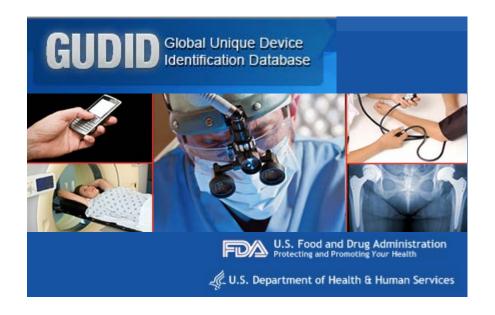
## **U.S. Food and Drug Administration**

# Global Unique Device Identification Database (GUDID) User Manual



Document Version 1.2
August 15, 2013

## **FDA GUDID** User Manual

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## **Section 1: Introduction**

## Overview of GUDID

The U.S. Congress passed legislation in 2007 and 2012 directing the Food and Drug Administration (FDA) to develop regulations establishing an authoritative unique device identification (UDI) system for medical devices. A UDI is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number, manufacturing date, and/or expiration date. In 2012, the FDA released a proposed rule requiring most medical devices distributed in the United States to carry a UDI. Over the past year, FDA designed and developed the Global Unique Device Identification Database (GUDID) to prepare for the implementation of the UDI final rule.

The GUDID is a database that aims to improve medical device safety and serve as the definitive source for identification information of medical devices used in the U.S. In order to collect all of the device related identification information, including the UDI, device labelers must submit data about the medical devices they market in the U.S to the GUDID. As medical devices evolve, the Labelers must update device related identification information in the GUDID.

## **Benefits of Unique Device Identification**

- Allows more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reduces medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhances our analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries.
- Provides a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Provides a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion as well as prepare for medical emergencies.
- Leads to the development of a medical device identification system that is recognized around the world.

### **About the GUDID User Manual**

#### Purpose of User Manual

This user manual provides an overview of GUDID user roles, functions and instructions on using the database.

It is organized by user role and responsibilities. Each section provides instructions and supporting graphics to users.

**NOTE**: The screens used in this document are **based on user roles and access to the database**. Depending on your user role, you may or may not have access to all screens and functions described in this manual.

# **Section 2: Getting Started**

## **Contents**

This section contains the following topics:

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## **Subsection 2.1: Using the Database**

# Browser Compatibility

#### **GUDID** currently supports the following browsers:

- Internet Explorer 9 and 10
- Mozilla FireFox 17-22

#### **Troubleshooting Internet Explorer Issues**

If you are using Internet Explorer (IE) 9 or 10 and see the following message, follow the instructions below to troubleshoot.

Warning!
Your web browser is not supported for this GUDID release. Please use a supported browser which is available under the About link. Sorry for any inconvenience.

Text: Warning! Your web browser is not supported for this GUDID release. Please use a supported browser which is available under the About link. Sorry for any inconvenience.

#### Turn off Compatibility View in Internet Explorer 9 and 10

- 1. Open GUDID in Internet Explorer.
- 2. See if the Compatibility View button appears in the Address bar. (If you don't see the button, there's no need to turn off Compatibility View.)

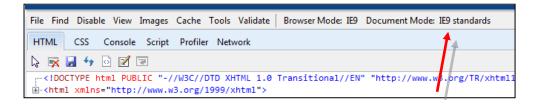


- 3. Tap or click the Compatibility View button to turn off Compatibility View.
- 4. The Compatibility View button should now appear grayed out:



#### **Change Mode and Document version**

- 1. Open GUDID in Internet Explorer.
- 2. Click F12 on the keyboard, or click the icon in the right hand corner and click on Developer Tools.
- 3. In the top toolbar set the Browser Mode to IE9/IE10 and the Document Mode to IE9 standards/IE10 standards.



#### Users Descriptions

There are two types of users who can access and change information in the GUDID: Coordinators and Labeler Data Entry (LDE) Users. Public Users, the third user role, can only search and retrieve information from GUDID, but cannot make changes to the records. Access to GUDID functionality is determined by user role and each user will see only the functions available to them.

