# Food and Drug Administration

## Center for Devices and Radiological Health

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

Version 2.1

December 2024

# DOCUMENT HISTORY

| Version Number | Authored by | Revision Date | Description of Change |
|---|---|---|---|
| 1.0 | Booz Allen Hamilton | April 24, 2014 | Initial Release |
| 2.0 | FDA UDI Staff | April 2019 | Updated to include technical GUDID changes as of revision date |
| 2.1 | FDA UDI Staff | December 2024 | Updated to remove references to FDA PT Codes |

# Table of Contents

# 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 AccessGUDID.

This document is intended primarily to provide labelers with information about submitting data to the Global Unique Device Identification Database (GUDID)[1,2]. 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[3] 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.

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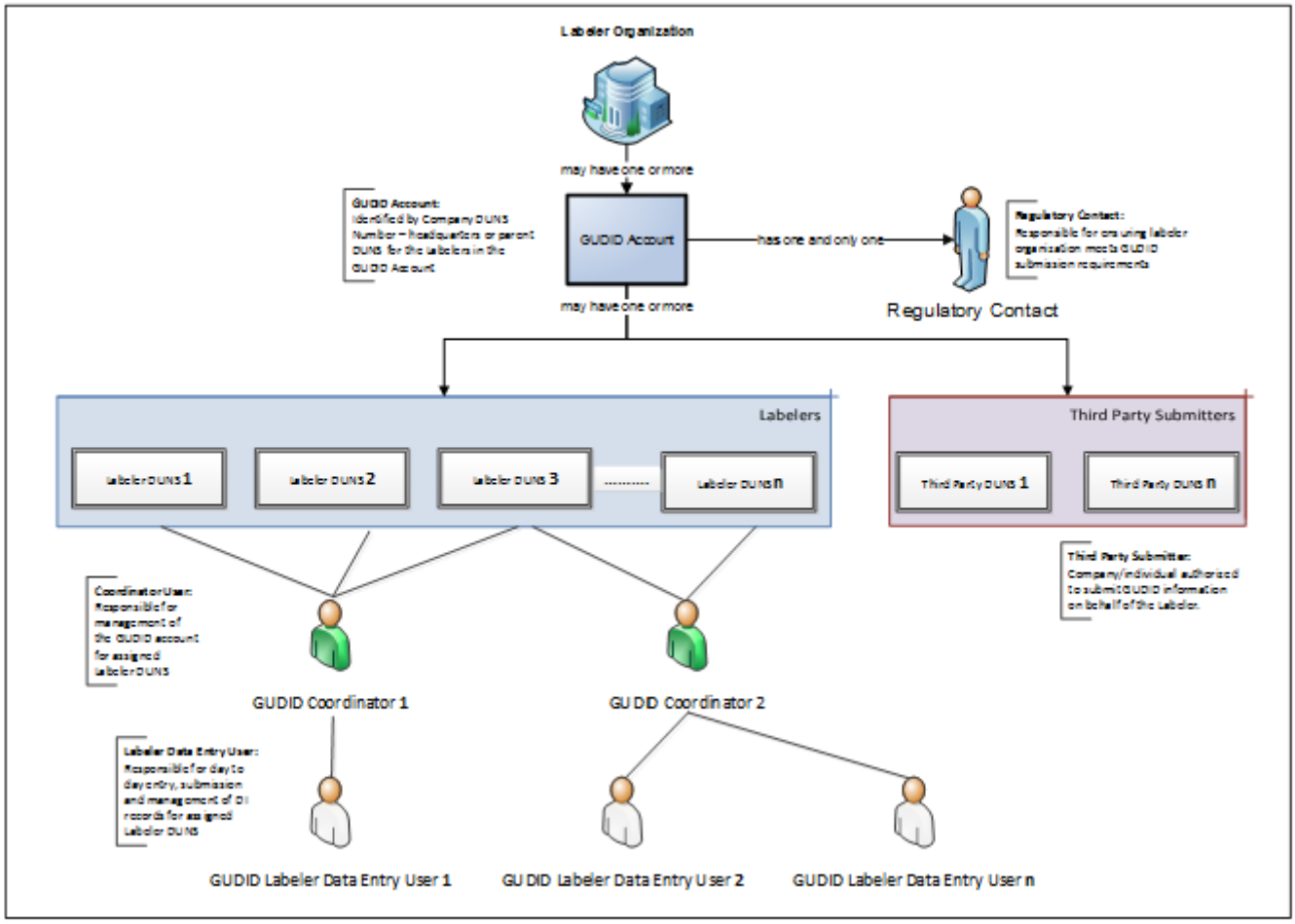
[1] "Labeler" is defined in 21 CFR 801.3 as "any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced 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" [2] 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).

[2] 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).

[3] 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 www.fda.gov/udi.

# 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*

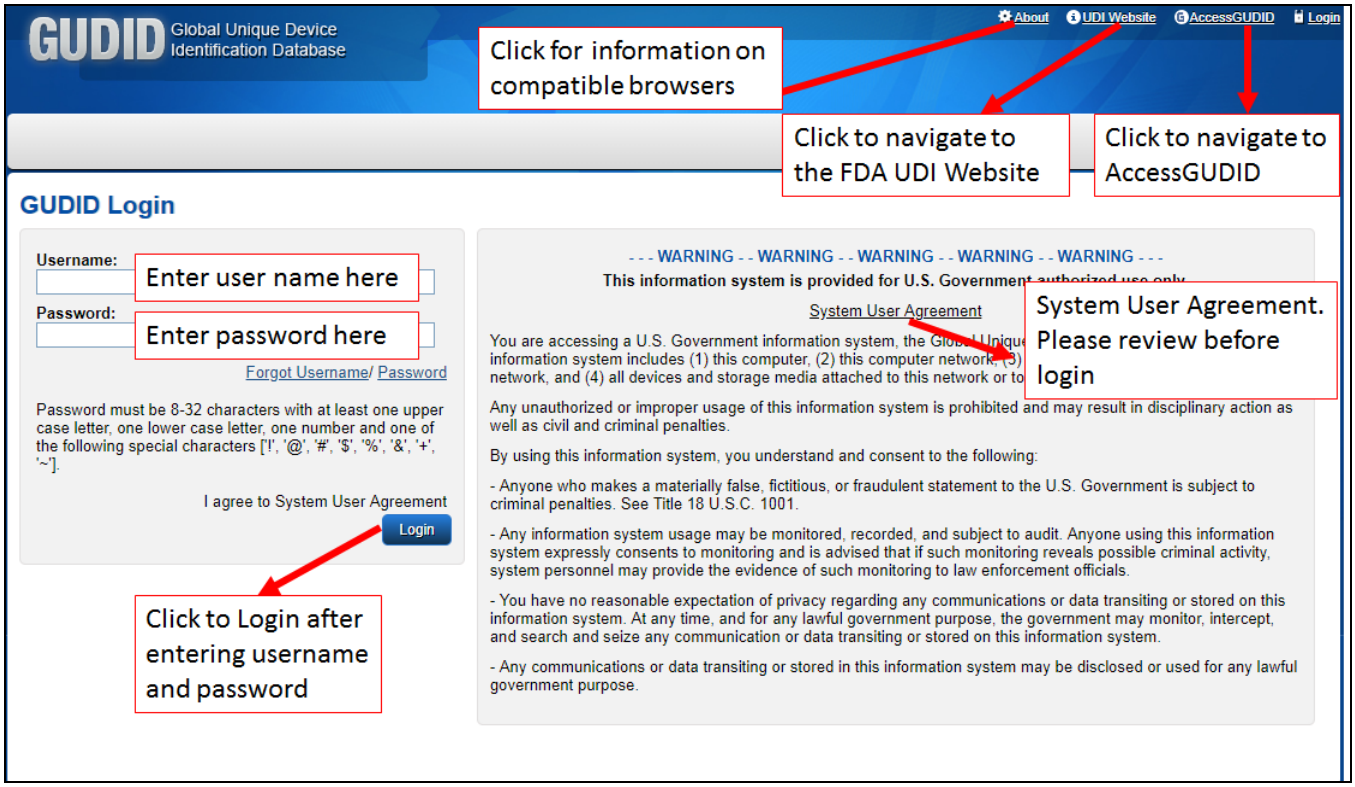
Users can view supported web browsers by clicking the **About** button on the top right-hand side of the main GUDID screen. GUDID currently supports the following browsers:

- 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.



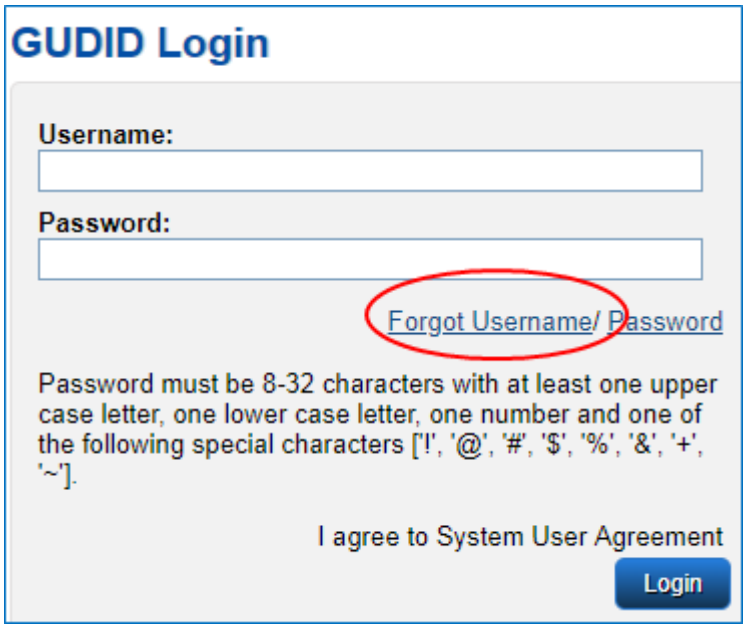

Please review the System User Agreement prior to logging into GUDID.
Each Labeler needs to establish one or more user accounts (see Section 4 **GUDID User Roles for Labelers** for more information) with a username and password. To log into GUDID, enter the username and password in the designated fields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

### 4.2.1 Username and Password

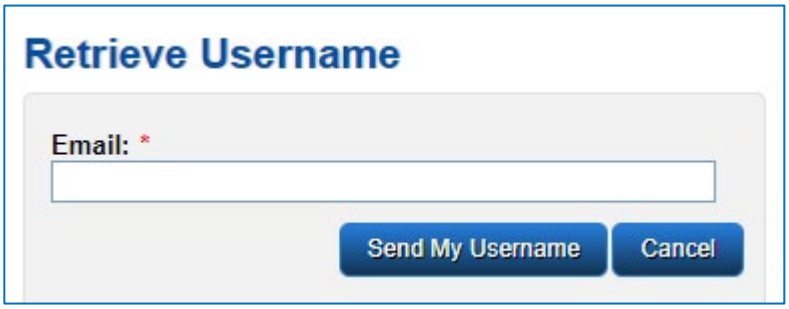
When the Organizational GUDID account is established, Coordinator and LDE users can be created and associated to the GUDID account. When users are created, you will receive a username and a temporary password by email. When you first log in, you will be prompted to enter the temporary password that you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




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



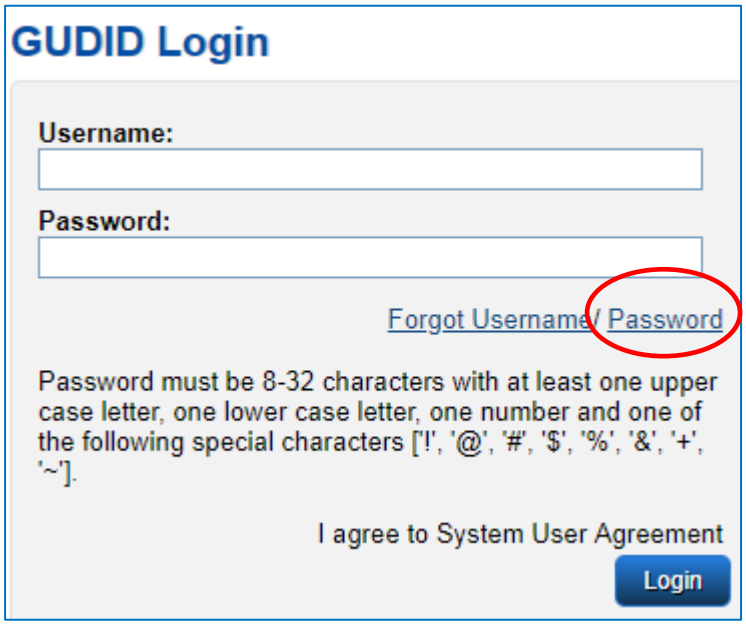

You will receive an email with the username.

