Pesticide Submissions Portal (PSP) User Guide

Environmental Protection Agency

Office of Pesticide Programs

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1 Introduction

The United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) developed the Pesticide Submission Portal (PSP) application to allow registrants to electronically submit pesticide application packages to EPA. PSP allows registrants to create and submit packages electronically. Applications for pesticide registration can be submitted, including forms, studies, and draft product labeling. Applicants need not submit multiple electronic copies of any pieces of their applications. In PR Notice 2011-3, EPA made clear that the requirement to submit multiple copies of data is applicable only to paper submissions. Similarly, EPA interprets the requirement to submit five copies of draft labeling in 40 CFR 152.50(e) to apply only to applications made on paper. As electronic submissions are easily reproducible, EPA will accept electronic applications containing one copy of all the required elements.

EPA encourages electronic submissions for the following regulatory actions:

- Product Registration – Section 3
    - New pesticide active ingredients
    - New pesticide products containing already-registered pesticide active ingredients
    - FIFRA 6(a)(2) study submissions
    - Amendments to registered pesticide products.
- Experimental Use Permit – Section 5
- Petitions for food tolerance
- Distributor products
- Notifications
- Inert Ingredient Request
- Pre-Application

A package created within PSP consists of all documents and metadata required by EPA to properly process the package. Users may also upload and submit packages created in the e-Submission XML format or the EPA e-Dossier Builder format.

In addition to preparing packages, users may also respond to Data Call-Ins (DCIs). DCI Acknowledgements, 90-Day Responses, and Data Submissions can be submitted through the portal. Both Generic Data Call-Ins (GDCIs) and Product-Specific Data Call-Ins (PDCIs) are supported.

1.1 Purpose

The purpose of this document is to provide instructions on how to use the PSP application. This document provides guidance on how to properly prepare a package for submission to EPA.

After reviewing this document, users will be able to:

- Access the PSP application via the Central Data Exchange (CDX)
- Generate root master record identification numbers (MRIDs)

- Navigate the PSP application and prepare packages for submission
- Upload batch packages in the e-Submission XML format
- Upload and modify packages created with e-Dossier Builder
- Submit packages to EPA for processing
- Respond to DCIs by submitting DCI Acknowledgements, 90-Day Responses, and Data Submissions.

2 System Requirements

To use the PSP application the following are required:

- An e-mail account
- A supported web browser with Java Script enabled and pop-up blockers disabled
- Internet access
- CDX username and password

2.1 Supported Browsers

For optimal performance, it is recommended that you use Google Chrome to access the PSP application. However, the following browsers are supported:

- Google Chrome 44 or above
    - Go to the following link to download:

      http://www.google.com/chrome
- Internet Explorer 11 (Internet Explorer 10 and below are not supported)
    - Go to the following link to download:

      http://windows.microsoft.com/en-US/internet-explorer/downloads/ie
- Mozilla Firefox 3.5 or above
    - Go to the following link to download:

      http://www.mozilla.com/en-US/firefox/all-older.html
- Safari 4 or above
    - Go to the following link to download:

      http://support.apple.com/kb/dl877

3 PSP Functionality

This section describes:

- The PSP User Roles
- How to access the PSP application
- How to navigate the PSP 'Home' screen
- How to access the PSP User Guide

3.1 PSP User Roles

Users can access the PSP application as one of two roles - Primary Submitter and Authorized Agent. As a Primary Submitter, you can view all packages and DCIs created for your company, sponsor and maintain Authorized Agent users' access to the PSP application, prepare and submit packages, and respond to DCIs.

Important: The Primary Submitter is intended to be an official representative of the associated company. However, if an agent registers as a Primary Submitter, they assume all the responsibilities of the Primary Submitter. These responsibilities include sponsoring Authorized Agents and managing their access.

As an Authorized Agent, you can only see the packages you created and are unable to sponsor other users' access to the PSP application. Authorized Agents may prepare and submit packages and respond to DCIs.

For more information about user roles and CDX registration, please refer to the 'OPP CDX Pesticide Submission Portal Registration User Guide' below:

https://cdx.epa.gov/content/documents/PSP/OPP_CDX_Pesticide_Submission_PortalRegistration_UserGuidev1.0p.pdf

3.2 Access PSP Application

To access the CDX 'Home' page, navigate to https://cdx.epa.gov/.

Exhibit 3-1 below shows a screen capture of the 'CDX 'Home' screen.

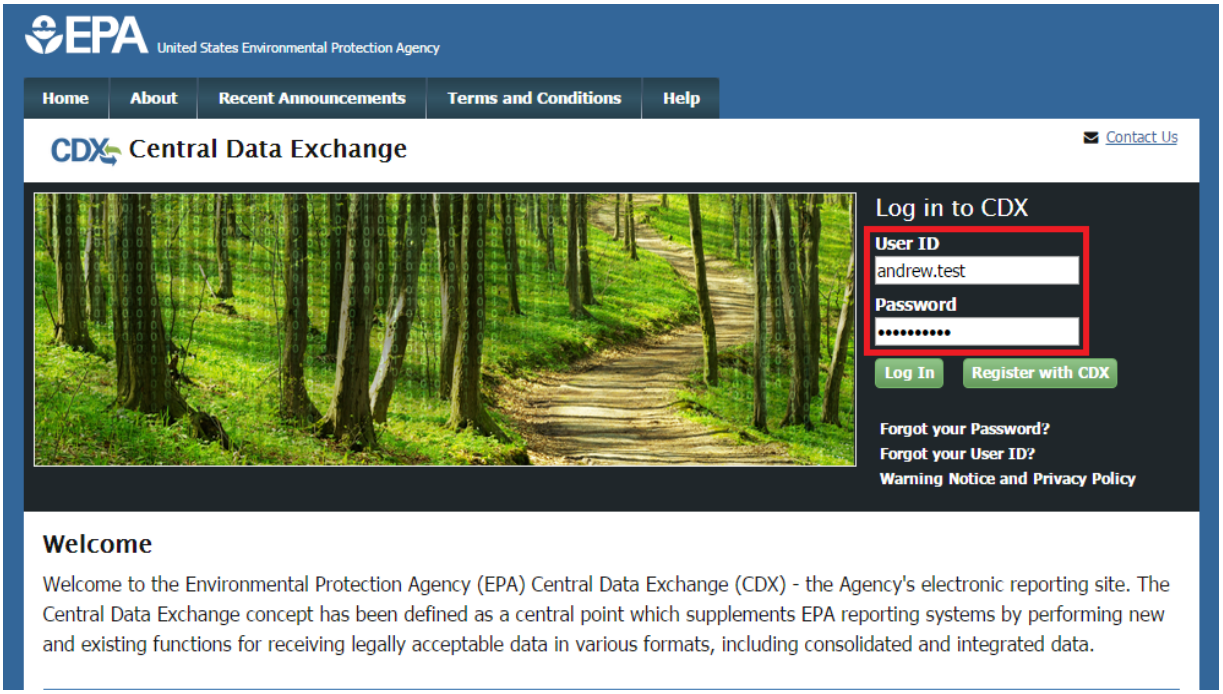


Exhibit 3-1: CDX Home Screen

Navigation: Enter a valid User ID and Password into the 'User ID' and 'Password' fields, and click the 'Log In' button.

After logging in, you will be navigated to the 'MyCDX' page. This page lists the program services with which you are associated as well as your status and role(s) for those services. If you are registered for the PSP application, you will see 'PSP: Pesticide Submission Portal' in the services list. 'Primary Submitter' and/or 'Authorized Agent' will appear as a blue link under the 'Role' column as shown in Exhibit 3-2 below.

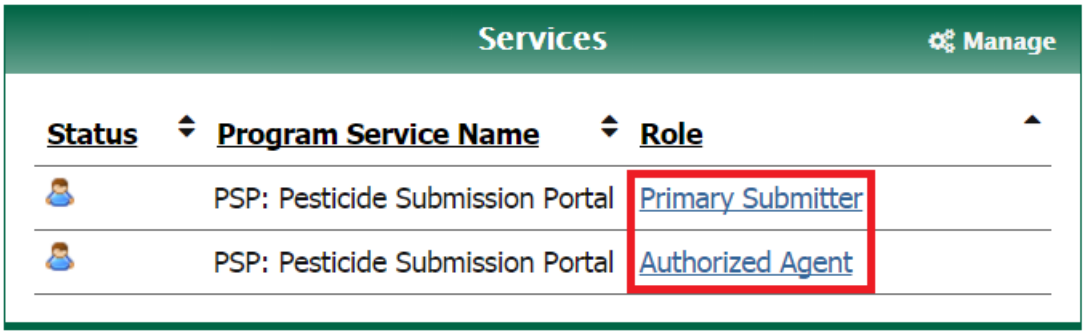


Exhibit 3-2: MyCDX Screen and Role Link

Navigation: Click a blue role link under the 'Role' column to enter the PSP application as that role.

Note: If you are associated with multiple companies, you will have to choose the organization name and company role/pesticide company number for which you are submitting. In this case, dropdown boxes will display upon clicking the 'Role' link. If you are not associated with multiple companies, proceed to the next section.

Exhibit 3-3 below displays the organization name and company role/pesticide company number dropdown boxes that appear when you are associated with multiple companies. The pesticide company number is located next to the role within the 'Program Client ID' dropdown box. In this case, '456' is the pesticide company number.

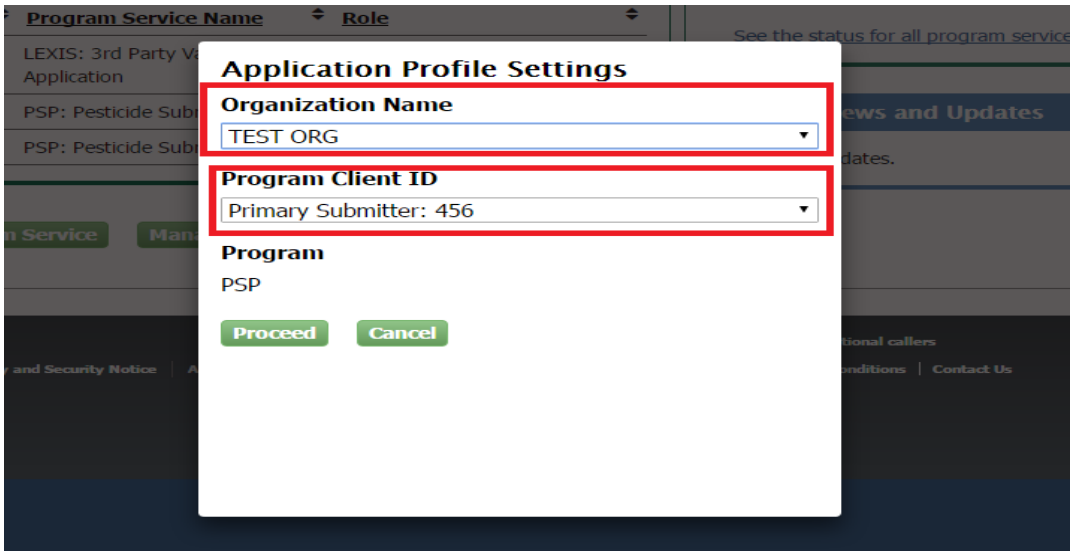


Exhibit 3-3: Choosing the Organization Name and Company Role/Pesticide Company Number

Navigation: Choose the organization name, company role/number, and then click the 'Proceed' button to enter the PSP application. After clicking 'Proceed,' you will be navigated to the PSP 'Home' screen.

3.3 PSP 'Home' Screen

The PSP 'Home' screen, shown in Exhibit 3-4, is the first screen within the PSP application. It provides you with links and tabs to access various screens within the application. To navigate to any of these screens, click the blue screen link or the screen tab located within the application header. The links and tabs provide the same functionality.

Your name, company, and role are displayed as a link in the application header. Clicking this link will log you out of both the PSP application and CDX. 'CDX Links' are displayed in the application footer. Clicking this link will display a list of CDX resources to which you may navigate. The CDX Helpdesk number is displayed next to 'CDX Links.'

The PSP 'Home' Screen contains the following links:

- **'Create New Package' –** Clicking this link will navigate you to the 'Create Passphrase' screen. After creating a passphrase for your package, you will be navigated to the 'Package Info' screen where you can begin the package creation process. For more information about creating packages, refer to **Section 5**.
- **'Continue Saved Packages' –** Clicking this link will navigate you to the 'Continue Saved Packages' screen. This screen lists in-progress packages with the 'Awaiting User Completion' status. For more information about continuing saved packages, refer to **Section 8**.

- **'Package Status' –** Clicking this link will navigate you to the 'Package Status' page. This screen lists packages submitted to EPA. For more information about checking a package's status, refer to **Section 11**.
- **'Upload XML e-Submission Packages' –** Clicking this link will navigate you to the 'Upload XML e-Submission Packages' screen. This screen allows you to upload and submit a package created using your company's IT systems in the e-Submission XML format. This page accepts zip files that contain an e-Submission XML and is meant for single application submissions. For more information about uploading XML e-Submission packages, refer to **Section 7.1**.
- **'Upload e-Dossier Builder Packages' –** Clicking this link will navigate you to the 'Upload a Package Created by e-Dossier Builder' screen. This screen allows you to upload and modify a package created using e-Dossier Builder. For more information about uploading e-Dossier Builder Packages, refer to **Section 7.2**.
- **'Data Call-In' –** Clicking this link will navigate you to the 'DCI List' screen. This screen allows you to submit DCIs and check their statuses.
- **'Voluntary Submission'** – Clicking this link will navigate you to the 'Voluntary Data Submission List' screen. This screen allows you to submit and manage voluntary data submissions.
- **'Generate Root MRIDs'** – Clicking this link will navigate you to the 'Generate Root MRIDs' screen where you can generate root MRIDs for use in study documents. A valid MRID is required for each 'Study' document type in a package. For more information about generating root MRIDs, refer to **Section 4**.

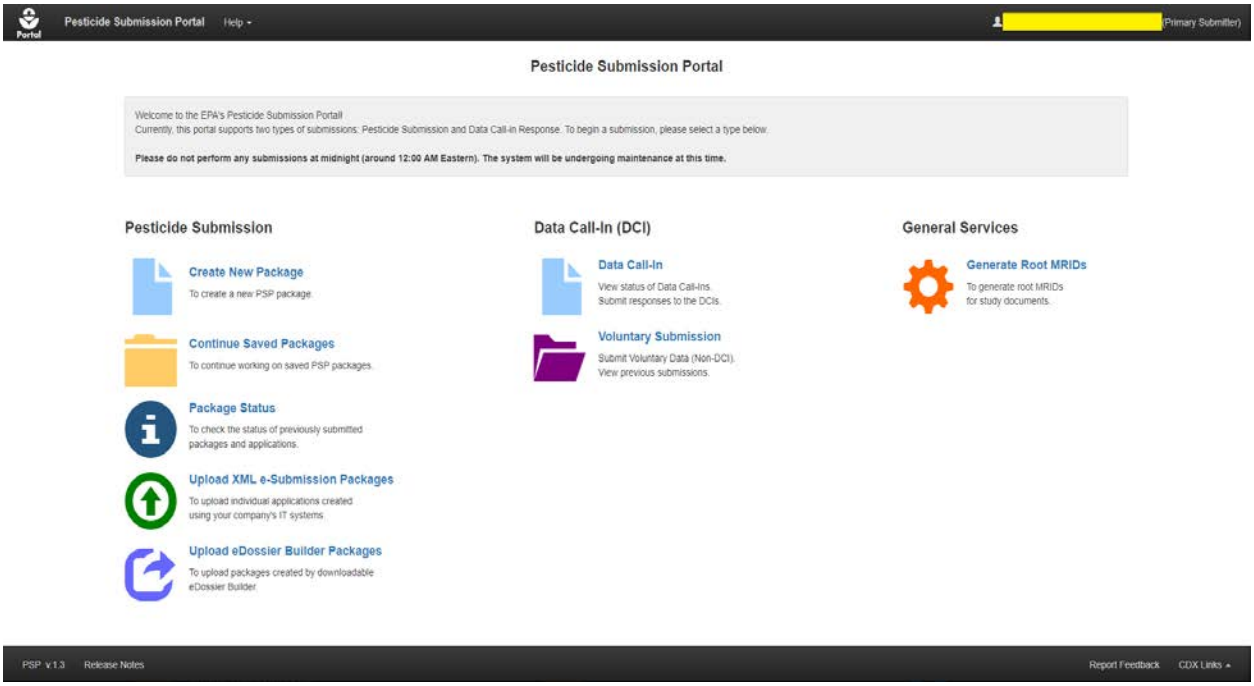


Exhibit 3-4: PSP Home Screen

3.4 Access the PSP User Guide

Users can access this user guide at any time within PSP's various screens. To access the user guide, click the 'Help' tab in the application header and click the 'Pesticide Submissions Portal User Guide' link. Exhibit 3-5 below displays a screen capture of the location of the user guide link within the 'Generate Root MRIDs' screen.

Exhibit 3-5: PSP User Guide Link

4 Generate Root MRIDs

EPA uses MRIDs to track and manage information submitted to the pesticide program. An MRID is a unique, eight-digit number assigned to each study submitted to EPA. The first six digits are referred to as the root MRID. To submit a package through the PSP application that will include a study, you must use a root MRID that was previously provided or generate a new root MRID through the PSP application.

When using MRIDs please keep the following in mind:

- The first MRID always ends in '00' and must be assigned to the transmittal document that describes the purpose of the submission and lists all of the included studies by title and MRID.
- MRIDs ending in '01' through '99' are available for assignment to supporting studies.
- If a submission includes more than 99 studies, you will need more than one root MRID.
- List studies on the transmittal document in MRID order without any breaks in sequence.
- Do not use MRIDs from the same root MRID for different submissions.
- Print the MRID ending in '00" on the upper right corner of page one of the transmittal document.
- Print each study's MRID on the upper right corner of the title page (page one).

You can access the ‘Generate Root MRIDs’ screen by clicking the ‘Generate Root MRIDs’ link on the PSP ‘Home’ screen or by clicking the ‘Generate Root MRIDs’ tab in the application header.

After clicking the ‘Generate Root MRIDs’ link, you will be navigated to the ‘Generate Root MRIDs’ screen. A text box labeled ‘Number of Root MRIDs’ will be displayed. Enter the necessary number of Root MRIDs and click the ‘Generate Root MRIDs’ button. Each root MRID can be used by up to ninety-nine (99) study documents in a single application.

Exhibit 4-1 below displays a screen capture of the ‘Generate Root MRIDs’ screen.

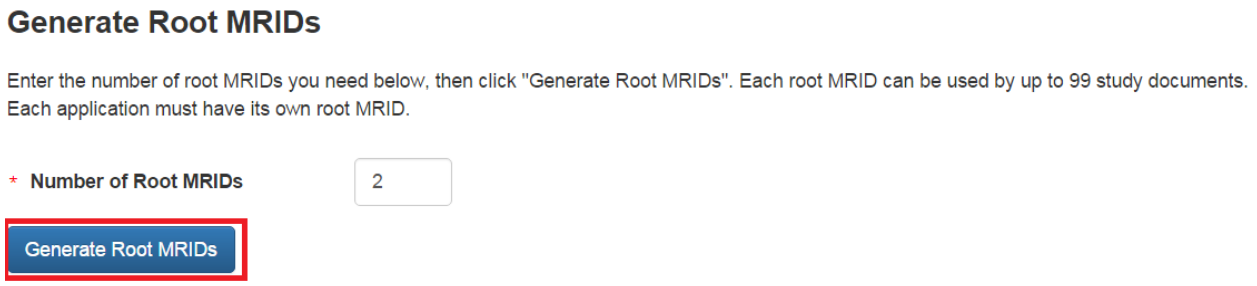


Exhibit 4-1: Generate Root MRIDs

Navigation: Enter the amount of necessary Root MRIDs and click the ‘Generate Root MRIDs’ button; a pop-up will display as the root MRIDs are generated. After system processing, the newly generated root MRIDs are displayed on screen. Record these root MRIDs, as you will need them later during the package creation process. The system will also send an email to the email account associated with your CDX account containing the generated root MRIDs. You can press the ‘Reset’ button to clear this screen of entries and generate additional root MRIDs.

Exhibit 4-2 below displays the root MRID generation results. Exhibit 4-3 below displays the MRID results email that is sent to the user.

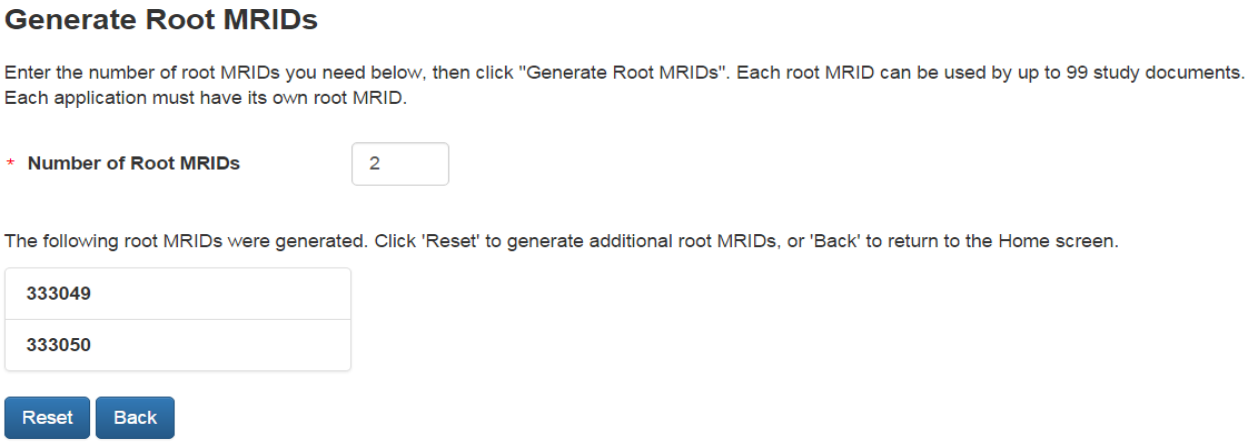


Exhibit 4-2: Generate Root MRIDs - Results

Exhibit 4-3: Example Root MRIDs Email

5 Prepare a Package for Submission Using PSP

This section describes the process to prepare a package for submission using the PSP application. If you plan to include study documents in your package, please refer to **Section 4** for instructions on how to generate Root MRIDs.

5.1 Create Package

You can begin the package creation process by clicking the 'Create New Package' link on the 'Home' page. You can return to the PSP 'Home' screen at any time by clicking the 'Portal' link at the top left of the screen.

Exhibit 5-1 below displays this option on the PSP 'Home' screen.

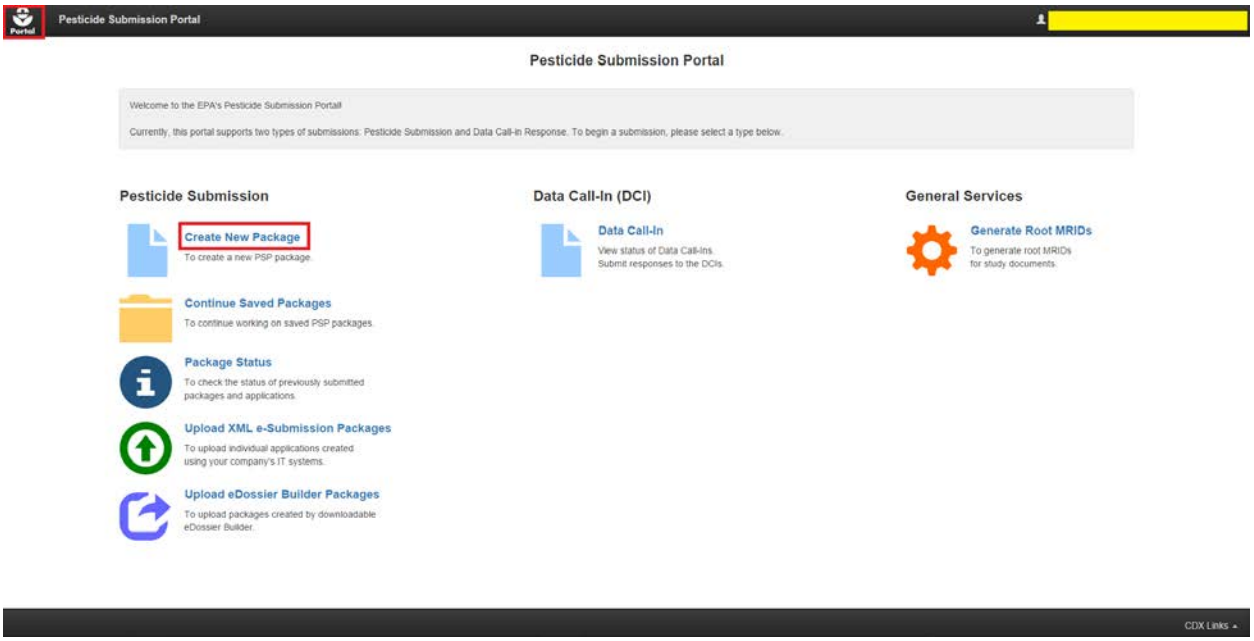


Exhibit 5-1: Create New Package Option

Navigation: Click the 'Create New Package' link to navigate to the 'Create Passphrase' screen and create a package.

5.2 Create Passphrase

A passphrase protects your package from unauthorized disclosure while it is being prepared and encrypts your package at both rest and submission. To associate a passphrase with a submission, enter a passphrase that is at least 8 characters long. To protect your package, your passphrase should contain a combination of letters and numbers. The passphrase you create may include spaces, but should **not** contain special characters (for example, +, and *). You can associate the same passphrase with multiple submissions.

You are responsible for remembering the passphrase and distributing it to only authorized persons for the package.

Important: If you forget the passphrase, you will be unable to access the package. If you lose or forget the passphrase, you must create a new package and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company.

Exhibit 5-2 below displays a screen capture of the 'Create Passphrase' screen.

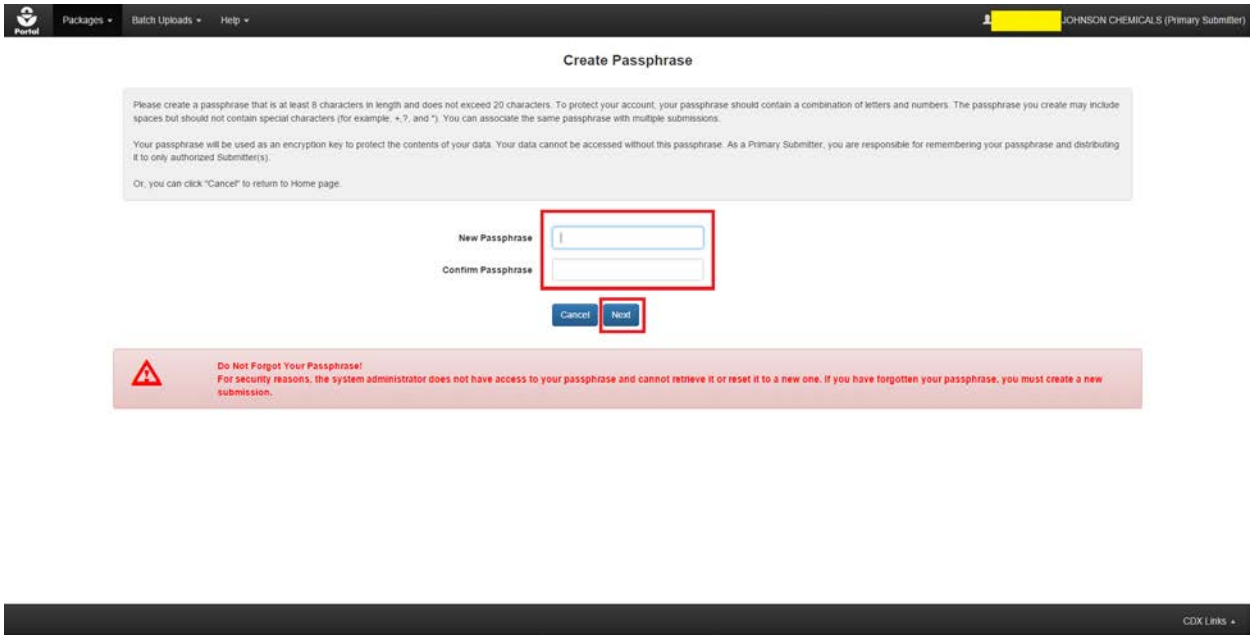


Exhibit 5-2: Create Passphrase Screen

Navigation: Create a passphrase and click the 'Next' button to navigate to the 'Package Info' screen.

5.3 Navigation Tree

The navigation tree is located on the left side of each screen. The bottom portion of the navigation tree contains tips (contextually based on the current screen) to guide you through the package creation process. You can perform the following functions using the navigation tree:

- **Collapse and Expand folders:** Each section of the package falls under a collapsible folder within the navigation tree, which allows you to save space or easily view items in the navigation tree. When a folder is expanded, you can click the folder title link to collapse that section of the navigation tree. When a folder is collapsed, you can click the folder title link to expand that section of the navigation tree.
- **Navigate between screens:** You can use the navigation tree to navigate between the various screens within the PSP application. You can click the screen title link to navigate to the selected screen.

Important: You are required to save all information entered on a particular screen before navigating to the next screen or all entered information will be lost. A prompt will appear after you click a link in the navigation tree indicating, 'Are you sure you want to leave the current page? Any unsaved changes will be lost.' If you click the 'OK' button, you will be taken to the requested screen without saving any of the data in the previous screen. If you click the 'Cancel' button, the prompt will close and you will not be taken to the requested screen.

The navigation tree on the left side of the screen will update once applications have been added to your package. The application name within the navigation tree can be clicked to hide or unhide the associated application.

