceable responsibilities. The use of the word "should" in this technical document means that something is suggested or recommended, but not required.

## **2. The GUDID Account**

To submit data to GUDID, labelers must first establish a GUDID Organization account. A Labeler Organization may have one or more GUDID accounts.

- GUDID utilizes DUNS<sup>3</sup> numbers to enable identification of labeler organizations.
- Labelers should manage their company information via the DUNS number and GUDID pulls company name and address from the D&B DUNS database.
- Each GUDID account is identified by the Organization DUNS Number.
  - The Organization DUNS number represents the labeler's view of the highest corporate level in the labeler organization; it may be the headquarters DUNS number, or the parent DUNS number for the labelers included in the GUDID account.
  - Please ensure that the name and address in the D&B DUNS database is accurate, as this number is
    used to identify the labeler organization in GUDID; company name and address are pulled from the
    DUNS database.
  - The organization DUNS number serves as the primary key for the GUDID account. Once used, it cannot be reused to create another GUDID account.

<sup>&</sup>lt;sup>1</sup> "Labeler" is defined in 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 without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler" <sup>2</sup> Under 21 CFR 830.300(a), the labeler must provide to GUDID the information required by 21 CFR Part 830 subpart E for each version or model required to bear a unique device identifier (UDI).

<sup>&</sup>lt;sup>2</sup> Under 21 CFR 830.300(a), the labeler must provide to GUDID the information required by 21 CFR Part 830 subpart E for each version or model required to bear a unique device identifier (UDI).

<sup>&</sup>lt;sup>3</sup> Data Universal Numbering System or D-U-N-S® Number is a unique nine-digit identification number assigned and managed by Dun & Bradstreet to business entities. For more information, visit

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

- The organization DUNS number can be used as a Labeler DUNS number
  - Each device record should be associated to a Labeler DUNS number, and is used to pull the labeler company name and address from the D&B DUNS database.
  - To ensure data consistency the company name associated to the Labeler DUNS number should match the company name that appears on the device label. Ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement; however, labelers are encouraged to work towards this model for new products and when making changes to existing products as appropriate.

The structure of the GUDID Account and the different user roles are shown below.



For information and instructions on how to obtain a GUDID account, visit <u>www.fda.gov/udi</u>.

# **3. GUDID User Roles for Labelers**

GUDID has three user roles for Labelers: Regulatory Contact, Coordinator and Labeler Data Entry (LDE) User.

## 3.1 Regulatory Contact

The GUDID Regulatory Contact is responsible for ensuring the labeler organization meets GUDID submission requirements. The Regulatory Contact does not have functional user role in GUDID i.e, no user-name or password to access the system is provided.

Each GUDID account must have a Regulatory Contact.

# 3.2 Coordinator

The Coordinator user serves as the 'gatekeeper' and manages the GUDID account for designated Labeler DUNS numbers. Coordinator responsibilities include:

- Maintain GUDID Account details, including necessary updates to Regulatory Contact, Organization and Labeler DUNS.
- Create Labeler Data Entry (LDE) User account(s)
- Assign Labeler DUNS number(s) to LDE(s).
- Serve as LDE user, if so desired; separate user name and password is provided for the LDE user role.
- View DI records. Note: Coordinator User cannot create DI records
- Serve as the first point of contact and respond to FDA inquiries related to GUDID data quality, incorrect or inconsistent data, and other submission/data specific questions.
- Unlock device records for data corrections. See Section 4.1.2.3 Unlock DI Record for more information.

# 3.3 Labeler Data Entry (LDE) User

Labeler Data Entry (LDE) users can enter, edit, view and maintain Device Identifier (DI) records in GUDID.

- Each GUDID account can have one or more LDE Users.
- Each LDE user can be assigned one or more Labeler DUNS numbers in a given GUDID account.
- A given Labeler DUNS Number can be assigned to more than one LDE user. The LDE users would then share responsibility for DI records associated to that Labeler DUNS number
- An LDE user:
  - Is responsible for data entry, submission, and management of device identification information for their designated Labeler DUNS into the GUDID.
  - Can serve as Regulatory Contact, if so desired.
  - Can serve as Coordinator user, if so desired; separate user name and password is provided for the Coordinator user role.

# 4. Getting Started with GUDID

## 4.1 Browser Compatibility

Users can view supported web browsers by clicking the **About** button on the top right-hand side of the main GUDID screen. GUDID currently supports the following browsers:

• Internet Explorer 11 or higher

- Mozilla Firefox 46 or higher
- Chrome 51 or higher

# 4.2 GUDID Main Screen and Logging into GUDID

The GUDID main screen allows users to login to access GUDID, the AccessGUDID web site and the FDA UDI website, and provides information about supported web browsers as seen below.



Please review the System User Agreement prior to logging into GUDID.

Each Labeler needs to establish one or more user accounts (see Section 4 **GUDID User Roles for Labelers** for more information) with a username and password. To log into GUDID, enter the username and password in the designated fields and click Login.

#### 4.2.1 Username and Password

When the Organizational GUDID account is established, Coordinator and LDE users can be created and associated to the GUDID account. When users are created, you will receive a username and a temporary password by email. When you first log in, you will be prompted to enter the temporary password that you received via email, and the system will prompt you to change the temporary password.

If you forget your username, and want to retrieve it:

• Click Forgot Username.

GUDID Login
Username:
Password:
Forgot Username/ Password
Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters ['!', '@', '#', '\$', '%', '&', '+', '~'].
I agree to System User Agreement
Login

• Enter the email address associated with the username and click Send My Username

Retrieve Us	ername	
Email: *		
	Send My Username	Cancel

You will receive an email with the username.

• If you have more than one account linked to your email, you will receive an email for each username in the GUDID.

Note: This function does not reset the password.

If you forget your password, and want to retrieve it:

• Click Password.

GUDID Login
Username:
Password:
Forgot Username Password
Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters ['!', '@', '#', '\$', '%', '&', '+', '~'].
I agree to System User Agreement

• Enter the username and email associated with the password.

Retrieve Password							
Username: *							
Email: *							
Send My Password	Cancel						

- You will receive two emails:
  - 1) Password reset notification
  - 2) A temporary password.
- Login to GUDID with your username and the temporary password.
- The system will prompt you to change the password.
- To change the password, enter the temporary password, and a new password. Confirm the new password by entering it again. Click **Change Password** to change the password.

X You must change your p	assword,	
User Details Change I	assword	
When changing your passwor '\$', '%', '&', '+', '~'].	it must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [1, '@'	', '#',
Username: *		
Current Password: Ente	r temporary password here	
New Password: * Confirm Password:	r new password here	
Re-e	nter new password here Click to change password Change Password	vord

#### 4.2.2 View and Edit User Profile

The User Profile screen allows users to update user details and change password as needed. To access the user profile screen, login to GUDID, and click on the drop-down menu next to the user name and user role on the top right-hand side as shown below.