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

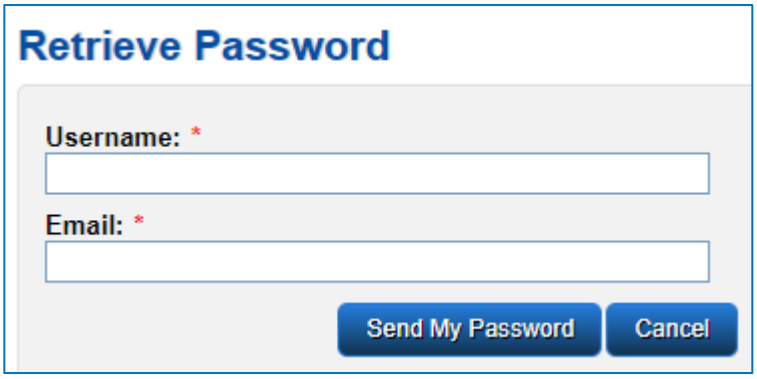
Note: This function does not reset the password.

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

- Click **Password**.



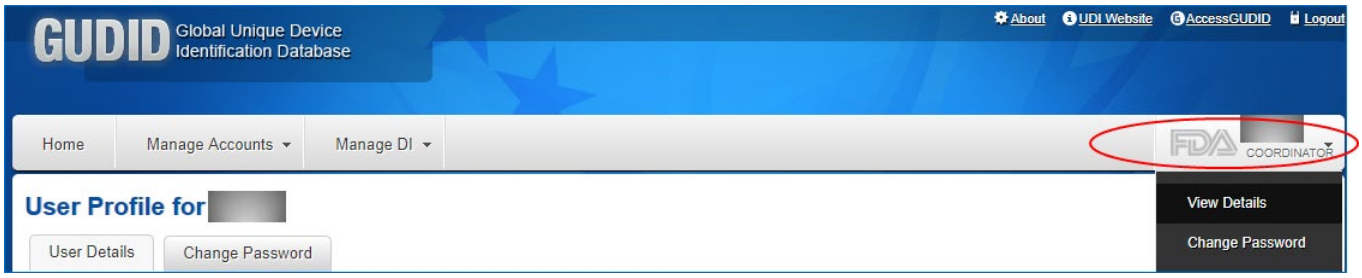

- Enter the username and email associated with the password.



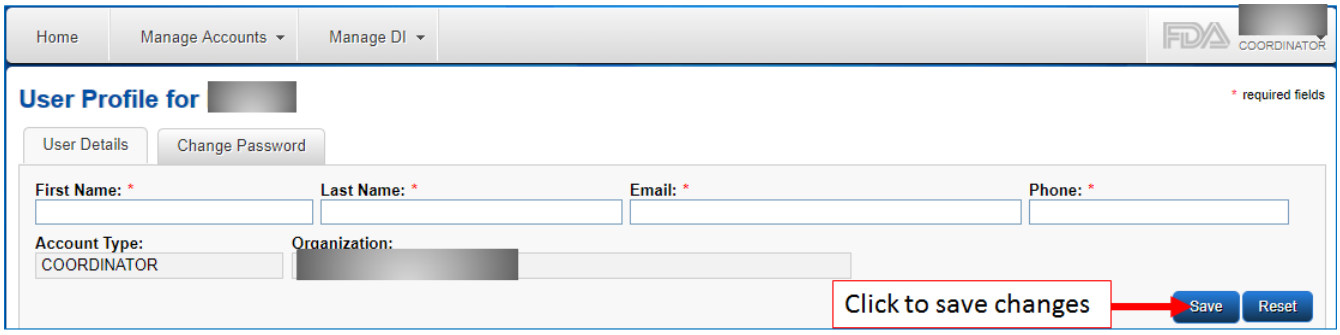

- You will receive two emails:
    1) Password reset notification
    2) A temporary password.
- Login to GUDID with your username and the temporary password.
- The system will prompt you to change the password.
- To change the password, enter the temporary password, and a new password. Confirm the new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

### 4.2.2 View and Edit User Profile

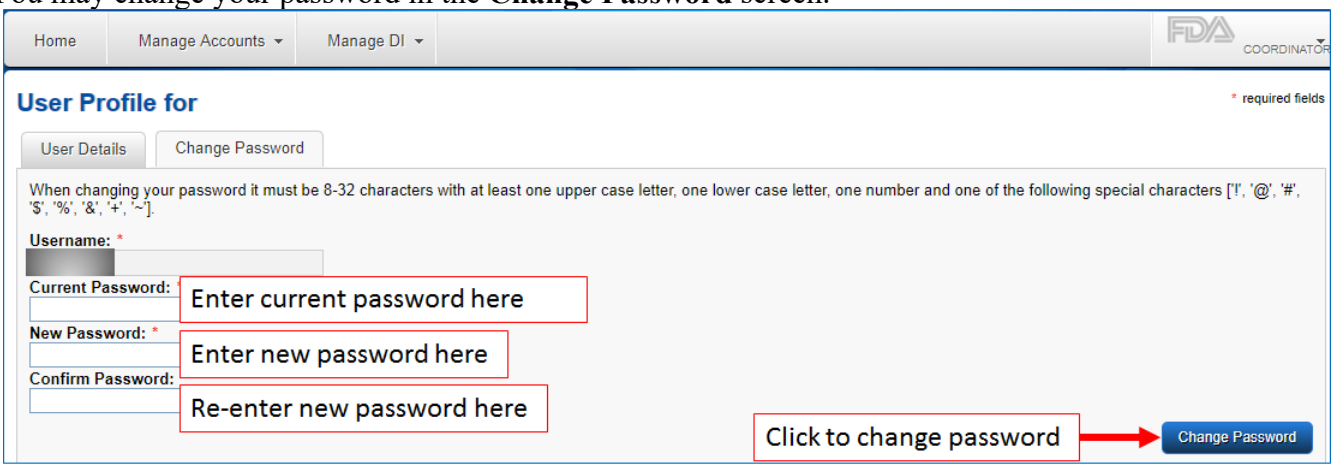
The User Profile screen allows users to update user details and change password as needed. To access the user profile screen, login to GUDID, and click on the drop-down menu next to the user name and user role on the top right-hand side as shown below.




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




You may change your password in the **Change Password** screen.




# 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.

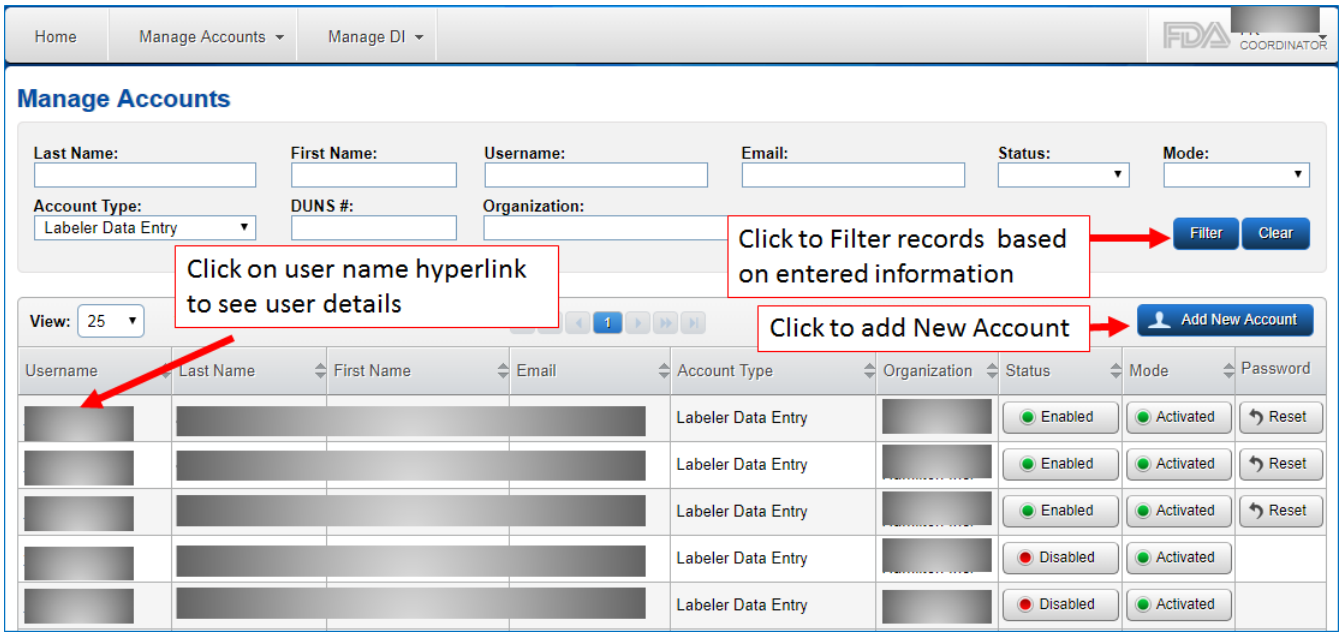
### 5.1.1 Manage Accounts

**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.**

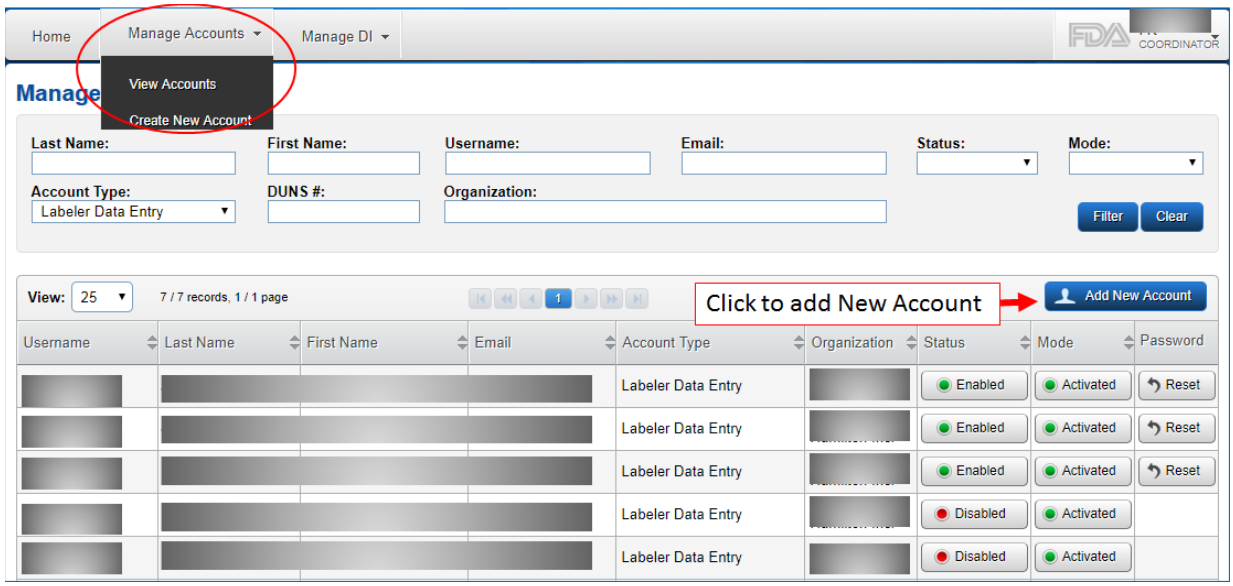
The results of the filter will appear in the table at the bottom of the page.