Exhibit 5-3 below displays the navigation tree.

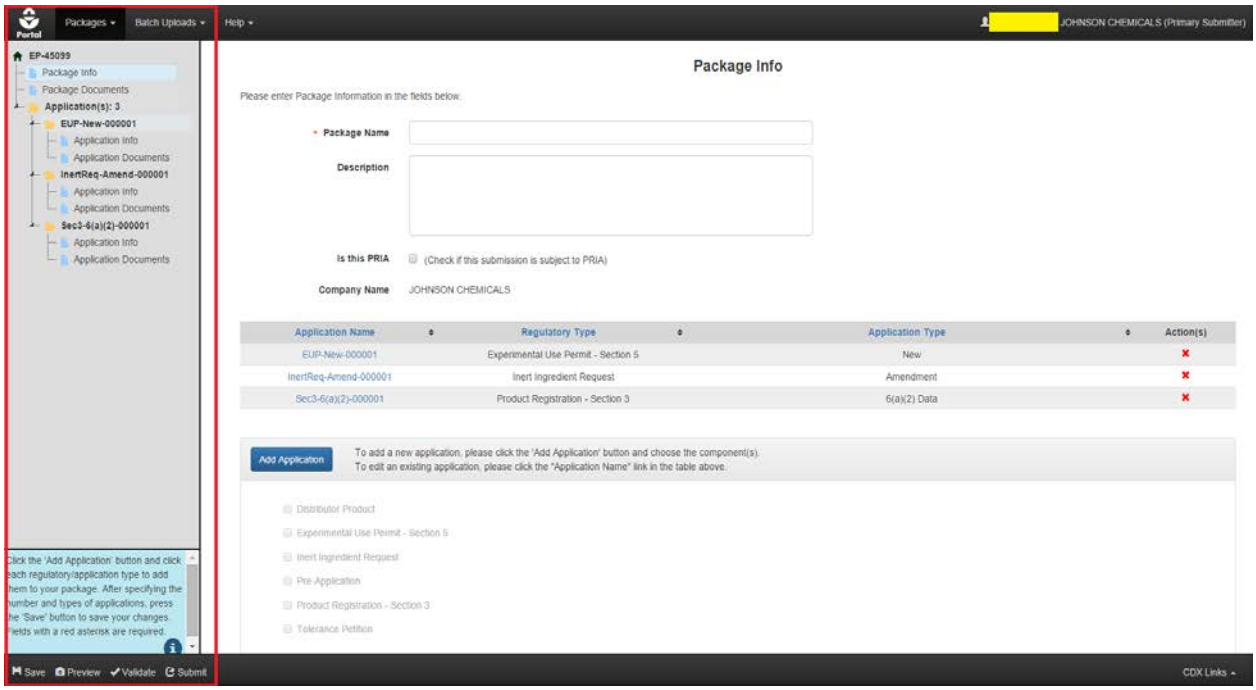


Exhibit 5-3: Navigation Tree

5.4 Application Footer

The application footer is located at the bottom of each screen. You can perform the following functions using the application footer:

The following exhibits, Exhibit 5-4, Exhibit 5-5, Exhibit 5-6, and Exhibit 5-7 show the different screen captures for the application footer:

- **Save:** You can click the 'Save' icon at any stage of completing a package. After you click the 'Save' icon, the data entered on the screen will save. The 'Save' function does not validate any data entered.

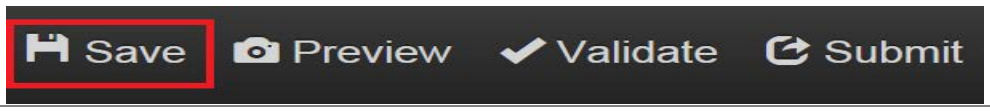


Exhibit 5-4: Application Footer – Save

- **Preview:** You can click the 'Preview' icon at any stage of completing a package to preview the submission. After you click the 'Preview' icon, a pop-up will display a PDF representation of the package.

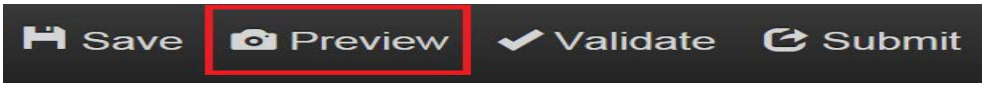


Exhibit 5-5: Application Footer – Preview

- **Validate:** You can click the 'Validate' icon at any stage of completing a package to check for certain types of errors in a submission. A validation pop-up window generates when you click the 'Validate' icon. The pop-up window displays a report of all validation errors relating to a failed validation. Please refer to **Section 9** if you need guidance about the validation process.

Exhibit 5-6: Application Footer – Validate

- **Submit:** You can click the 'Submit' icon to submit the package after you have completed all required sections. After you click the 'Submit' icon and press 'OK' in the pop-up window that generates, you will be brought to the 'Submitter Information' screen. Refer to **Section 10** for guidance on the submission process.

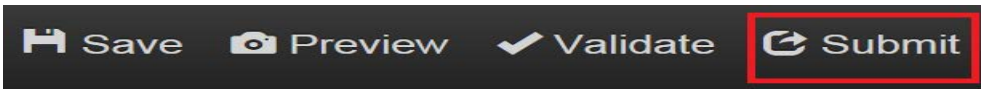


Exhibit 5-7: Application Footer – Submit

- **Help Links:** You can click any of the Help links, located within the 'CDX Links' dropdown at the bottom of each screen, at any stage of completing a package.

  If you click the 'CDX Homepage' link, you will be taken to the CDX Homepage at:

  - **http://www.epa.gov/cdx/**

  If you click the 'MyCDX Homepage' link, you will be taken to the CDX Login at:

  - **https://dev.epacdx.net/CDX/MyCDX**

  If you click the 'EPA Homepage' link, you will be taken to the EPA Homepage at:

  - **http://www.epa.gov/**

If you click the ‘Terms and Conditions’ link, you will be taken to the CDX Terms and Conditions screen at:

- **https://cdx.epa.gov/Terms**

If you click the ‘Privacy Notice’ link, you will be taken to the CDX Privacy and Security Notice screen at:

- **https://cdx.epa.gov/privacy.asp**

Exhibit 5-8 below shows the screen capture of the application footer ‘Help’ links:

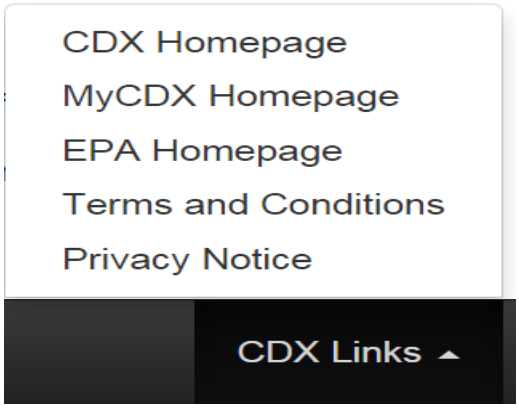


Exhibit 5-8: Application Footer – Help Links

5.5 ‘Package Info’ Screen

The ‘Package Info’ screen (see Exhibit 5-9) allows you to record information about your package as well as add applications to your package. The navigation tree on the left side of the screen will populate as applications are added to your package. You can click any link in the navigation tree to navigate to that portion of your package. All fields marked with a red asterisk are required. The following fields are displayed on the ‘Package Info’ screen:

- **Package Name:** Enter a name for the package. This is a required field.
- **Description:** Enter a description for the package. This is an optional field.
- **Is this PRIA:** Designate if the package is subject to Pesticide Registration Improvement Extension Act (PRIA) fees. This is an optional field.
- **Company Name:** The name of the company for which you are submitting. This field is not editable and is pulled from CDX.

To add applications to your package, click the ‘Add Application’ button and then click the check box next to one or more of the regulatory types listed below:

- Distributor Product
- Experimental Use Permit – Section 5
- Inert Ingredient Request
- Pre-Application

- Product Registration – Section 3
- Tolerance Petition

Clicking a Regulatory Type check box will reveal its associated Application Type(s). You can click the checkbox next to an Application Type to select it. Multiple Regulatory and Application types can be selected on this screen. After clicking an application check box, you will be able to designate how many applications of that type will be included in your package.

Important: The Distributor Product regulatory type follows a different workflow than the other regulatory types. The selection of different application types for Distributor Products takes place on the 'Application Info' screen. Please see **Section 6** for guidance on preparing Distributor Product applications. Exhibit 5-9 below displays a screen capture of the 'Package Info' screen.

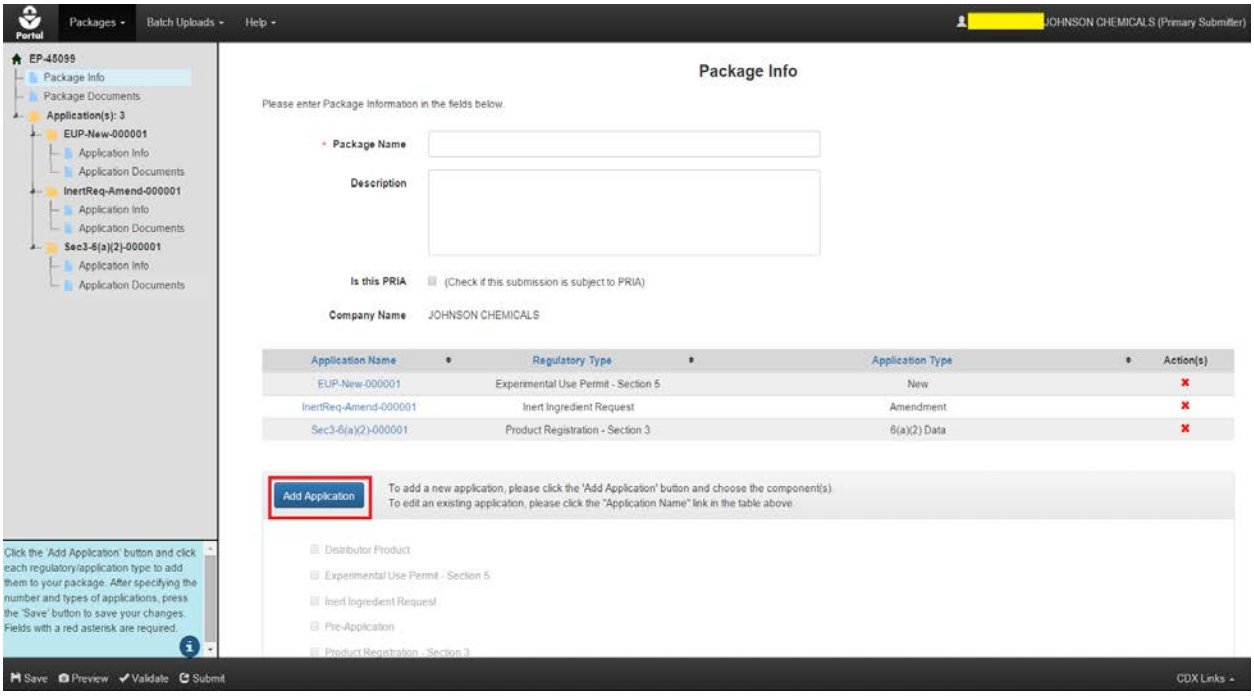


Exhibit 5-9: Package Info Screen

Navigation: Fill out all necessary fields on the 'Package Info' screen. Click the 'Add Application' button.

Exhibit 5-10 below displays the process of adding and saving applications to your package.

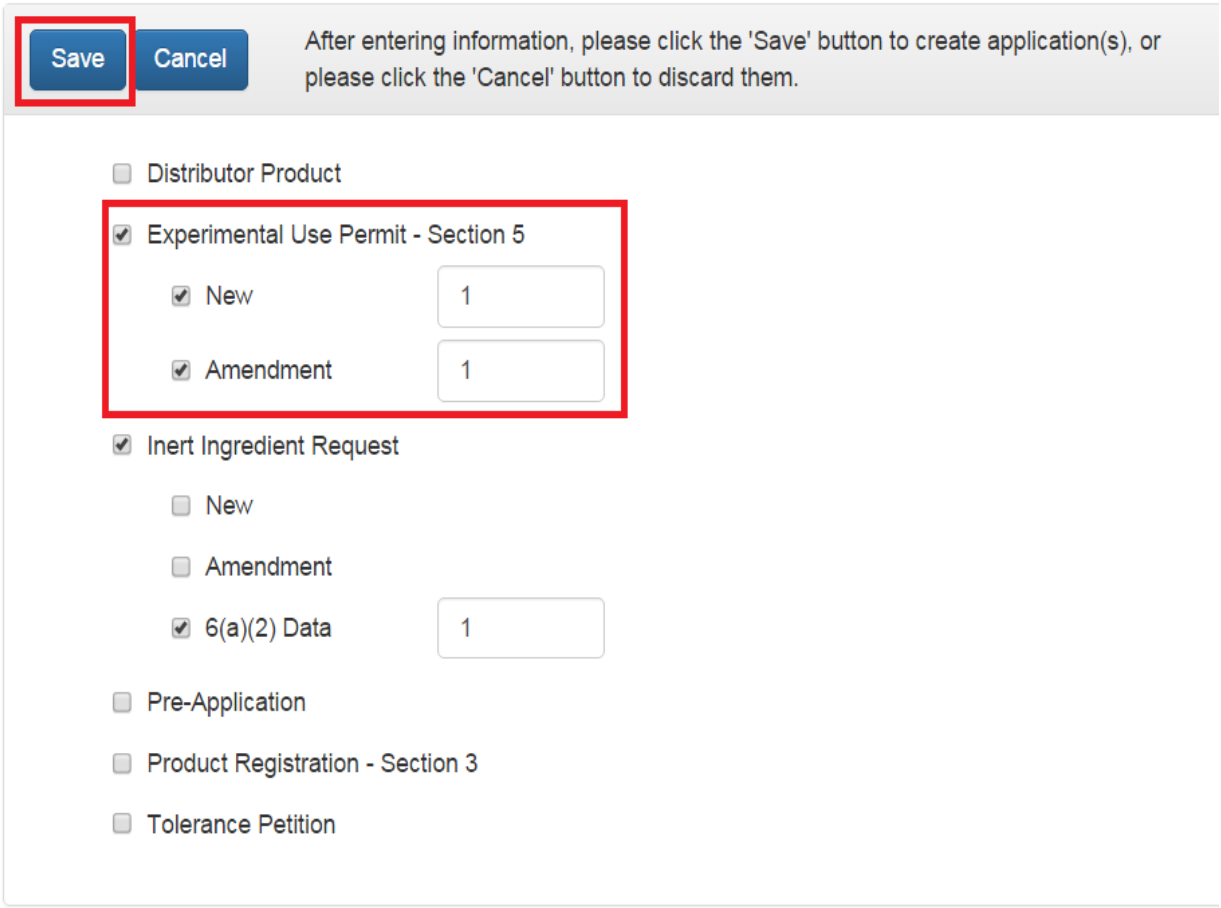


Exhibit 5-10: Choose and Save Applications

Navigation: Select Regulatory type(s) and Application Type(s). After selecting an Application Type, enter the number of that type of application that will be in your package and click the 'Save' button.

Exhibit 5-11 below displays a screen capture of the completed ‘Package Info’ screen.

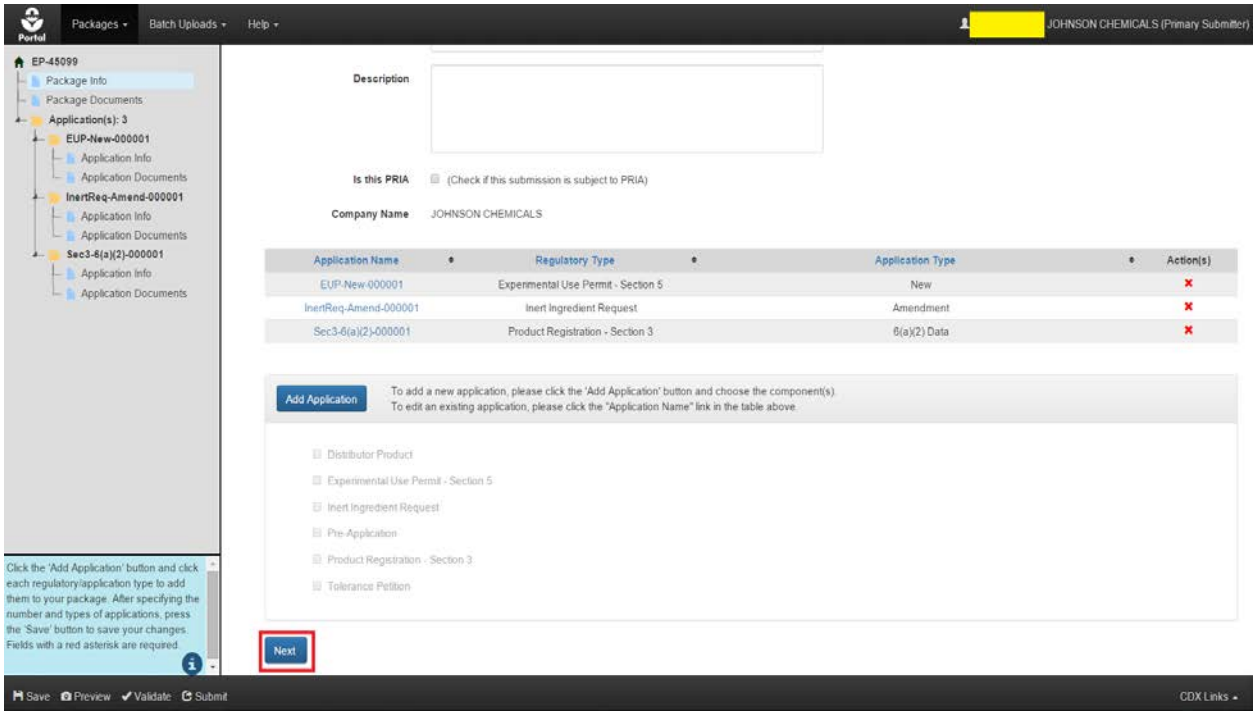


Exhibit 5-11: Completed Package Info Screen

Navigation: After saving the applications to your package, a table will appear on screen displaying the ‘Application Name,’ ‘Regulatory Type,’ ‘Application Type,’ and ‘Action(s)’ columns. You can delete applications from your package by clicking the red ‘x’ icon in the ‘Actions’ column. You will have to confirm deletion via a pop-up window before the application will be deleted. Clicking the blue link under the ‘Application Name’ column will take you to the ‘Application Info’ screen for that application. The application names default to a placeholder name that you may change on their respective ‘Application Info’ screen. You can add more applications by clicking the ‘Add Application’ button. After entering all requisite information on the ‘Package Info’ screen and adding all applications, click the ‘Next’ button to navigate to the ‘Documents for the Package’ screen.

5.6 ‘Documents for the Package’ Screen

The ‘Documents for the Package’ screen (see Exhibit 5-12) allows you to upload and attach package-level documents to your package. You will also be able to associate information with each uploaded document by filling out the requisite fields. Several validation rules are in place for this screen to ensure data quality and prevent errors.

Click the ‘Add’ button to enter information and upload documents. After clicking the ‘Add’ button, the fields become editable. Fill out all necessary fields and click the ‘Browse…’ button to select and upload a document. Click the ‘Save’ button to save your changes.

Important: At least one package-level document is required. Document file names cannot exceed 200 characters. Examples of package-level documents include:

- Submission Cover Letters

- Transmittal Documents
- Payment Receipts

The following fields are displayed on the ‘Document for the Package’ screen:

- **Package Name:** The name given to a package. This field is not editable.
- **Document Type:** Select the document type for the uploaded file. This is a required field.
- **Document Upload:** Click the ‘Browse…’ button and select a file to upload. Empty files, duplicate file names, and .exe files are not allowed into the system. Document file names should not exceed 255 characters. This is a required field.
- **Document Date:** Specify a date, such as the creation date, to link to a document. This is an optional field.
- **Document Group:** Enter a group to which the document is related. This is an optional field.
- **Admin Number:** Enter the Admin Number, Registration Number, or special local need (SLN) number. Please refer to **Appendix B – Admin Number** for more information about admin numbers.
- **Contains CBI?:** Indicate whether the document contains confidential business information (CBI). This is a required field. For document types that should not include CBI, a read-only text will display the following, “Please do not include CBI in the upload for this document type.”
- **Comment:** Add comments to the document being submitted. This is an optional field.
- **Document Title –** Only visible when the ‘Other’ Document Type is selected. Enter a title for the document. This is an optional field.

Exhibit 5-12 below displays a screen capture of the ‘Documents for the Package’ screen.

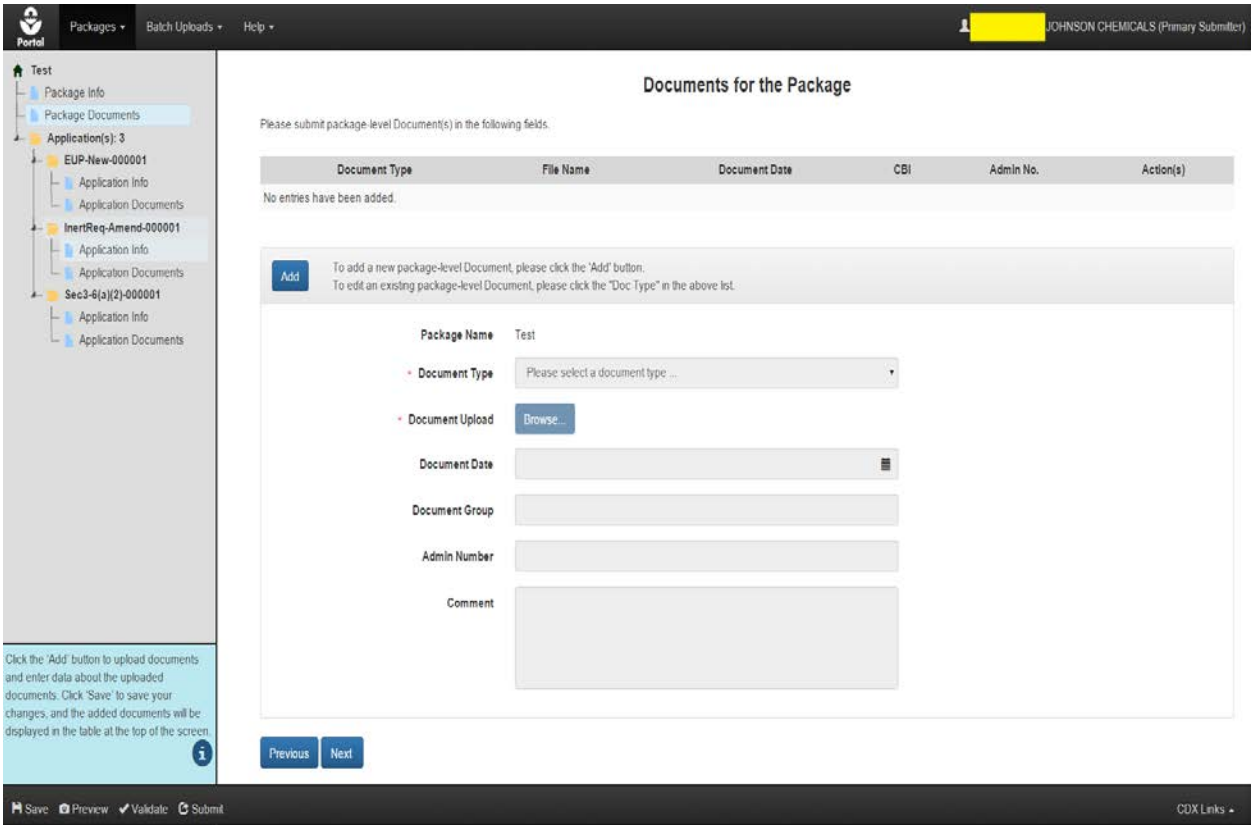


Exhibit 5-12: Documents for the Package Screen

Navigation: Click the ‘Add’ button to upload a document and enter all required information. Click the ‘Save’ button after entering all requisite information. After clicking ‘Save,’ the uploaded document is displayed in a table at the top of the screen.

Exhibit 5-13 below displays the table that appears on the ‘Documents for the Package’ screen once documents are added.

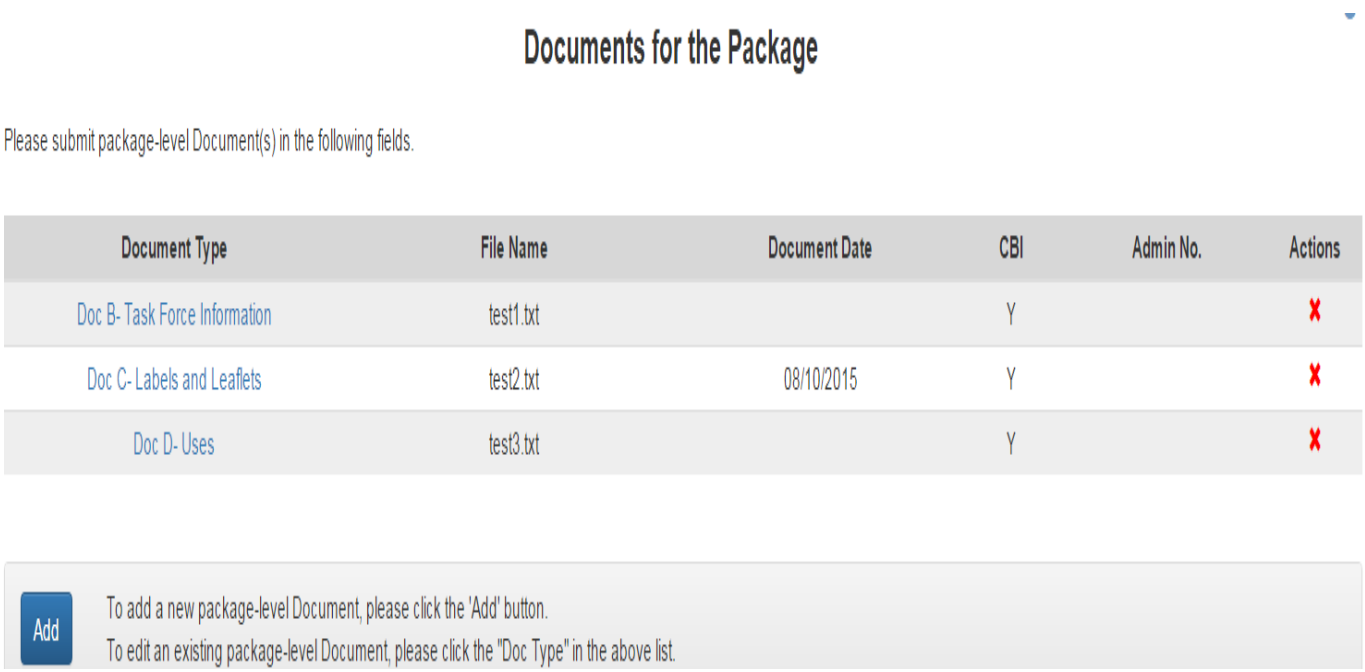


Exhibit 5-13: Documents for the Package Table

Navigation: You can remove uploaded documents by clicking the red 'x' icon in the 'Actions' column of this table. To edit the details of a document, click the blue link in the 'Document Type' column. You can add as many documents as needed by clicking the 'Add' button again.

After uploading all necessary documents, click the 'Next' button to navigate to the 'Application Info' screen for the first application in your package.

5.7 Application Info Screen

The 'Application Info' screen (see Exhibit 5-14) allows you to enter information about an application included in your package. The fields on this screen are generated based on the application type selected on the 'Package Info' screen. Not all fields will be shown for each Application Type and Regulatory Type combination.

The following fields are displayed on the 'Application Info' screen:

- **Application Name:** Enter the name for the application. The system will assign a default name if no name is specified. This is a required field.
- **Initial Submission:** Select whether the application is an initial submission. This is a required field.
- **Description:** Enter a description for the application. The copy icon next to the 'Description' field allows you to copy the package description text that was entered on the 'Package Info' screen. This is an optional field.
- **Admin Number:** Enter the Admin Number, Registration Number, or SLN number. This is a required field. Please refer to **Appendix B – Admin Number** for more information about Admin Number.
- **Regulatory Type:** The Regulatory Type of the application. This field is not editable.

- **Application Type:** The Application Type of the application. This field is not editable.
- **Product Name:** Enter the name of the product. This is a required field.
- **Ingredient Name:** Enter the name of the ingredient. This is a required field.
- **Parent Section 3 No.**: Enter the Parent Section 3 Registration Number associated with Me-Too, SLN, Distributor Product, or another type of registration. This is a required field.
- **Product/Risk Manager:** Select the risk manager for the selected Regulatory Type and Application Type combination. The 'Product/Risk Manager' dropdown is populated based on the chosen application and regulatory type. This is a required field.
- **Me-Too Indicator:** Enter a "final" Me-Too Indicator for particular Regulatory Type – Application Type combinations. This is a required field.
- **Petition Type:** Enter a final Petition Type for a particular Regulatory Type – Application Type combination. This is a required field.
- **Fast Track:** Enter a "final" Fast Track Indicator for particular Regulatory Type – Application Type combinations. This is a required field.
- **Remarks:** Provide questions, notes, or other remarks. This field is optional.
- **Mark for Review:** The 'Mark for Review' check box allows you to mark a page so that it can be returned to at a later time. Clicking this check box highlights the screen in red within the navigation tree and you will have to uncheck this option before you can pass validation of the package. This field is optional.

Exhibit 5-14 below displays a screen capture of the 'Application Info' screen.