GUDID Global Unique Device Identification Database		vice	About 🕸	i UDI Website	CACCESSGUDID	ii <u>Logout</u>
		base				
Home	Manage Accounts 👻	Manage DI 👻		$\langle$	FDA COOF	RDINATOR
User Pre	ofile for				View Details	
User Deta	ils Change Password				Change Passv	word

You may update your contact information on the User Profile screen.

Home	Manage Accounts 👻	Manage DI 👻				
User Prof	ile for					* required fields
User Details	Change Password					
First Name:	*	Last Name: *	Email: *		Phone: *	
Account Typ COORDINA	e: Or FOR	ganization:				
				Click to save ch	nanges	Save Reset

You may change your password in the Change Password screen.

Home	Manage Accounts 👻	Manage DI 👻				
User Pro	ofile for					* required fields
User Deta	ils Change Passwor	d				
When chan '\$', '%', '&', '	ging your password it must +', '~'].	be 8-32 characters w	ith at least one upp	per case letter, one lower	case letter, one number and one of the following	ng special characters ['!', '@', '#',
Username:	*					
Current Pa	ssword: Enter cur	rent passwor	d here			
New Passv Confirm Pa	Enter nev	w password h	ere	-		
	Re-enter	new passwor	d here		Click to change password	Change Password

# **5. GUDID Functionality**

GUDID provides two access levels for users, defined by two user roles, namely *Coordinator* and *Labeler Data Entry (LDE) User*. Both roles may be assigned to a single individual. Each GUDID account may have multiple Coordinator and LDE users. The following sections will provide information on the functionality available in GUDID for each user role.

## 5.1 Coordinator

Coordinator users serves as the 'gatekeeper' and manages the GUDID account for their designated Labeler DUNS numbers. Coordinators may access GUDID by logging in with the username and password as indicated in Section 4.2 GUDID Main Screen and Logging into GUDID. The Coordinator home page is displayed at login as shown below. There are 4 main areas of functionality available for Coordinators in GUDID:

- Manage Accounts: allows creation and management of user accounts, namely LDE users
- Manage DI: view and manage Device Identifier (DI) records that have been submitted to the GUDID, i.e., Published, Unpublished and Deactivated DI records; this includes ability to *Unlock* device record for data corrections.
- Draft DI: view Draft DI records



The next few sections will describe each of these functional areas in greater detail.

#### 5.1.1 Manage Accounts

**Manage Accounts** allows the Coordinator to create, view and manage Labeler Data Entry (LDE) user accounts for their assigned Labeler DUNS Number(s). This functionality may be accessed by clicking the **Manage Accounts** button or by using the top menu **Manage Accounts** drop down as shown below.



Upon entry, **Manage Accounts** will display all the LDE user accounts available for you in a table. You can filter for a specific account by typing in one or more of the fields provided – **Last Name, First Name, User Name, Email, Status, Mode, DUNS Number, Organization** (i.e., Labeler Company Name).

Enter the information you desire to filter-by into the field, and then click Filter.

The results of the filter will appear in the table at the bottom of the page.

Home Manage Accounts	Manage DI 👻					TOR		
Manage Accounts								
Last Name: Account Type:	First Name: DUNS #:	Username: Organization:	Email:	Status:	Mode:	]		
Click on	user name hype	rlink	Click to Filt on entered	er records based information	Filter Clear			
View: 25	Eirst Name		Click to a	add New Account	Add New Account	d		
	T list Maine		Labeler Data Entry	Criganization      Criatus     Enabled	Activated Seset			
			Labeler Data Entry	Enabled	Activated Seset	t		
			Labeler Data Entry	Enabled	d Activated Seset	t		
			Labeler Data Entry	Disable	d Activated			
			Labeler Data Entry	Disable	d Activated			

If there are no existing accounts, and you need to create new accounts, see below.

#### 5.1.1.1 Create New Account

Coordinators can create new LDE user accounts. While in the **Manage Accounts** section, the functionality can be accessed either by clicking the **Create New Account** button or by using the top menu **Manage Accounts**→ **Create New Account** drop down as shown below.

Home Manage Accounts	Manage DI 👻				
Manage View Accounts					
Create New Account Last Name: Account Type: Labeler Data Entry	First Name: DUNS #:	Username: Organization:	Email:	Status:	Mode:
View: 25  7/7 records, 1/1 Username	page ⊕ First Name	Email	Click to add	New Account	Add New Account
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Disabled	Activated
			Labeler Data Entry	Disabled	Activated

The *Create New Account* page opens as shown below. Enter the required information to create a new LDE user account.

- General Information: enter LDE user contact information here
- Organization Information: prepopulated with Labeler company Organization DUNS number and address. This cannot be edited by Coordinators. Please contact the <u>FDA UDI Help Desk</u> for any changes
- Labeler DUNS: prepopulated with all Labeler DUNS associated to the Labeler Organization, that are available for the Coordinator user creating the LDE user account. Check the box to assign Labeler DUNS to LDE users as needed. LDE users may only create and view DI records for the Labeler DUNS they are

assigned. You may check or uncheck the box as shown in the screen below to make changes to the LDE user account.

**<u>TIP:</u>** Coordinator users may manage access and entry of device information into GUDID by:

- assigning specific Labeler DUNS to specific users to manage who has access to which DI records.
- An LDE user may have multiple Labeler DUNS assigned
- The same Labeler DUNS may be assigned to multiple LDE users.

All changes must be saved by clicking the Save button.

Home	Manage Accounts 👻	Manage DI	l <del>v</del>				F			
Create I	Create New Account required fields									
					Click to save ch	anges	Save	Reset Cancel		
General Info	ormation		You may enter	LDE user conta	act Information h	ere				
Account T Labeler D	ype:* Data Entry ▼									
Username	Username: * First Name: * Email: * Phone: *									
Organizatio	ion DUNS #: *	Compa	zation Informat ny Organizatio	n DUNS and Ad	dress, this canno	Labeler ot be edited				
			, ,							
Address 1		Addres	ss 2:	City: Rockville	State/Province MD	: ZIP / Postal: 20852-4279	USA	y:		
Labeler DU	NS List of La	beler DUN	IS associated to	the Organizat		opulated				
	You can a	issign or r	emove a Label	er DUNS assign	ment to the LDE	user by	P/Postal	Country		
	checking	/unchecki	ing the box			3	897-5699	USA		
					Port Saint Lucie	FL 34	953-5132	USA		

#### 5.1.1.2 Edit Existing Account Details

Click on the username link to see account details as shown below. The Account Details button shows:

- General Information: shows user contact information, which can be edited
- Organization Information: shows the Labeler company Organization DUNS number and address. This cannot be edited by Coordinators. Please contact the <u>FDA UDI Help Desk</u> for any changes
- Regulatory Contact: this information cannot be edited by Coordinators. Please contact the <u>FDA UDI</u> <u>Help Desk</u> for any changes
- Labeler DUNS: shows all the Labeler DUNS associated to the Labeler Organization and assigned to a given user. LDE users may be assigned specific DUNS as needed. LDE users may only create and view DI records for the Labeler DUNS they are assigned. You may check or uncheck the box as shown in the screen below to make changes to the LDE user account.

All changes must be saved by clicking the Save button.