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.




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

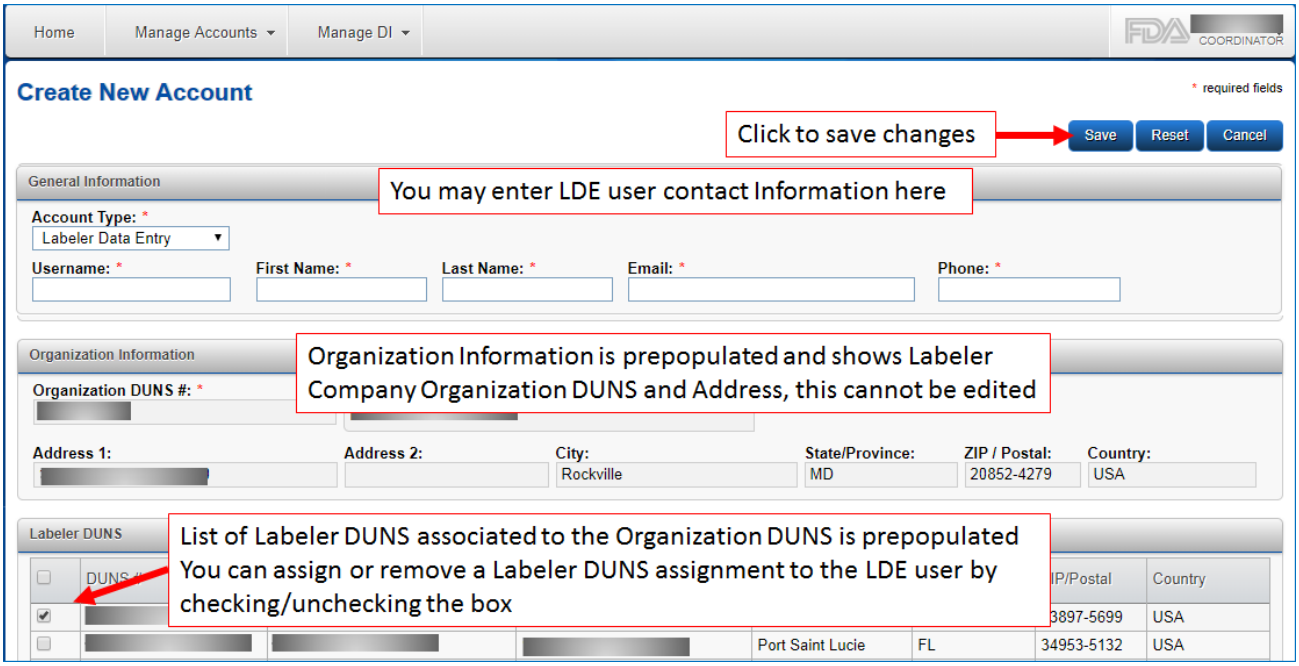
- General Information: enter LDE user contact information here
- Organization Information: prepopulated with Labeler company Organization DUNS number and address. This cannot be edited by Coordinators. Please contact the FDA UDI Help Desk for any changes
- Labeler DUNS: prepopulated with all Labeler 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.

***TIP:*** 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.



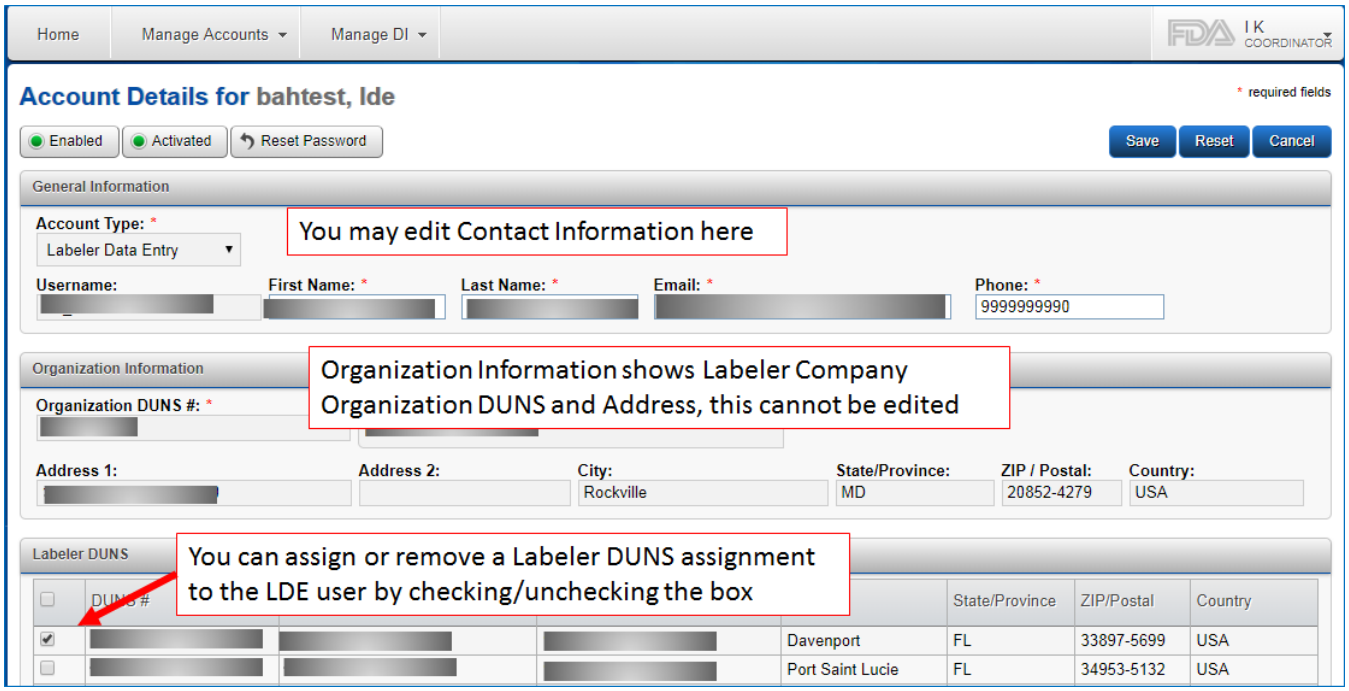

### *5.1.1.2 Edit Existing Account Details*

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 FDA UDI Help Desk for any changes
- Regulatory Contact: this information cannot be edited by Coordinators. Please contact the FDA UDI Help Desk 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 FDA UDI Help Desk



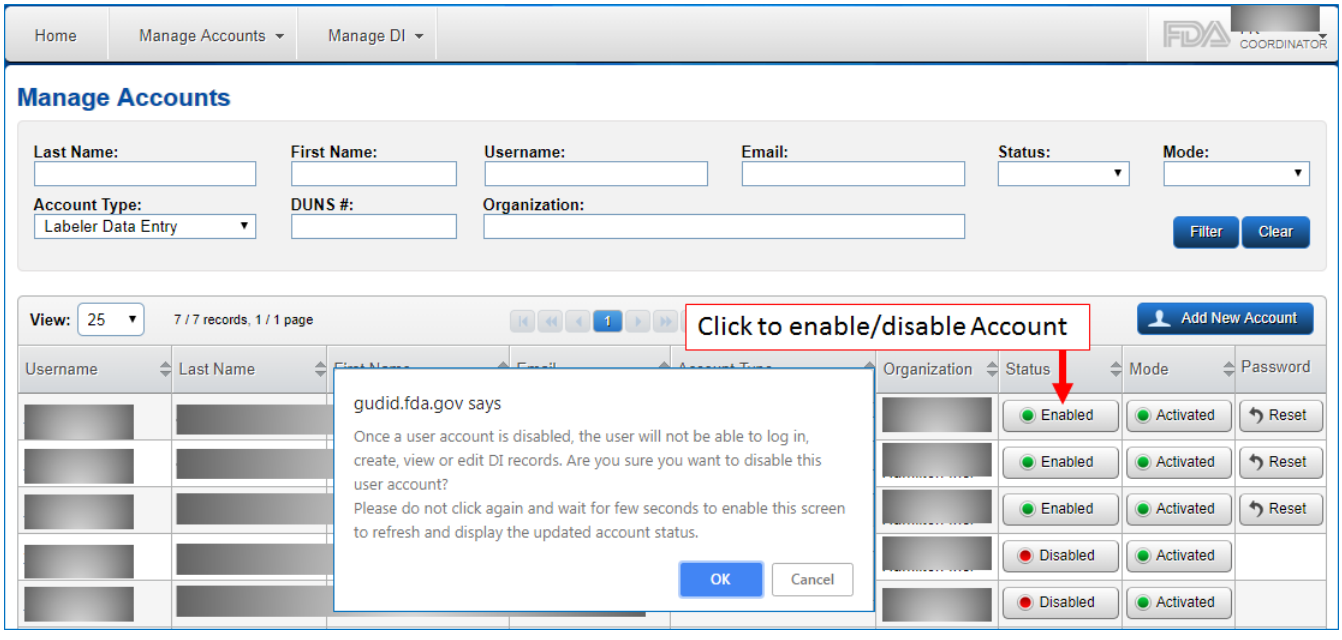

### *5.1.1.3 Account Status and Mode*

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.