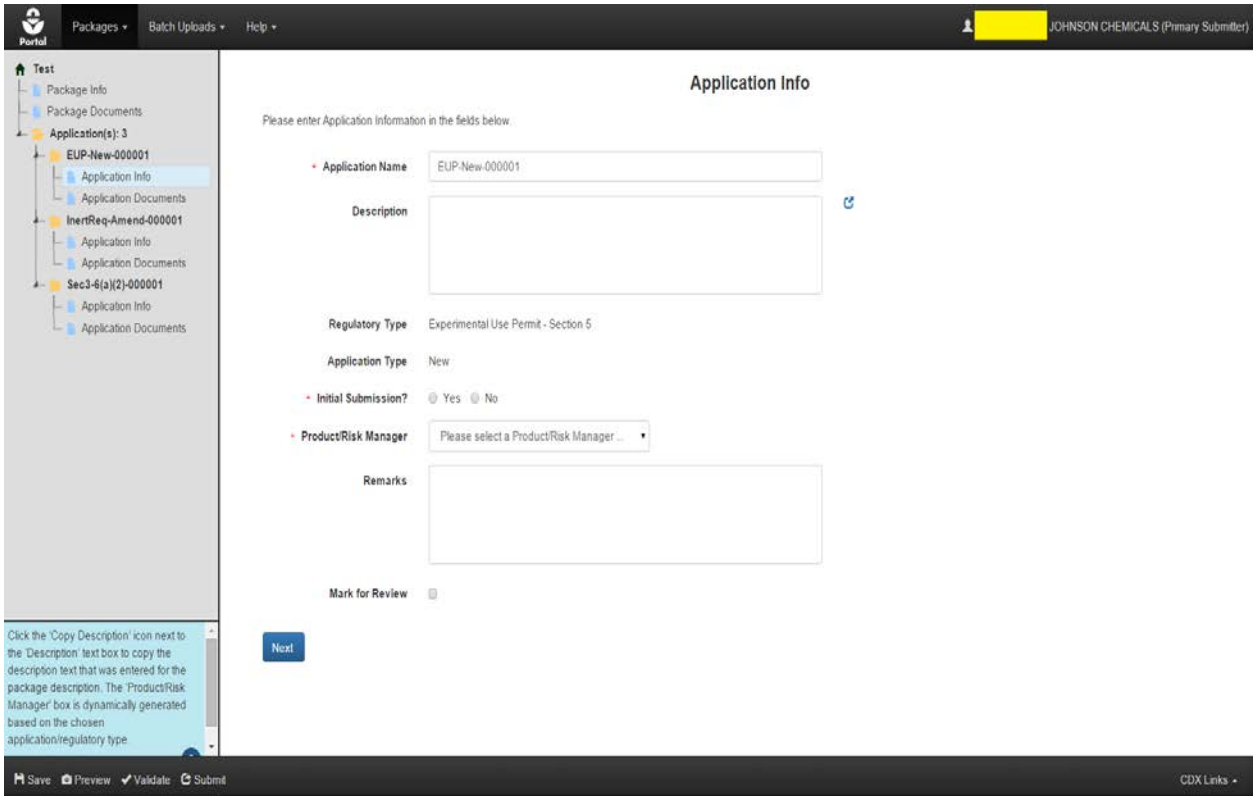


Exhibit 5-14: Application Info Screen

Navigation: After entering all required information, press the 'Next' button to navigate to the 'Documents for the Application' screen for the associated application.

5.8 Documents for the Application Screen

The 'Documents for the Application' screen (see Exhibit 5-15) allows you to upload and attach documents to an application within a package. You will also be able to associate information with each uploaded document by filling out the requisite fields. Fields are displayed based on the chosen document type and sub-type. Not all fields will be shown for each document type and sub-type combination.

Important: At least one application-level document is required for each application. Document file names cannot exceed 200 characters. Examples of application-level documents include:

- Forms
- Labels
- Studies

Important: If you would like to add a study document to an application, proceed to **Section 5.8.1** below and return to this section. Once you have filled out the information for all of your applications, proceed to **Section 10.**

The following fields are displayed on the 'Documents for the Application' screen:

- **Package Name:** The name given to the package. This field is not editable.

- **Application Name:** The name given to the application. This field is not editable.
- **Document Type:** Select the document type for the uploaded file. This is a required field.
- **Document Sub-Type:** Select the document sub-type for the uploaded file. Available sub-types are based on the document type chosen. This is a required field.
- **Document Upload:** Click the 'Browse…' button and select a file to upload. Empty files, duplicate file names, and .exe files are not allowed into the system. Document file names should not exceed 255 characters. This is a required field.
- **Document Title:** Enter the title of the document. This is an optional field.
- **Document Author:** Enter the name of the person who generated the contents of the document. If there are multiple authors, use commas to separate the names. This is an optional field.
- **Document Date:** Enter a date, such as the creation date, to be linked to the document. This can be either a required or optional field based on the document type and document sub-type.
- **Document Group:** Enter the document group to which the document is related. This is an optional field.
- **Contains CBI?:** Indicate whether the document contains CBI. This is a required field. For document types that should not include CBI, a read-only text will display the following, "Please do not include CBI in the upload for this document type."
- **Page Count:** Enter the number of pages in a study. This is a required field.
- **Doc MRID:** A MRID Number associated with a particular application cannot be reused with any other application or packages. Please refer to **Section 4** for information about how to generate root MRIDs. A basic validation, ensuring that the MRID is an eight-digit number, is performed on this field. The MRID is also validated against the backend at submission. This is a required field for study documents.
- **Lab Report Number:** Enter the internal identification number for a study used by the lab that produced the study. This is an optional field.
- **Guideline Number:** Enter the "Guideline Number" associated with a study. This is an optional field.
- **Comment:** Enter comments about the document. This is an optional field.

Exhibit 5-15 below displays a screen capture of the 'Documents for the Application' screen.

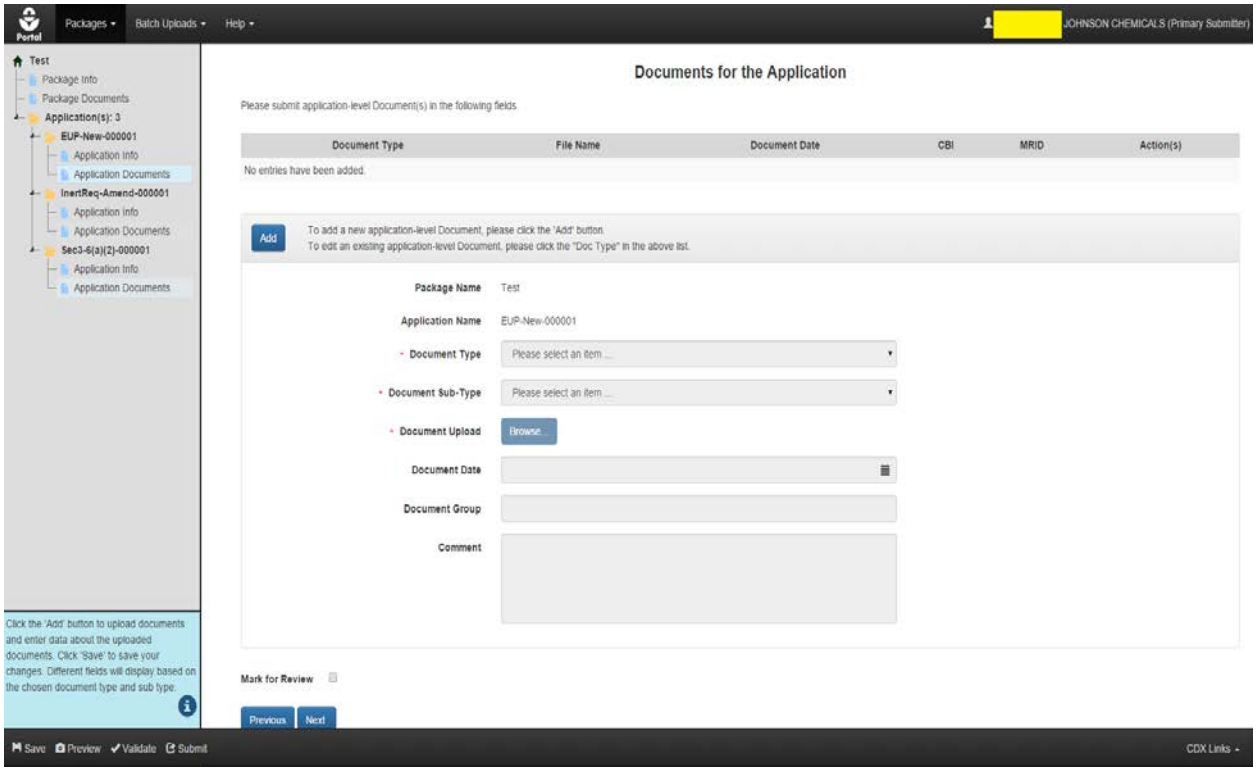


Exhibit 5-15: Documents for the Application Screen

Navigation: Click the ‘Add’ button to enter information and upload documents. After clicking the ‘Add’ button, the fields become editable. Different fields will display based upon the chosen document type and sub-type. Fill out all necessary fields and click the ‘Browse…’ button to select and upload a document. Click the ‘Save’ button to save your changes.

Exhibit 5-16 below displays a screen capture of the ‘Documents for the Application’ table.

Document Type	File Name	Document Date	CBI	MRID	Actions
Doc B- Task Force Information	testzip.zip		Y		
Other	test4.txt	08/11/2015	Y		
Doc E- MRLs	test-ok.zip		Y		

Exhibit 5-16: Documents for the Application Table

Navigation: After clicking the ‘Save’ button, the uploaded document is displayed in a table at the top of the screen. As with the ‘Package Info’ screen, you can click the red ‘x’ icon in the ‘Actions’ column of this table to remove any uploaded documents. You can also click the blue link in the ‘Document Type’ column to edit the details of that document. You can add as many documents as needed by clicking the ‘Add’ button again.

Exhibit 5-17 below displays the ‘Next’ button, which allows the user to proceed to the next ‘Application Info’ Screen.

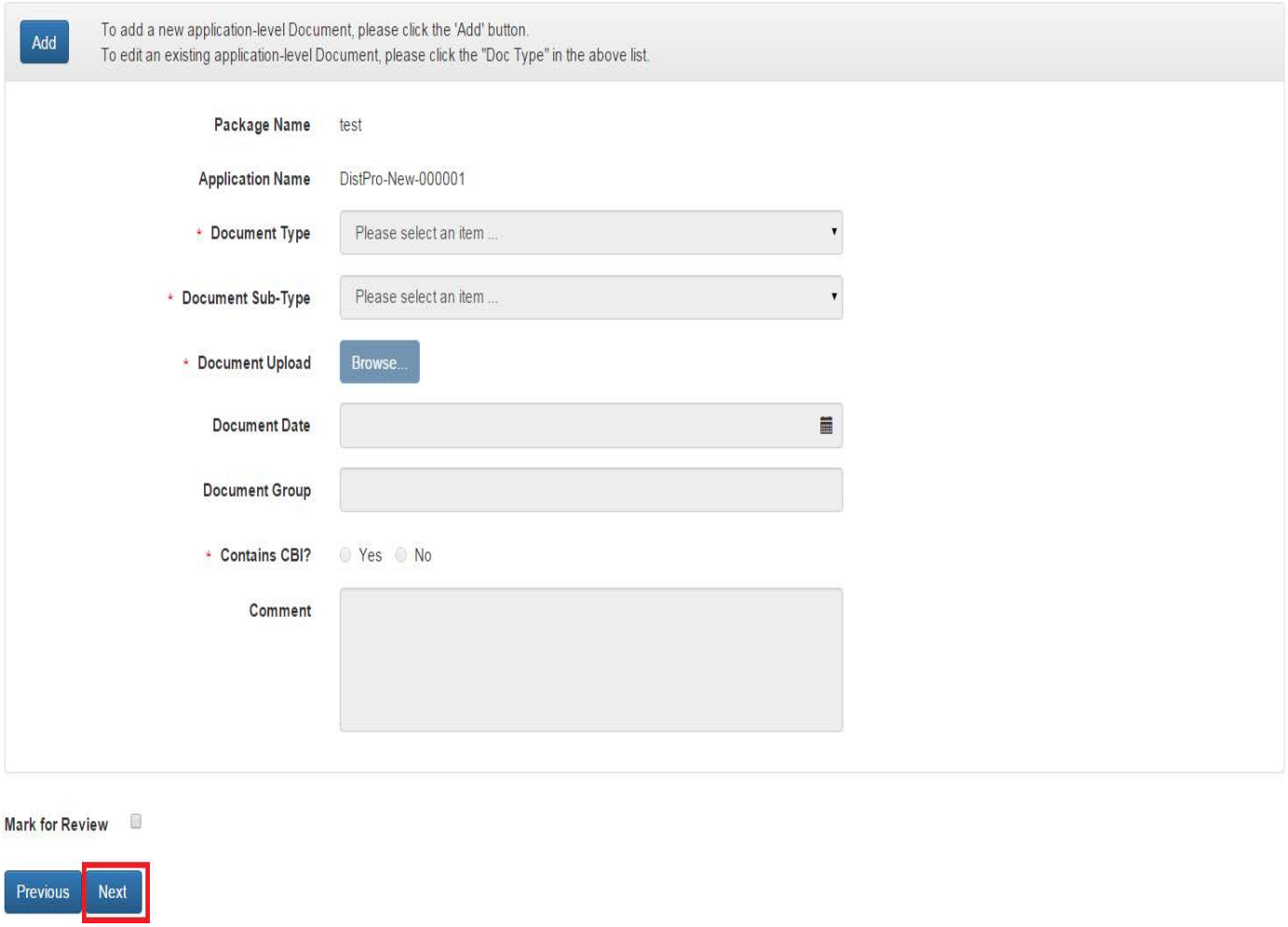


Exhibit 5-17: Proceeding to the Next Application Info Screen

Navigation: After uploading all the necessary documents, click the ‘Next’ button to navigate to the ‘Application Info’ screen for the next application in your package. If there are no subsequent applications to edit, the button will read ‘Submit.’ Proceed to **Section 10** if you see a ‘Submit’ button.

Note: You will have to progress through the ‘Application Info’ and ‘Documents for the Application’ screen for each application in your package. You should not start the submission process until you have filled out the information for all of your applications.

5.8.1 Adding a Study Document on the Documents for the Application Screen

If you would like to add a study document to an application, navigate to that application by clicking its ‘Application Documents’ link within the navigation tree. Click the ‘Add’ button and enter data into all the requisite fields. Choosing the ‘Study’ document type will display the ‘Doc MRID’ field. You will need a six-digit root MRID for each application in your package. If you

need guidance on generating a root MRID, please refer to **Section 4** at the beginning of this document.

Note:

- A root MRID can only be used in a single application. Documents within different applications cannot use the same root MRID.
- Eight-digit MRIDs must be unique for all 'Study' sub-type documents in a package. 'Study Profile' and 'Supplemental Study Data' sub-type documents can share the same eight-digit MRID and should carry the MRID of the parent study.

When entering a MRID, enter the six-digit root followed by a two-digit sequential number for each document uploaded. For example, when adding the first study document, you would append the digits '01' to the root MRID 333049. For the next study document (assuming that the document sub-type is 'Study') you would append '02' to the 333049 root MRID. As such, the first document would have a MRID of 33304901, and the second document would have a MRID of 33304902.

Exhibit 5-18 below displays study documents that have been saved to an application.

Documents for the Application

Please submit application-level Document(s) in the following fields.

Document Type	File Name	Document Date	CBI	MRID	Actions
Study	test4.txt	08/10/2015	Y	33304903	
Study	Test3.txt	08/11/2015	Y	33304901	
Study	Test2.txt	08/11/2015	Y	33304902	

Exhibit 5-18: 'Documents for the Application' Table

6 Distributor Product Applications

This section describes how to prepare the five types of Distributor Product applications that PSP supports. The five types of Distributor Product applications are as follows:

- New Distributor Product
- Add Alternate Distributor Name to an Existing Distributor Product
- Cancel a Single Distributor Product (Including All Distributor Product Names for This Product)
- Cancel a Single Distributor Product Name
- Reinstate a Cancelled Distributor Product

6.1 Adding Distributor Products to Your Package

To add Distributor Products to your package, navigate to the 'Package Info' screen. Once on the 'Package Info' screen, click the 'Add Application' button. Click the check box next to the 'Distributor Product' Regulatory Type. Enter the number of Distributor Product Applications you will require and press the 'Save' button. Once saved, the Distributor Product will appear in a table on the 'Package Info' screen. The application will also appear in the navigation tree.

Exhibit 6-1 below displays adding a Distributor Product Regulatory Type to a package.

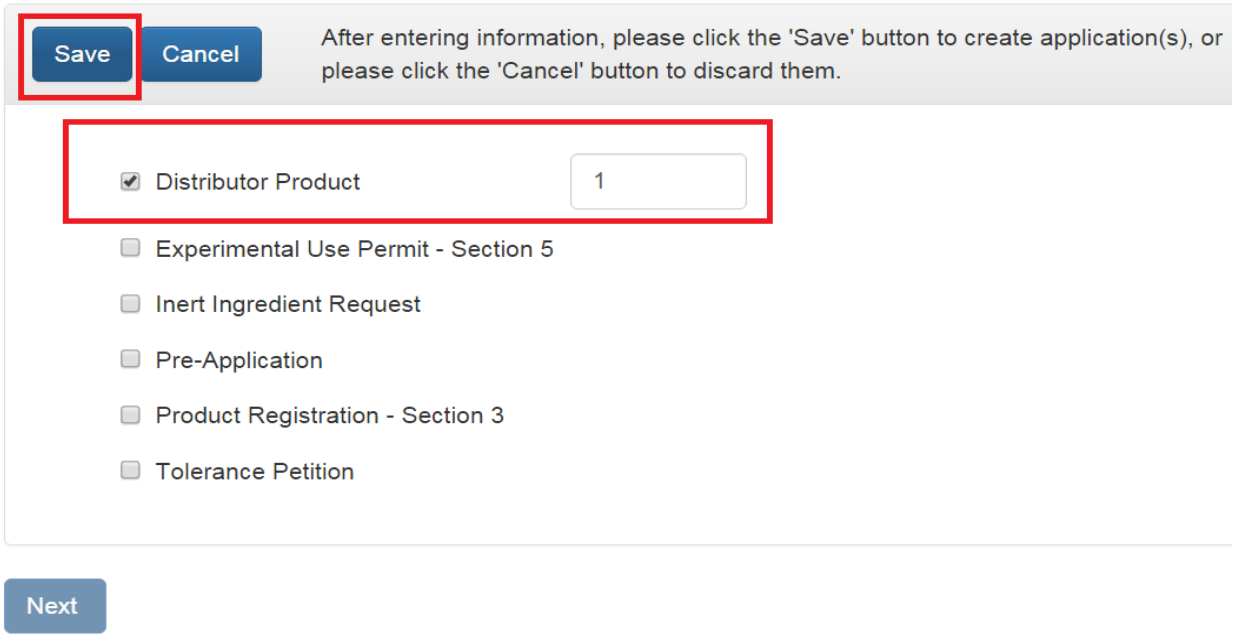


Exhibit 6-1: Adding a Distributor Product to a Package

Navigation: Select the check box next to 'Distributor Product' and indicate the required number of applications in the text box. Click the 'Save' button once finished. Navigate to the 'Application Info' screen for your Distributor Product via the navigation tree.

Once on the 'Application Info' screen for your Distributor Product, you will see the following fields:

- **Regulatory Type:** The regulatory type of the application. This field is not editable.
- **Basic Product Registration No:** The Basic Product Registration Number of the Distributor Product. It is also known as the Parent Section 3 Number. This field is required.
- **Distributor Company Number:** The company number of the Distributor. This field is required.
- **Application Type:** The type of application. There are five potential Distributor Product application types. This field is required.

Fields will dynamically change based on the chosen Distributor Product application type.

Exhibit 6-2 below displays the initial Distributor Product 'Application Info' screen before any applications are chosen.

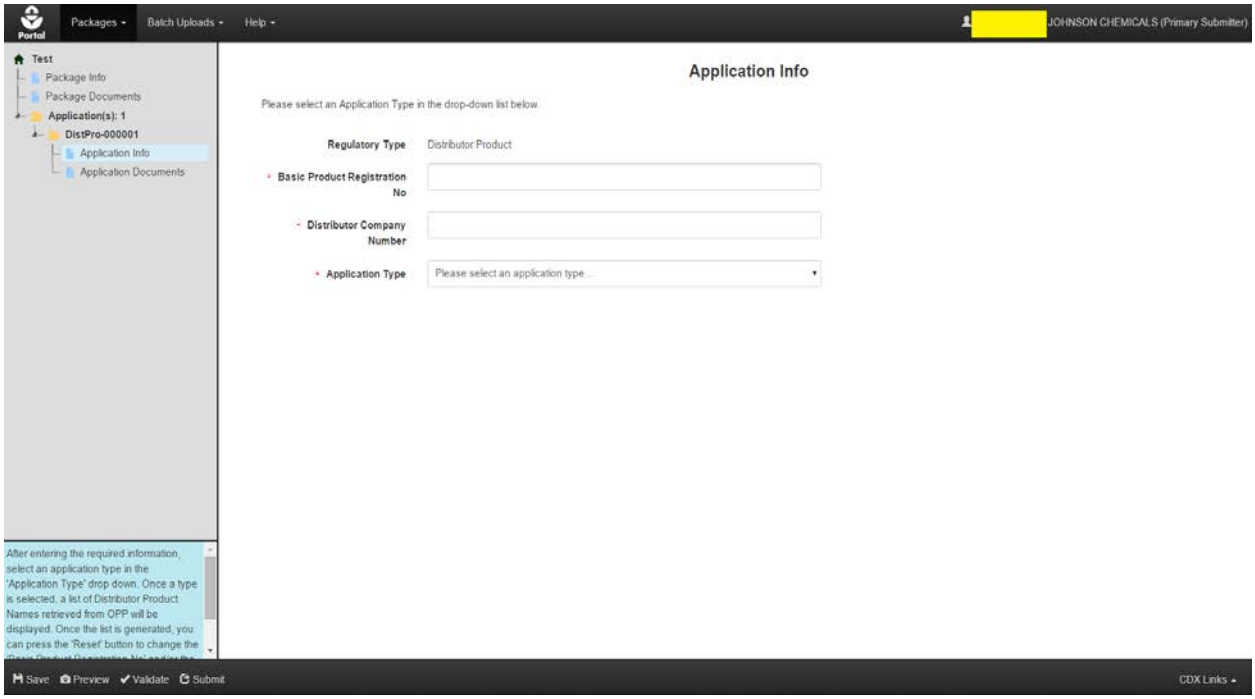


Exhibit 6-2: Initial Distributor Product Application Info Screen

Navigation: Enter all required information and choose a Distributor Product application type. Once all information is entered and a Distributor Product type is chosen, the screen will darken and a spinning status wheel will appear. The system will generate and display a list of active and inactive Distributor Product names based on the entered information and application type.

Note: The system will validate your current company number with the entered 'Basic Product Registration No' to ensure that you are accessing PSP with the correct submitting organization.

Note: A list of Distributor Product names will be generated for all Distributor Product application types except for 'New' Distributor Products.

6.1.1 New Distributor Products

After entering the ‘Basic Product Registration No’ and ‘Distributor Company Number’ on the ‘Application Info’ screen, choose the ‘New Distributor Product’ option from the ‘Application Type’ dropdown. Once the ‘New Distributor Product’ option is chosen, additional fields will appear on screen.

The additional fields are as follows:

- **Application Name:** The name of the application. You can change the name of the application for easier identification. A default name will be generated by the system. This field is required.
- **Distributor Product Name:** The name of the Distributor Product. This field is required.
- **Description:** Description of the application. This field is optional.
- **Remarks:** Allows the user to provide questions, notes, or other remarks. This field is optional.

Exhibit 6-3 below displays a screen capture of the ‘Application Info’ screen for the ‘New Distributor Product’ application type.

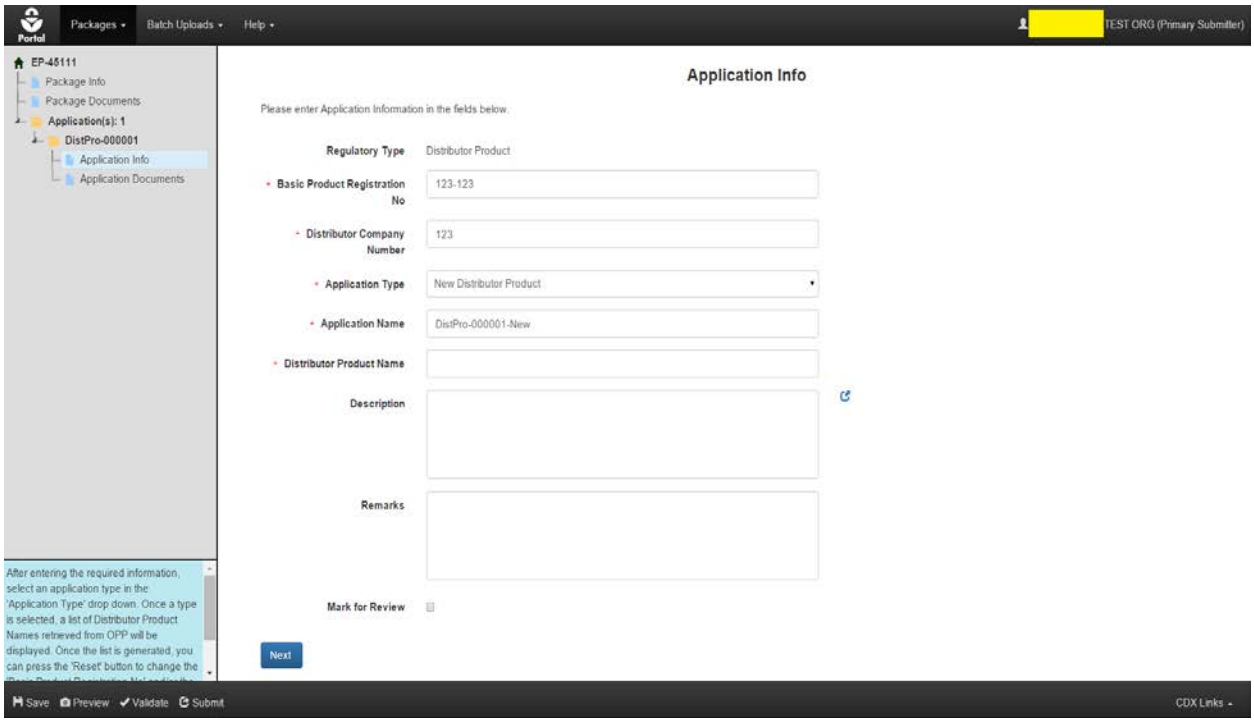


Exhibit 6-3: New Distributor Product Application Info Screen

Navigation: Enter information into all required fields and click the ‘Next’ button.

Note: The ‘Documents for the Application’ screen functions the same for all regulatory/application types. For assistance with completing the ‘Documents for the Application’ screen, please refer to **Section 5.8.**

6.1.2 Add Alternate Distributor Name to an Existing Distributor Product

After entering the ‘Basic Product Registration No’ and ‘Distributor Company Number’ on the ‘Application Info’ screen, choose the ‘Add Alternate Distributor Name to an Existing Distributor Product’ option from the ‘Application Type’ dropdown.

The screen will darken and a spinning status wheel will appear. Once the system has finished processing, a list of Distributor Product Names will appear on screen along with their status. Additional fields will also appear on screen. The additional fields are as follows:

- **Application Name:** The name of the application. You can change the name of the application for easier identification. A default name will be generated by the system. This field is required.
- **Distributor Product Name:** The name of the Distributor Product. This field is required.

You have two options on this screen.

1. You may choose to enter a new Distributor Product name (indicated by the ‘Use New Distributor Product Name’ radio button). After reviewing the table, enter a new Distributor Product name in the ‘Distributor Product Name’ field.
2. Use an inactive Distributor Product name (indicated by the ‘Use Inactive Distributor Product Name’ radio button). Upon selecting this radio button option, the table will update and only display Distributor Products names with an ‘Inactive’ status. Select the radio button next to the name you would like to use.

Exhibit 6-4 below displays the ‘Use New Distributor Product Name’ radio button.