See the chart below for descriptions of each user's role.

Type of User	Description
Coordinator	The Coordinator is a device labeling organization user and can create, edit, enable, disable, and deactivate Labeler Data Entry (LDE) user accounts based on the Labeler DUNS number(s) assigned to their account. The Coordinator can also reset passwords for LDE user accounts
Labeler Data Entry (LDE) User	The LDE user is also from a device labeling organization and can create, edit, and publish DI records based on Labeler DUNS number(s) assigned to their accounts.
Public User	Public Users are allowed to search DI Records. Public Users do not login to the system.  Users will be able to search using the quick search and advanced search options. Quick Search will enable a user to search by Device Identifiers, Company Name, Brand Name, and Version or Model Number. Advanced Search will enable a user to perform a more comprehensive search on all searchable GUDID attributes.  Note: The Public Search function is temporarily disabled and will be enabled at a future date when the database is populated.

## **Subsection 2.2: Common Functions**

#### Overview of Common GUDID Functions

This table details the various functions available to users throughout GUDID based on their user role.

Function	lcon/Link	Description
About	<b>♦</b> <u>About</u>	Obtain system information, including supported browsers.
Advanced Search	Advanced Search	Navigate to Advanced Search with the Advanced Search link.
		Note: This link is temporarily disabled and will be enabled when Public Search is made available.
GUDID Logo	GUDID Global Unique Device Identification Database	Navigate to home screen from any page by clicking on the GUDID logo.
User Guide	10 User Guide	Open the System User Guide PDF file.
Quick Search	Search Advanced Search	Conduct Quick Search by inputting a value. Quick Search will return DI Records that have a match in one of four fields: Device Identifier, Company Name, Brand Name, and Version or Model Number.
		Note: This functionality is temporarily disabled and will be enabled when Public Search is made available.
Search (Menu	Search ▼	Navigate to quick or advanced search by using the drop-down Search menu.
Drop- down)		Note: This menu is temporarily disabled and will be enabled when Public Search is made available.
Coordinator & Labeler Data Entry (LDE) User Specific Functions		
Forgot Password	Password	Request a password reset and receive an email with a temporary password for their account.
Forgot User Name	Forgot Username/	Request username be sent to the email address listed in account profile.
Login	<b>a</b> <u>Login</u>	Navigate to the login page with the login link.

#### **Main Page**

#### URL: https://gudid.fda.gov/gudid

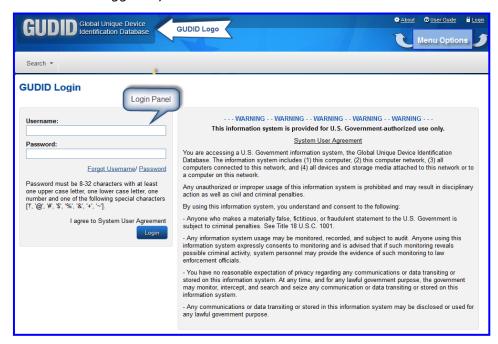
The *Main Page* is displayed as shown below. From this page you can login, search, among other functions among other functions as described in this document.



#### **Login Screen**

From the GUDID log in screen, enter your username and pasword for account management or data entry. Please review the System User Agreement prior to logging into the GUDID.

Note: When the Search functionality is enabled, Users DO NOT need to log into the GUDID to conduct DI record searches (only public data will be available when the user is not logged in).



#### Username and Password

To retrieve a forgotten username, click **Forgot Username**. Enter email address associated with the username, and then click **Send My Username**. You will receive an email with the username. If you have more than one account linked to you 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, click **Password**. Enter username and email associated with the password. Click **Send My Password**. You will receive two emails: 1) Password reset notification; 2) Temporary password. Login to the GUDID with the temporary password and your username. The system will then ask you to change your password.