***TIP:*** 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.

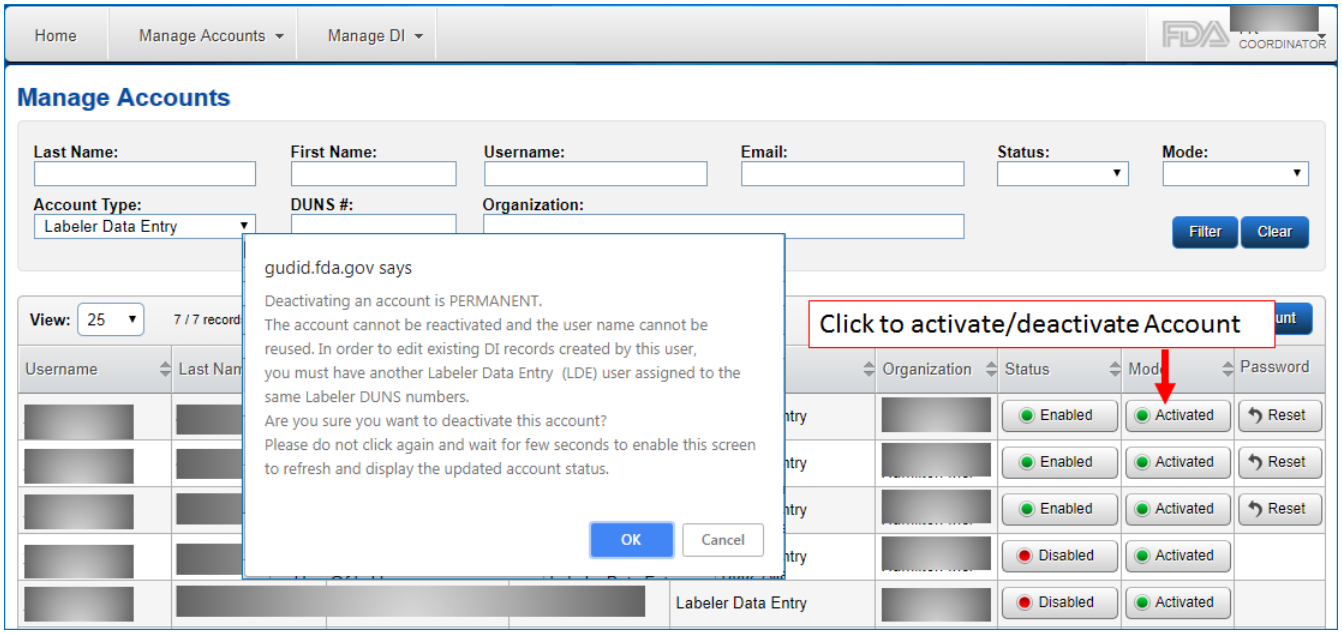
The Coordinator may enable/disable a LDE user account by clicking on the **Enable/Disable** button as shown below. Re-enabling a disabled GUDID user account automatically changes the user's password to a temporary password. The user is notified of the change via an automated email and must change the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



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

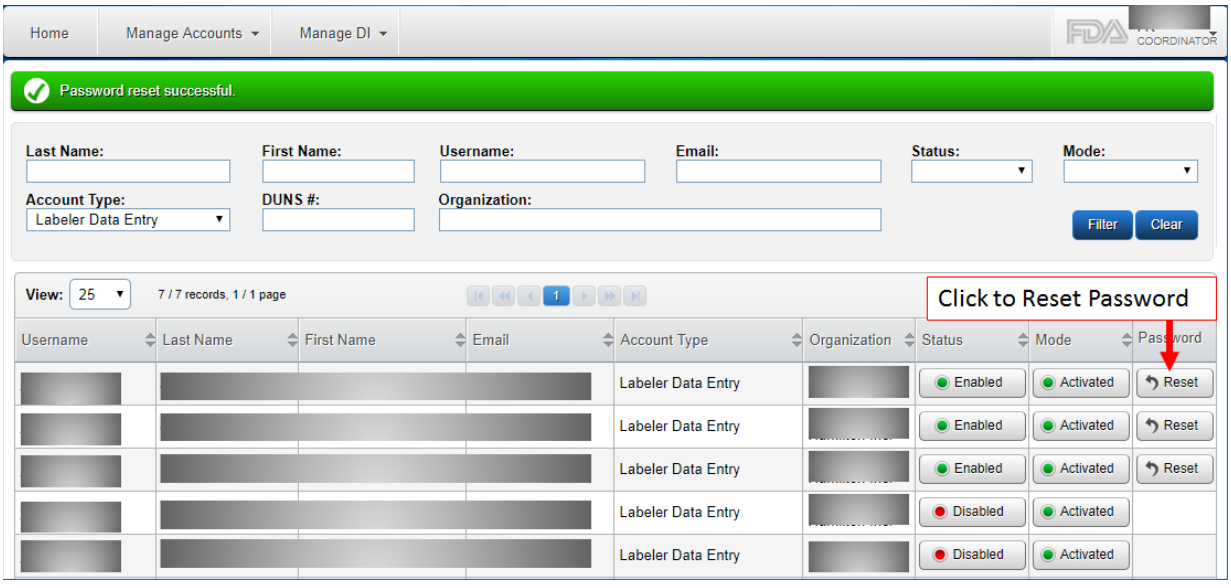
- **Activated** Account: A user with an activated account may login to GUDID.
- **Deactivated** Account: A user with a deactivated account may not login to GUDID. Deactivated accounts cannot be reactivated or recovered. The system warns the user as shown below.

**TIP: 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.




### *5.1.1.4 Password Reset*

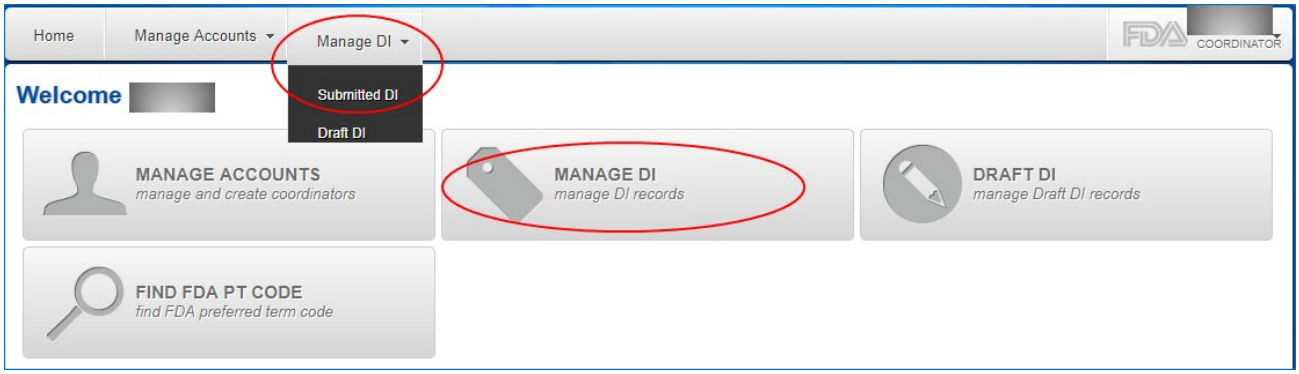
The Coordinator can initiate a password reset for a LDE user by clicking the **Reset** button as shown below. Users will be notified via an automated email and must change the temporary password before access to GUDID is restored.




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 FDA UDI Help Desk.

### 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.




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

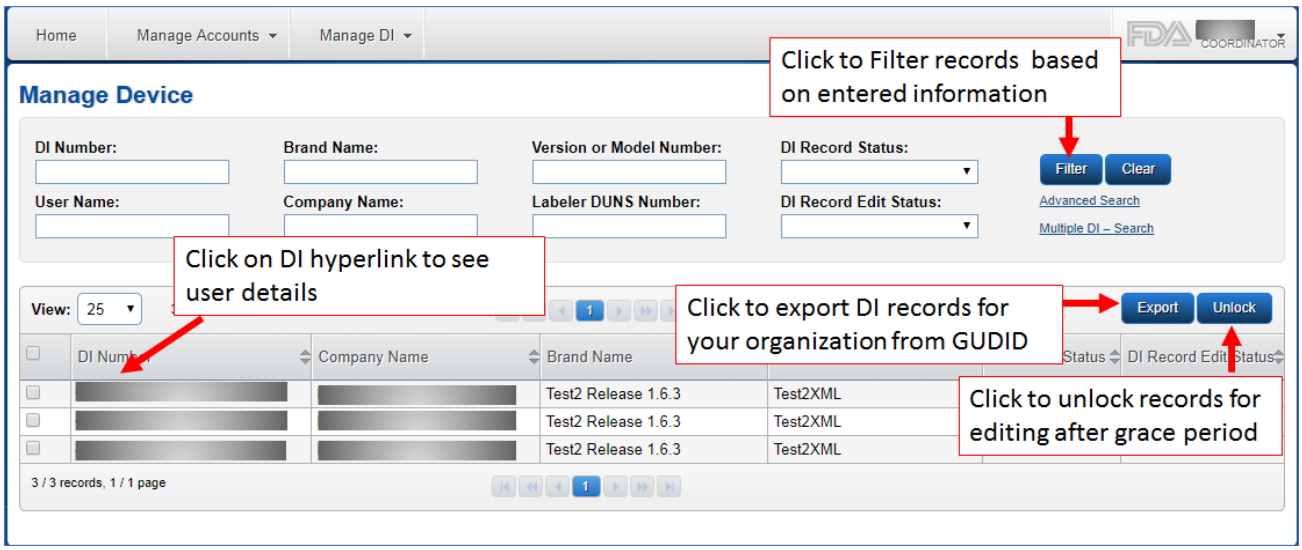
- Published DI record is a record that has been submitted to the GUDID. After the grace period completes, device information will be made available for search and retrieval by the public. Refer to Section **6 Release of GUDID Data for Public Use** for more information. During the DI record grace period, 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 GUDID Guidance 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.

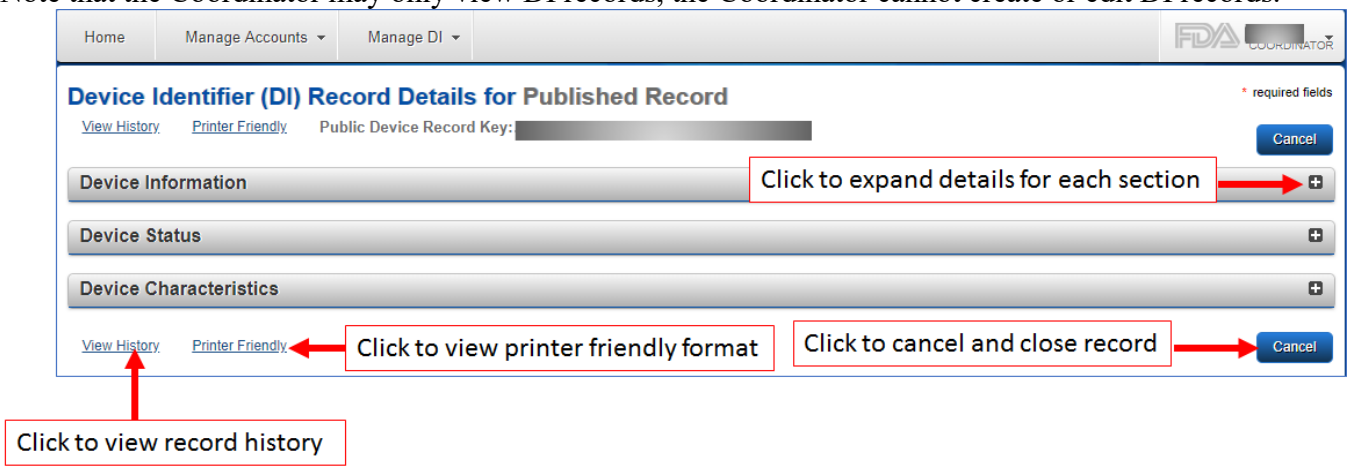


### 5.1.2.1 View DI Record

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.




### 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 AccessGUDID. 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'[4].

- 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 AccessGUDID and OpenFDA, and DI record edits are restricted; specifically, edits to the New DI trigger data elements[5] are not allowed.