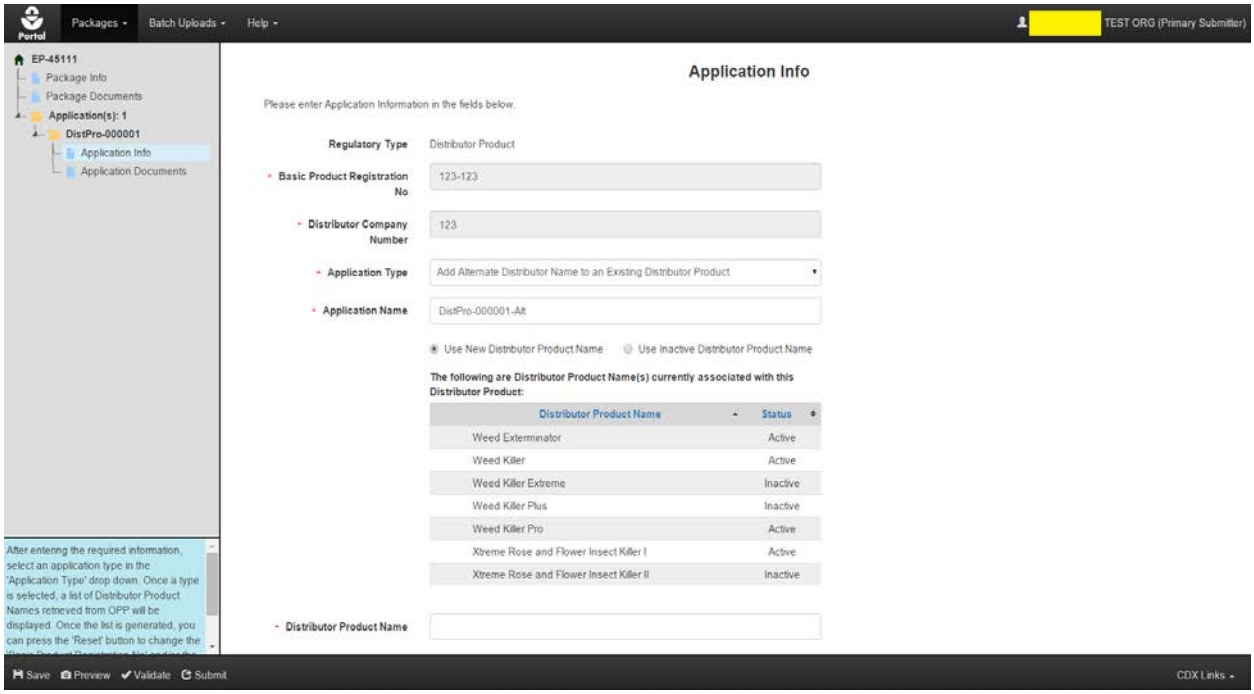


Exhibit 6-4: Add Alternate Distributor Name to an Existing Distributor Product: First Option

Navigation: Enter a name into the 'Distributor Product Name' field and click the 'Next' button. Exhibit 6-5 below displays the 'Use Inactive Distributor Product Name' radio button option.

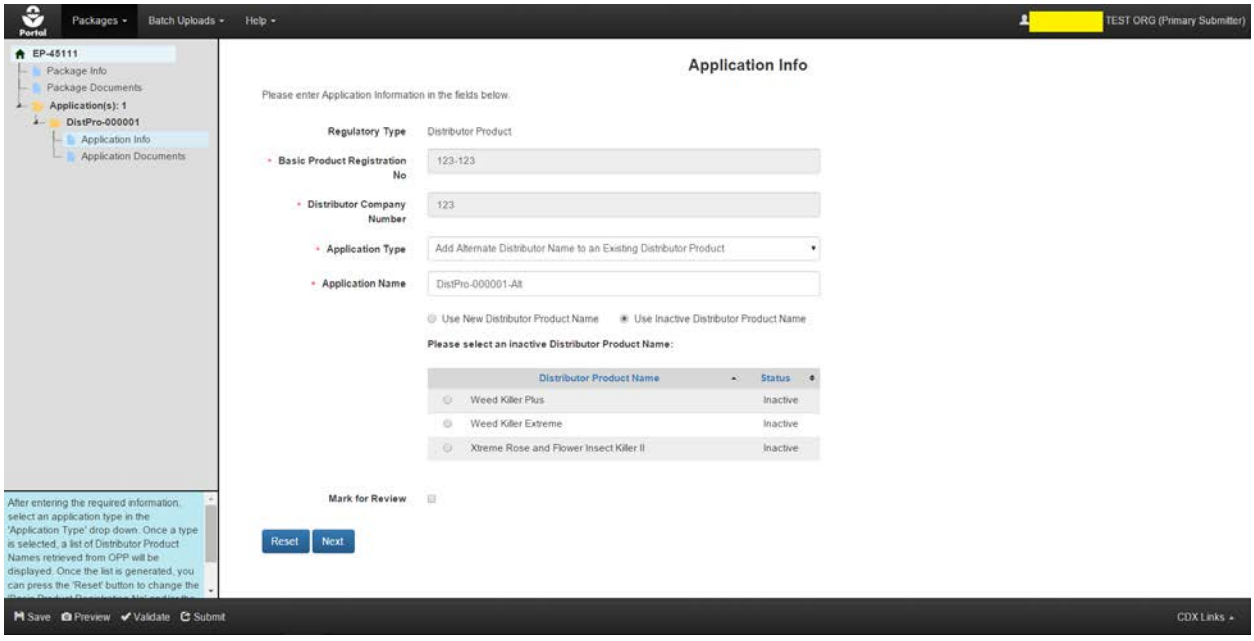


Exhibit 6-5: Add Alternate Distributor Name to an Existing Distributor Product: Second Option

Navigation: Select a Distributor Product Name and click the 'Next' button.

6.1.3 Cancel a Distributor Product (Including All Distributor Product Names for This Product

After entering the ‘Basic Product Registration No’ and ‘Distributor Company Number’ on the ‘Application Info’ screen, choose the ‘Cancel a Distributor Product (Including All Distributor Product Names for This Product)’ option from the ‘Application Type’ dropdown.

The screen will darken and a spinning status wheel will appear. Once the system has finished processing, a list of active Distributor Product Names will appear on screen. An additional field will also appear on screen. The additional field is as follows:

- **Application Name:** The name of the application. You can change the name of the application for easier identification. A default name will be generated by the system. This field is required.

Text above the table will read: “These Distributor Product Names will be deleted together with the Distributor Product:”

Exhibit 6-6 below displays the ‘Cancel a Distributor Product (Including All Distributor Product Names for This Product)’ application type.

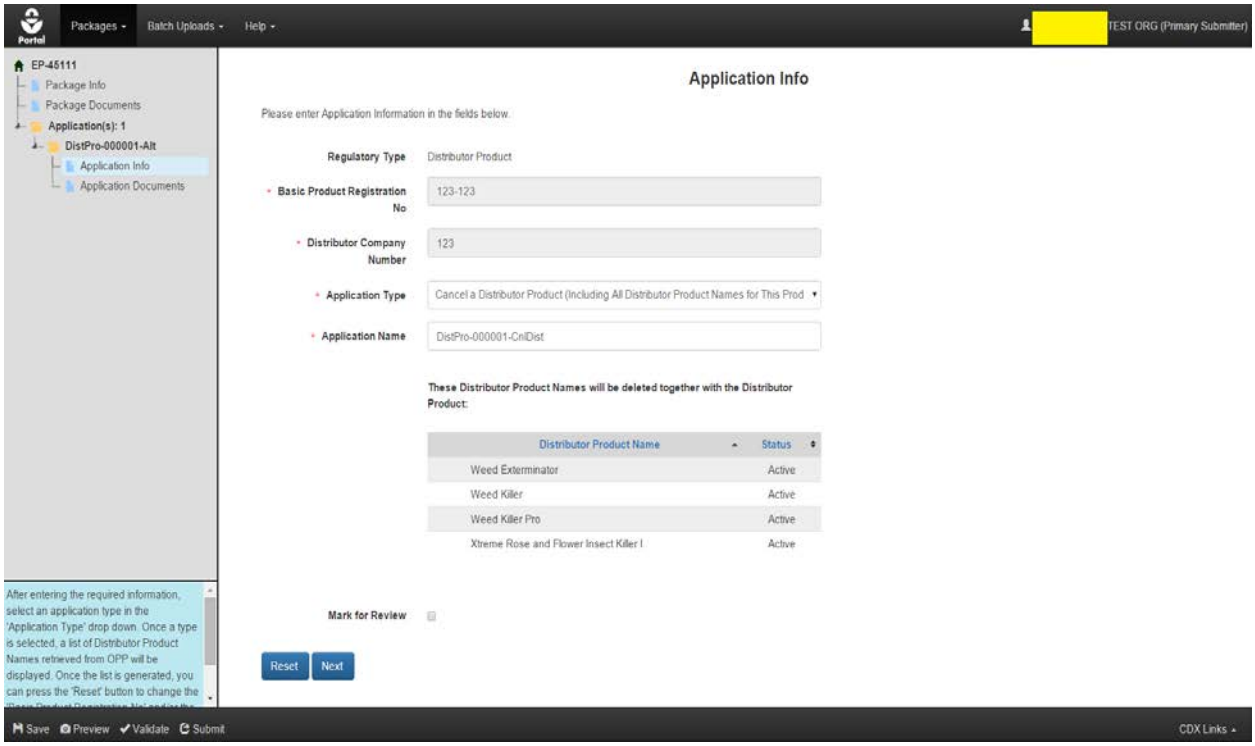


Exhibit 6-6: Cancel a Distributor Product (Including All Distributor Product Names for This Product) Application Info Screen

Navigation: Confirm the list of Distributor Product names and click the ‘Next’ button.

6.1.4 Cancel a Single Distributor Product Name

After entering the ‘Basic Product Registration No’ and ‘Distributor Company Number’ on the ‘Application Info’ screen, choose the ‘Cancel a Single Distributor Product Name’ option from the ‘Application Type’ dropdown.

The screen will darken and a spinning status wheel will appear. Once the system has finished processing, a list of active Distributor Product Names will appear on screen. An additional field will also appear on screen. The additional field is as follows:

- **Application Name:** The name of the application. You can change the name of the application for easier identification. A default name will be generated by the system. This field is required.

Text above the table will read: “Please select an active Distributor Product Name you would like to cancel:”

Exhibit 6-7 below displays the ‘Cancel a Single Distributor Product Name’ application type.

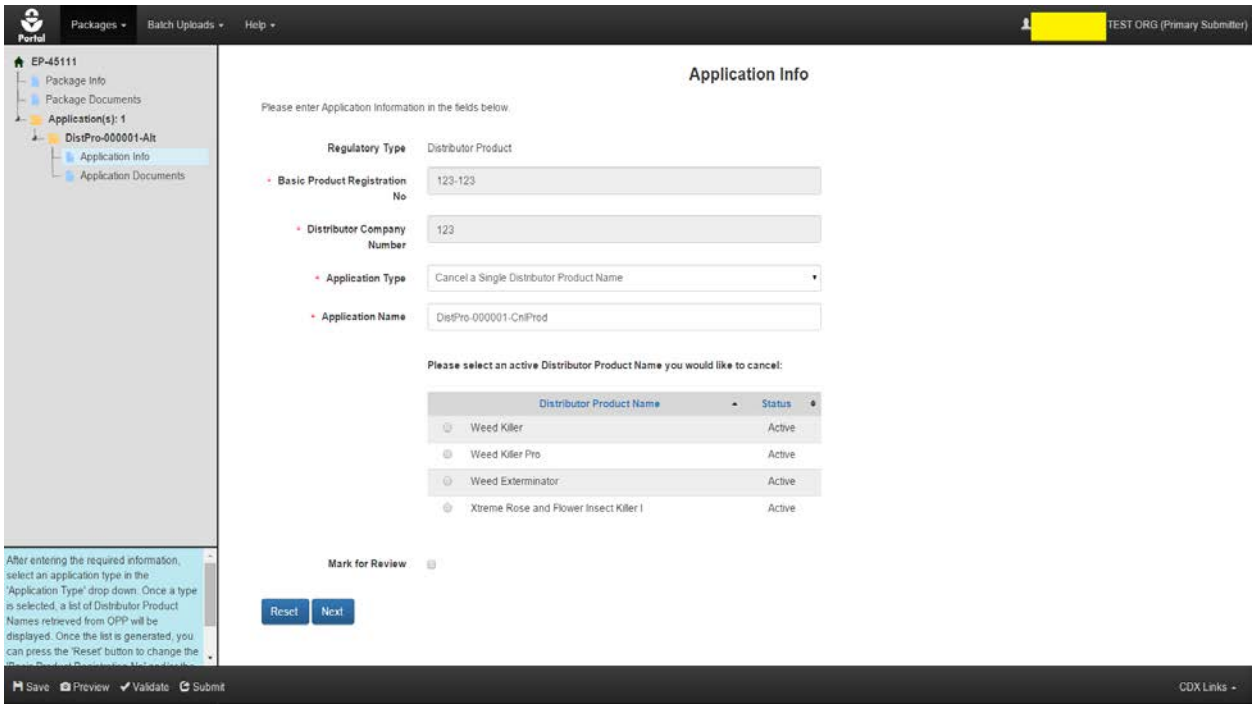


Exhibit 6-7: Cancel a Single Distributor Product Name Application Info Screen

Navigation: Select the radio button next to the active Distributor Product Name that you would like to cancel. Click the ‘Next’ button.

6.1.5 Reinstate a Cancelled Distributor Product

After entering the ‘Basic Product Registration No’ and ‘Distributor Company Number’ on the ‘Application Info’ screen, choose the ‘Reinstate a Cancelled Distributor Product’ option from the ‘Application Type’ dropdown.

The screen will darken and a spinning status wheel will appear. Once the system has finished processing, a list of inactive Distributor Product Names will appear on screen. An additional field will also appear on screen. The additional field is as follows:

- **Application Name:** The name of the application. You can change the name of the application for easier identification. A default name will be generated by the system. This field is required.

Text above the table will read: “Please select one or more inactive Distributor Product Name(s) you would like to reinstate along with the Distributor Product:”

Exhibit 6-8 below displays the ‘Reinstate a Cancelled Distributor Product’ application type.

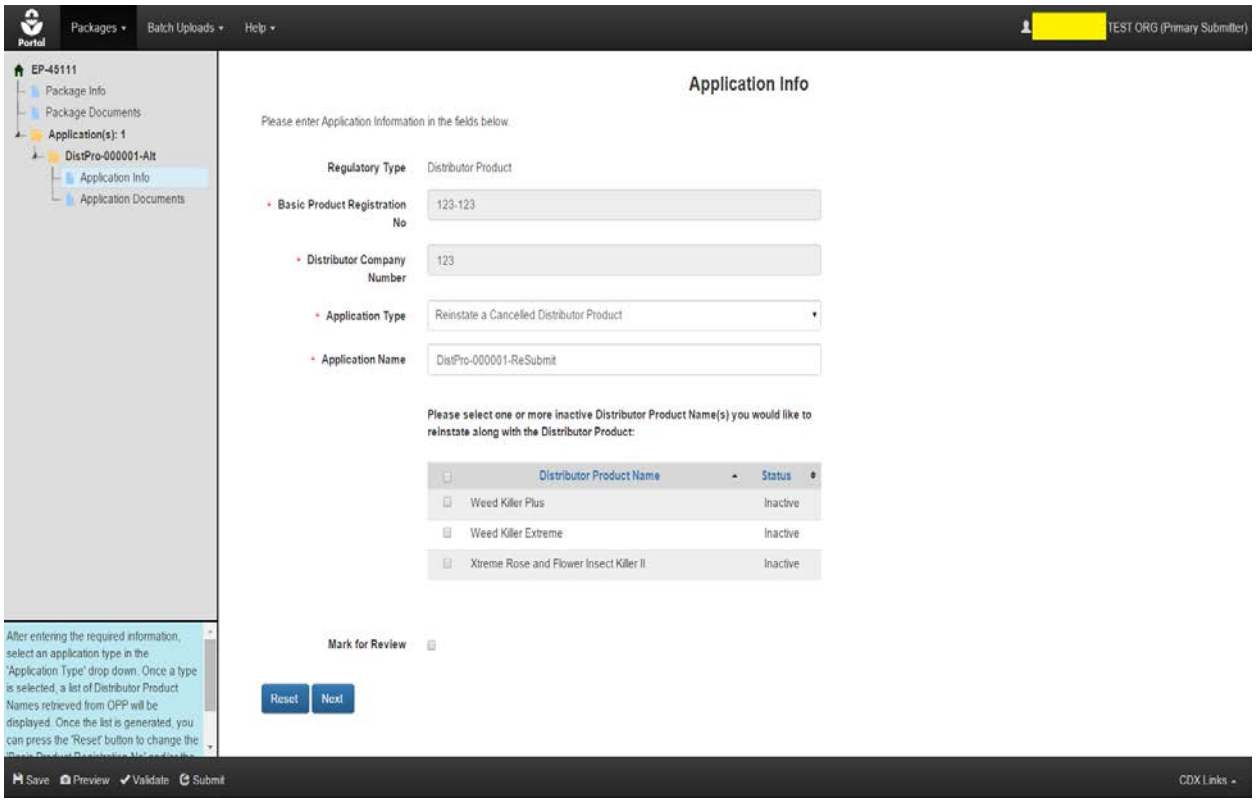


Exhibit 6-8: Reinstate a Cancelled Distributor Product Application Info Screen

7 Batch Upload

The batch upload functionality of the PSP application allows you to upload packages created using the e-Dossier Builder application or your company's IT systems in the XML e-Submission format.

Important: Document file names within batch uploads cannot exceed 200 characters.

7.1 Upload Packages in the XML e-Submission Format

7.1.1 Home screen

To upload a package created using your company's IT systems in the XML e-Submission format, click the 'Upload XML e-Submission Packages' link on the 'Home' screen.

Exhibit 7-1 below displays the 'Upload XML e-Submission Packages' option on the 'Home' screen.

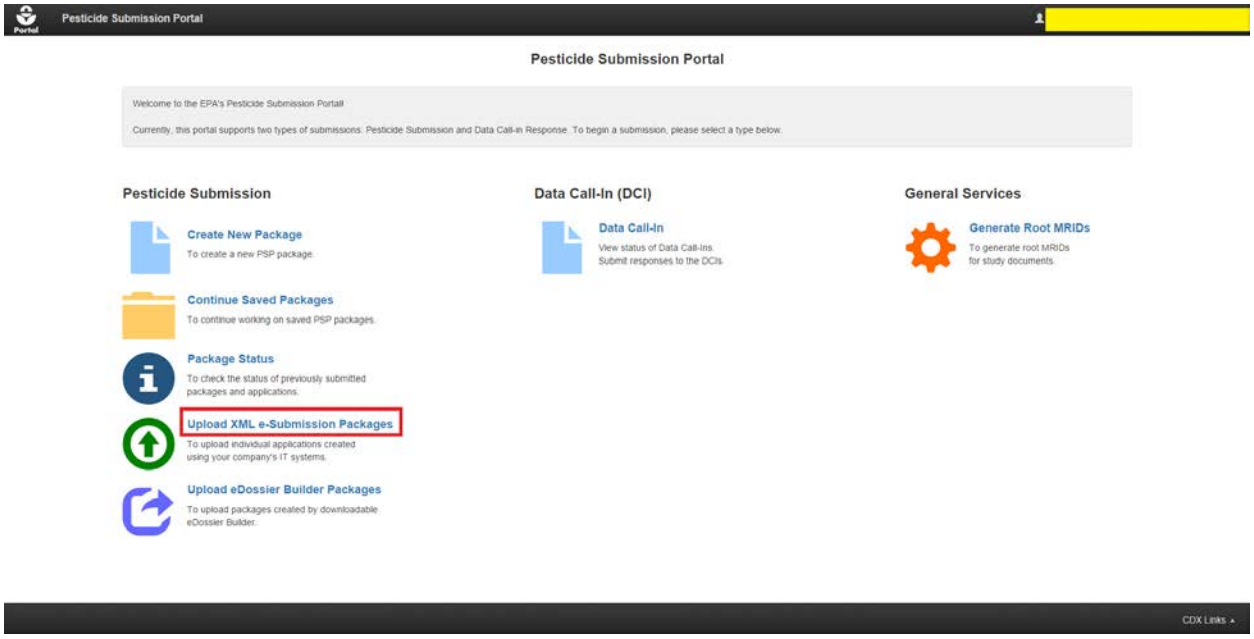


Exhibit 7-1: Selecting 'Upload XML e-Submission Packages' Option

Navigation: Click the 'Upload XML e-Submission Packages' link on the home screen.

7.1.2 Upload Packages Screen

Click the 'Browse…' button to upload a package created using your company's IT systems in the XML e-Submission format.

Important: Please ensure that files within your package do not contain special characters. Also, the XML within your package should have an e-PRISM prefix as the first part of the file name.

After uploading the package, press the ‘Submit’ button to submit the package to OPP. You will be navigated to the ‘Create Passphrase’ screen to create a passphrase that will encrypt your uploaded package.

Important: If you forget the passphrase, you will be unable to access the package. If you lose or forget the passphrase, you must create a new package and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company.

You will need this passphrase to access the copy of record for your batch upload. The submission process will begin once you have created the passphrase. If you need assistance creating a passphrase, please reference **Section 5.2** above. If you need assistance with the package submission process, please refer to **Section 10**. If your package does not pass validation, you will have to make modifications to the package contents and XML and then resubmit via the ‘Upload XML e-Submission Packages’ option.

Exhibit 7-2 below displays a screen capture of the ‘Upload XML e-Submission Packages’ screen.

Note: This screen will provide you a link to the correct page for uploading e-Dossier packages if you mistakenly upload an e-Dossier package.

Exhibit 7-2: Navigate the Upload XML e-Submission Packages Screen

Navigation: Click the ‘Browse…’ button and upload a package created using your company’s IT systems in the XML e-Submission format. After the package is uploaded, click the ‘Submit’ button to start the submission process.

7.2 Upload e-Dossier Builder Packages

7.2.1 Home Screen

To upload a package created using the e-Dossier Builder, click the ‘Upload eDossier Builder Packages’ link on the ‘Home’ screen.

Exhibit 7-3 below displays the ‘Upload eDossier Builder Packages’ option on the ‘Home’ screen.

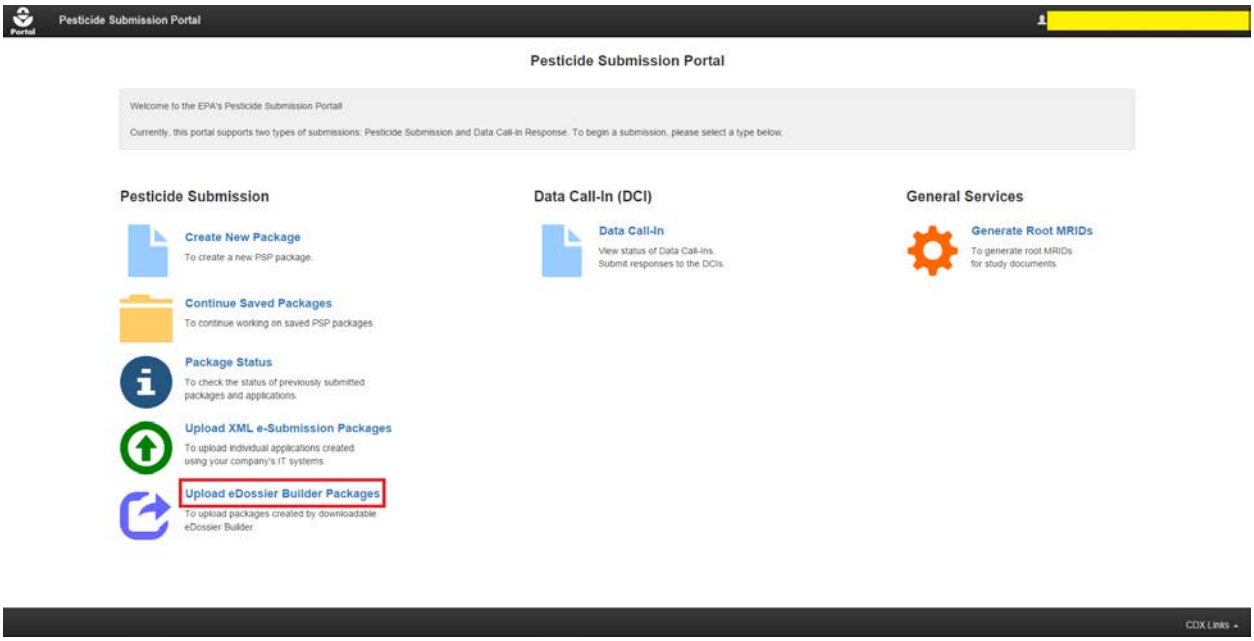


Exhibit 7-3: Selecting ‘Upload eDossier Builder Packages’ Option

Navigation: Click the ‘Upload eDossier Builder Packages’ link on the ‘Home’ screen.

7.2.2 Upload eDossier Builder Packages Screen

Click the ‘Browse…’ button to upload a package created using the e-Dossier Builder. After uploading the package, press the ‘Submit’ button.

Important: Please ensure that files within your package do not contain special characters. Also, your package should contain a main.xml file, which eDossier Builder automatically creates upon finalizing a package.

You will be navigated to the ‘Create Passphrase’ screen to create a passphrase that will encrypt your uploaded package. You will need this passphrase to access your package.

Important: If you forget the passphrase, you will be unable to access the package. If you lose or forget the passphrase, you must create a new package and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original

creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company.

If you need assistance creating a passphrase, please reference **Section 5.2**. Uploaded e-Dossier Builder packages are converted into an online PSP form after being submitted. After creating a passphrase for your package, all package data will populate onto the necessary PSP application and you will be navigated to the 'Package Info' screen to name your package. You may then proceed with package validation and submission as you would with a package created using the PSP application. If you need assistance with package creation and submission, please reference **Section 5** and **Section 10,** respectively.

Note: This screen will provide you a link to the correct page for uploading packages created by your company's IT systems in the XML e-Submission format if you mistakenly upload the wrong package type.

Exhibit 7-4 below displays a screen capture of the 'Upload eDossier Builder Packages' screen.

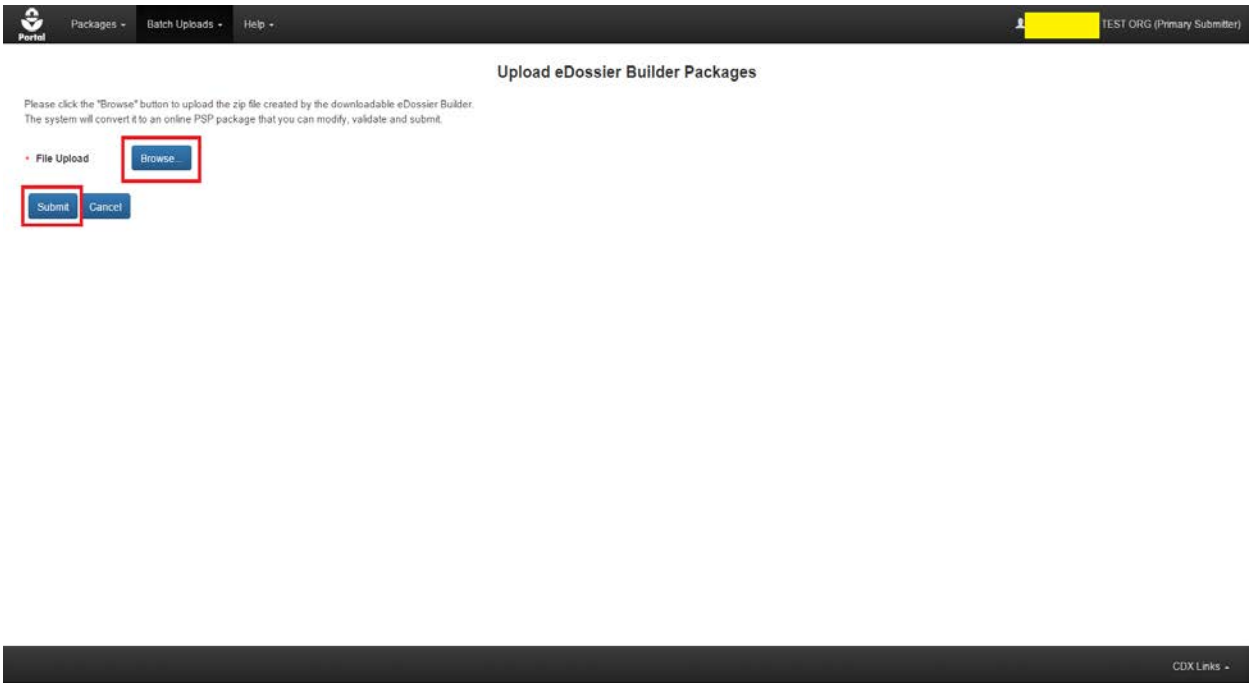


Exhibit 7-4: Navigate the Upload e-Dossier Builder Packages Screen

Navigation: Click the 'Browse…' button and upload a package created using the e-Dossier Builder application. After the package is uploaded, click the 'Submit' button. You will be navigated to the 'Create Passphrase' screen.

8 Continue Saved Packages

You can return to a saved package at any time via the ‘Continue Saved Packages’ screen. This option is located on the ‘Home’ screen and within the ‘Packages’ dropdown in the application header.

The ‘Continue Saved Packages’ screen allows you to view and access all packages with a status of ‘Awaiting User Completion.’ All packages, which have not yet been submitted, will have this status. You can create a new package from this screen by clicking the ‘Create New Package’ button. You can also delete packages by clicking the ‘Delete’ icon in the ‘Actions’ column. To access a package, click the blue link within the ‘Package ID’ column to navigate to the ‘Enter Passphrase’ screen for that package.

Exhibit 8-1 below displays a screen capture of the ‘Continue Saved Packages’ screen.