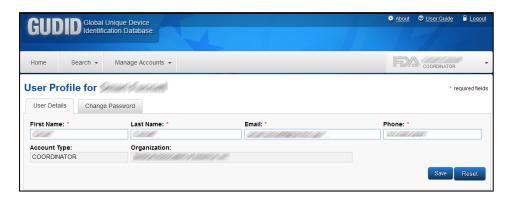


You must change your temporary password to access GUDID functions. Enter the temporary password, a new password, and confirm your new password. Click **Change Password**. A confirmation message will appear at the top of the page.

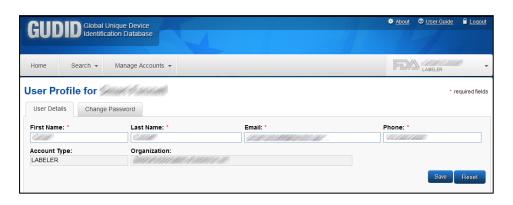
#### View and Edit User Profile

To view the **User Profile**, click on the dropdown menu next to the username and role in the right hand corner. On the **User Profile** screen, you can make updates and save changes by clicking **Save** on the *User Detail* tab, or Change your password on the *Change Password* tab.

#### Coordinator:



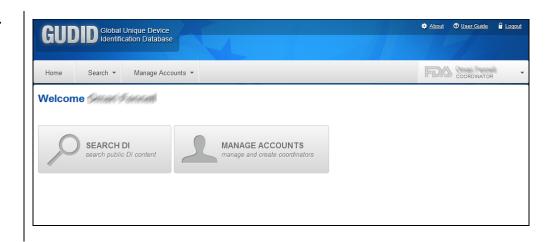
#### Labeler Data Entry User:



#### **Subsection 2.3 Coordinator**

#### **Overview of Functionality for Coordinator Role**

#### Coordinator Homepage



#### Search DI

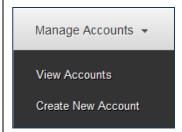
Search DI allows a Coordinator to search for public DI records.

Note: This functionality is temporarily disabled and will be enabled when Public Search is made available.

## Manage Accounts



Manage Accounts allows a Coordinator to view and manage Labeler Data Entry Accounts for their assigned Labeler DUNS Numbers.



The drop-down menu of Manage Accounts allows a Coordinator to navigate to View Accounts or Create New Account.

# Access the Database

To begin, Login to GUDID as a Coordinator (see Subsection 2.2 for detailed information).

The home screen is displayed at login, see figure below.

Click the **Manage Accounts** button or select the **Manage Accounts** from the menu bar.

Note: A username and temporary password will be sent when an account has been created. At the first login, you will be required to change your password (see Username and Password section under Subsection 2.2 for detailed information).



## Manage Accounts

Upon entry, Manage Accounts will display all accounts available for you in a table. Click on the username to see account details.

You can filter for a specific account by typing in any of the fields provided – Last Name, First Name, User Name, Email, Status, Mode, etc. Enter information into the field you desire to filter by, and then click **Filter**. The results of the filter appear in the table at the bottom of the page. Click on the username to see account details.



You can edit the account details, and then click Save.

## Account Status and Mode

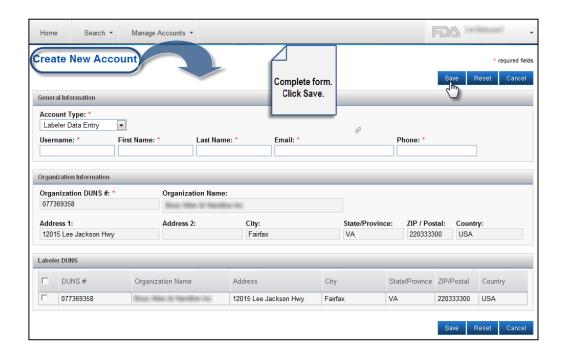
An account can have an enabled or disabled status. An enabled account is able to login in to GUDID. A disabled account cannot login to GUDID and must have the account re-enabled by a coordinator. Re-enabling the account automatically changes the user's password to a temporary password and notifies the user of the change via an automated email. The temporary password must be changed before GUDID access is restored.