[4] For Published DI records, the grace period is set to 7 calendar days and starts the day after the DI Record Publish Date.
[5] 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 AccessGUDID and OpenFDA on the next scheduled release date of GUDID data.
- All prior published versions of a given record will remain accessible on AccessGUDID and OpenFDA 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

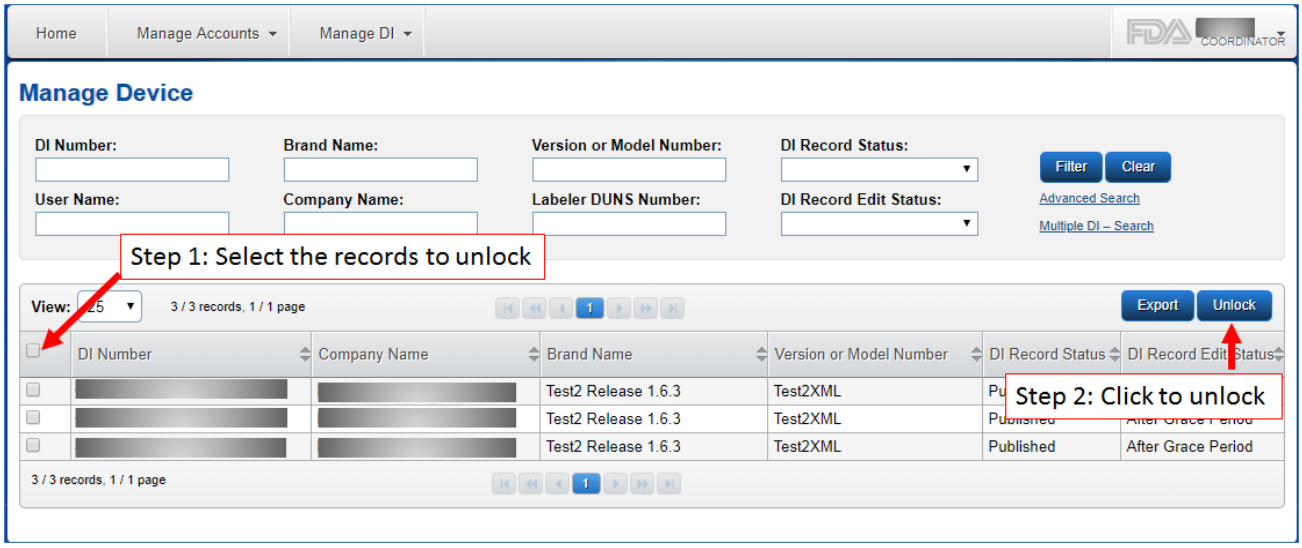
#### 5.1.2.3.2 Unlocking DI Records

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

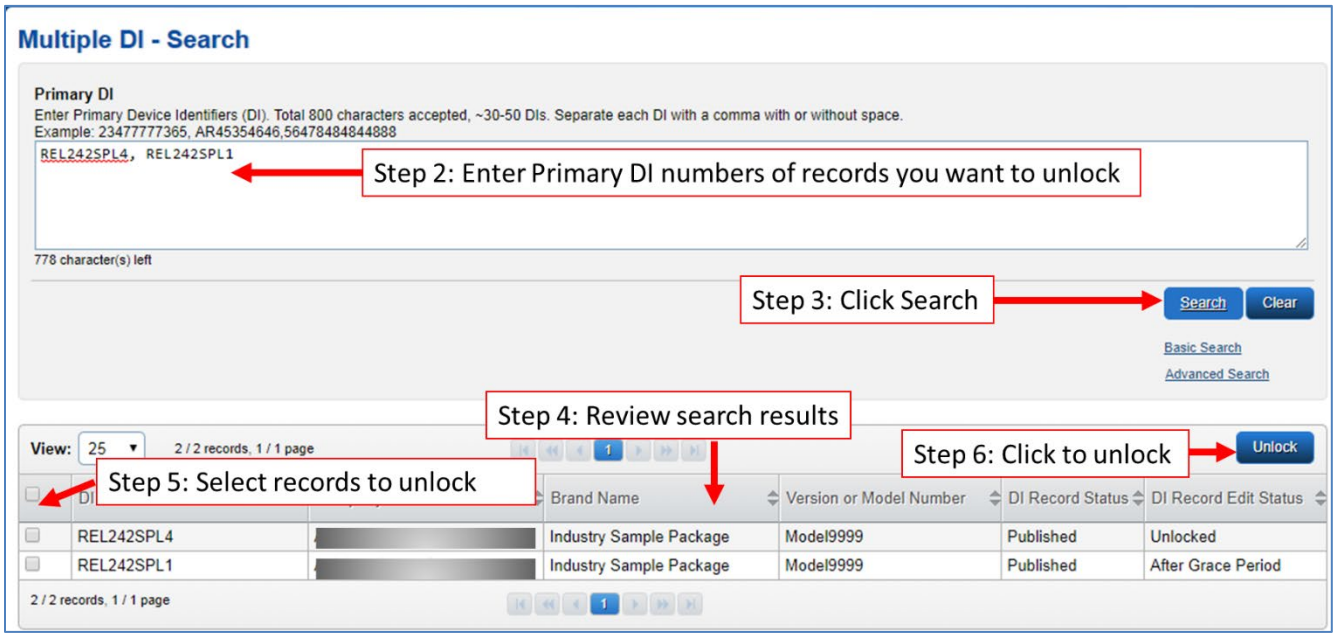
1) Record may be unlocked by filtering for specific record(s) to unlock by typing in any of the fields provided as indicated in Section **5.1.2 Manage DI**

***TIP:*** 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.

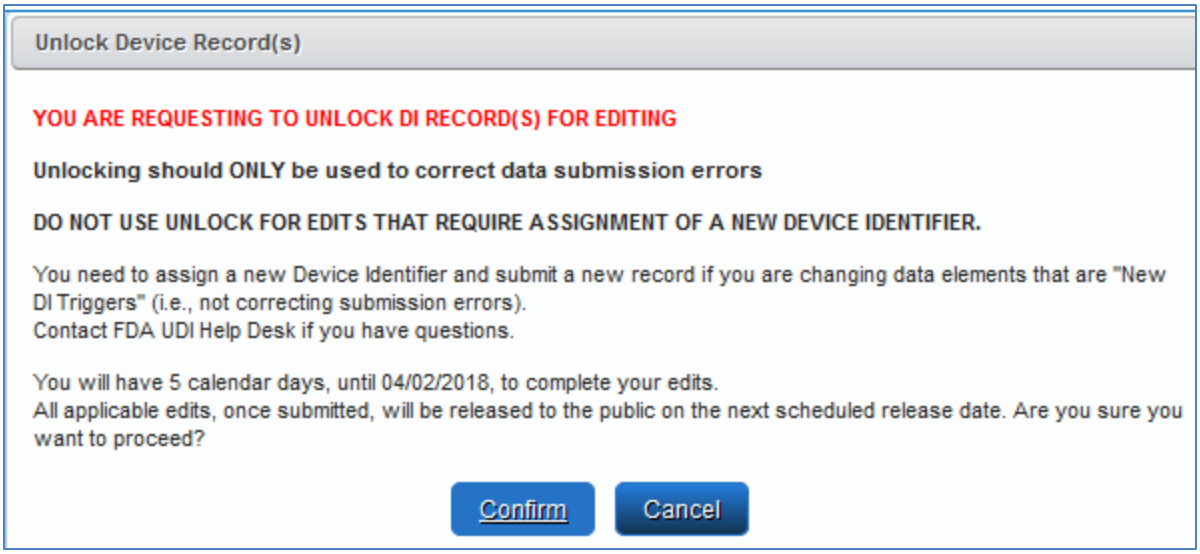
- Select the records to unlock on the left side of the screen
- Click on **Unlock**




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**

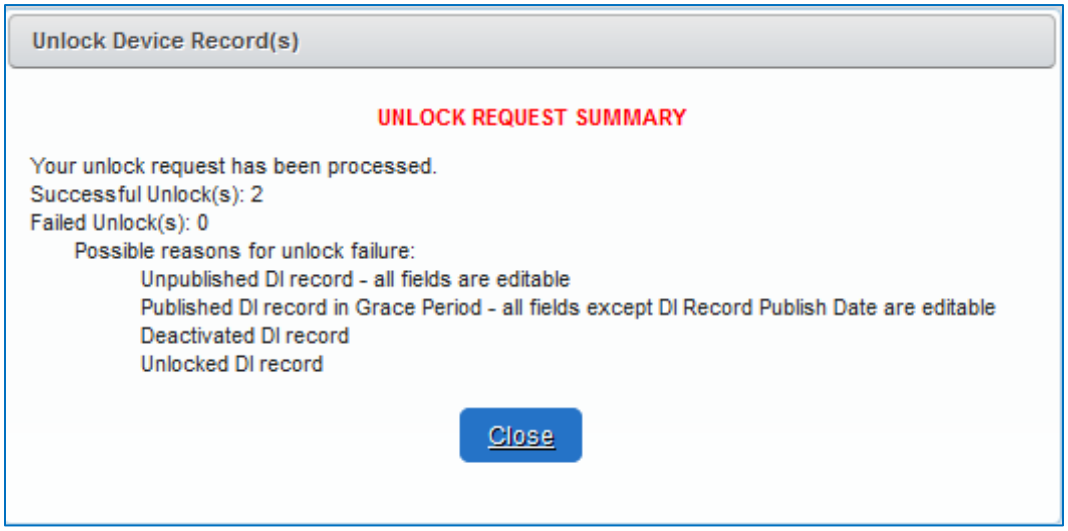



- After you select records and click **Unlock** using either of the above options, the pop-up dialog box below will appear.




- 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.




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

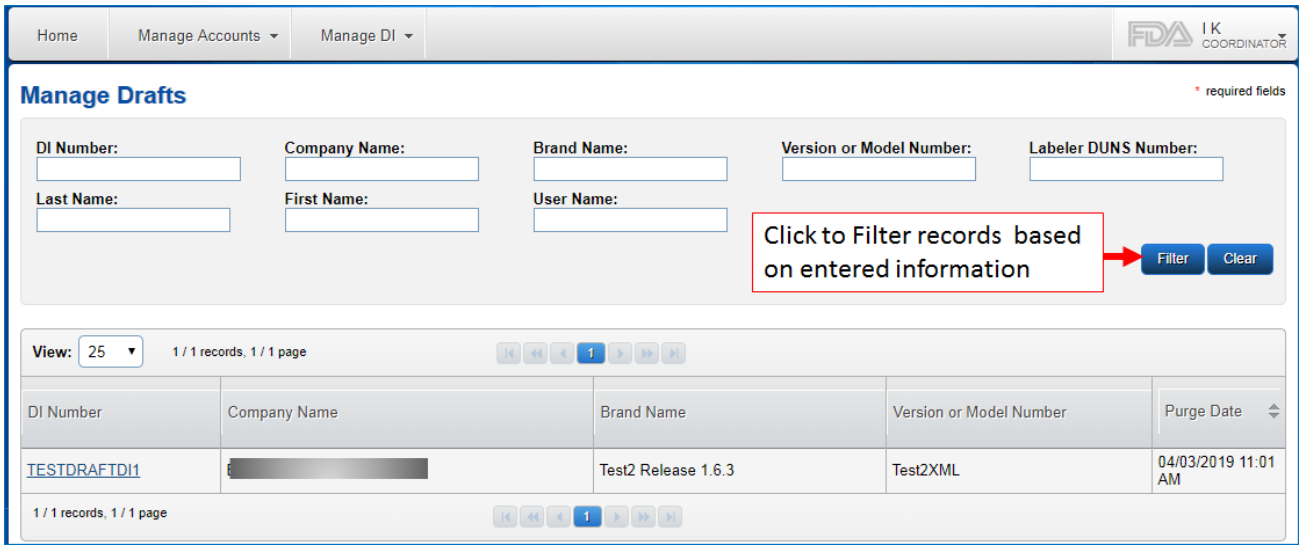

- Draft DI Record allows labelers to prepopulate and save a DI record with the available information via the GUDID Web Interface.
- Users may also create Draft DI records to get familiar with creating and saving DI records in GUDID

For more information on the DI record life cycle and the record statuses, please review the GUDID Guidance 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).