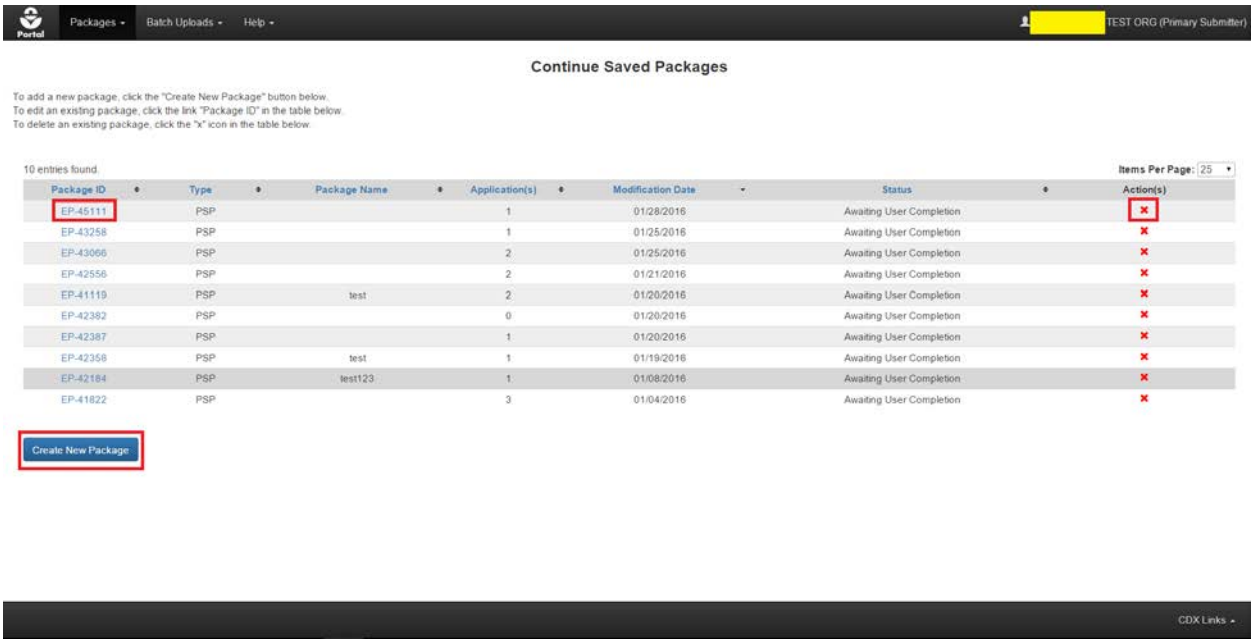


Exhibit 8-1: Continue Saved Packages Screen

Navigation: Click the blue link in the ‘Package ID’ column to navigate to the ‘Enter Passphrase’ screen for the selected package. After entering the passphrase you will be able to continue editing the package.

Click the ‘Create New Package’ button to start the package creation process for a new package. You can remove packages on this screen by clicking the ‘Remove’ icon in the ‘Actions’ column.

8.1 Enter Passphrase Screen

To edit a package you must first enter the passphrase that was used to encrypt that package. The ‘Enter Passphrase’ screen allows you to enter the passphrase associated with the submission.

Exhibit 8-2 below displays a screen capture of the ‘Enter Passphrase’ screen.

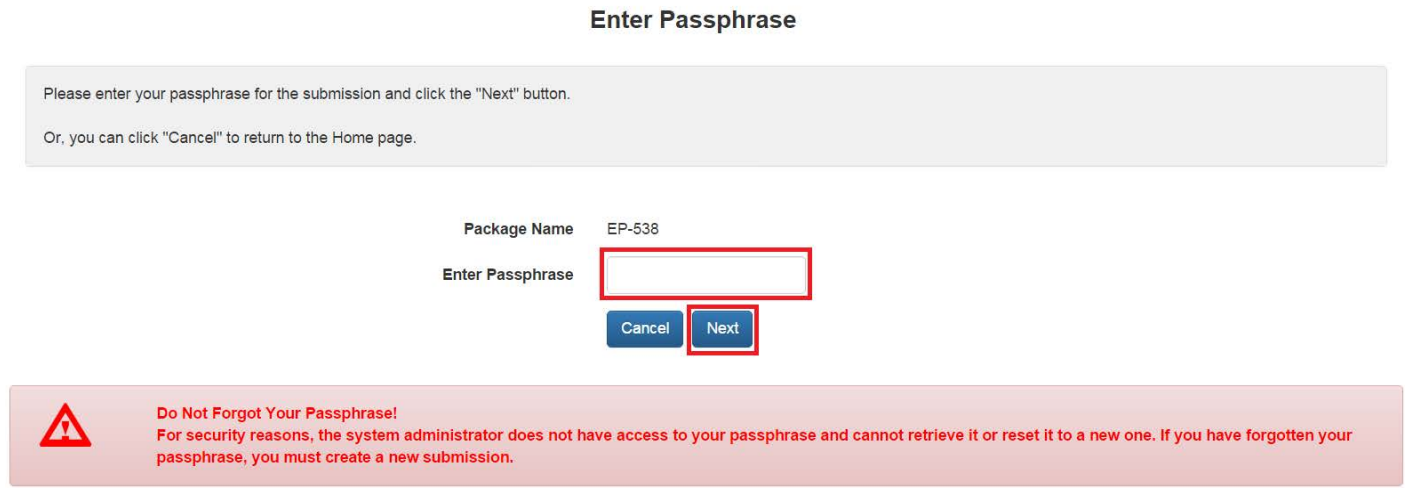


Exhibit 8-2: Enter Passphrase Screen

Navigation: Enter the passphrase that you originally created and associated with the package and click the 'Next' button to navigate to the 'Package Info' screen, seen below in Exhibit 8-3.

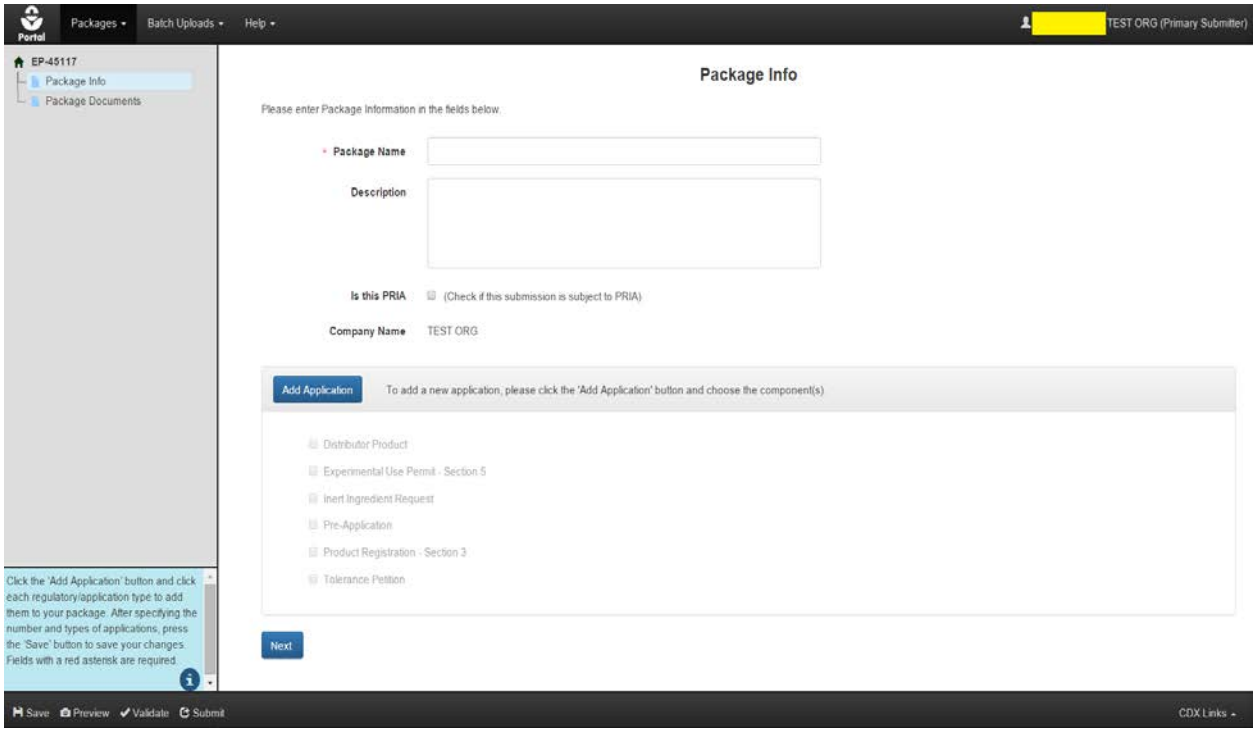


Exhibit 8-3: Package Info Screen

9 Validate

You can click the ‘Validate’ icon at any stage of completing a PSP package. The ‘PSP Package Validation’ pop-up window is displayed when you click the ‘Validate’ icon. The ‘PSP Package Validation’ pop-up window displays a report of all validation errors. During the validation process, the application validates each screen of the PSP package to find missing and invalid data.

Validation Errors: Errors can be fixed by clicking the error link. The links will display the *Screen Title Name* (e.g., Package Info) and the associated error. After you click a link, the main application screen will display the section where the error occurred so you can easily fix the error. Once you have fixed the error, click the ‘Validate’ icon again to refresh the ‘PSP Package’ pop-up window. If the information you fixed passes validation, the error will be removed from the ‘PSP Package Validation’ pop-up window. You must fix all validation errors in order to submit the package.

You can close the ‘PSP Package Validation’ pop-up window by clicking the ‘X’ button located at the top right of the window.

Exhibit 9-1 below shows the screen capture for the ‘PSP Package Validation’ pop-up window:

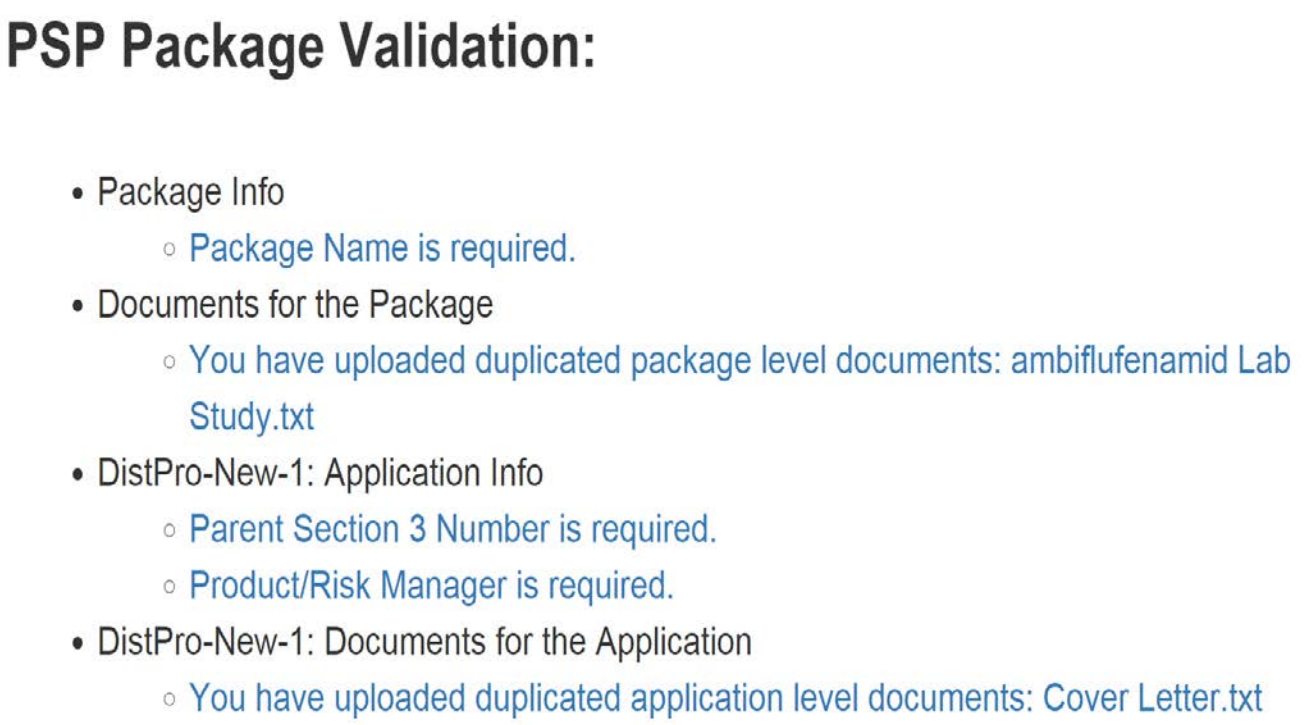


Exhibit 9-1: PSP Package Validation Pop-Up Window

10 Submit Package to EPA via CDX

Both Primary Submitters and Authorized Agents have the ability to sign and submit a PSP package to EPA. Once you complete all required information and pass validation, the system will allow you to submit.

10.1 Submitter Information Screen

Click the ‘Submit’ icon located in the application footer of the PSP application to access the ‘Submitter Information’ screen. The system requires you to review your contact information provided during CDX registration and serves as a reminder for which company you are submitting.

Exhibit 10-1 displays a screen capture of the ‘Submitter Information’ screen.

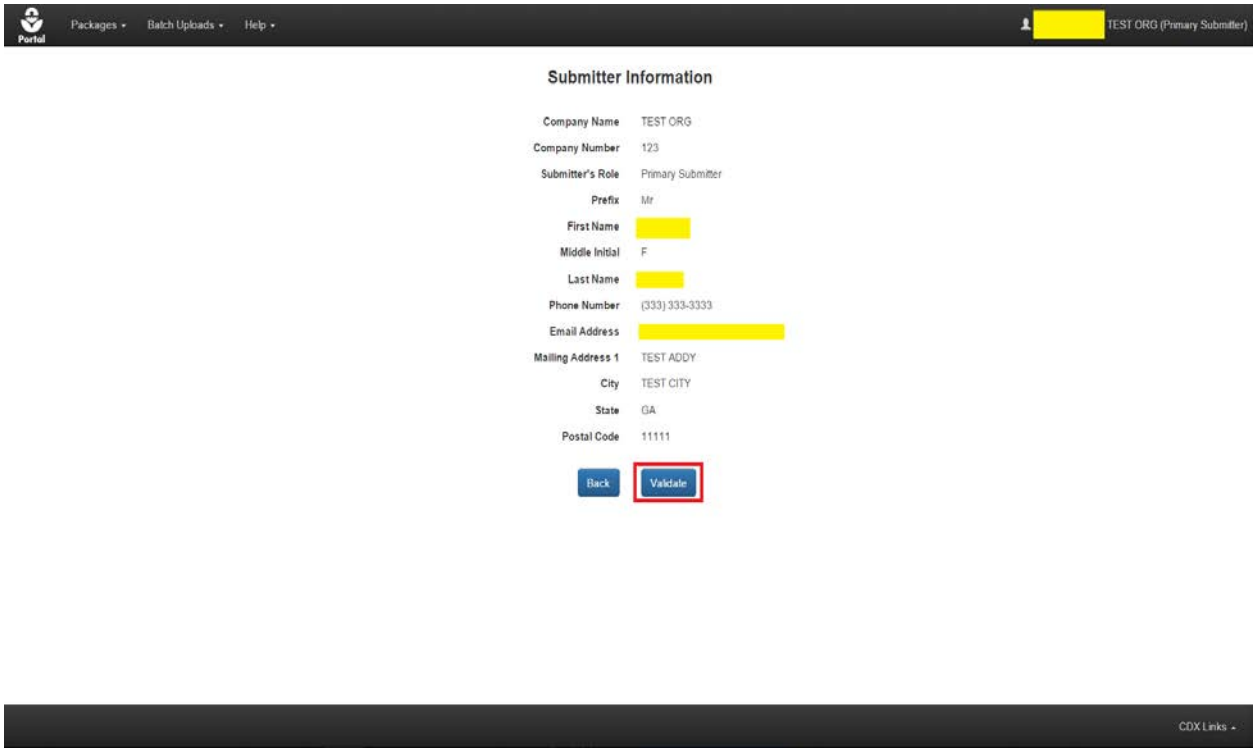


Exhibit 10-1: Submitter Information Screen

Navigation: Click the ‘Validate’ button, the screen will darken and a spinning status wheel will appear while your package is checked for validation errors and viruses. After the validation process completes, you will be navigated to the ‘Submission Process: Validate’ screen.

10.2 Submission Process: Validate Screen

The ‘Submission Process: Validate’ screen notifies you if your package contains validation errors. If validation errors or viruses are found within your package, the screen will display a red ‘X’ icon and text on the screen will read: “Validation errors and/or viruses were found.” A pop-up window containing a list of validation errors will also appear. All validation errors must be resolved before a package can be successfully submitted. For more information about validation,

refer to **Section 9**. If your package passes validation, the screen will display a green 'Checkmark' icon and text on the screen will read: "No validation errors were found. No viruses were found."

Exhibit 10-2 below displays the screen capture for when no viruses or validation errors are found.

Exhibit 10-2: Validation Passed

Navigation: Click the 'Continue' button to proceed to the 'Submission Process: PDF Generation' screen.

Exhibit 10-3 below displays a screen capture of the 'Submission Process: PDF Generation' screen.

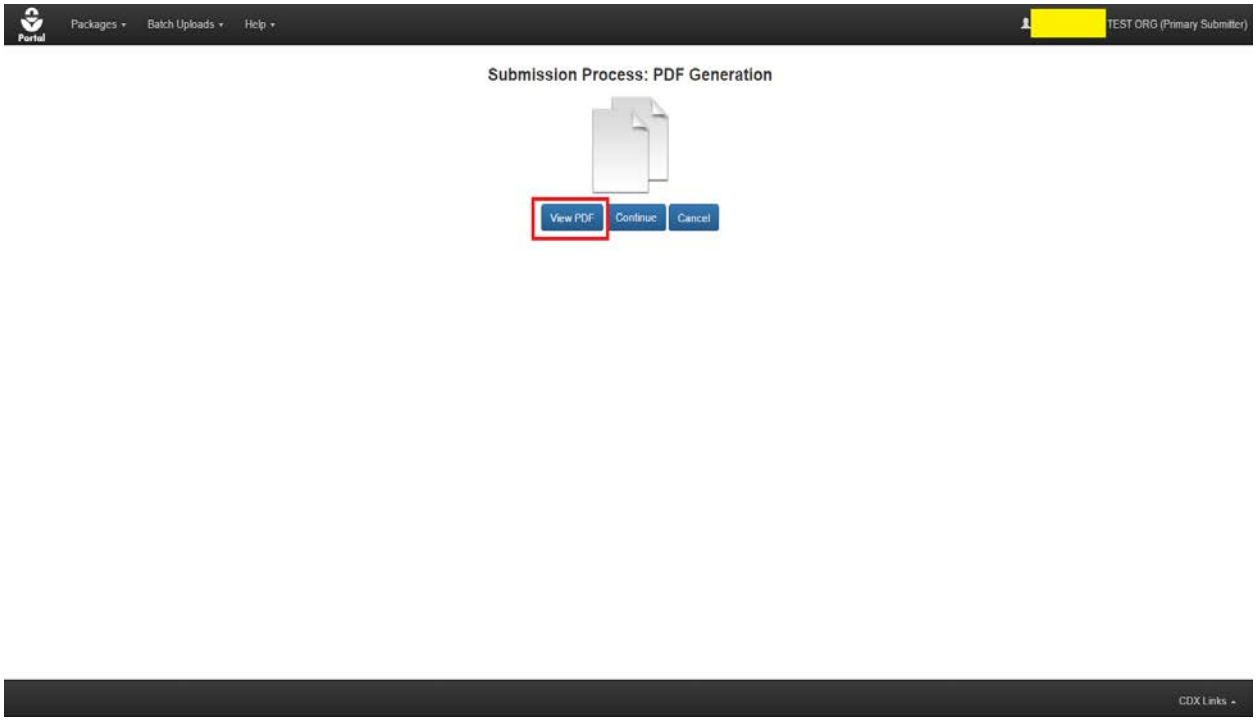


Exhibit 10-3: PDF Generation

Navigation: Click the 'View PDF' button to see a PDF representation of your package and its contents. After viewing and/or printing the PDF, you can click the 'Continue' button to proceed to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' screen.

10.3 Submission Process: 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' Screen.

EPA's Cross-Media Electronic Reporting Rule (CROMERR) provides the legal framework for electronic reporting under EPA's regulatory programs. CROMERR sets performance-based, technology-neutral system standards and provides a streamlined, uniform process for Agency review and approval of electronic reporting. The CROMERR program ensures the enforceability of regulatory information collected electronically by EPA and EPA's state, tribal, and local government partners.

On this screen you will enter your CDX credentials, answer a 20-5-1 question associated with your CDX account, and certify your submission. For additional information about the 20-5-1 questions, please refer to the CDX PSP Registration User Guide. If your package is successfully submitted, you will receive a 'Success' confirmation. You will also receive an email from the CDX Help Desk once your package has been successfully transmitted to OPP. Exhibit 10-4 below displays a screen capture of the 'CROMERR Submission' screen.

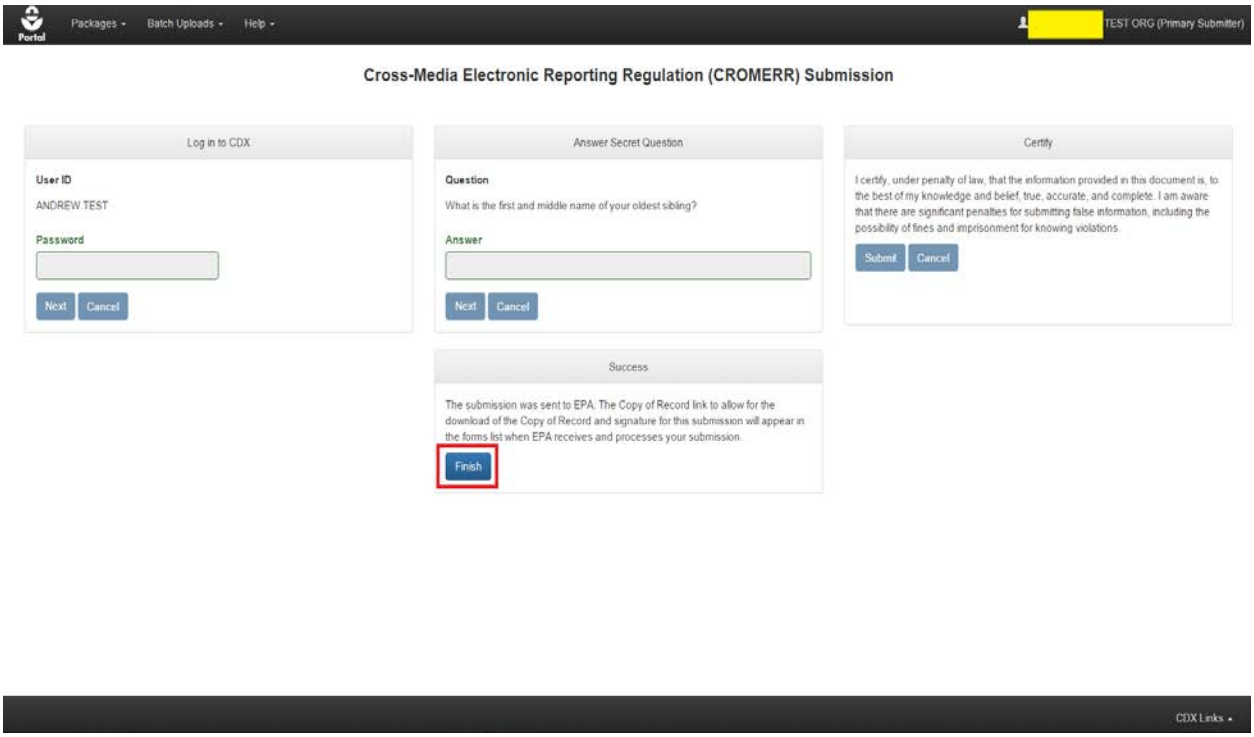


Exhibit 10-4: CROMERR Screen

Navigation: After successfully submitting your package, click the 'Finish' button to proceed to the 'Package Status' page, where you can view the details of submitted packages. Exhibit 10-5 below displays a sample package transmission email.

Your PSP package (test) for THE DOW CHEMICAL CO. (123) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):
PreApp-New-000001: CDX_2015_000073

Company Name: THE DOW CHEMICAL CO.
Company Number: 123

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

Exhibit 10-5: Package Transmission Email

11 Check Package Status and Download Copy of Record

The ‘Package Status’ screen allows you to check the status and details of your submitted packages. You can check the tracking numbers of your applications on this screen, as well as download a copy of record for your package. You can filter the packages on this screen by using the ‘Submission Type’ and ‘Submission Status’ dropdowns. The status and submission date are also shown. You will have to enter the passphrase used to encrypt the package, your CDX password, and the answer to a 20-5-1 secret question to access the copy of record.

Refer to the ‘Package Status Legend’ within Exhibit 11-1 for the meanings of the different statuses.

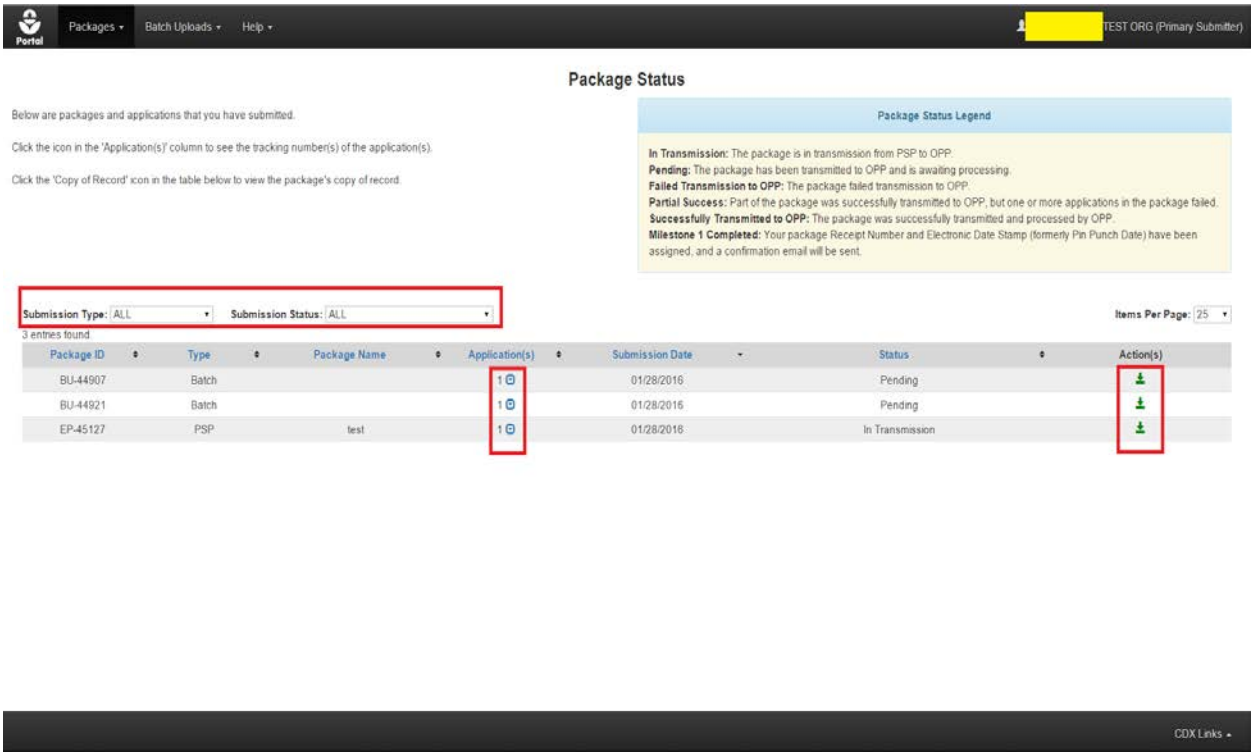


Exhibit 11-1: Package Status Screen

Navigation: Clicking the ‘Show Detail’ button next to the application number will display the tracking numbers associated with the applications in a submitted package. Clicking the ‘Copy of Record’ button in the ‘Actions’ column will allow you to download a copy of record for your application. Click the ‘Copy of Record’ button to proceed to the ‘Cross-Media Electronic Reporting Regulation (CROMERR)’ screen shown in Exhibit 11-2.

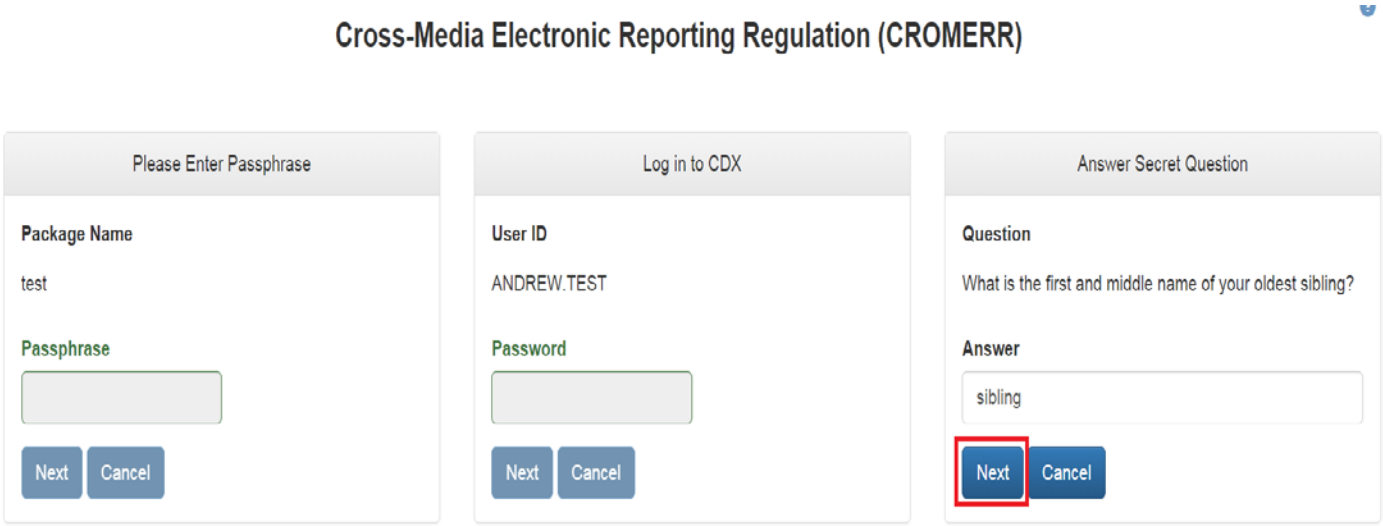


Exhibit 11-2: Navigate the CROMERR Screen

Navigation: Enter the correct data into the fields and click the 'Next' button to proceed to the 'Copy of Record' screen.