Coordinator users should make sure that GUDID Account details, including, updates to Regulatory Contact, Organization and Labeler DUNS are accurate. For these updates, please contact the <u>FDA UDI Help Desk</u>

Home	Manage Accounts 👻	Manage DI 👻					F		
Account Details for bahtest, Ide * required fields									
Enabled	Activated     See	Password					Save	Reset Cancel	
General Inf	ormation								
Account 1 Labeler [	ype: * Data Entry ▼	You may edi	t Contact Inforr	mation here					
Username _	Username: First Name: * Last Name: * Email: * Phone: * 9999999990								
Organizatio Organizat	n Information ion DUNS #: *	Organizati Organizati	on Information on DUNS and A	shows Labele ddress, this ca	er Company annot be edite	ed			
Address 1	:	Address 2:	City: Rock	ville	State/Province MD	e: ZIP / Pos 20852-42	tal: Countr 279 USA	<b>y</b> :	
Labeler DU	NS You can a	ssign or rem	ove a Labeler [	UNS assignm	ent				
	to the LD	E user by ch	ecking/uncheck	king the box		State/Province	ZIP/Postal	Country	
					Davenport	FL	33897-5699	USA	
					Port Saint Lucie	FL	34953-5132	USA	

#### 5.1.1.3 Account Status and Mode

GUDID user accounts can have one of two account statuses: enabled or disabled.

- Enabled Account: A user with an enabled account may login to GUDID.
- **Disabled** Account: A user with a disabled account may not login to GUDID. Disabled accounts may be re-enabled, allowing the user to access the account again.

<u>*TIP:*</u> The **disable** feature should be used to manage user accounts that may not use the account for extended periods of time but are expected to return and reuse GUDID. For example, when users take extended leave.

The Coordinator may enable/disable a LDE user account by clicking on the **Enable/Disable** button as shown below. Re-enabling a disabled GUDID user account automatically changes the user's password to a temporary password. The user is notified of the change via an automated email and must change the temporary password before access to GUDID is restored.

Home Manage Accounts	▪ Manage DI ▪					FDA	COORDINATOR
Manage Accounts							
Last Name: Account Type: Labeler Data Entry	First Name: DUNS #:	Username: Organization:	Email:		Status:	Mode:	▼ Ciear
View: 25  7/7 records, 1/ Username Last Name	1 page gudid.fda.gov Once a user acco create, view or e user account? Please do not cli to refresh and di	Image: Construction       Says       bunt is disabled, the user will       dit DI records. Are you surf       ck again and wait for few signay the updated account	ill not be able to log in, e you want to disable this seconds to enable this screen t status.	organization	CCOUNT	Add Net Mode	<ul> <li>Account</li> <li>Password</li> <li>Reset</li> <li>Reset</li> <li>Reset</li> </ul>

GUDID user accounts can be in one of two modes: activated or deactivated.

- Activated Account: A user with an activated account may login to GUDID.
- **Deactivated** Account: A user with a deactivated account may not login to GUDID. <u>Deactivated</u> <u>accounts cannot be reactivated or recovered.</u> The system warns the user as shown below.

**<u>TIP</u>: Deactivating** an account permanently removes all access to the user, and the account cannot be reactivated or recovered. An account should be deactivated when the user will no longer need to access GUDID, for example, if the user leaves the company or is no longer in a job role that requires access to GUDID.

Home Manage Accour	nts 👻 Manage DI 👻					FDA	COORDINATOR
Manage Accounts							
Last Name: Account Type: Labeler Data Entry	First Name: DUNS #:	Username: Em Organization:	ail:		Status:	▼ Mode:	Ciear
View: 25 View: 7/7 record	gudid.fda.gov says Deactivating an account is The account cannot be rea reused. In order to edit exi you must have another Lat	PERMANENT. ctivated and the user name cannot be sting DI records created by this user, beler Data Entry (LDE) user assigned to the		Click to activ	r <b>ate/deactiva</b> n ≑ Status	ate Accoun	t unt Password
	same Labeler DUNS numb Are you sure you want to c Please do not click again a	ers. Jeactivate this account? nd wait for few seconds to enable this screen	ntry		Enabled	Activated	Reset
	to refresh and display the o	updated account status.	ntry	, , , , , , , , , , , , , , , , , , , ,	Enabled	Activated     Activated	Reset
		OK Cancel	ntry	,	Disabled	Activated	
		Labeler Data	Entry		Disabled	Activated	)

#### 5.1.1.4 Password Reset

The Coordinator can initiate a password reset for a LDE user by clicking the **Reset** button as shown below. Users will be notified via an automated email and must change the temporary password before access to GUDID is restored.

Home Manage Account	s 🔹 Manage DI 👻				
Password reset successful.					
Last Name:	First Name:	Username:	Email:	Status:	Mode:
Account Type: Labeler Data Entry ▼	DUNS #:	Organization:			Filter Clear
View: 25 • 7 / 7 records,	1 / 1 page		×	Click to	o Reset Password
Username 💠 Last Name	🗢 First Name	🗢 Email	Account Type	Organization 💠 Status	\$ Mode \$ Password
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Enabled	Activated     Reset
			Labeler Data Entry	Disabled	Activated
			Labeler Data Entry	Disabled	Activated

Please note that a Coordinator user may update LDE user accounts. However, creating and updating Coordinator user accounts needs to be requested by contacting the <u>FDA UDI Help Desk</u>.

#### 5.1.2 Manage DI

*Manage DI* allows the Coordinator user to view and manage Device Identifier (DI) records that have been submitted to the GUDID. The functionality may be accessed by clicking the **Manage DI** button or by using the top menu **Manage DI Submitted DI** drop down as shown below.

Home Manage Accounts  Manage DI		
Welcome Submitted DI Draft DI MANAGE ACCOUNTS manage and create coordinators	MANAGE DI manage DI records	DRAFT DI manage Draft DI records
FIND FDA PT CODE find FDA preferred term code		

Submitted DI refers to DI records in the in the Published, Unpublished and Deactivated status.

- Published DI record is a record that has been submitted to the GUDID. After the grace period completes, device information will be made available for search and retrieval by the public. Refer to Section 6 Release of GUDID Data for Public Use for more information. During the DI record grace period, the record may be edited. Once the grace period completes, the record will have limited editing.
- Unpublished DI Record is a record that has been submitted to the GUDID with a future DI Record Publish Date. On the Publish Date, the system will automatically change the record status to *Published*.
- Deactivated DI records are records that have been deleted from GUDID.

For more information on the DI record life cycle and the record statuses, please review the <u>GUDID Guidance</u> document.

Upon entry, **Manage DI** will display all DI records associated to the Labeler DUNS assigned to the Coordinator.

• You can filter for a specific DI record by typing in any of the fields provided – DI Number, Brand Name, Version or Model Number, User Name (of the LDE user who entered the DI record), Company Name, Labeler DUNS Number. Records can also be filtered by the DI Record Status and DI Record Edit Status.

Enter information you desire to filter-by into the field, and then click Filter.