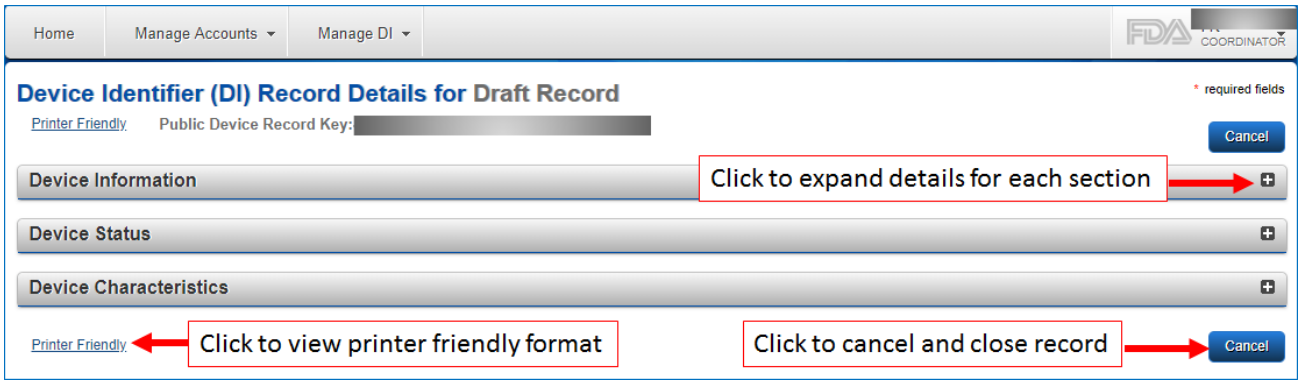
Enter information you desire to filter-by into the field, and then click Filter.
The results of the filter will appear in the table at the bottom of the page.




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.




## 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 GMDN Agency.

### *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.

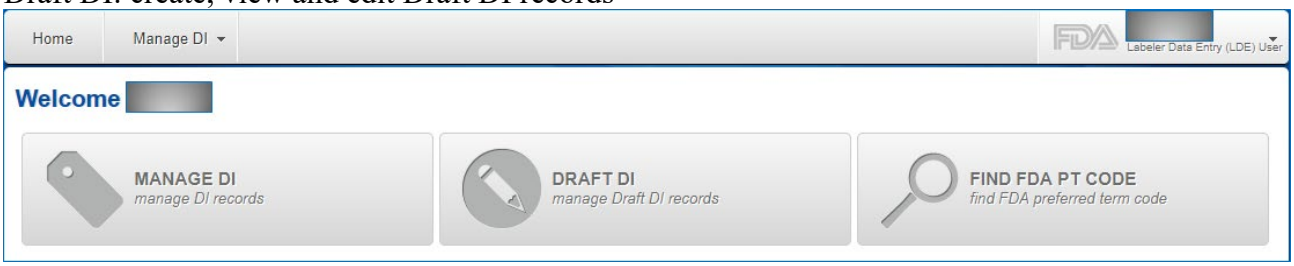
- Once a DI record has been published in the GUDID with an active GMDN code, that assignment remains until deliberately changed by the labeler/LDE. There is no automatic update of GMDN terms within the GUDID.

- 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:

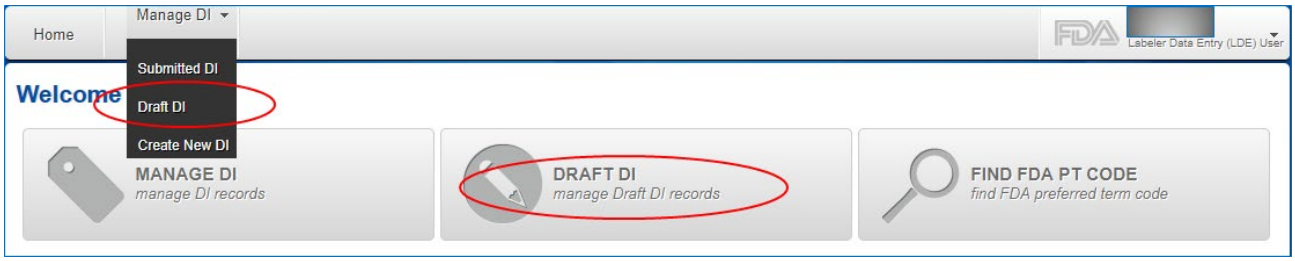
- Manage DI: create, view, edit and manage Device Identifier (DI) records
- Draft DI: create, view and edit Draft DI records




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.

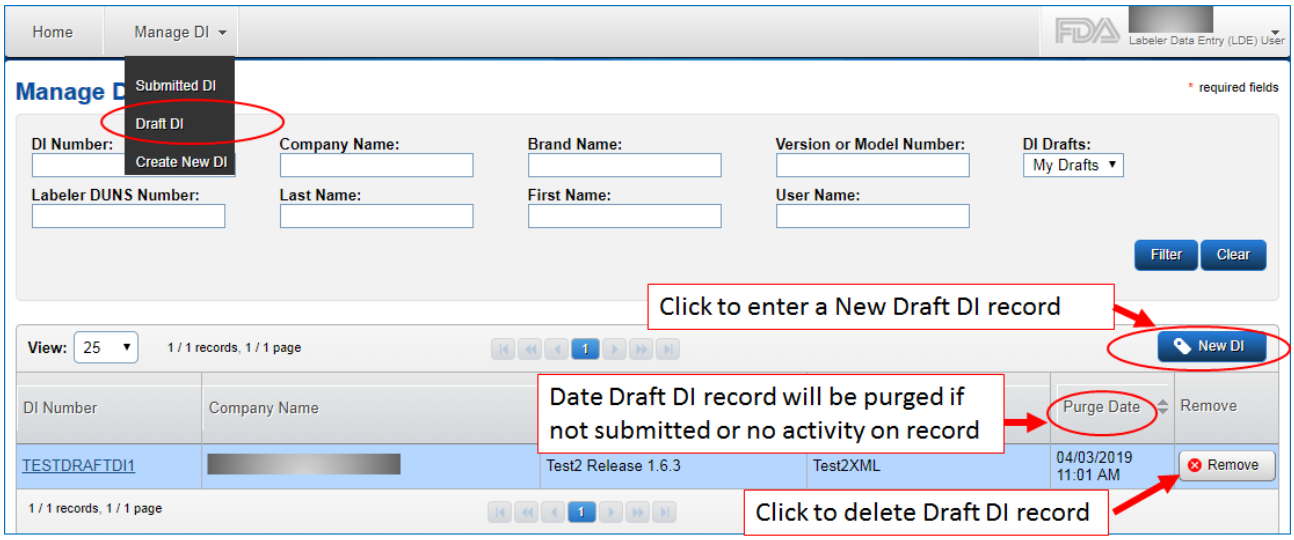



For more information on viewing existing Draft DI records, please see Section **4.1.3 Coordinator User Viewing Draft DI Record.**

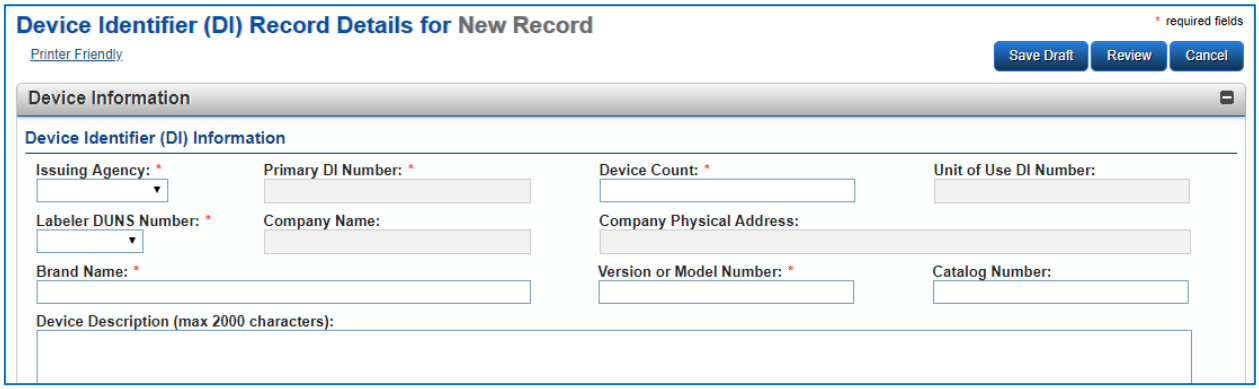
Note that Draft DI records are purged or deleted from GUDID if there is no activity for 180 days on the record. The *Purge Date* shown in the screen shot below provides the information to allow you to manage your record submissions.

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

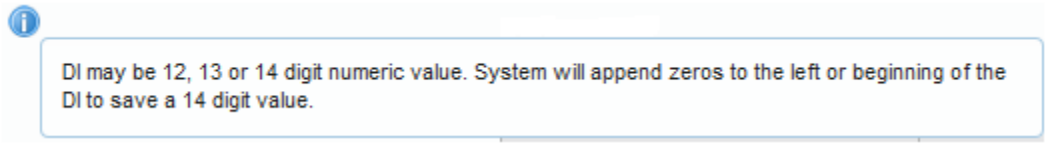
- Click on **New DI** button or by using the top menu **Manage DI→Draft DI** drop down as shown below.




Window opens for record entry.




- 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 here.
  - 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.