11.1 'Copy of Record' Screen

The 'Copy of Record' screen allows you to download a copy of record for your package as well as download copies of files within your package. Click the 'Download Document' icon within the 'Actions' column to download the requisite materials.

Exhibit 11-3 below displays a screen capture of the 'Copy of Record' screen.

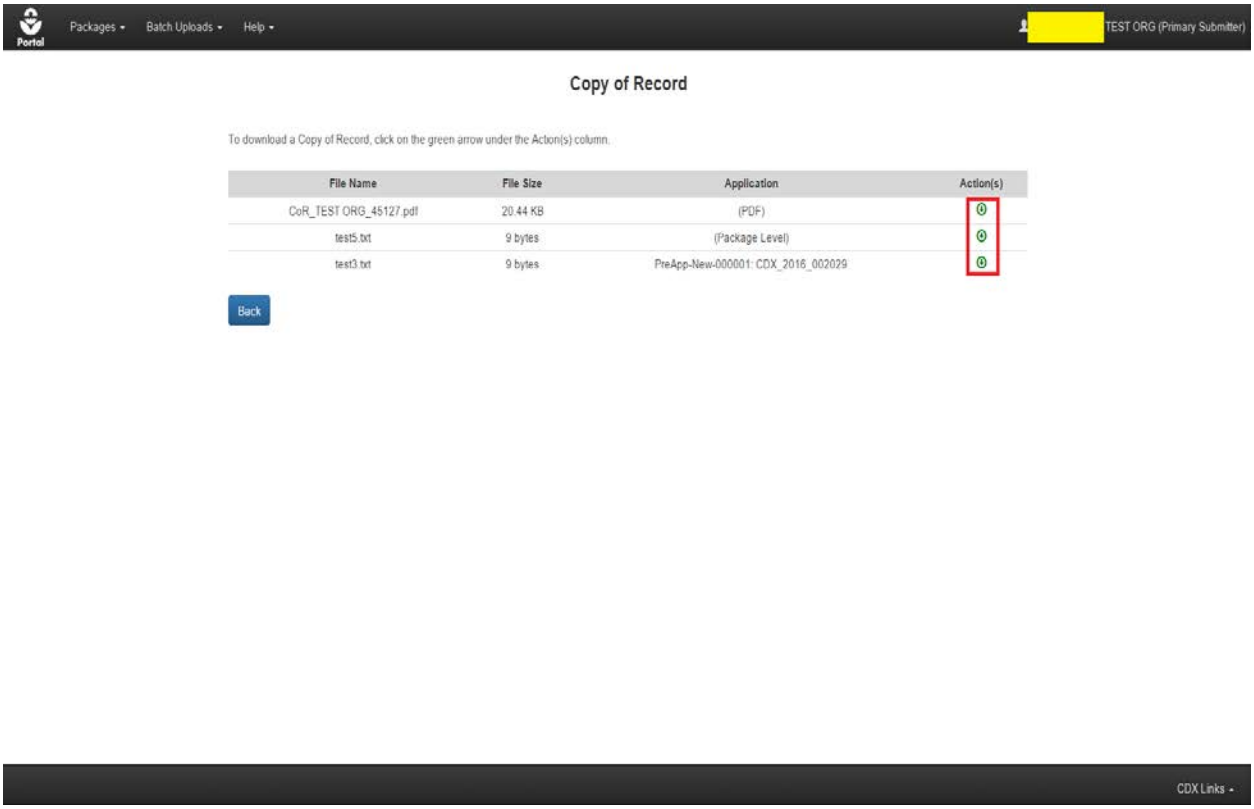


Exhibit 11-3: Copy of Record Screen

Navigation: Click the 'Download Document' icon within the 'Actions' column to download copies of the materials within your package.

12 Respond to DCIs

PSP allows users to see and respond to both GDCIs and PDCIs that OPP has assigned for specific chemicals and products. Through PSP, users can review DCI information and submit DCI Acknowledgements, 90-Day Responses, and Data Submissions. Users will also be able to download a copy of record for their responses. **Note:** You will receive a notification email from OPP when a DCI is awaiting your completion in PSP. To access your DCIs, click on the 'Data Call-In' link on the PSP 'Home' screen. Upon clicking the link, you will be navigated to the 'DCI List' screen.

Exhibit 12-1 below displays the 'Data Call-In' link on the PSP 'Home' page.

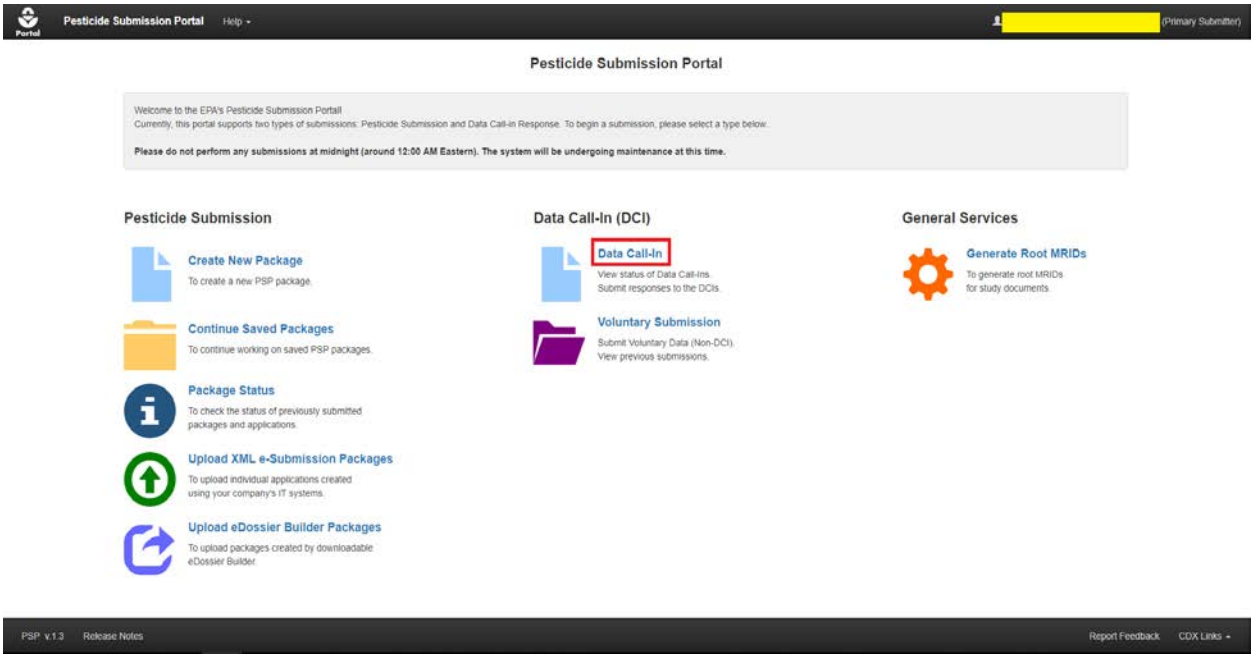


Exhibit 12-1: Data Call-In Link

Important: Document file names uploaded within the DCI section of PSP cannot exceed 200 characters.

Navigation: Click the 'Data Call-In' link on the PSP 'Home' screen.

12.1 DCI List Screen

The 'DCI List' screen allows you to see the details and statuses of DCIs that have been assigned to your company. The type of DCI (PDCI or GDCI) is indicated as the first part of the 'DCI Number.' You may go back to the 'Home' screen by clicking the 'Portal' link at the top left of the screen. The list of DCIs can be sorted by the various columns. They may also be filtered using the drop down filters available above the list. Once any portion of a DCI is submitted, a 'Show Detail' icon will appear next to the DCI number. This icon will reveal the tracking numbers associated with the DCI. Please see the screenshot below for reference. Using the filters and sorting feature will allow you to manage and customize your displayed list of DCIs. The 'DCI Acknowledgement,' '90-Day Response,' and 'Data Submission' columns can have any of the statuses indicated in the 'Data Call-In & Response Legend.' These statuses indicate which

point you are at within the DCI submission process. Exhibit 12-2 below displays the 'DCI List' screen.

Important: Starting with PSP version 1.4, the 'Data Call-In & Response Legend' is now located in the application header next to the 'Help' button. The legend can be accessed by clicking this 'Status Legend' button in the header. The legend modal can be seen in Exhibit 12-3 below.

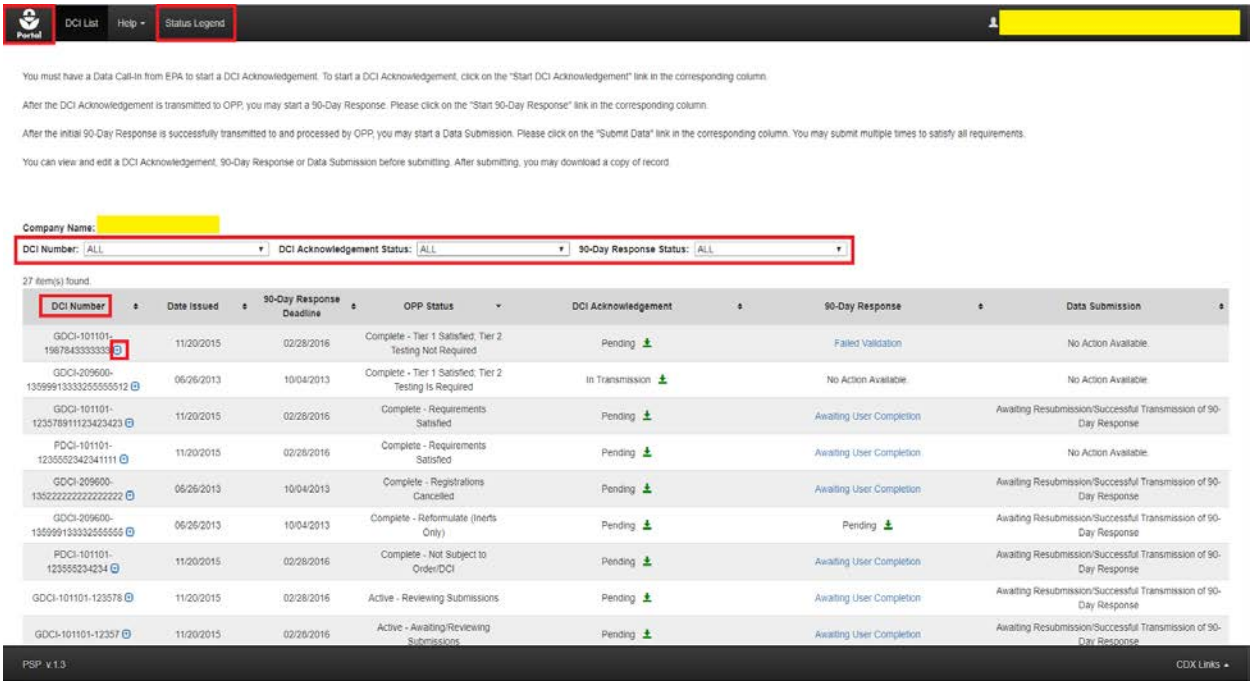


Exhibit 12-2: DCI List Screen

Navigation: Review the DCI information on screen. If necessary, sort or filter the list of DCIs.

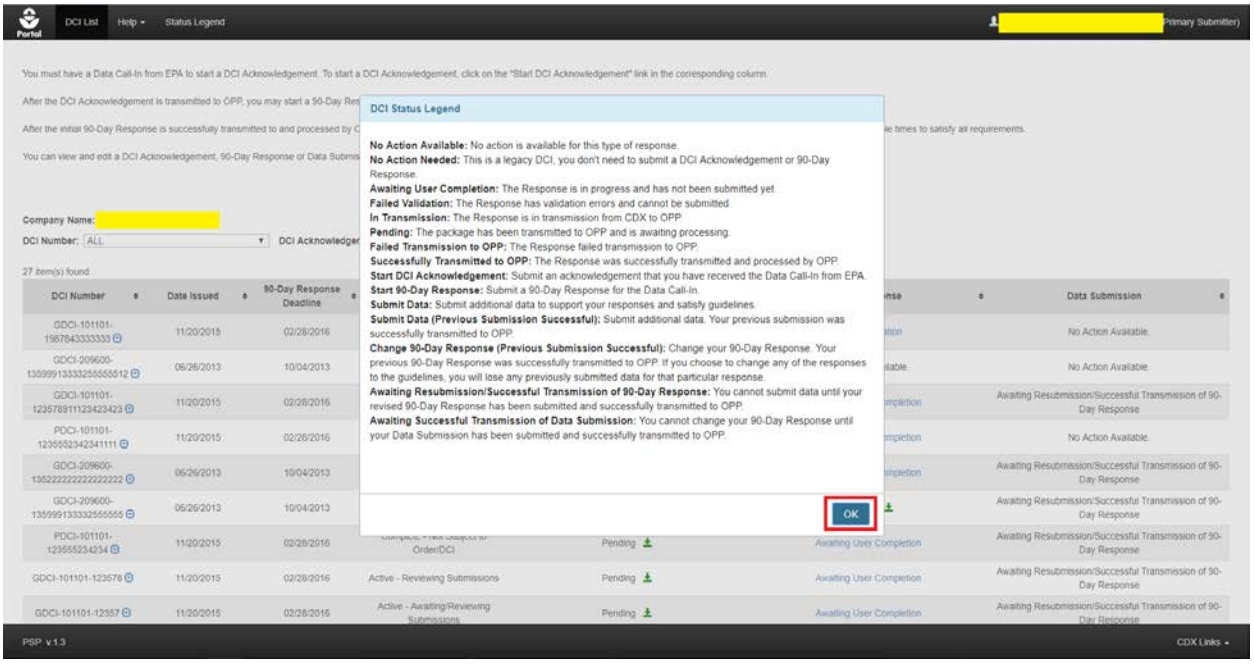


Exhibit 12-3: DCI Status Legend Modal

Navigation: After clicking the 'Status Legend' button in the application header, review the 'DCI Status Legend' modal. To close the modal, click the 'OK' button.

12.2 DCI Acknowledgement

The DCI acknowledgement is a simple form that allows you to confirm you have received the DCI from OPP and will submit the requisite data. To begin a DCI Acknowledgement, click the 'Start DCI Acknowledgement' link in the list as seen in Exhibit 12-4 below.

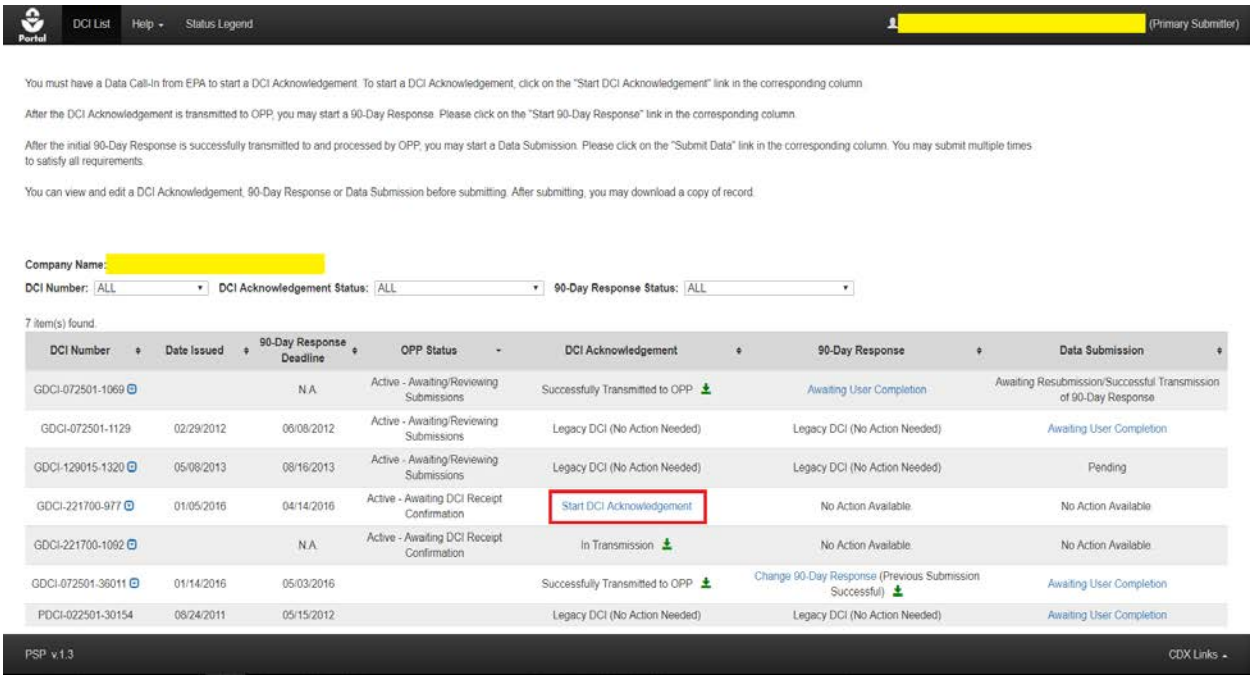


Exhibit 12-4: Start DCI Acknowledgement Link

Navigation: Click the 'Start DCI Acknowledgement' link.

After clicking the link, you will be navigated to the 'DCI Acknowledgement' screen, seen in Exhibit 12-5 below. You will see a list of DCI information displayed on screen, as well as two checkboxes on the right side of the screen. Click the first checkbox to acknowledge receipt of the DCI. The second checkbox is optional; it allows you to indicate whether you are an agent for the specified company. After clicking the first checkbox, a blue 'Submit' button will appear on screen. Click this 'Submit' button once you are ready to begin the submission process.

Note: The process of completing the DCI Acknowledgement form is the same for both GDCIs and PDCIs.

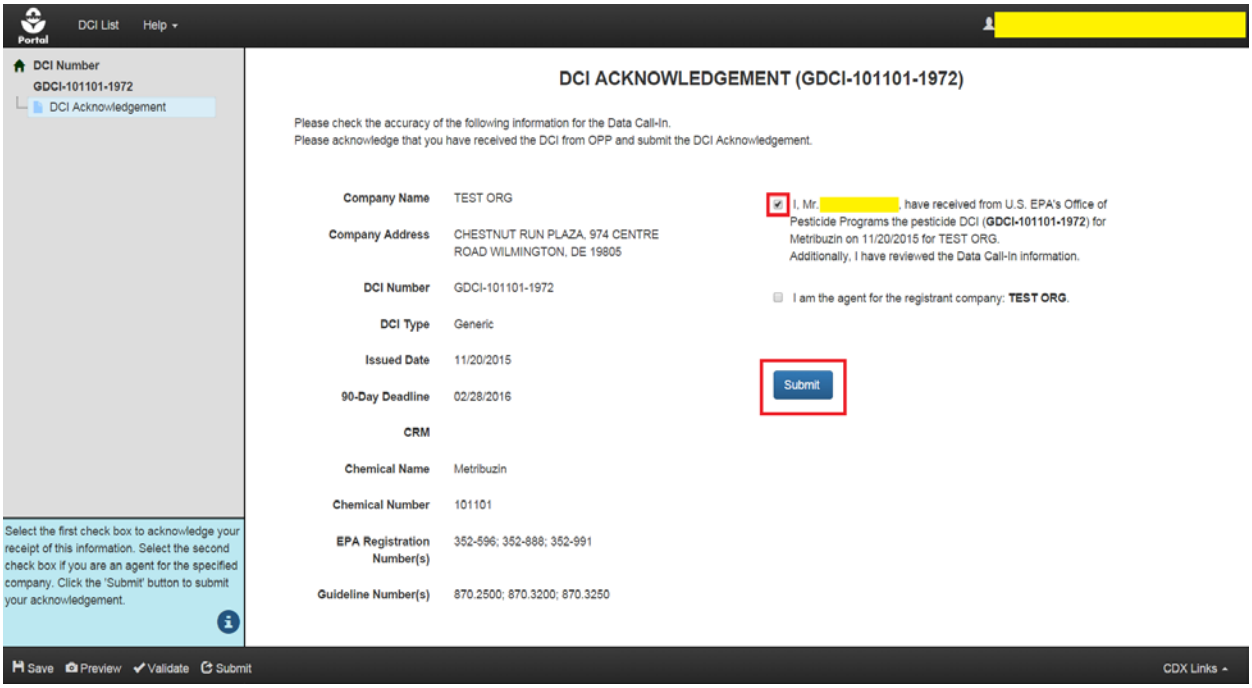


Exhibit 12-5: DCI Acknowledgment Screen

Navigation: Click the first checkbox and the second checkbox (optional). Click the 'Submit' button to begin the submission process.

After clicking 'Submit,' click 'OK' in the pop-up window that appears. The submission process for DCIs is identical to the one for submitting PSP packages. Please refer to **Section 10** for assistance with the submission process. Once you have finished the submission process, you will be navigated back to the 'DCI List' screen. The DCI Acknowledgement you submitted will have a status of 'In Transmission' under the 'DCI Acknowledgement' column. There will also be a green 'Copy of Record' icon next to the status.

Important: You will not be able to start the 90-Day Response until the DCI Acknowledgement status changes to 'Pending.' When the status of the DCI Acknowledgement changes to 'Pending,' the 'Start 90-Day Response' link will appear in the '90-Day Response' column. The timing of these status changes will vary. Exhibit 12-6 below demonstrates the 'DCI List' screen with the 'Pending' DCI Acknowledgement.

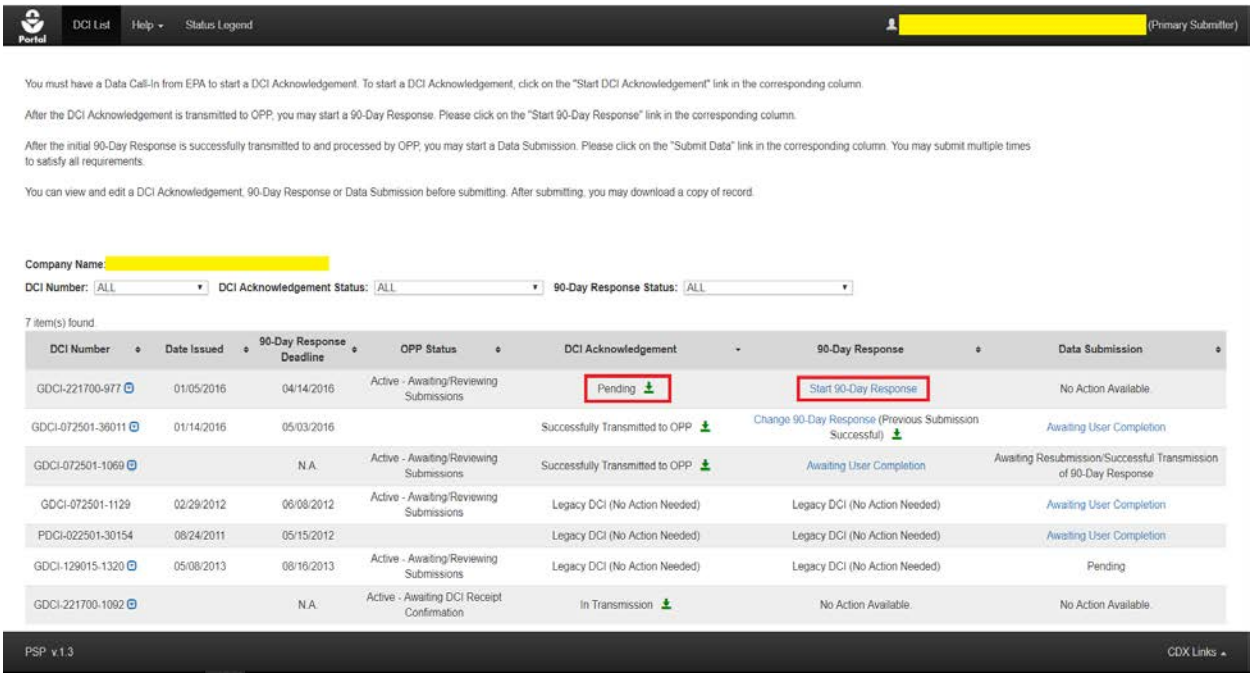


Exhibit 12-6: 'Pending' DCI Acknowledgement

You will also receive a notification email from the CDX Help Desk indicating that your DCI Acknowledgement was successfully transmitted to OPP as seen in Exhibit 12-7 below.

Your DCI Acknowledgement of Receipt (GDCI-101101-1972) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_DCI_2016_000001.

Your 90-Day Response is now open and you can start the submission.

Company Name: TEST ORG
Company Number: 123

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

Exhibit 12-7: DCI Acknowledgement Email

12.3 90-Day Response

The 90-Day Response allows you to review and respond to studies/guidelines as outlined in the DCI. After indicating whether or not you will satisfy the DCI data requirements, you will get the opportunity to respond to each guideline and provide additional documents/data as necessary. The following sections detail 90-Day Responses for both PDCIs and GDCIs. To start a 90-Day Response, click the 'Start 90-Day Response' link under the '90-Day Response' column as seen in Exhibit 12-6 above. You will have to create a passphrase for your 90-Day Response; please refer to **Section 5.2** for assistance with creating a passphrase.

Important: If you forget the passphrase to your DCI, you will be unable to access it. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company. The same passphrase must be used throughout the life of the DCI.

12.4 GDCI 90-Day Response

The following sections detail the process of completing and submitting a GDCI 90-Day Response. GDCIs may contain multiple EPA Registration Numbers. Unlike PDCIs, GDCIs contain a single list of guidelines regardless of the number of EPA Registration Numbers. If you choose to cancel or claim a generic data exemption for **ALL** EPA Registration Numbers, you will not have to respond to any associated guidelines. Otherwise, any guideline responses you indicate will be applied to all the EPA Registration Numbers for which you have agreed to satisfy data requirements. Please refer to the subsequent GDCI sections for more details.

Important: If you forget the passphrase to your DCI, you will be unable to access it. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company. The same passphrase must be used throughout the life of the DCI.

12.4.1 GDCI 90-Day Response Submission Screen

After clicking the 'Start 90-Day Response' link, you will be navigated to the '90-Day Response Submission' screen. This screen contains summary information about the DCI. You can also upload DCI-level documents on this screen. A navigation tree is also present, pictured below in Exhibit 12-8.

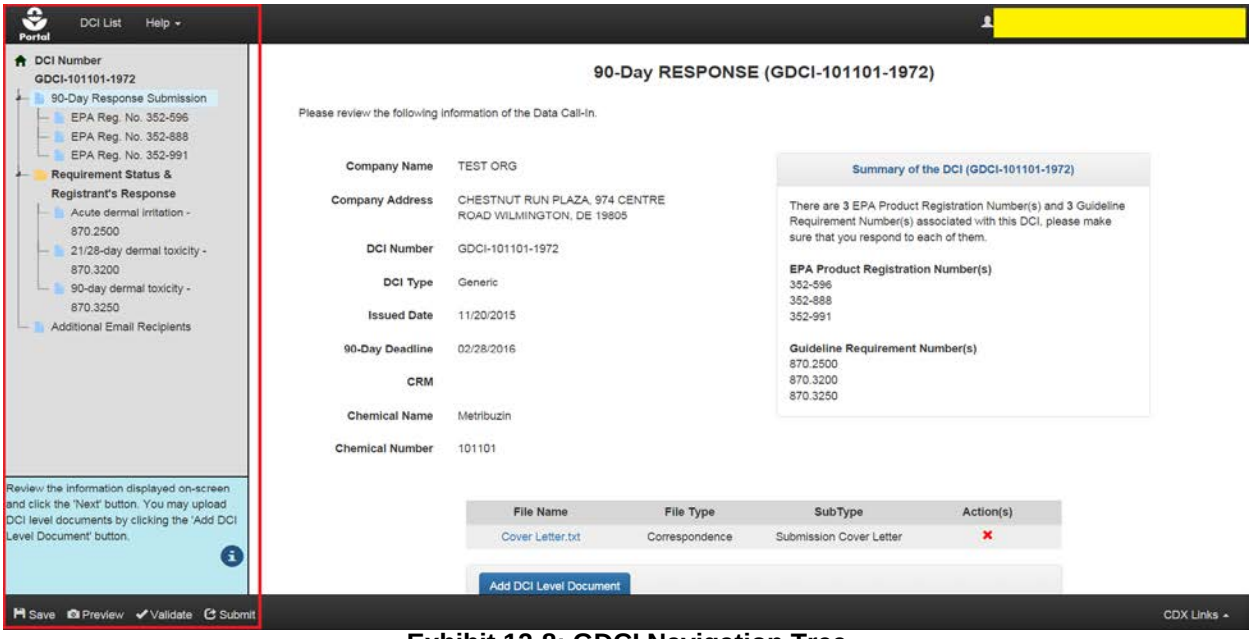


Exhibit 12-8: GDCI Navigation Tree

The following fields are displayed on the '90-Day Response Submission' screen:

- **Company Name:** The name of the company for which the DCI was issued. This field is not editable.
- **Company Address:** The address of the company for which the DCI was issued. This field is not editable.
- **DCI Number:** The DCI number. This field is not editable.
- **DCI Type:** Indicates whether the DCI is a GDCI or PDCI. This field is not editable.
- **Issued Date:** The date the DCI was issued. This field is not editable.
- **90-Day Deadline:** The 90-Day deadline of the DCI. This field is not editable.
- **CRM:** The Chemical Review Manager. This field is not editable.
- **Chemical Name:** The name of the chemical associated with the DCI. This field is not editable.
- **Chemical Number:** The number of the chemical associated with the DCI. This field is not editable.