The results of the filter will appear in the table at the bottom of the page.

Home	Manage Accounts 👻	Manage DI 👻				Click to Filter r	ecords based	
Manage	Device					on entered info	ormation	
DI Number:		Brand Name:	V	ersion or Model Nu	imber:	DI Record Status:	▼ Filter	Clear
User Name	Company Name: I		Labeler DUNS Number: DI Record Edit		DI Record Edit Status:	Advanced Search		
	Click on I	OI hyperlink t	o see				indigio Di -	
View: 25	View: 25 Vie				Click to	export DI recor	ds for 🗾 🔶	Export Unlock
DI Nu	mba	Company Name	\$	Brand Name	your or	ganization from	GUDID Status	DI Record Edit Status
				Test2 Release 1.6.3	3	Test2XML	Click to unlo	ck records for
				Test2 Release 1.6.3	3	Test2XML	editing after grace period	
				Test2 Release 1.6.3	3	Test2XML	cutting utter	Brace period
3 / 3 records, 1	/ 1 page		R et					

#### 5.1.2.1 View DI Record

Click on the *DI Number* hyperlink to see DI record details as shown below. The DI Record details screen opens as shown below.

- Each DI record has 3 sections Device Information, Device Status and Device Characteristics. The '+' may be clicked to expand and view each section
- *View History* hyperlink opens a pop-up box that provides information on entry and updates made to the record.
- Printer Friendly hyperlink allows the DI record to be printed for review

Note that the Coordinator may only view DI records, the Coordinator cannot create or edit DI records.

Home	Manage Accounts 👻	Manage DI 👻				
Device I	dentifier (DI) Re	cord Details	for Published Record			* required fields
View History	Printer Friendly Pu	blic Device Record	l Key:			Cancel
Device In	formation			Cl	ick to expand details for each sec	tion 🗕 🖬
Device St	tatus					0
Device C	haracteristics					0
View History	Printer Friendly	Click to vie	ew printer friendly forma	at	Click to cancel and close record	Cancel
		_				
k to view	record history					

#### 5.1.2.2 Export DI Record

The Export functionality on the Manage DI page allows Labeler organization users, both Coordinators and LDE Users, to download records submitted to GUDID for their assigned Labeler DUNS in in XML format.

- All records submitted may be exported or you may filter for specific record(s) for export by typing in any of the fields provided as indicated in Section 4.1.2, Manage DI section.
- Click the **Export** button.
- If you export less than 100 device records, the system will return an XMLfile.
- If you export more than 100 device records, the system will provide you a zip file.
- Download the file

Alternatively, if your records are published and have passed the grace period, you can export via <u>AccessGUDID</u>. Please note that not all fields are available for export via AccessGUDID. See Section 6, Release of GUDID Data for Public Use for more information on publicly available GUDID data.

#### 5.1.2.3 Unlock DI Record

When a GUDID DI record is initially submitted (either by manual data entry via the GUDID Web Interface or as a GUDID HL7 SPL submission) and published, the record starts the 'grace period'<sup>4</sup>.

- During the grace period, all DI record data element values may be edited, except the DI Record Publish Date. Labelers are encouraged to use the grace period as a review period to ensure their records are accurate and make any updates as needed.
- After the grace period passes, the record is released to the public on <u>AccessGUDID</u> and <u>OpenFDA</u>, and DI record edits are restricted; specifically, edits to the New DI trigger data elements<sup>5</sup> are not allowed.

<sup>&</sup>lt;sup>4</sup> For Published DI records, the grace period is set to 7 calendar days and starts the day after the DI Record Publish Date.

<sup>&</sup>lt;sup>5</sup> New DI trigger data elements are those, which when changed, require a new Device Identifier to be assigned.

Refer to the GUDID Data Elements Reference Table on for more information on which data elements may be edited after the grace period.

However, ability to make data corrections, including corrections to the New DI trigger elements is necessary to ensure quality device identification information is available to the public. The ability to "unlock" a device record(s) for error correction after the grace period was therefore implemented as part of GUDID Release 2.2 enhancements. Note that the unlock functionality should not be used to submit edits to data elements when new Device Identifier assignment is necessary, resulting in entry of a new device record in GUDID.

#### 5.1.2.3.1 Unlock Functionality Overview

- GUDID Coordinator user can unlock device records for editing via the GUDID Web Interface.
- Any Published DI record that has passed grace period (i.e., after-grace-period) can be unlocked.
- A single record or multiple records may be unlocked at any given time.
- The record will remain unlocked for 5 calendar days (starting the day after the record is unlocked) to submit edits.
- Once unlocked, all data elements except the DI Record Publish Date may be edited.
- Edits for unlocked records can be submitted either via the GUDID Web Interface (by the GUDID LDE user) or the GUDID HL7 SPL submission option
- Records will be locked upon successful processing of the submitted edits (or after completion of the 5-calendar day unlock period, whichever is earlier).
- Updated information will be released to public users on <u>AccessGUDID</u> and <u>OpenFDA</u> on the next scheduled release date of GUDID data.
- All prior published versions of a given record will remain accessible on <u>AccessGUDID</u> and <u>OpenFDA</u> as device record history
- unlocked. The unlock functionality should be used to unlock published DI records. If a user attempts unlock the following types of records, the unlock process will fail and the system will notify the user via the Unlock Request Summary popup and system generated email.
  - Draft DI record
  - Unpublished DI record
  - Deactivated DI record
  - Published DI record within grace period
  - Published DI record that is already unlocked

#### 5.1.2.3.2 Unlocking DI Records

The *Unlock* functionality is available on the **Manage Device** page. There are two ways to select records for unlocking.

 Record may be unlocked by filtering for specific record(s) to unlock by typing in any of the fields provided as indicated in Section 5.1.2 Manage DI

<u>*TIP:*</u> Selecting DI Record Status as *Published* and DI Record Edit Status as *After Grace Period* and then clicking **Filter** will provide all records that are eligible to be unlocked.

- Select the records to unlock on the left side of the screen
- Click on Unlock

Home Manage Acc	counts 👻 Manage DI 👻				
Manage Device					
DI Number: User Name:	Brand Name: Company Name:	Version or Model Number: Labeler DUNS Number:	DI Record Status: V DI Record Edit Status:	Filter Advanced Se	Clear
Step 1: 5	Select the records to un		•	<u>Multiple DI –</u>	Export Unlock
DI Number	Company Name	Brand Name	Version or Model Number	DI Record Status	DI Record Edit Status
		Test2 Release 1.6.3	Test2XML	Pu Step 2: C	lick to unlock
		Test2 Release 1.6.3	Test2XML	Puonaneu	Alter Orace Ferrou
		Test2 Release 1.6.3	Test2XML	Published	After Grace Period
3 / 3 records, 1 / 1 page					

2) Enter specific records to unlock by clicking on *Multiple DI – Search* hyperlink as shown below.