An account can also be in activated or deactivated mode. The default for each account is activated mode. If an account is set to deactivated, then the account cannot access GUDID and that account cannot be recovered.

On the Manage Accounts and Account Details screen you can change the status and mode by clicking **Enabled/Disabled** and **Activated**. You can also reset the user's password which will cause the user to receive a temporary password via email.

# Create New Account

To create a new account, click **Add New Account** on the Manage Accounts screen. After clicking **Add New Account** on the Manage Accounts page, create a new account by entering the required information. When complete, click **Save**.



## Subsection 2.4: Labeler Data Entry (LDE) User

#### Overview of Functionality for Labeler Data Entry (LDE) User Role

#### Labeler Data Entry User Homepage



#### **Search DI Records**



Search DI allows a LDE User to search for public DI records.

Note: This link is temporarily disabled and will be enabled when Public Search is made available.

# Manage DI Records (drop-down)



Manage DI allows a LDE User to create and manage DI records for their assigned Labeler DUNS numbers.

The Manage DI drop down allows an LDE User to navigate to Submitted DI, Draft DI, or Create New DI functionality.

# Manage DI Records (icon)



The **Manage DI** icon will navigate the user to their Submitted DI records. This includes Published and Unpublished DI Records.

# Draft DI Records (icon)

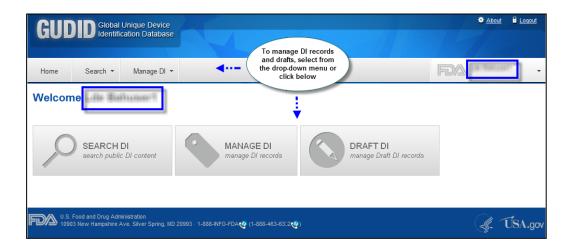


The **Draft DI** icon will navigate the user to their Draft DI records. The Draft DI records can only be viewed by the user that created the record.

# Access the Database

To begin, login as LDE use (see Login section under Subsection 2.2 for detailed information).

The home screen is displayed at login, see figure below. Click the **Manage DI** and **Draft DI** buttons or **Manage DI** from the menu bar.



#### Manage Device Identifier (DI) Records

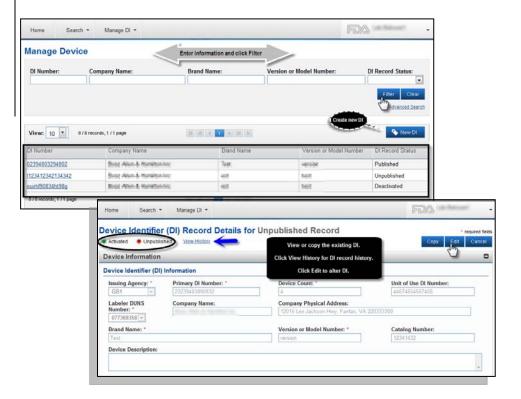
Upon entry, on the Manage Devices page, published and unpublished DI records available for view will be displayed in the table. Click on a DI number to see DI record details.

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, or DI Record Status (Published/Unpublished). Enter information into the field you desire to filter by and click filter. Results will appear in table at bottom of screen. Click the DI Number link to open a DI record.

Open a published DI record from the Manage Device list. You will see on the top left of the screen that the DI record is Published.

Open an unpublished DI record from the Manage Device list. You will see on the top left of the screen that the DI record is Unpublished.

Note: A published DI record cannot move to any other state without intervention from FDA Staff.