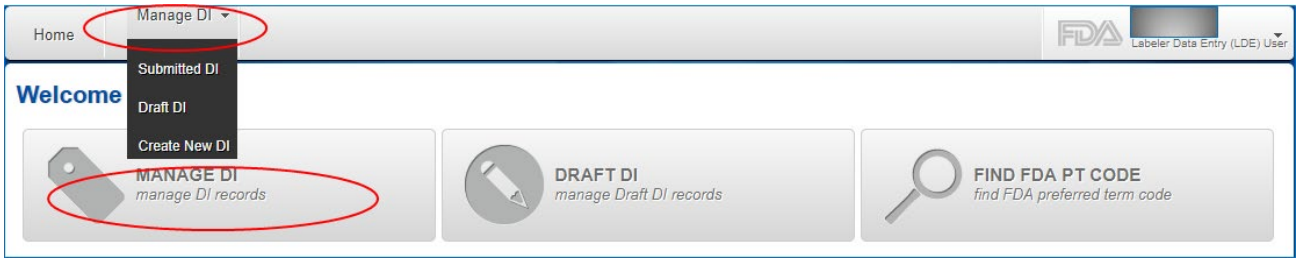



- Click **Save Draft** to save the record in draft format and work on it in the future
- If the record is ready for submission, you may click **Review**, which will run all business rules.
- If the record passes review, the record may be submitted.
- If record fails review, it may be saved as a draft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




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

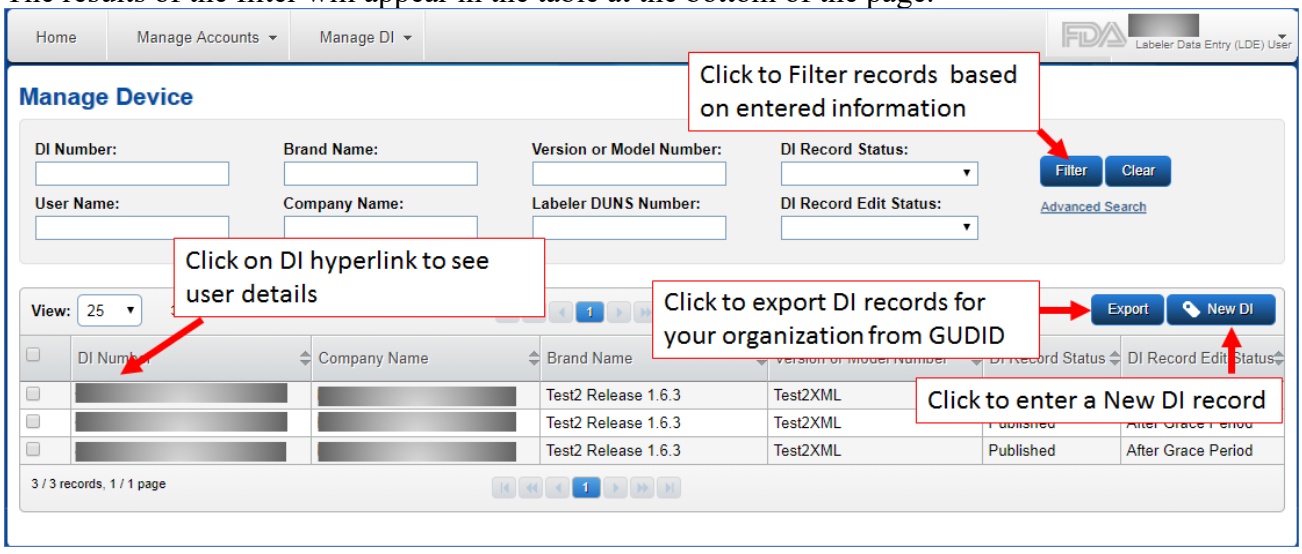
- Published DI record is a record that has been submitted to GUDID and will be made available for search and retrieval by the public after the DI record grace period completes. During the DI record grace period, the record may be edited. Once the grace period completes, the record will have limited editing.
- 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 GUDID Guidance document.

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

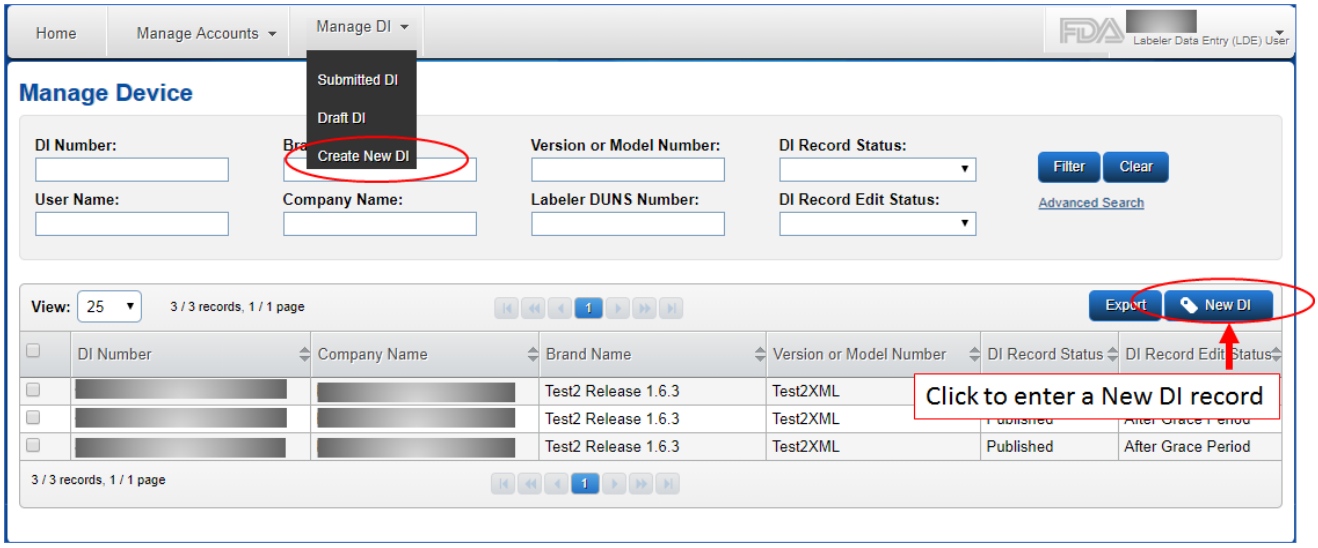
- You can filter for a specific DI record by typing in any of the fields provided – DI Number Brand Name, Version or Model Number, User Name (of the LDE user who entered the DI record), Company Name, Labeler DUNS Number. Records can also be filtered by the DI Record Status and DI Record Edit Status.

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.

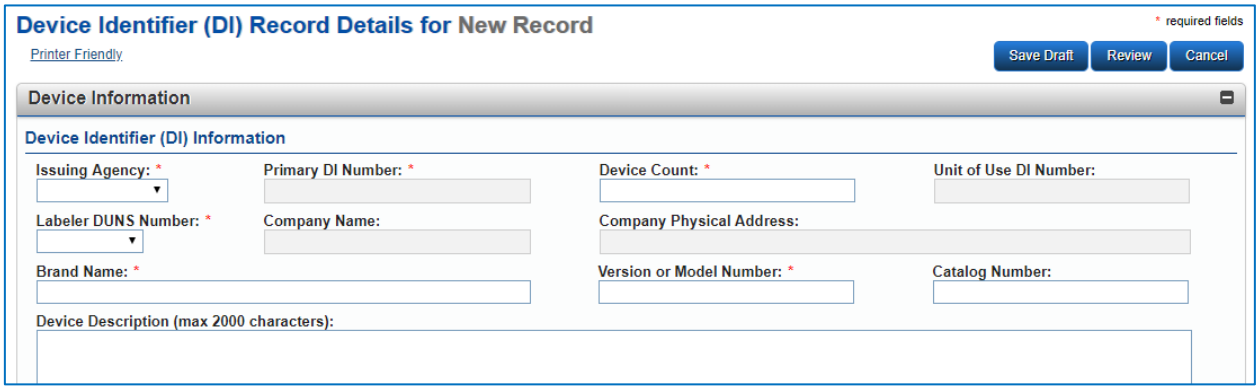



### *5.2.2.1 Create and Submit a New DI Record*

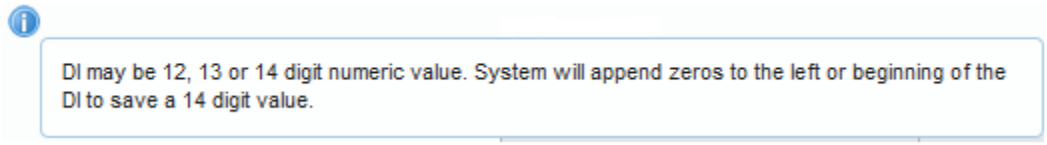
Labeler Data Entry users can create new Device Identifier (DI) records. While in the **Manage Device** section, the functionality can be accessed by clicking the **Create New DI** button or by using the top menu **Manage DI→ Create New DI** drop down as shown below.




The New DI record page opens as shown below.




- 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 here.
    - 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

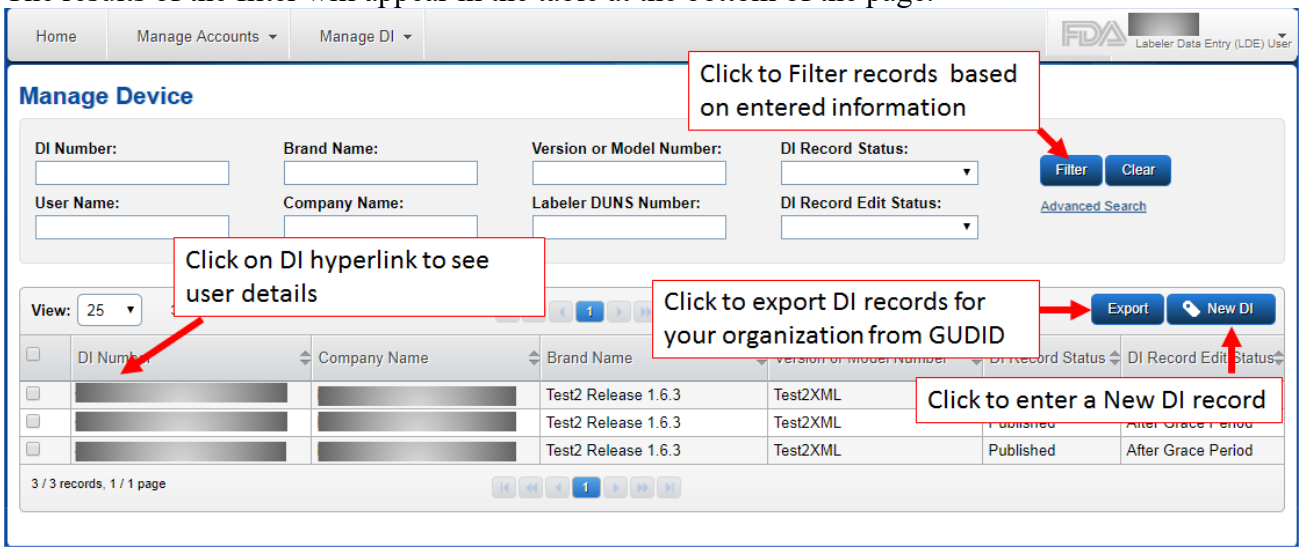
#### *4.2.2.2 View DI Record*

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

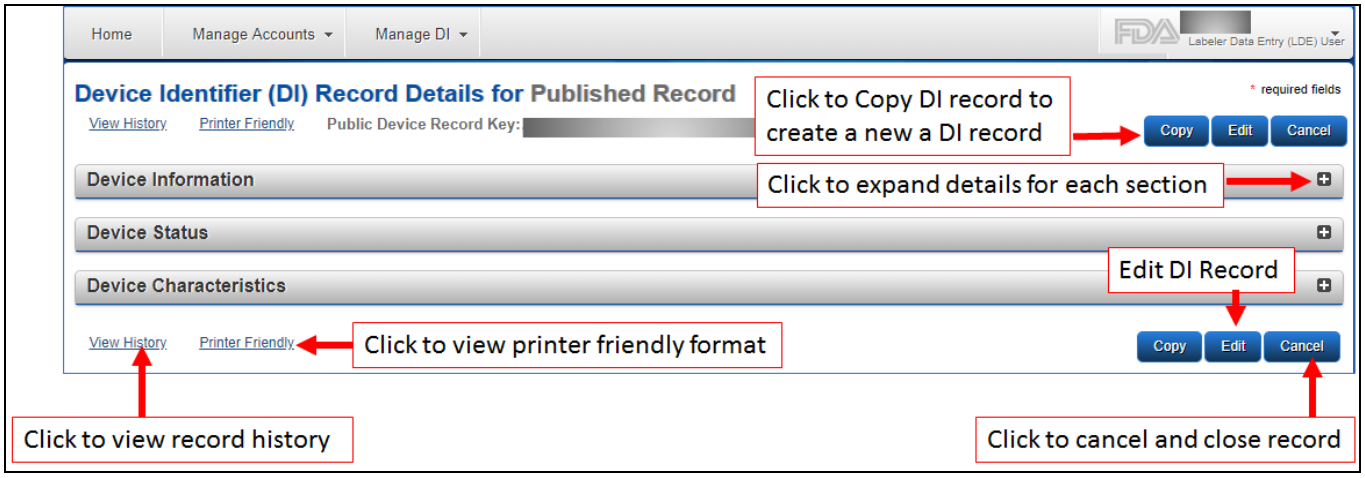
Name, Labeler DUNS Number. Records can also be filtered by the DI Record Status and DI Record Edit Status.