- Enter Primary DI numbers for the records you want to unlock. Approximately30-50 DI records may be entered at one time, depending on the length of the DI number.
- Click Search
- Review search results
- Select the records you wish to unlock
- Click Unlock

Multiple DI - Search				
Primary DI Enter Primary Device Identifiers (DI). Total 800 characters accepted, ~ Example: 23477777365, AR45354646,5647848484888	~30-50 DIs. Separate each DI with a com	ma with or without space.		
Step 2: El	nter Primary DI numbe	rs of records you wa	ant to unlock	]
778 character(s) left				
		Step 3: Click Search	)	Search Clear
				Basic Search Advanced Search
	Step 4: Review searc	n results		
View: 25 V 2/2 records, 1/1 page		Step	6: Click to unl	ock -Unlock
Step 5: Select records to unlock	Brand Name	Version or Model Number	DI Record Status	DI Record Edit Status
REL242SPL4	Industry Sample Package	Model9999	Published	Unlocked
REL242SPL1	Industry Sample Package	Model9999	Published	After Grace Period
2 / 2 records, 1 / 1 page				

• After you select records and click **Unlock** using either of the above options, the pop-up dialog box below will appear.



- Select Cancel if you DO NOT wish to begin the unlock process.
- Select Confirm if you wish to continue and unlock your records.

After you click **Confirm**, the system will process your unlock request and provide a popup with a summary of the process.

Unlock Device Record(s)
UNLOCK REQUEST SUMMARY
Your unlock request has been processed. Successful Unlock(s): 2 Failed Unlock(s): 0 Possible reasons for unlock failure: Unpublished DI record - all fields are editable Published DI record in Grace Period - all fields except DI Record Publish Date are editable Deactivated DI record Unlocked DI record

- An automated system generated email will be sent to the Coordinator who initiated the Unlock process. The email will indicate number of records that were successfully unlocked, number that failed unlock and reasons for failure.
- Your selected records have now been unlocked for editing.
- The DI Record Edit Status for unlocked records will be shown as Unlocked
- You may view, print or export records for review.
- You can update and resubmit your records immediately after unlocking them. You will have 5 calendar days, starting from the day after a record is unlocked, to complete your updates and submit. After 5 calendar days, if a record has not been updated and resubmitted, it will be automatically relocked by the system.

#### 5.1.2.3.3 Editing Unlocked DI Records

Unlocked records may be edited via the GUDID Web Interface or via the GUDID HL7 SPL submission option. See Section **4.2.2.4** Edit DI Record for more information on editing DI records.

• After a record is edited and resubmitted, the system will relock the record and reset its DI Record Edit

Status to *After Grace Period*. Updates will be sent to <u>AccessGUDID</u> and <u>OpenFDA</u> on the next scheduled release date.

<u>*TIP:*</u> Updates made to unlocked records should be reviewed prior to submission. Records will be locked immediately, and updates will be sent to <u>AccessGUDID</u> on the next scheduled release.

• A record that is unlocked and not updated will be locked after 5 calendar days, and its DI Record Edit Status will be set to 'After Grace Period'. The record may be unlocked again if necessary; however, we suggest you initiate unlock once you are ready to make the updates in GUDID.

Please note that the history of all edits is maintained and will be made available on AccessGUDID.

#### 5.1.3 Coordinator User Viewing Draft DI Record

*Draft DI* allows Coordinator user to view all Draft Device Identifier (DI) records that have been entered for their assigned Labeler DUNS Numbers. This functionality may be accessed by clicking the **Manage DI** button or by using the top menu **Manage DI Draft DI** drop down as shown below.



• Draft DI Record allows labelers to prepopulate and save a DI record with the available information via the GUDID Web Interface.

• Users may also create Draft DI records to get familiar with creating and saving DI records in GUDID For more information on the DI record life cycle and the record statuses, please review the <u>GUDID Guidance</u> document.

Upon entry, **Draft DI** will display all the Draft DI records associated to the Labeler DUNS assigned to the Coordinator.

• You can filter for a specific DI record by typing in any of the fields provided – DI Number, Company Name, Brand Name, Version or Model Number, Labeler DUNS Number, and Last Name, First Name and User Name (of the LDE user who entered the DI record).

Enter information you desire to filter-by into the field, and then click Filter.

The results of the filter will appear in the table at the bottom of the page.

Home	Manage Accounts 🔻	Manage DI 👻					F		
Manage	Manage Drafts * required fields								
DI Number Last Name	:	Company Name: First Name:	Brand N User Na	Name: ame:	Version or Mo	del Number:	Labeler DUNS N	umber:	
					Click to Fil on entered	ter records ba	ased	Filter Clear	
View: 25	1 / 1 records, 1 / 1	page		<b>1 &gt; &gt;&gt; H</b>					
DI Number	DI Number Company Name		Brand Name		Version or Model Number		Purge Date 🛛 🌲		
TESTDRAFT			I	Test2 Release 1.6.3		Test2XML		04/03/2019 11:01 AM	
1 / 1 records,	1 / 1 page								

Click on the *DI Number* hyperlink to see DI record details as shown below. The DI Record details screen opens as shown below.

- Each DI record has 3 sections Device Information, Device Status and Device Characteristics. The '+' may be clicked to expand and view each section
- Printer Friendly hyperlink allows the DI record to be printed for review

Note that the Coordinator may only view Draft DI records, they can NOT create or edit Draft DI records.

Home	Manage Accounts 👻	Manage DI 👻			FL			
Device	Device Identifier (DI) Record Details for Draft Record  'required fields							
Printer Frie	ndly Public Device Rec	ord Key:				Cancel		
Device I	nformation				Click to expand details for each section			
Device S	itatus					0		
Device 0	haracteristics					0		
Printer Frie	ndly Click to	view printer	friendly format		Click to cancel and close record	Cancel		

#### 5.1.4 GMDN PT Code

21 CFR 830.310(b)(13) requires GUDID submissions to include the Global Medical Device Nomenclature (GMDN) Preferred Term code(s) for each version or model of a device . The GMDN Preferred Term is a system of internationally agreed descriptors used to represent common device types for grouping or categorization. A GMDN Preferred Term (PT) can be identified by the GMDN PT Code and is obtained from the GMDN Agency. Note that the GMDN is not a code set owned by FDA. For any questions regarding GMDN Codes or how to access a full list of these terms, please contact the <u>GMDN Agency</u>.

#### 5.1.4.1 Maintaining GMDN Codes

Labelers should ensure the data in their DI records is accurate and up-to-date, including GMDN codes.

• Once a DI record has been published in the GUDID with an active GMDN code, that assignment remains until deliberately changed by the labeler/LDE. There is no automatic update of GMDN terms within the GUDID.

- If GMDN Term information changes, the updated information must be submitted within 10 business days of the change per 21 CFR 830.330(b).
- If you maintain a membership with GMDN, the GMDN Agency notifies you when your terms have been modified or made obsolete. If not, it would be your responsibility to review and update your GMDN terms periodically or when required to by validation rules.
- If a GMDN term becomes obsolete, the labeler/LDE should update the GMDN term to pass validation when updating any other DI record attribute.