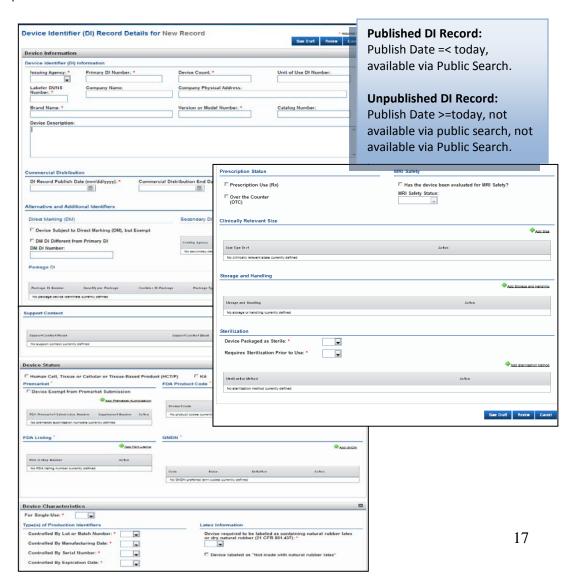


#### Create New DI Record

When you click the New DI button, the DI Record Details screen will open up. Complete the **DI Record Details** for a new DI record. Click **Save Draft** if you have not completed the form (you must include the Primary Issuing Agency and Primary DI Number to save as draft). Draft DI records will appear on the Drafts DI screen for future editing (system will purge Draft DI records after 180 days).

Click **Review** after you have completed the DI record. The system runs business rules on entered information to ensure all entries are valid and all required fields have values. If the DI record has errors, the user must correct the errors and click review again. Once the record is validated, the system notifies the user that the Review was successful. When the user clicks **Submit**, the DI record will be in Published or Unpublished state based on the DI Record Publish Date.

- DI Record Publish Date =< today, Published DI record, available via Public Search.
- DI Record Publish Date >=today, Unpublished DI record, not available via public search.



## Edit Existing DI Record

Open a published DI record from the list. You will see on the top left of the screen that the DI record is **Published**. Click **Edit** at the top or bottom right of the page. Update the information as you desire. Note that Published DIs have edit rules limiting the fields you can edit after the 7 calendar day grace period. After editing, click Review and Submit to save changes.

Open an unpublished DI record from the list. You will see on the top left of screen that the DI record is **Unpublished**. Click **Edit** at the top or bottom of the page. Change the form as needed. After editing, click Review and Submit to save changes.



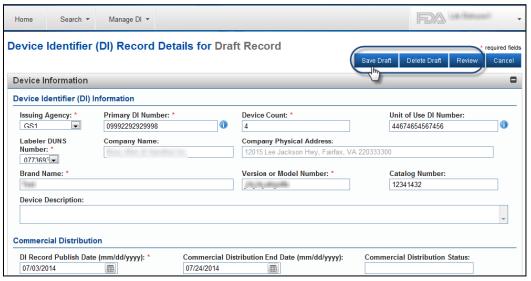
#### Manage and Edit Draft DI Record

To manage draft DI records, click the Draft DI record button or Draft DI record link under the Manage DI dropdown. You will be returned with all of the Draft DI Records. You can choose to remove a Draft DI record permanently by clicking the **Remove** button.

To narrow the list of results, you can filter by DI Number, Company Name, Brand Name, and Version or Model Number. The results of the filter appear in the table at the bottom of the page.

Click a DI number to open the DI Record Detail. You can **Edit, Save Draft**, **Delete Draft**, **Review**, or **Cancel**. The **Save Draft** button will save the draft as long as the DI record contains a primary issuing agency and primary DI number. The **Delete Draft** button will permanently remove the draft. The **Review** button will perform validation on the DI record and if it passes, the record can be submitted. The **Cancel** button will cancel all changes and return the DI record back to its last saved version.





# Copy Existing DI Record

Only Published and Unpublished DI records can be copied. To copy a DI record, go to the Manage DI screen and click on the DI Number you would like to copy. Click Copy to create a copy of the DI record. The copied data displays on the DI Record Details for New Record form.





Manage DI Record Advanced Search To perform an advanced search on DI records that are available for editing, click on the **Manage Device** screen and then click **Advanced Search**. The **Manage DI Advanced Search** screen displays with search fields. Manage DI Advanced Search will enable you to perform a comprehensive search using search operators to find DI records. If you are not sure of the exact spelling of a data element, you can select **Spell Like** and it will retrieve records with a similar spelling.