The 'Summary of the DCI' table on the right side of the screen displays the EPA Product Registration Numbers and Guideline Requirement Numbers associated with the DCI.

The document upload section contains the following document types:

- Correspondence
    - Submission Cover Letter
    - Voluntary Cancellation / Use Deletion
    - Time Extension Request

- Study
    - Transmittal Document

Please note: If you upload any study documents, you must have a corresponding Transmittal Document uploaded at the DCI level. If you upload studies in subsequent data submissions, you must have a new transmittal document for each of those data submissions.

Exhibit 12-9 displays the ’90-Day Response Submission’ screen.

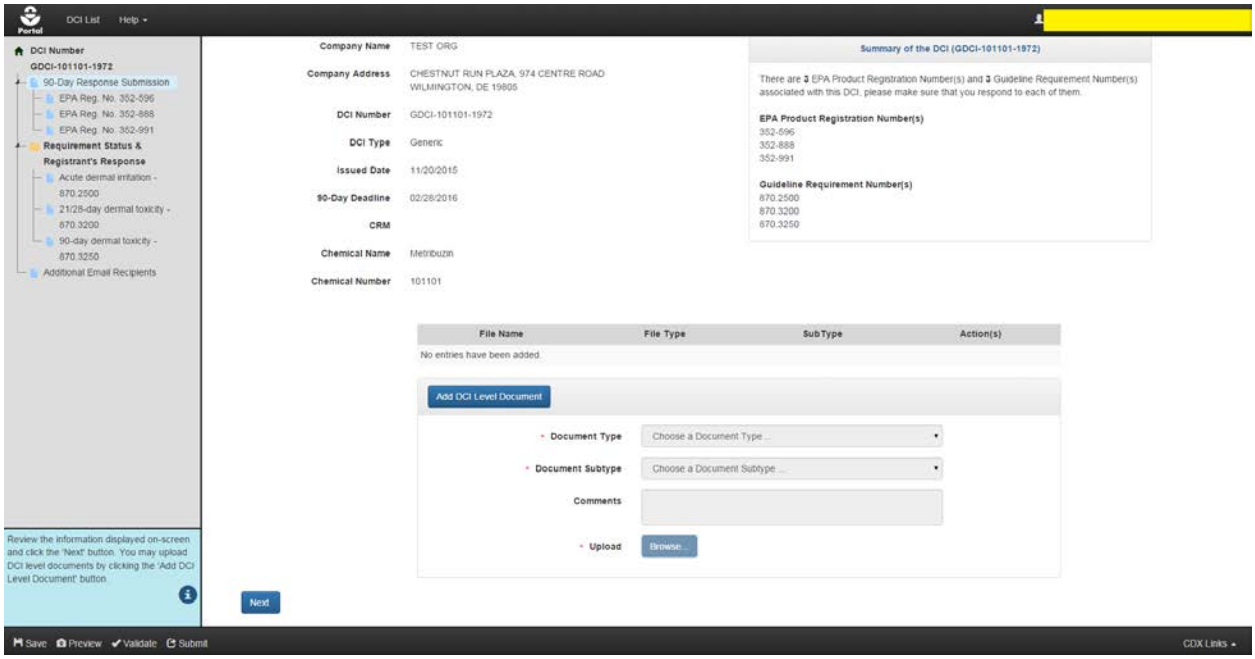


Exhibit 12-9: GDCI 90-Day Response Submission Screen

Review all displayed information and upload DCI level documents if necessary. To upload documents, click the ‘Add DCI Level Document’ button. After clicking the button, choose a ‘Document Type’ and ‘Document Subtype’ and upload files by clicking the ‘Browse…’ button. You may also enter comments if desired. After selecting a document for upload, click the ‘Save’ button. Any uploaded documents will display in the documents table in the center of the screen. You may remove any uploaded documents by clicking the red ‘Delete’ icon in the ‘Action(s)’ column. Refer to Exhibit 12-10 below.

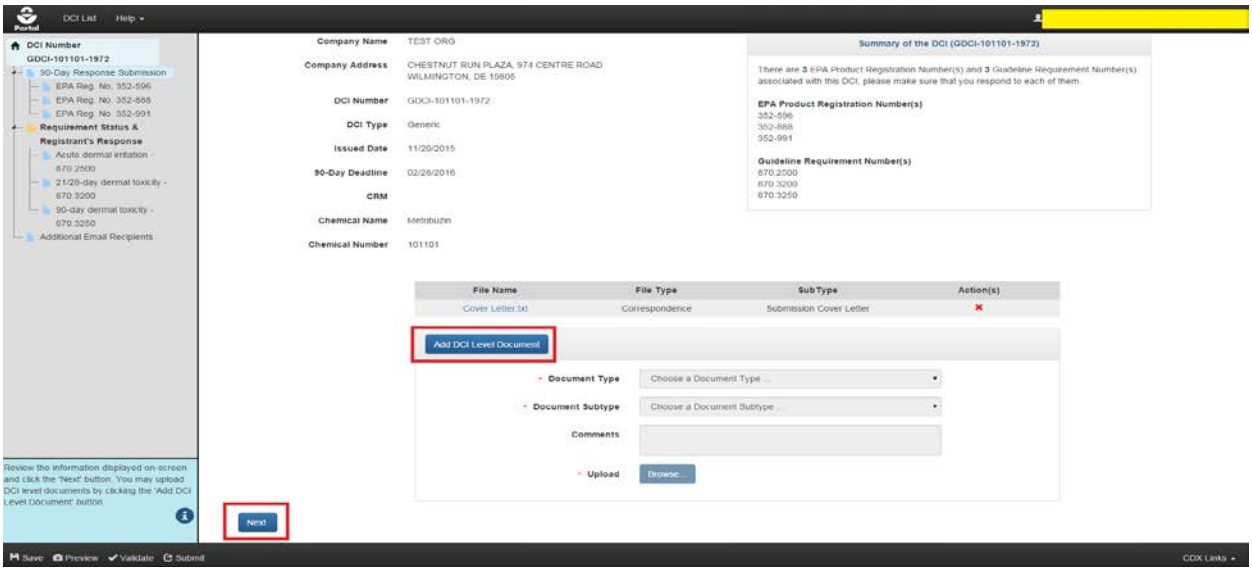


Exhibit 12-10: Navigate the GDCI 90-Day Response Submission Screen

Navigation: Review the displayed information and upload DCI level documents if desired. Click the 'Next' button.

Note: For information about the 'Save,' 'Preview,' 'Validate,' and 'Submit' buttons in the application footer, proceed to **Section 5.4**. Otherwise, proceed to the next section.

12.4.2 GDCI EPA Product Registration Screen

This screen contains basic information about an EPA Registration Number. On this screen, you may choose one of three radio button options. Select a radio button option for each EPA Registration Number (if more than one) before proceeding to the 'Requirement Status & Registrant Response' section.

The following information is displayed on the 'EPA Product Registration' screen:

- **EPA Registration Number:** The EPA Registration Number associated with the DCI. This field is not editable.
- **Product Name:** The Name of the product associated with the DCI. This field is not editable.

The following radio button options are available:

- **I wish to cancel this product registration voluntarily:** Selecting this option will cause a file upload section to appear.

  Exhibit 12-11 below demonstrates this selection. A document must be uploaded to support the cancellation. Click the 'Add Document' button, choose a 'Document Type' and 'Subtype,' and upload a document via the 'Browse…' button. Any uploaded documents will appear in the documents table in the center of the screen. You can delete added documents by clicking the red 'Delete' icon in the 'Action(s)' column. The document types are as follows:

  - Correspondence
    - Company Letter

- General Correspondences

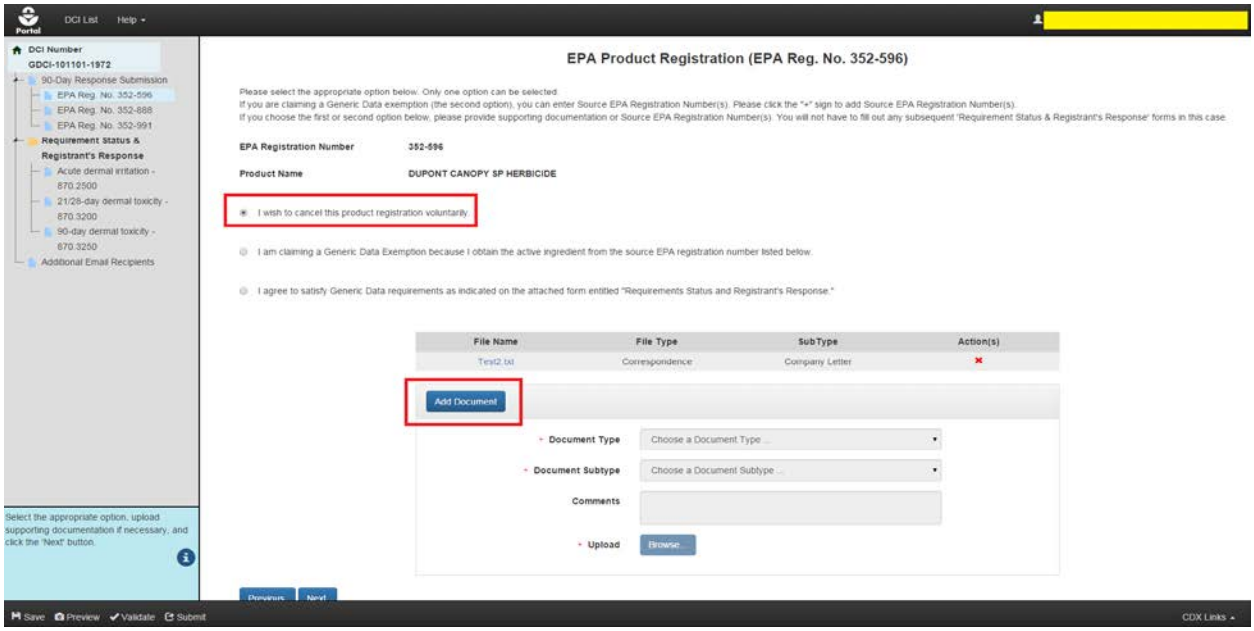


Exhibit 12-11: GDCI Voluntary Cancellation

Navigation: Upload a supporting document and click the 'Next' button to respond to the other registration numbers (if any).

- **I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below:** Selecting this option will cause a 'Source EPA Registration Number' text box to appear. Exhibit 12-12 below demonstrates this selection. You may enter multiple Source EPA Registration Numbers by clicking the blue 'Add Another Source EPA Registration Number' link. You may delete any added numbers by clicking the red 'Delete' icon next to the text box. After you have finished adding numbers, click the 'Next' button.

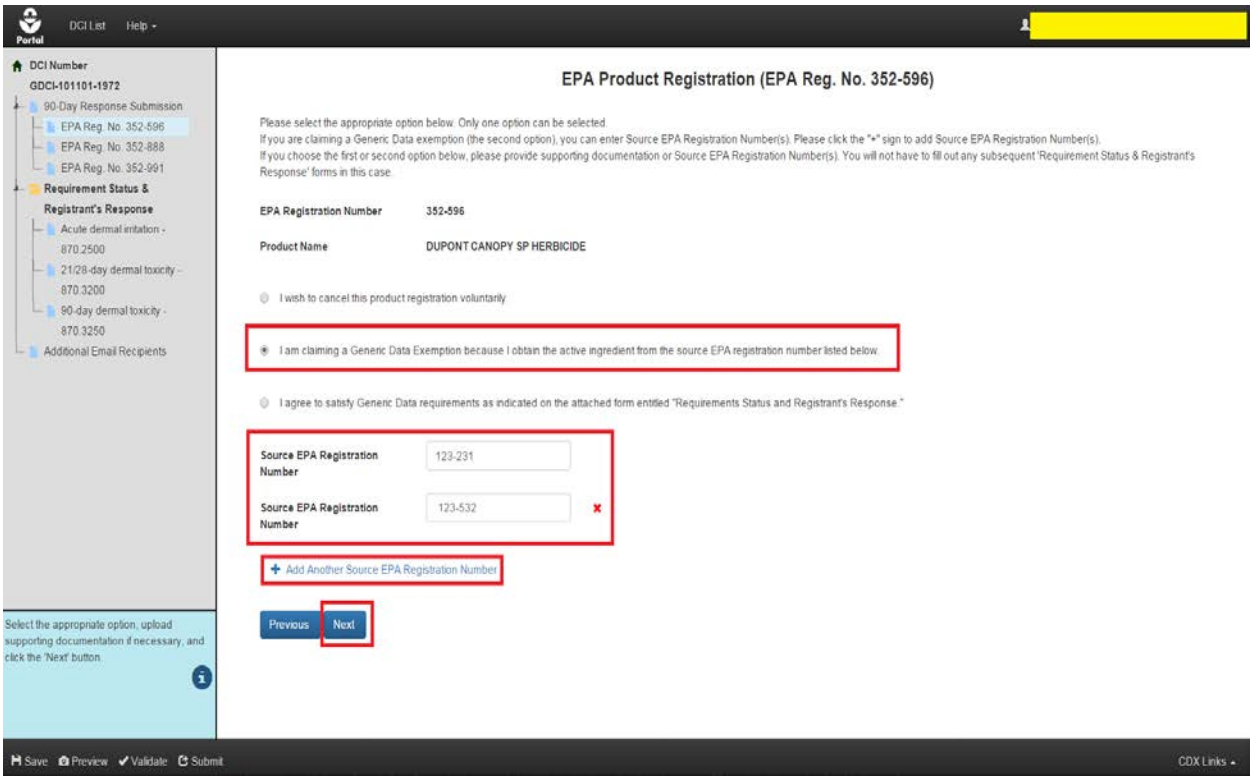


Exhibit 12-12: GDCI Generic Data Exemption

Note: All entered Source EPA Registration Numbers will be validated during submission or when you press the ‘Validate’ button in the Application Footer.

Navigation: Enter all required ‘Source EPA Registration Numbers’ and click the ‘Next’ button to respond to the other registration numbers (if any).

- **I agree to satisfy Generic Data requirements as indicated on the attached form entitled “Requirements Status and Registrant’s Response”:** Selecting this option requires no additional data. Exhibit 12-13 below demonstrates this selection. After selecting this option, click the ‘Next’ button; you can continue navigating through the DCI.

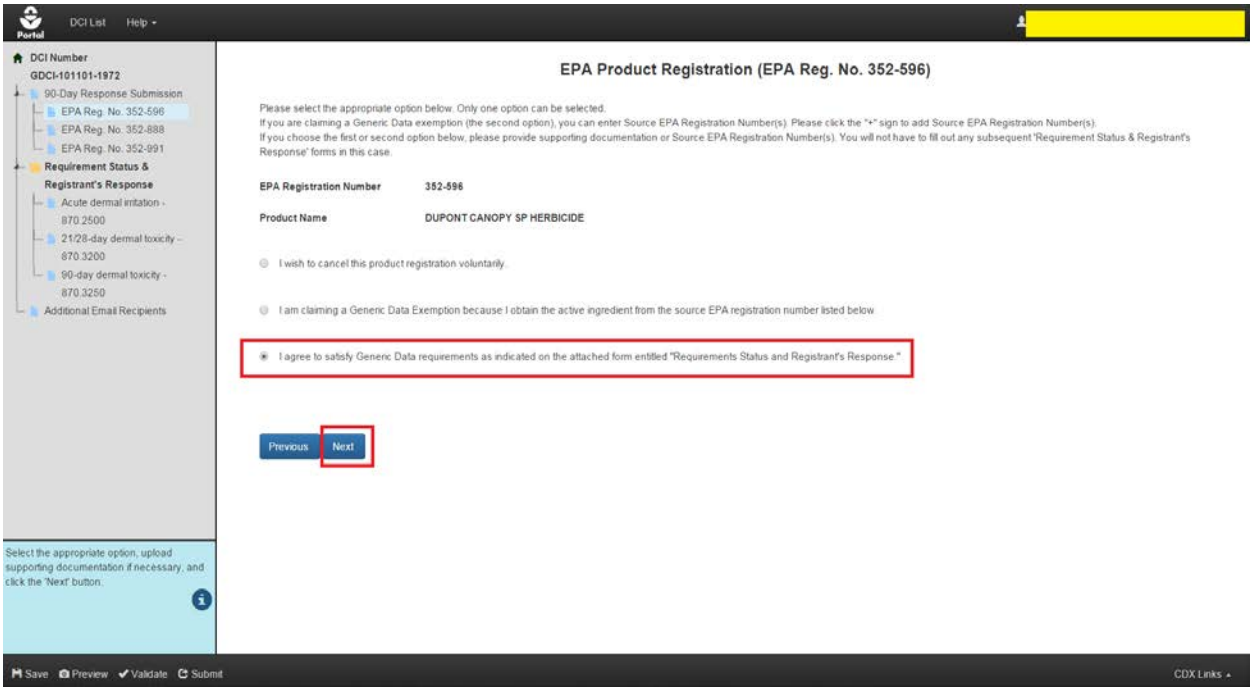


Exhibit 12-13: GDCI Agree to Satisfy Data Requirements

Navigation: After selecting this option, click the 'Next' button to respond to the other registration numbers (if any).

Note: If an option has been selected for all EPA Registration Numbers, click the 'Next' button to proceed to the 'Requirement Status & Registrant's Response' section (**Section 12.4.3**).

Important: Your responses to the guidelines in the 'Requirement Status & Registrant's Response' section will only apply to the EPA Registration Numbers for which you agreed to satisfy the Generic Data requirements (third radio button). If you select the first or second radio button for **ALL** EPA Product Registration Numbers, you will not have to fill out responses for any of the guidelines. In this case, a gray strikethrough line will appear in the navigation tree and red text will appear on the guideline pages. See Exhibit 12-14 below for reference.

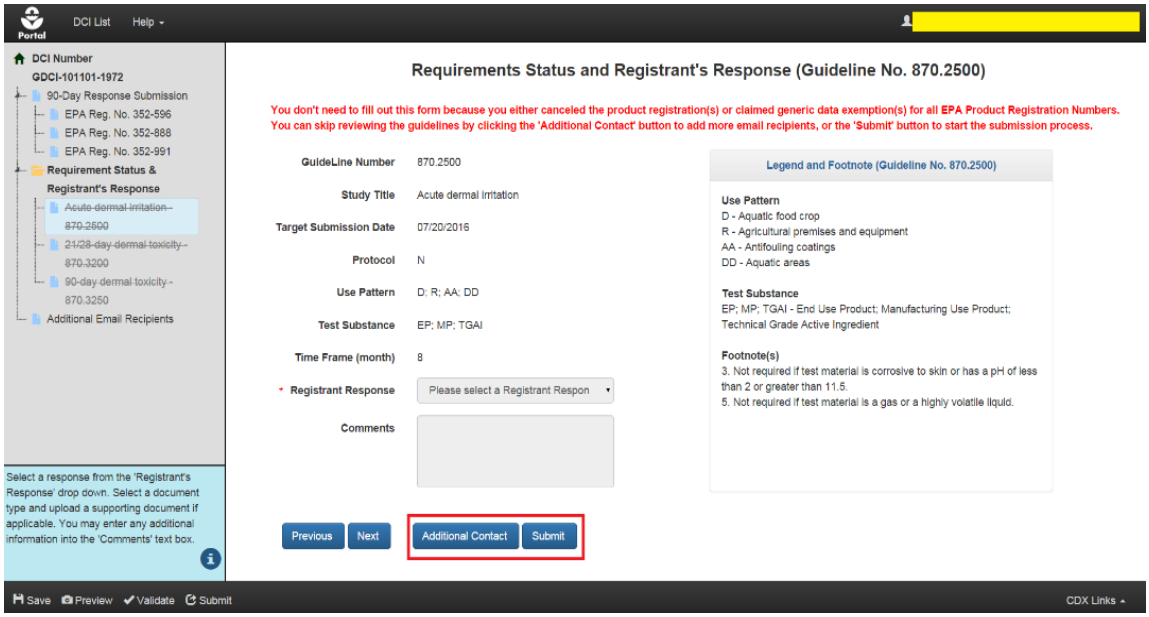


Exhibit 12-14: GDCI Response to Guidelines Not Needed

Navigation: Since no guidelines require a response, you may click the ‘Additional Contact’ button to specify additional email recipients for DCI email updates, or the ‘Submit’ button to begin the submission process.

12.4.3 GDCI Requirements Status and Registrant’s Response Screen

This screen contains information about a Guideline Number within the DCI. On this screen, you may choose a response from the ‘Registrant Response’ dropdown. After selecting a response, additional fields or a document upload section may appear so that you can submit data to support your response. You may also enter comments about the response into the ‘Comments’ text box. You must respond to all guidelines before submitting the 90-Day Response.

The following information is displayed on the ‘Requirements Status and Registrant’s Response’ screen:

- **GuideLine Number:** The Guideline Number associated with the DCI. This field is not editable.
- **Study Title**: The study associated with the guideline. This field is not editable.
- **Target Submission Date:** The targeted date for submission. This field is not editable.
- **Protocol:** The protocol for the guideline. This field is not editable.
- **Use Pattern:** The use pattern for the guideline. This field is not editable.
- **Test Substance:** The test substance for the guideline. This field is not editable.
- **Time Frame (month):** The time frame for the guideline. This field is not editable.
- **Required Information:** The required documents for the particular ‘Registrant Response’ selected. This field is not editable.

You may select a response for the guideline via the ‘Registrant Response’ drop down. You can also copy a response to all guidelines within a DCI by clicking the blue icon next to the ‘Registrant Response’ drop down and clicking ‘OK’ in the pop-up window. This will ensure that all guidelines have the selected response applied to them. You can later change the response for the affected guidelines if you wish. See Exhibit 12-15 below.

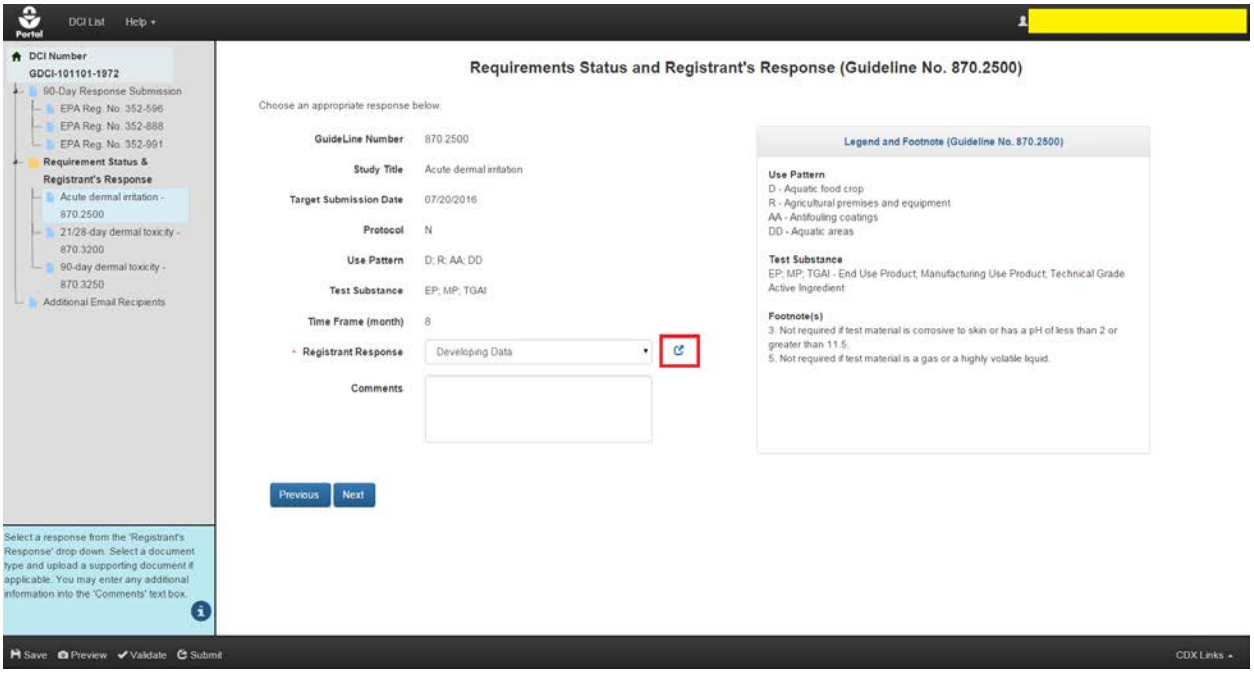


Exhibit 12-15: ‘Copy Response Code to Other Guidelines’ Button

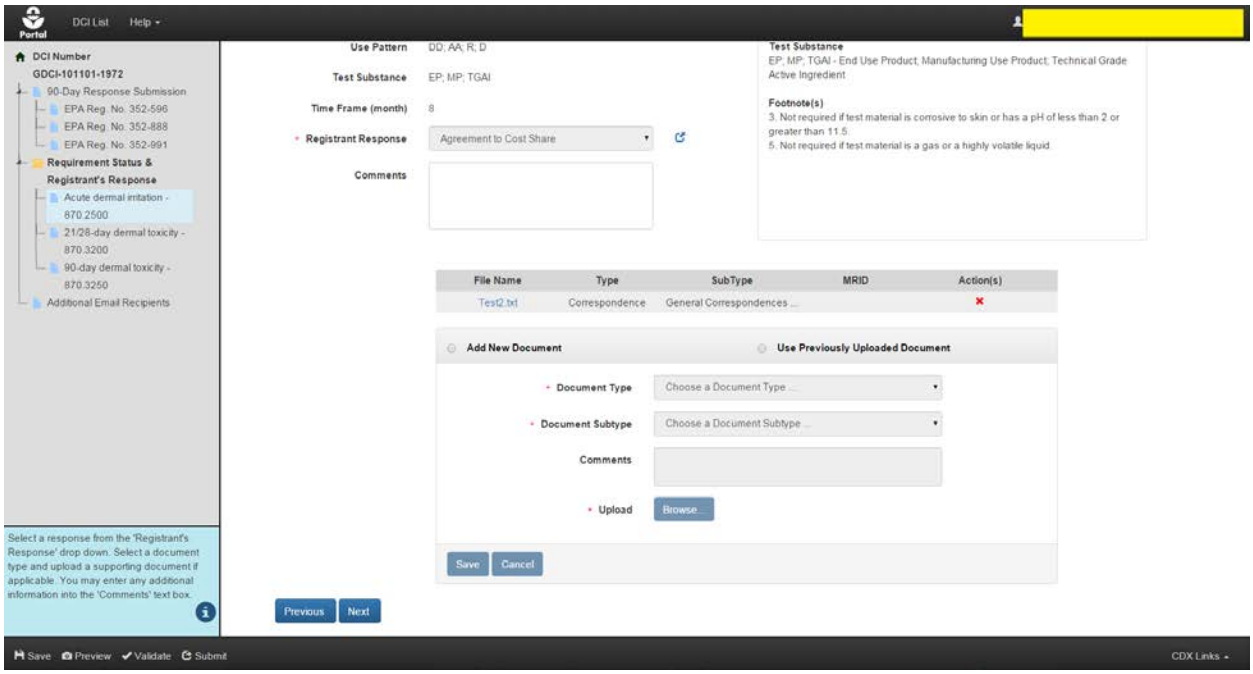
The possible responses for ‘Registrant Response’ are:

- **Developing Data:** Selecting this response indicates that you will provide study data at a later date. There is no document upload or data required as part of the 90-Day Response submission for this response. If you choose ‘Developing Data,’ you can click ‘Next’ to proceed to the next guideline.
- **Agreement to Cost Share:** This response requires at least one ‘General Correspondence’ document upload. When selecting a response that requires a file upload, there are two radio buttons available. The ‘Add New Document’ radio button should be used when you want to upload a new document to the response. Click the ‘Add New Document’ radio button. The document types are as follows:
    - Form
        - Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data.
    - Correspondence
        - General Correspondences

Select the ‘Correspondence’ document type and the ‘General Correspondences’ subtype. Enter any comments if necessary. Upload a document via the ‘Browse…’ button. Click the ‘Save’ button. The uploaded document will appear in the documents table in the center of the screen. You may delete an uploaded document by clicking the red ‘Delete’ icon in the ‘Action(s)’

column. After uploading a document, you will not be able to change your 'Registrant Response' selection. You will have to delete all uploaded documents before you can change your response. See Exhibit 12-6 below.

Exhibit 12-16: Agreement to Cost Share



Navigation: Click the 'Add New Document' radio button. Select a document type and subtype and upload a document via the 'Browse…' button. Click the 'Save' button and click 'Next' if you are finished uploading documents to the response. Clicking 'Next' will navigate you to the next guideline in the DCI.

The 'Use Previously Uploaded Document' radio button allows you to reference a document that has already been uploaded so that it does not have to be uploaded again. Your response codes must match between guidelines if you want to reuse documents. After selecting the 'Use Previously Uploaded Document' radio button, a drop down list of uploaded files will appear within the file upload section. Simply select the document you would like to reuse from the 'Uploaded Documents' section and click the 'Reuse' button. The referenced document will appear in the documents table. You may remove the reference to an uploaded document by clicking the yellow icon in the 'Action(s)' column. See Exhibit 12-17 and Exhibit 12-18 below.