### 5.2 Labeler Data Entry (LDE) User

Labeler Data Entry (LDE) users are the 'worker-bees' of GUDID. They can enter, edit, view and maintain Device Identifier (DI) records in GUDID. LDE users may access GUDID by logging in with the username and password as indicated in Section 4.2 GUDID Main Screen and Logging into GUDID. The LDE user home page is displayed at login as shown below. There are 2 main areas of functionality available for LDE Users in GUDID:

- Manage DI: create, view, edit and manage Device Identifier (DI) records
- Draft DI: create, view and edit Draft DI records

Home Manage DI 👻		Labeler Data Entry (LDE) User
Welcome		
MANAGE DI manage DI records	DRAFT DI manage Draft DI records	FIND FDA PT CODE find FDA preferred term code

The next few sections will describe each of these functional areas in greater detail.

#### 5.2.1 LDE User Creating Draft DI

*Draft DI* allows LDE user to create, edit, view and manage Draft Device Identifier (DI) records for their assigned Labeler DUNS Numbers. The functionality may be accessed by clicking the **Draft DI** button or by using the top menu **Manage DI→Draft DI** drop down as shown below.

Home	Manage DI 👻		Labeler Data Entry (LDE) User
Welcome	Submitted DI Draft DI Create New DI		
	MANAGE DI manage DI records	DRAFT DI manage Draft DI records	FIND FDA PT CODE find FDA preferred term code

For more information on viewing existing Draft DI records, please see Section 4.1.3 Coordinator User

#### Viewing Draft DI Record.

Note that Draft DI records are purged or deleted from GUDID if there is no activity for 180 days on the record. The *Purge Date* shown in the screen shot below provides the information to allow you to manage your record submissions.

To create a new Draft DI record, from the Manage Drafts page:

• Click on New DI button or by using the top menu Manage DI→Draft DI drop down as shown below.

Home Manage DI 👻				Labeler Data Entry (LDE) User
Manage D Submitted DI				* required fields
Draft DI DI Number: Create New DI Labeler DUNS Number: Last Name:	e: Brand Name: First Name:	Use	sion or Model Number: r Name:	DI Drafts: My Drafts ▼
				Filter Clear
		Click to enter	r a New Draft DI re	ecord
View: 25 • 1 / 1 records, 1 / 1 page		Þ		New DI
DI Number Company Name	Date Dra not subm	Date Draft DI record will be purged if not submitted or no activity on record		
TESTDRAFTDI1	Test2 Release 1	1.6.3	Test2XML	04/03/2019 11:01 AM
1 / 1 records, 1 / 1 page		Click	to delete Draft D	l record

Window opens for record entry.

Device Identifier (DI)	Device Identifier (DI) Record Details for New Record       * required fields         Printer Friendly.       Save Draft       Review       Cancel					
Device Information						
Device Identifier (DI) Inform	nation					
Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:			
Labeler DUNS Number: *	Company Name:	Company Physical Address:				
Brand Name: *		Version or Model Number: *	Catalog Number:			
Device Description (max 2000	) characters):					

- Enter device information
- As you enter data into GUDID, note the following:
  - Refer to the GUDID Data Elements Reference Table (DERT), which provides detailed information on each GUDID data element, data entry pointers and edit rules before and after grace period. The DERT is available on the UDI website <u>here.</u>
  - The system will guide you through with prompts and error messages. Click on the blue "i" icon on the screen for helpful tips and information as shown below.

0	
	DI may be 12, 13 or 14 digit numeric value. System will append zeros to the left or beginning of the DI to save a 14 digit value.

- Click Save Draft to save the record in draft format and work on it in the future
- If the record is ready for submission, you may click **Review**, which will run all business rules.
- If the record passes review, the record may be submitted.
- If record fails review, it may be saved as a draft until ready for submission. Records can only be submitted once they pass **Review**.

#### 5.2.2 Manage DI

*Manage DI* allows LDE user to create, view, edit and manage Device Identifier (DI) records. The functionality may be accessed by clicking the **Manage DI** button or by using the top menu **Manage DI Submitted DI** 

drop down as shown below.

Home Manage DI		Labeler Data Entry (LDE) User
Welcome Draft DI		
Create New DI MANAGE DI	DRAFT DI	FIND FDA PT CODE
manage Di records	manage Draft DI records	find FDA preferred term code

Submitted DI refers to DI records in the Published, Unpublished and Deactivated status.

- Published DI record is a record that has been submitted to GUDID and will be made available for search and retrieval by the public after the DI record grace period completes. During the DI record grace period, the record may be edited. Once the grace period completes, the record will have limited editing.
- Unpublished DI Record is a record that has been submitted to GUDID with a future DI Record Publish Date. On the Publish Date, the system will automatically change the record status to *Published*.
- Deactivated DI records are records that have been deleted from GUDID.

For more information on the DI record life cycle and the record statuses, please review the <u>GUDID Guidance</u> document.

Upon entry, **Manage DI** will display all the DI records associated to the Labeler DUNS assigned to the LDE user.

 You can filter for a specific DI record by typing in any of the fields provided – DI Number Brand Name, Version or Model Number, User Name (of the LDE user who entered the DI record), Company Name, Labeler DUNS Number. Records can also be filtered by the DI Record Status and DI Record Edit Status.

Enter information you desire to filter-by into the field, and then click Filter.

The results of the filter will appear in the table at the bottom of the page.

Home	Manage Accounts 👻	Manage DI 👻						FD	Labeler Data Entry (LDE) User
Manage	Manage Device         Click to Filter records based on entered information						d		
DI Number	:	Brand Name: Version Company Name: Labeler		Version or Model Labeler DUNS Nu	Number:	r: DI Record Status:		Filter	Clear
View: 25	Click on DI hyperlink to see user details			Click to export DI records for		<b></b>	Export 💊 New DI		
	umb	Company Name	. 4	Brand Name	your or	ganization fro		record Status	DI Record Edit Status
				Test2 Release 1	.6.3	Test2XML	Click to	enter a	New DI record
				Test2 Release 1	.6.3	Test2XML		biisneu	Alter Grace Lenou
				Test2 Release 1	.6.3	Test2XML	Pu	blished	After Grace Period
3 / 3 records,	1 / 1 page								

#### 5.2.2.1 Create and Submit a New DI Record

Labeler Data Entry users can create new Device Identifier (DI) records. While in the **Manage Device** section, the functionality can be accessed by clicking the **Create New DI** button or by using the top menu **Manage DI** $\rightarrow$  **Create New DI** drop down as shown below.

Home Manage Acc	ounts 👻 Manage DI 👻			FL	Labeler Data Entry (LDE) U
Manage Device DI Number: User Name:	Submitted DI Draft DI Bra Create New DI Company Name:	Version or Model Number: Labeler DUNS Number:	DI Record Status: DI Record Edit Stat	Filter US: Advance	Clear d Search
View: 25 🔻 3 / 3 reco	rds, 1 / 1 page				Explort 💊 New DI
DI Number	🗢 Company Name	Brand Name	Version or Model Nur	nber 🔶 DI Record State	us 🗢 DI Record Edit Status
		Test2 Release 1.6.3	Test2XML	Click to enter a	New DI record
		Test2 Release 1.6.3	Test2XML		Alter Orace Ferrou
		Test2 Release 1.6.3	Test2XML	Published	After Grace Period
3 / 3 records, 1 / 1 page					

The New DI record page opens as shown below.