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.




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

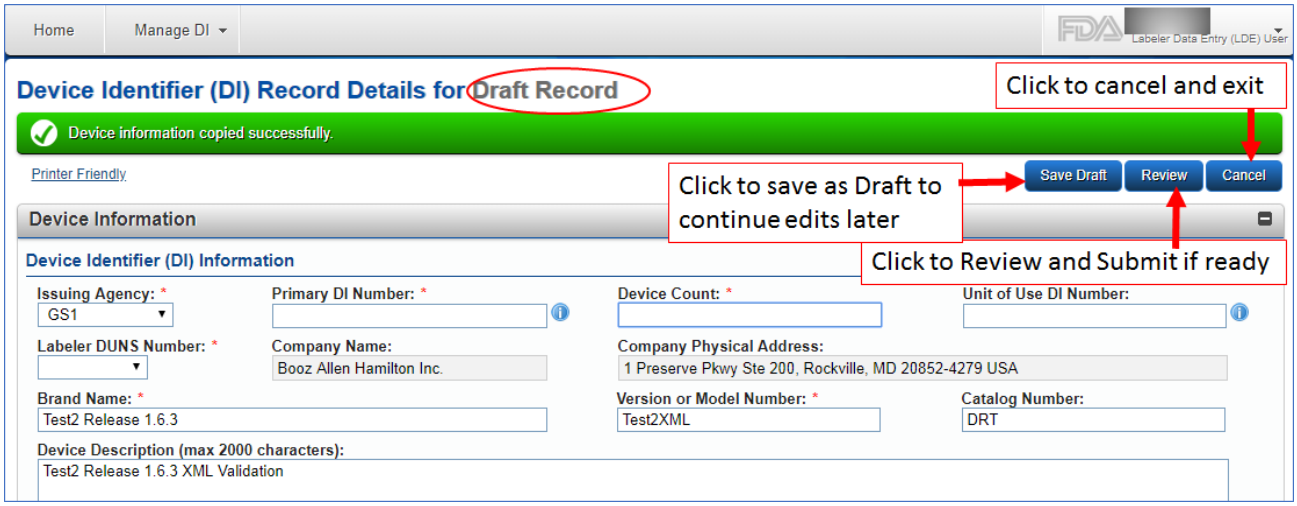



### *4.2.2.3 Copy DI Record*

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.




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

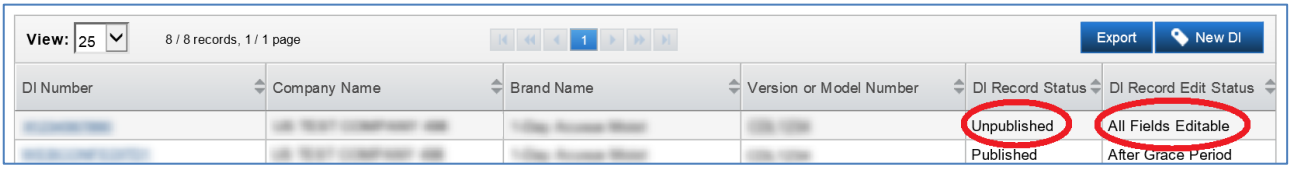
### *5.2.2.4 Edit DI Record*

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:

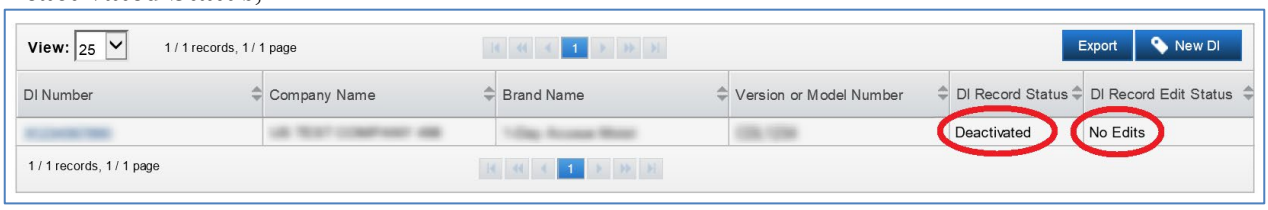
- **Draft Status**, a draft DI record, all fields are editable
- **Unpublished Status**: DI record with a future Publish Date that has been submitted to GUDID; all data elements are editable




- **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*

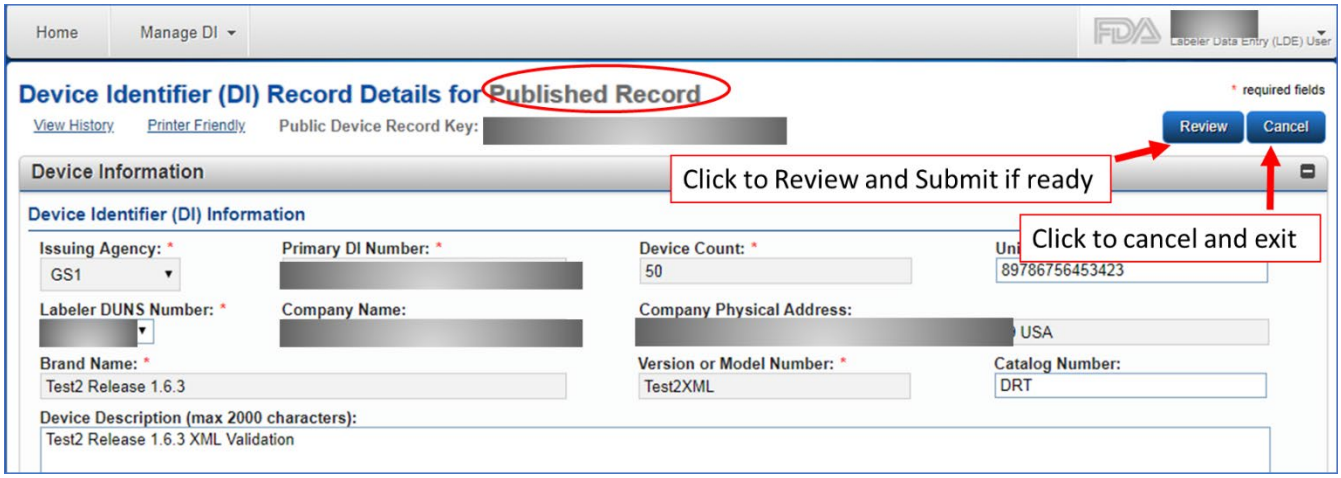
- After Grace Period, Limited Editing: after the Grace Period, limited editing is allowed, specifically, edits to the New DI trigger data elements[6] are not allowed
- Unlocked, all data elements are editable, except the *DI Record Publish Date*. Records need to be unlocked by the Coordinator user, so 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




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.



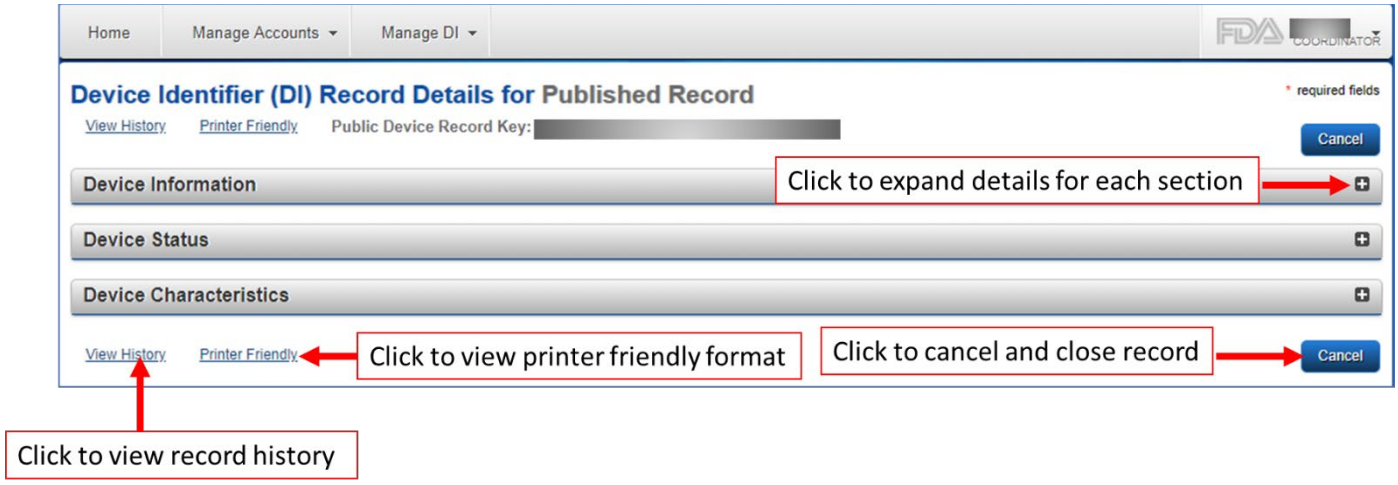

### *5.2.2.5 Exporting DI Records*

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

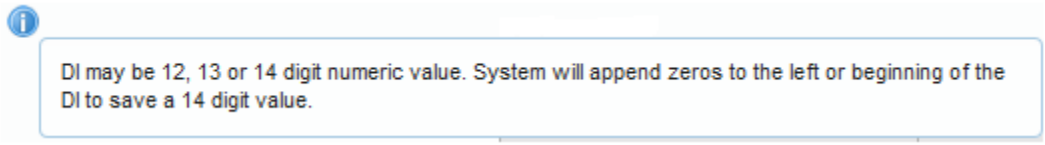
Each DI record has 3 sections as shown below– Device Information, Device Status and Device Characteristics. The '+' may be clicked to expand and view each section.

[6] New DI trigger data elements are those, which when changed, require a new Device Identifier to be assigned.




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 here.
- 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.




# 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 AccessGUDID and OpenFDA. The device information available on AccessGUDID and OpenFDA is the most recent data submitted to the GUDID that has completed the "grace period" after initial publication. Data on AccessGUDID 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 GUDID Data Elements Reference Table (DERT) 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 AccessGUDID and OpenFDA

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 FDA Unified Registration and Listing System/Device Registration and Listing Module (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
  - 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 here. To review and update confidentiality designations to proprietary names for existing listings, please contact Device Registration and Listing Office at reglist@cdrh.fda.gov.

## 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 FDA UDI Help Desk 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