Device Identifier (DI) Record Details for New Record         * required fields           Printer Friendly         Save Draft         Review         Cancel							
Device Information							
Device Identifier (DI) Inform	Device Identifier (DI) Information						
Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:				
Labeler DUNS Number: *	Company Name:	Company Physical Address:					
Brand Name: *		Version or Model Number: *	Catalog Number:				
Device Description (max 2000	) characters):						

- Enter device information
- As you enter data into GUDID, please note the following:
  - Refer to the GUDID Data Elements Reference Table (DERT), which provides detailed information on each data element, data entry pointers and DI edit rules. The DERT is available on the UDI website <u>here.</u>
  - The system will guide you through with prompts and error messages. Click on the blue "i" icon on the screen for helpful tips and information as shown below.



- Click Save Draft to save the record in draft format and work on it in the future
- If the record is ready for submission, you may click **Review**, which will run all business rules.
- If the record passes review, the record may be submitted by clicking the Submit button
- If the record fails review, it may be saved as a draft until ready for submission

#### 4.2.2.2 View DI Record

As indicated in Section **4.1.2 Manage DI**, upon entry, **Manage DI** will display all the DI records associated to the Labeler DUNS assigned to the LDE user.

• You can filter for a specific DI record by typing in any of the fields provided – DI Number Brand Name, Version or Model Number, User Name (of the LDE user who entered the DI record), Company

Name, Labeler DUNS Number. Records can also be filtered by the DI Record Status and DI Record Edit Status.

Enter information you desire to filter-by into the field, and then click Filter. The results of the filter will appear in the table at the bottom of the page.

Home	Manage Accounts 👻	Manage DI 👻						FD	Labeler Data Entry (LDE) User
Manage Device					Click to Filter records based on entered information			1	
DI Number: Brand Name: Ve		/ersion or Model Number: DI Record Status:		Filter	Clear				
User Nam	e:	Company Name:	Labeler DUNS Number:		DI Record Edit Status:		Advanced S	Search	
Click on DI hyperlink to see									
View: 25	View: 25 Vie			Click to export DI records for				Export 🔷 New DI	
DI N	umba	Company Name	e 🌲	Brand Name	your o	rganization fro		vecord Status	DI Record Edit Status     Status     €
	-			Test2 Release 1	.6.3	Test2XML	Click to	enter a l	New DI record
				Test2 Release 1	.6.3	Test2XML		nisneu	Alter Orace Lenou
				Test2 Release 1	.6.3	Test2XML	Pub	olished	After Grace Period
3 / 3 records,	1 / 1 page				H				

Click on the *DI Number* hyperlink to see DI record details as shown below. The DI Record details screen opens as shown below.

- Each DI record has 3 sections Device Information, Device Status and Device Characteristics. The '+' may be clicked to expand and view each section
- The Copy function reduces data entry burden by allowing LDE users to copy an existing DI record.
- Edit button opens a DI record for editing. Data elements that can be edited and those that cannot are determined by DI record edit business rules and DI record states.
- *View History* hyperlink opens a pop-up box that provides information on entry and updates made to the record.
- *Printer Friendly* hyperlink allows the DI record to be printed for review

Home Manage Accounts 👻 Manage DI 👻	Labeler Data Entry (LDE) User
Device Identifier (DI) Record Details for Published Record           View History         Printer Friendly           Public Device Record Key:	Click to Copy DI record to create a new a DI record
Device Information	Click to expand details for each section
Device Status	Edit DI Record
Device Characteristics	
View History Printer Friendly Click to view printer friendly form	Copy Edit Cancel
Click to view record history	Click to cancel and close record

#### 4.2.2.3 Copy DI Record

Published and Unpublished DI records can be copied. The *Copy* feature enables the user to copy all data values of a DI record to a new DI record, except for the Primary DI number and package information, saving manual data entry time. To copy a DI record:

• Open the DI record you want to copy. Click Copy

- DI record data is copied into a new draft record, except for Primary Device Identifier and Package Information
- Enter a new Primary DI for the new record
- Enter package information if appropriate
- Make other edits to the copied information as appropriate for the new record. Please review the entire record a to ensure all data is accurate and correct for the new record.
- You can save the record as a *draft* record by clicking on **Save Draft.** This will allow you to work on it later before submitting.
- If the record is ready for submission, you may click **Review**, which will run all business rules.
- If the record passes review, the record may be submitted.
- If record fails review, it may be saved as a draft until ready for submission.

Home	Manage DI 👻						FDA	Labeler Data Entry (LDE) User
Device Identifier (DI) Record Details for Oraft Record Click to cancel and exit								
Device information copied successfully.								
Printer Friendly	Printer Friendly,				Click to save as Draft to			Review Cancel
Device Info	Device Information				continue edits later			
Device Ident	Device Identifier (DI) Information					Click to Re	view and Su	bmit if ready
Issuing Ager GS1	ncy: * ▼	Primary DI Number: *	0	Device	Count: *	Uni	it of Use DI Number	0
Labeler DUN	S Number: *	Company Name:	Company Physical Address:					
	<ul> <li>Booz Allen Hamilton Inc.</li> </ul>			1 Pres	eserve Pkwy Ste 200, Rockville, MD 20852-4279 USA			
Brand Name: *			Version or Model Number: * Ca		alog Number:			
Test2 Releas	Test2 Release 1.6.3			Test2XML DR		T		
Device Description (max 2000 characters):								
Test2 Releas	se 1.6.3 XML Valid	ation						

<u>*TIP*</u>: Please review the <u>GUDID Guidance</u> document for more on the DI record life cycle, copying and editing DI records

#### 5.2.2.4 Edit DI Record

Labeler Data Entry users can edit DI records. The data element values that can be edited in a DI record are determined by the DI Record Status and the DI Record Edit Status.

#### 5.2.2.4.1 DI Record Status and Edit Status

Below are the 4 DI record status and associated edit statuses:

- Draft Status, a draft DI record, all fields are editable
- Unpublished Status: DI record with a future Publish Date that has been submitted to GUDID; all data elements are editable

View: 25 🗸	8 / 8 records, 1 /	1 page	Export New I			Export 💊 New DI
DI Number	÷	Company Name	Brand Name	Version or Model Numb	er 💠 DI Record Status	DI Record Edit Status 💠
11.20408C1880		us for contrast as	1 Day Access Mont	000.000	Unpublished	All Fields Editable
Inclusion and the second		on their constraint and	1 Day Access Meet	1000.1000	Published	After Grace Period

- **Published Status**: DI record with a Publish Date today or in the past and has been submitted to GUDID. Data elements available for editing for a Published DI record depends on the grace period, and there are three edit statuses as indicated below
  - In Grace Period, all data elements are editable, except *DI Record Publish Date*

- After Grace Period, Limited Editing: after the Grace Period, limited editing is allowed, specifically, edits to the New DI trigger data elements<sup>6</sup> are not allowed
- Unlocked, all data elements are editable, except the *DI Record Publish Date*. Records need to be unlocked by the Coordinator user, so LDE users may edit. The *Unlock* feature allows for data corrections, including corrections to the New DI trigger elements to ensure quality device identification information is available to the public. For more information, please refer to Section 5.1.2.3 Unlock DI Record.
- Deactivated Status, no edits allowed

View: 25 💙 1 / 1 records	, 1 / 1 page			Export 💊 New DI	
DI Number	Company Name	Brand Name	Version or Model Number	DI Record Status	
10.2000 TMM		1-Day Access Month	COL 1994	Deactivated No Edits	
1 / 1 records, 1 / 1 page		H 44 ( 1 ) H H			

To edit an eligible DI records:

- Open the DI record you want to copy. Click Edit
- DI record opens for editing. Data element values that may be edited will be enabled for editing depending on the DI record status and DI record edit status as indicated above.
- After your edits are complete, click **Review**, which will run all business rules.
- If the record passes review, the record may be submitted.
- If record fails review, you can fix errors and click **Review** again or click **Cancel** to exit and not save any edits.

evice Identifie	er (DI) Record Details for	Iblished Record	* required field
View History Printer	Friendly Public Device Record Key:		Review Cancel
Device Informatio	n	Click to Review an	nd Submit if ready
Device Identifier (D	I) Information		
Issuing Agency: * GS1 •	Primary DI Number: *	Device Count: * 50	Uni Click to cancel and exit
Labeler DUNS Number: * Company Name:		Company Physical Address:	USA
Brand Name: *		Version or Model Number: *	Catalog Number:
Test2 Release 1.6.3 Device Description ( Test2 Release 1.6.3	max 2000 characters): XML Validation	Test2XML	DRT

#### 5.2.2.5 Exporting DI Records

The Export functionality on the Manage DI page allows Labeler organization users, both Coordinators and LDE Users, to download records submitted to GUDID for their assigned Labeler DUNS in XML format. For details on the Export functionality, please refer to Section **5.1.2.2 Export DI Record** 

# **6. Device Identifier Record**

Each DI record has 3 sections as shown below– Device Information, Device Status and Device Characteristics. The '+' may be clicked to expand and view each section.

<sup>&</sup>lt;sup>6</sup> New DI trigger data elements are those, which when changed, require a new Device Identifier to be assigned.

Home	Manage Accounts 👻	Manage DI 👻			
Device I	dentifier (DI) Re	cord Details for Pu	blished Record		* required fields
View History	Printer Friendly Pul	blic Device Record Key:			Cancel
Device Ir	formation			Click to expand details for each section	on 🗕 🖬
Device S	tatus				0
Device C	haracteristics				0
View History	Printer Friendly	Click to view prin	er friendly form	at Click to cancel and close record	Cancel

#### Click to view record history

A

As you enter data into GUDID, please note the following:

- Refer to the GUDID Data Elements Reference Table (DERT), which provides detailed information on each data element, data entry pointers and edit rules before and after grace period. The DERT is available on the UDI website <u>here.</u>
- The system will guide you through with prompts and error messages. Click on the blue "i" icon on the screen for helpful tips and information as shown below.

DI may be 12, 13 or 14 digit numeric value. System will append zeros to the left or beginning of the DI to save a 14 digit value.

# 7. Release of GUDID Data for Public Use

Device identification information from GUDID is made available for everyone, including patients, caregivers, health care providers, hospitals, and industry via <u>AccessGUDID</u> and <u>OpenFDA</u>. The device information available on <u>AccessGUDID</u> and <u>OpenFDA</u> is the most recent data submitted to the GUDID that has completed the "grace period" after initial publication. Data on <u>AccessGUDID</u> is updated every business day, so the most up to date information can be searched or downloaded from this site. Majority of the data is released on these portals, with the exception of a few. Please refer to the <u>GUDID Data Elements Reference Table (DERT)</u> to identify which data elements are released and which are not.

## 7.1 FDA Premarket Submission Number

FDA premarket submission numbers provide an essential link to information about device safety and effectiveness; therefore, in July 2018, FDA began releasing this information as part of the device information made available via <u>AccessGUDID</u> and <u>OpenFDA</u>

FDA is acutely sensitive to the critical nature of business confidentiality, such as the relationship between a manufacturer and a private label distributor. To determine whether to make public a premarket number in GUDID, the confidentiality information provided as part of device listing information submitted to the <u>FDA</u> <u>Unified Registration and Listing System/Device Registration and Listing Module</u> (FURLS/DRLM) is used. The DRLM database allows users to specify whether a proprietary (brand) name is confidential.

- If a proprietary name has been marked confidential in DRLM as part of the device listing information, the corresponding premarket numbers in GUDID DI record(s) is not made public.
- If a proprietary name has not been marked confidential, the corresponding premarket submission numbers in the GUDID DI record(s) is made public.

Specifically:

- For each DI record in GUDID, the associated listing number will be used to look up the confidentiality designation for the proprietary (brand) name in the DRLM database. NOTE: There may be multiple listing numbers per DI record in GUDID and multiple DI records may be associated to a single listing number.
- Premarket number(s) will NOT be made public if **any** proprietary name for a listing number has a confidentiality designation = Y (Yes) in the DRLM database.
- Premarket number(s) will be made public if:
   all proprietary name(s) for a listing number have a confidentiality designation = N (NO) in the DRLM database, AND the designated establishment activity for the associated listing number is any of the following:
  - Manufacture Medical Device
  - Remanufacture Medical Device
  - Repack or Relabel Medical Device
  - Reprocess Single-Use Device
  - o Develop Specifications But Do Not Manufacture At This Facility
  - Complaint File Establishment per 21 CFR 820.198

So please thoroughly review the confidentiality designations assigned to the DRLM proprietary names. To assign confidentiality designations to proprietary names for new listings, you may refer to Step 14B of the instructions available <u>here</u>. To review and update confidentiality designations to proprietary names for existing listings, please contact Device Registration and Listing Office at <u>reglist@cdrh.fda.gov</u>.

# 8. When to Reach Out to the FDA

Please reach out to the FDA by submitting a ticket to the FDA UDI Help Desk for help on the following:

- GUDID Account changes, including updates to Regulatory Contact and Coordinator user(s)
- Adding/editing/deleting third party submitters
- Adding Labeler DUNS numbers
- Updating company information due to mergers or acquisitions.
- Deleting device records with errors

You may contact the <u>FDA UDI Help Desk</u> for questions regarding UDI and GUDID.

For assistance with registration and listing status, please contact the Registration and Listing Office at: Phone: 301-796-7400, reglist@cdrh.fda.gov

# 9. Additional Resources

## FDA UDI Rule GUDID Guidance Document GUDID Data Elements Reference Table HL7 SPL Implementation Package of Files FDA UDI Helpdesk Division of Industry and Consumer Education (DICE) Electronic Submissions Gateway (ESG) AccessGUDID

**OpenFDA**