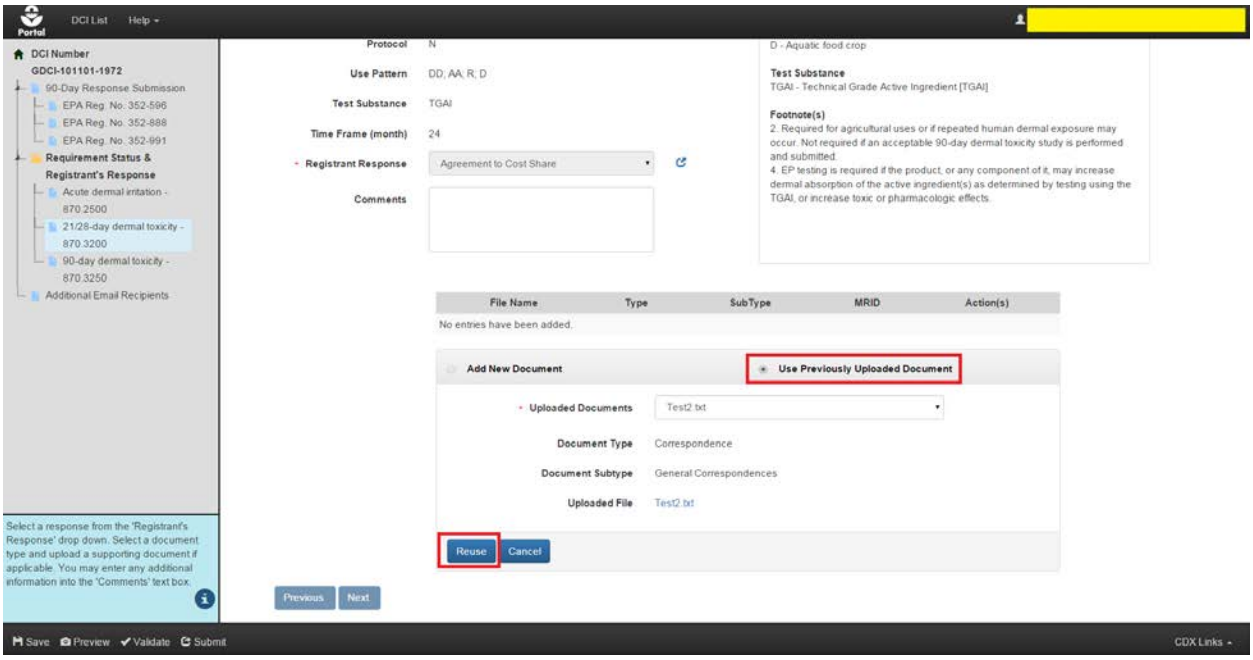


Exhibit 12-17: Reuse Document Option

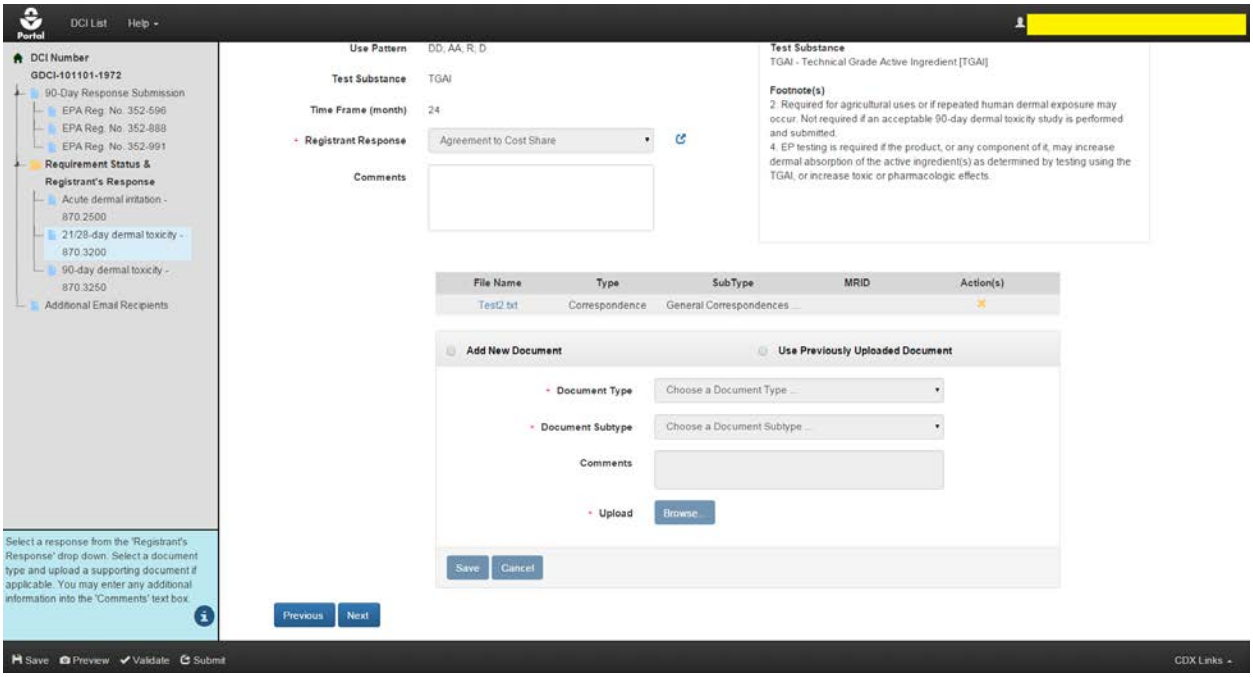


Exhibit 12-18: Reused Document in the Documents Table

Navigation: Click the 'Use Previously Uploaded Document' radio button. If any documents are available for reuse, select the appropriate document from the 'Uploaded Documents' drop down. If no documents are available for reuse, you will get an appropriate message. Click the 'Reuse' button and click 'Next' if you are finished uploading documents to the response. Clicking 'Next' will navigate you to the next guideline in the DCI.

- **Offer to Cost Share:** This response requires at least one ‘General Correspondence’ and one ‘Form 8570-32 (Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data)’ document upload. This response has the same document types as ‘Agreement to Cost Share.’ Upload the necessary documents and click the ‘Next’ button to proceed to the next guideline.
- **Submitting Existing Data:** This response allows you to upload study documents. It features the standard file upload feature, but also allows you to enter an MRID for your study via the ‘MRID’ field. For assistance with generating a root MRID, please refer to **Section 4**. The document types are as follows:
    - Study
        - Data Entry Spreadsheet Template (DEST)
        - Data Waiver Request
        - Protocol
        - Study
        - Study Profile
        - Supplemental Study Data
        - Transmittal Document
        - Water Monitoring Data

Upload all necessary documents and click the ‘Next’ button to proceed to the next guideline. See Exhibit 12-19.

Note: The MRIDs you enter will be validated during submission or when you press the ‘Validate’ button within the application footer.

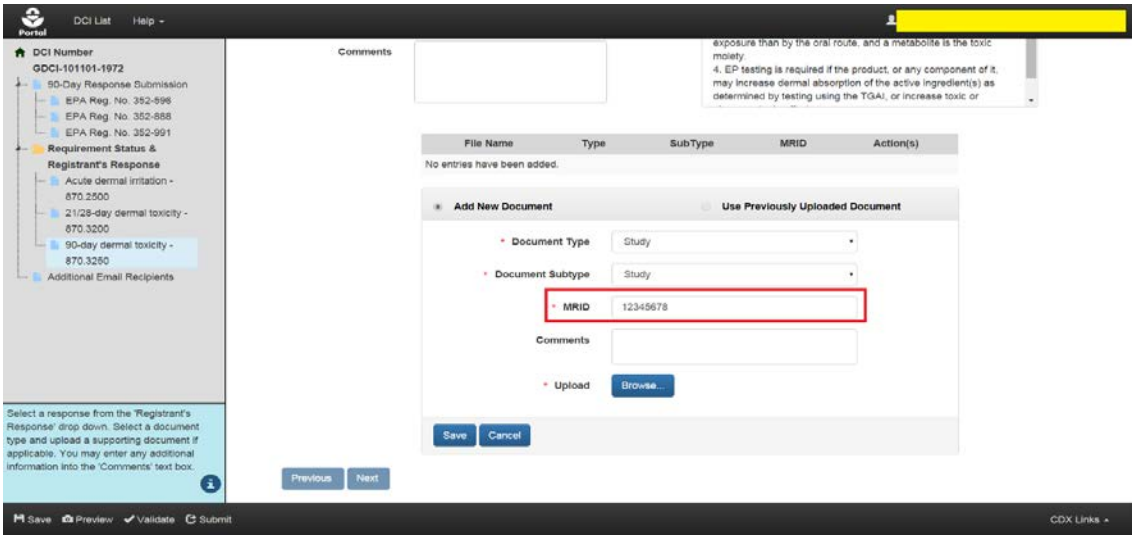


Exhibit 12-19: Submitting Existing Data

Navigation: Upload all necessary documents, enter MRIDs, and click the ‘Next’ button to proceed to the next guideline.

- **Upgrading a Study:** This response allows you to upload study documents. It features the standard file upload feature, but also allows you to enter an MRID for your study via the 'MRID' field. For assistance with generating a root MRID, please refer to **Section 4**. This response has the same document types and features as the 'Submitting Existing Data' response.
- **Citing a Study:** This response allows you to cite studies. It features an 'MRID Number' field so that you may enter the MRID of the studies you are citing. You can click the 'Cite an additional MRID Number' link to cite multiple studies. You can also delete MRIDs by clicking the red 'Delete' icon next to the 'MRID Number.' See Exhibit 12-20 below.

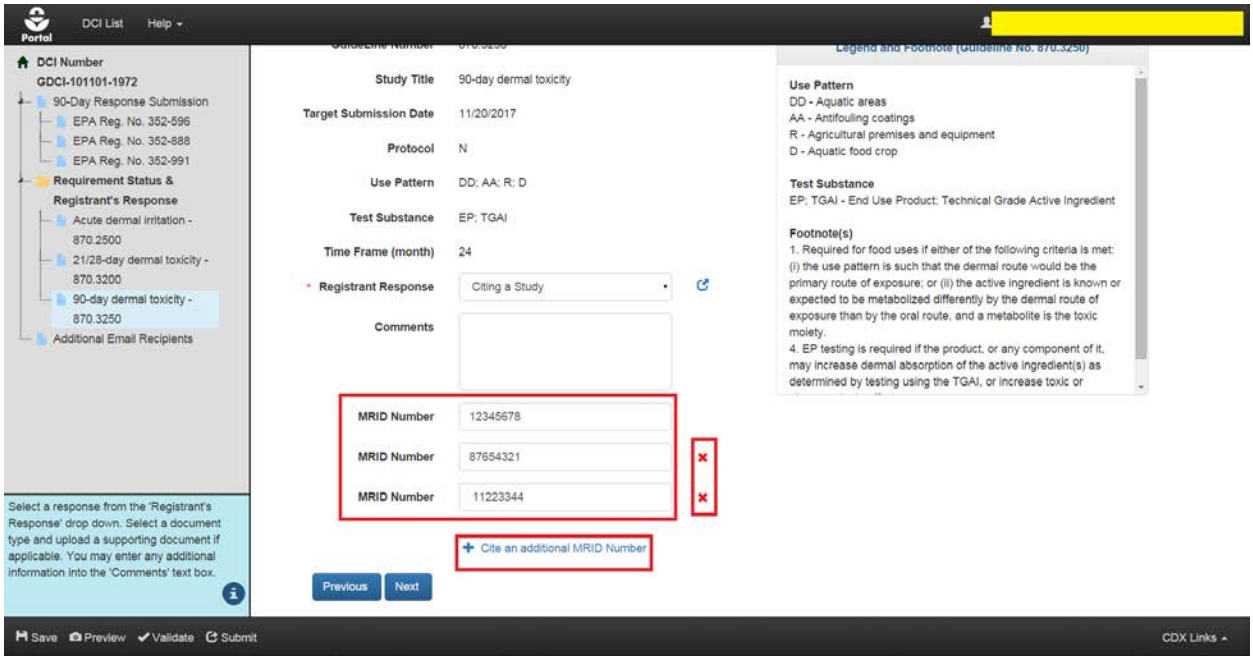


Exhibit 12-20: Citing a Study

Navigation: Enter the necessary MRIDs and click the 'Next' button to proceed to the next guideline.

- **Deleting Uses:** This response features the same file upload feature found in other responses. The document type and subtype are as follows:
    - Label
        - Draft

Upload the necessary documents and click the 'Next' button to proceed to the next guideline.

- **Low Volume/Minor Use Waiver Request:** This response features the same file upload feature found in other responses. The document type and subtype are as follows:
    - Correspondence
        - Waiver Request

Upload the necessary documents and click the 'Next' button to proceed to the next guideline.

- **Waiver Request:** This response features the same file upload feature found in other responses. The document type and subtype is the same as the ‘Low Volume/Minor Use Waiver Request’ response. Upload the necessary documents and click the ‘Next’ button to proceed to the next guideline.

12.4.4 Additional Email Recipients and GDCI Submission Process

After all guidelines have been responded to, you may indicate additional email recipients on the ‘Additional Email Recipients’ screen. This screen allows you to indicate additional email addresses to which DCI notification emails will be sent. By default, these emails are only sent to the PSP account that performs the submissions. These emails will inform the recipients when 90-Day Responses and Data Submissions are submitted to OPP.

Click the ‘Add a new email address’ link. An ‘Email Address’ text field will appear. Enter the email address of the desired recipient. If you would like to add more than one email address, click the 'Add a new email address’ link as many times as necessary. You can use the red ‘x’ icon in order to delete entered addresses.

Once you are finished entering email addresses, click the ‘Submit’ button to begin the submission process. Press ‘OK’ in the pop-up that appears. See Exhibit 12-21 below.

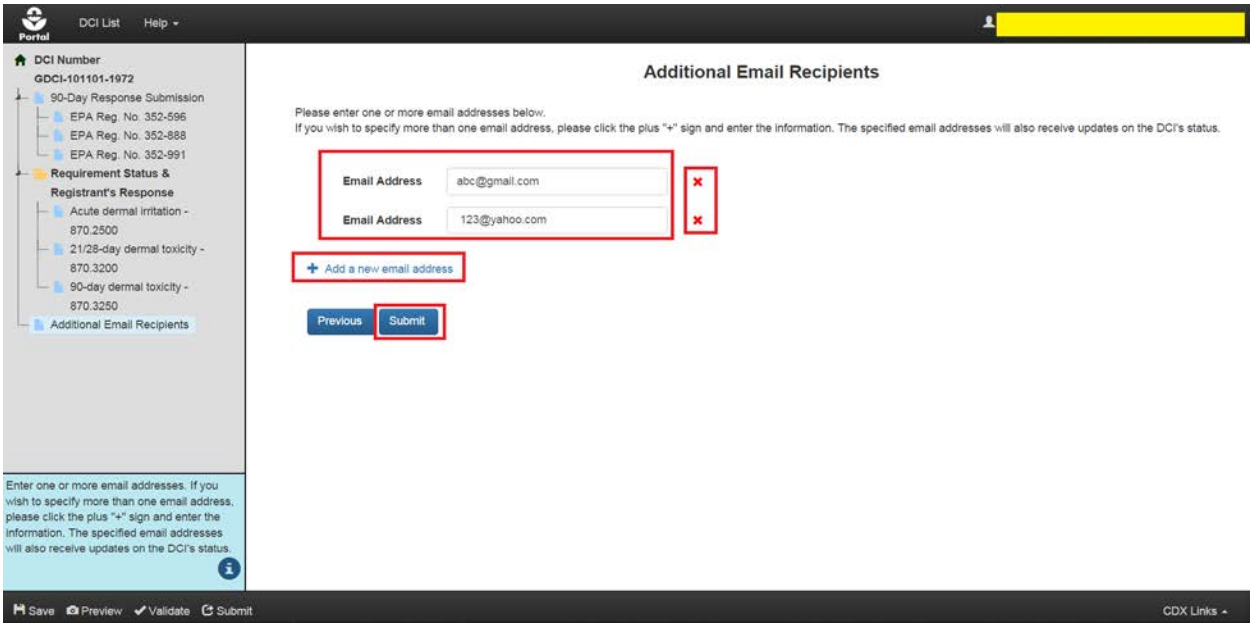


Exhibit 12-21: Additional Email Recipients

Please refer to **Section 10** for assistance with the submission process. After you have successfully submitted the DCI, you will be navigated back to the ‘DCI List’ screen. Your submitted DCI will have a status of ‘In Transmission.’

Important: You will be able to submit data once your DCI ’90-Day Response’ status changes to ‘Successfully Transmitted to OPP.’ See Exhibit 12-22 below.

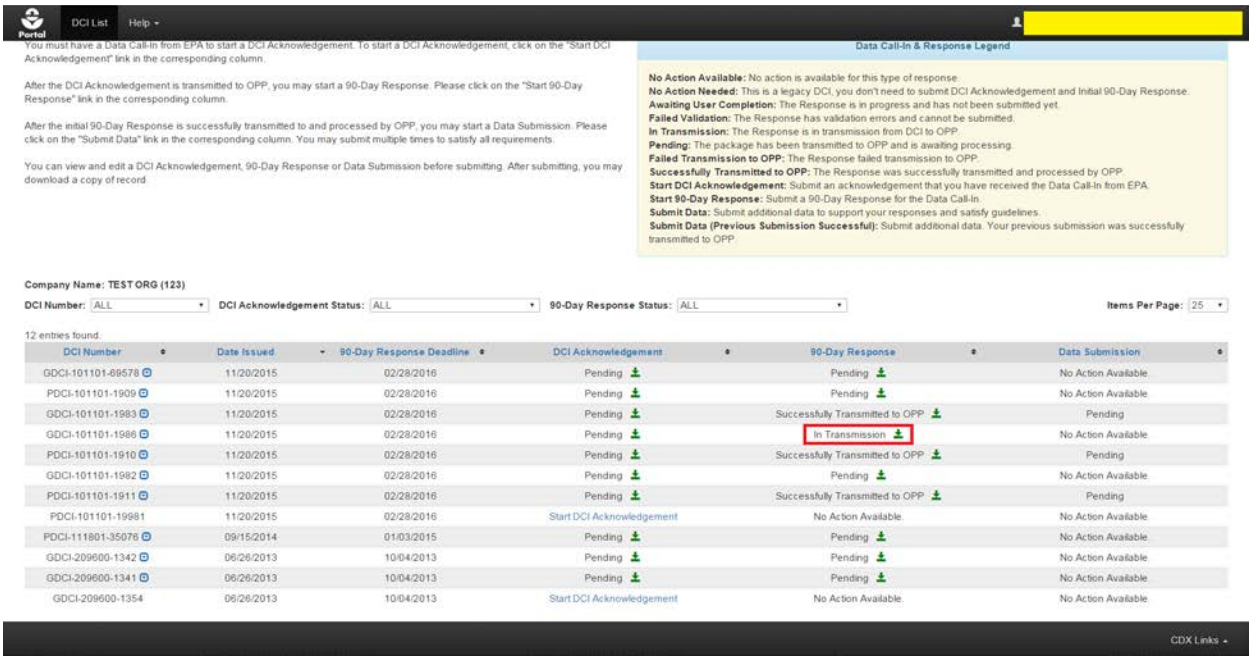


Exhibit 12-22: DCI List After Submission

In addition, you will receive an email stating that your 90-Day Response Submission was successfully transmitted to OPP. An example of this email is seen below in Exhibit 12-23.

Your 90-Day Response Submission (GDCI-101101-1972) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_DCI_2016_000003.

Below are the guideline(s) included in this response:
Acute dermal irritation - 870.2500
21/28-day dermal toxicity - 870.3200
90-day dermal toxicity - 870.3250

Once your 90-Day Response is processed by OPP, you can start additional data submission.

Company Name: TEST ORG
Company Number: 123

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

Exhibit 12-23: GDCI 90-Day Response Email Notification

12.5 PDCI 90-Day Response

The following sections detail the process of completing and submitting a PDCI 90-Day Response. PDCIs may contain multiple EPA Registration Numbers. Unlike GDCIs, the guidelines are grouped under each EPA Registration Number. This allows you to respond to the guidelines differently based on the EPA Registration Number provided.

If you choose to cancel a product registration, you will not have to fill out any of the guidelines associated with that registration. However, the other product registrations and their guidelines will remain unaffected. Please refer to the subsequent PDCI sections for more details.

Important: If you forget the passphrase to your DCI, you will be unable to access it. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company. The same passphrase must be used throughout the life of the DCI.

12.5.1 PDCI 90-Day Response Submission Screen

After clicking the ‘Start 90-Day Response’ link, you will be navigated to the ‘90-Day Response Submission’ screen. This screen contains summary information about the DCI. You can also upload DCI-level documents on this screen. A navigation tree is also present, pictured below in Exhibit 12-24.

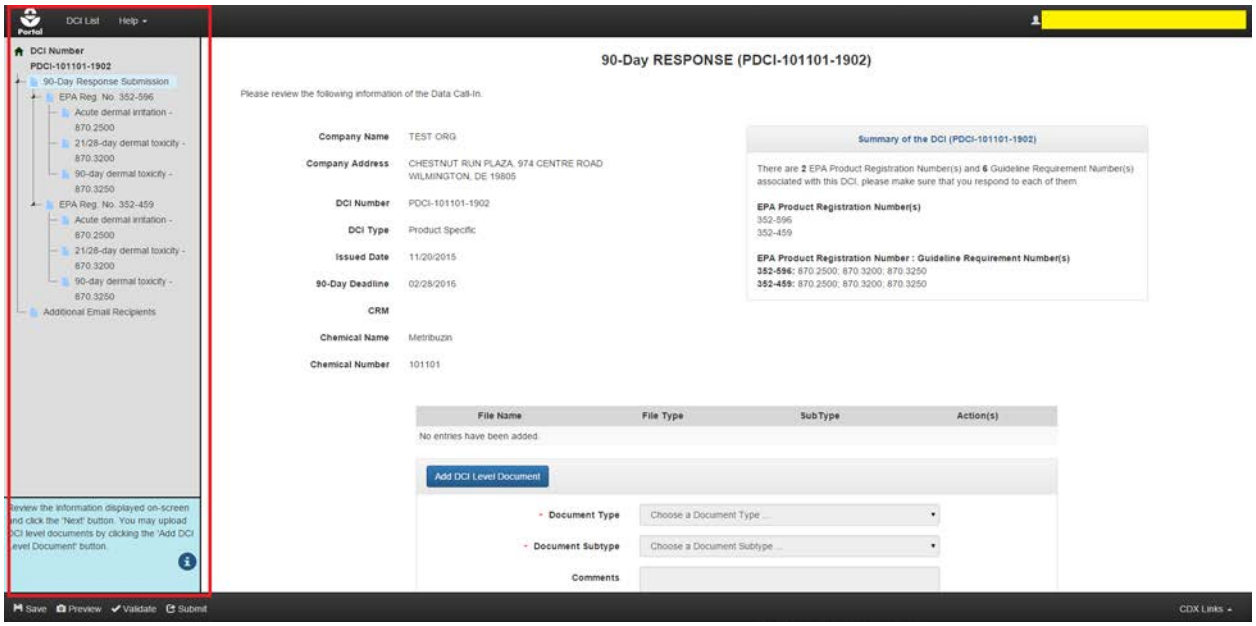


Exhibit 12-24: PDCI Navigation Tree

Since the ’90-Day Response Submission’ screen is the same for both GDCIs and PDCIs, please refer to **Section 12.4.1** for a detailed description of the items on this page.

Navigation: Review the displayed information and upload DCI level documents if desired. Click the ‘Next’ button.

Note: For information about the ‘Save,’ ‘Preview,’ ‘Validate,’ and ‘Submit’ buttons in the Application Footer, proceed to **Section 5.4**. Otherwise, proceed to the next section.

12.5.2 PDCI EPA Product Registration Screen

This screen contains basic information about an EPA Registration Number. On this screen, you may choose one of three radio button options. Select a radio button option for each EPA Registration Number (if more than one) before proceeding to the 'Requirement Status & Registrant Response' section.

The following information is displayed on the 'EPA Product Registration' screen:

- **EPA Registration Number:** The EPA Registration Number associated with the DCI. This field is not editable.
- **Product Name:** The Name of the product associated with the DCI. This field is not editable.

The following radio button options are available:

- **I wish to cancel this product registration voluntarily:** Selecting this option will cause a file upload section to appear.

  Exhibit 12-25 below demonstrates this selection. A document must be uploaded to support the cancellation. Click the 'Add Document' button, choose a 'Document Type' and 'Subtype' and upload a document via the 'Browse…' button. Any uploaded documents will appear in the documents table in the center of the screen. You can delete added documents by pressing the red 'Delete' icon in the 'Action(s)' column. The document types are as follows:

  - Correspondence
    - Company Letter
    - General Correspondences

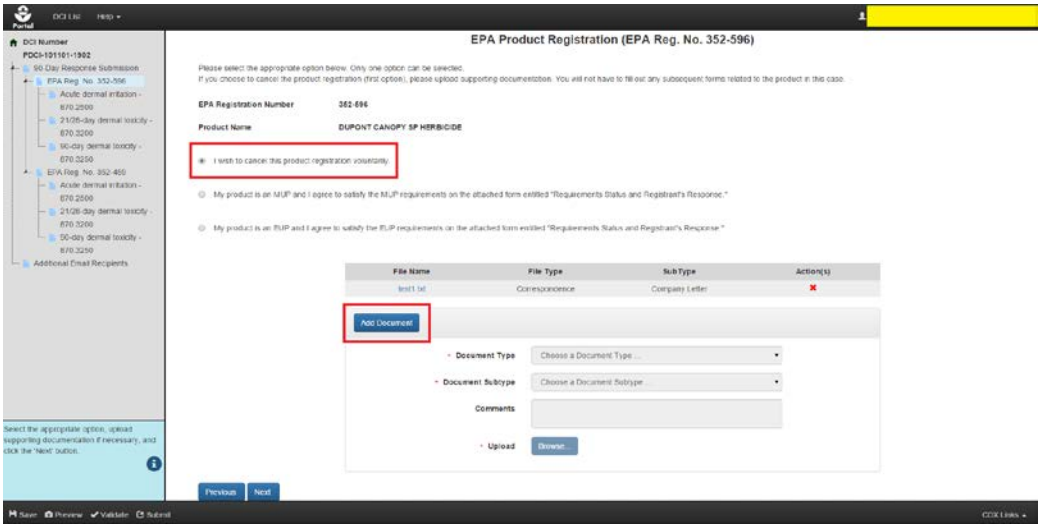


Exhibit 12-25: PDCI Voluntary Cancellation

Navigation: Upload a supporting document and click the 'Next' button.

Important: Selecting this option means that you will not have to respond to any of the guidelines grouped under that specific EPA Product Registration Number. A gray strikethrough line will appear in the navigation tree and red text will appear on the associated guideline pages. See Exhibit 12-26 below for reference.

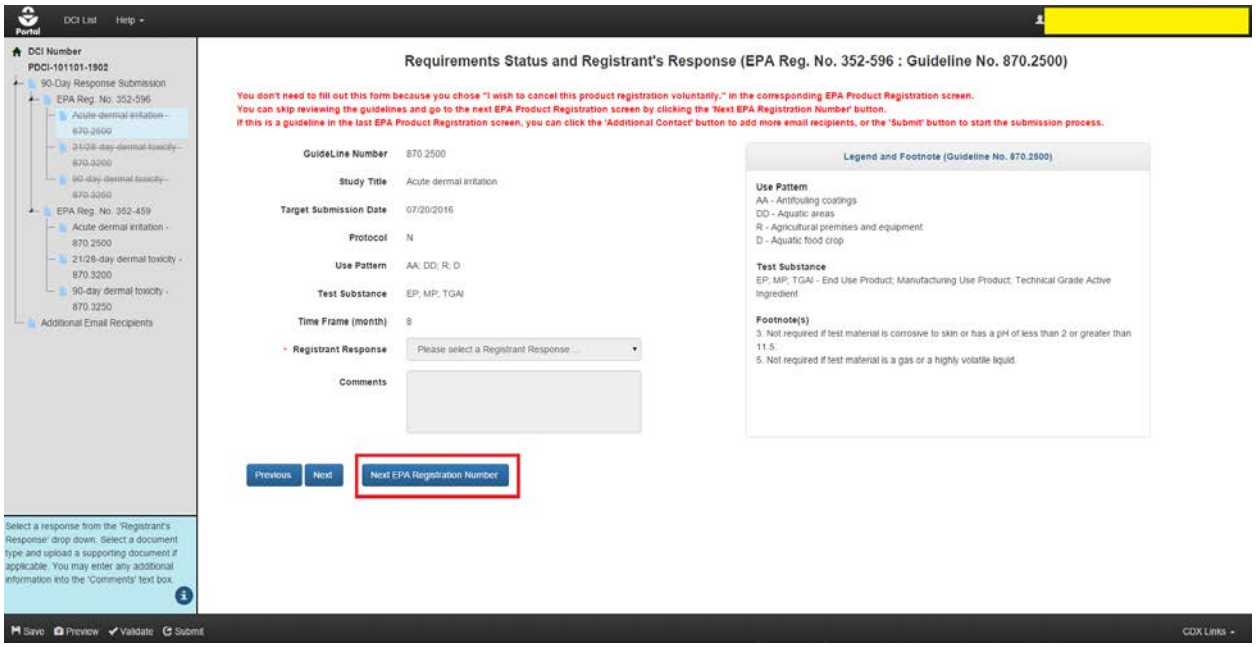


Exhibit 12-26: PDCI Response to Guidelines Not Needed

Navigation: Since no guidelines under this EPA Production Registration Number require a response, you may click the 'Next EPA Registration Number' button to proceed to the next registration number.

- **My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response:** Selecting this option requires no additional data. Exhibit 12-27 below demonstrates this selection. After selecting this option, click the 'Next' button; you can continue navigating through the DCI.
- **My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response:** Selecting this option requires no additional data.
- Exhibit 12-28 below demonstrates this selection. After selecting this option, click the 'Next' button; you can continue navigating through the DCI.

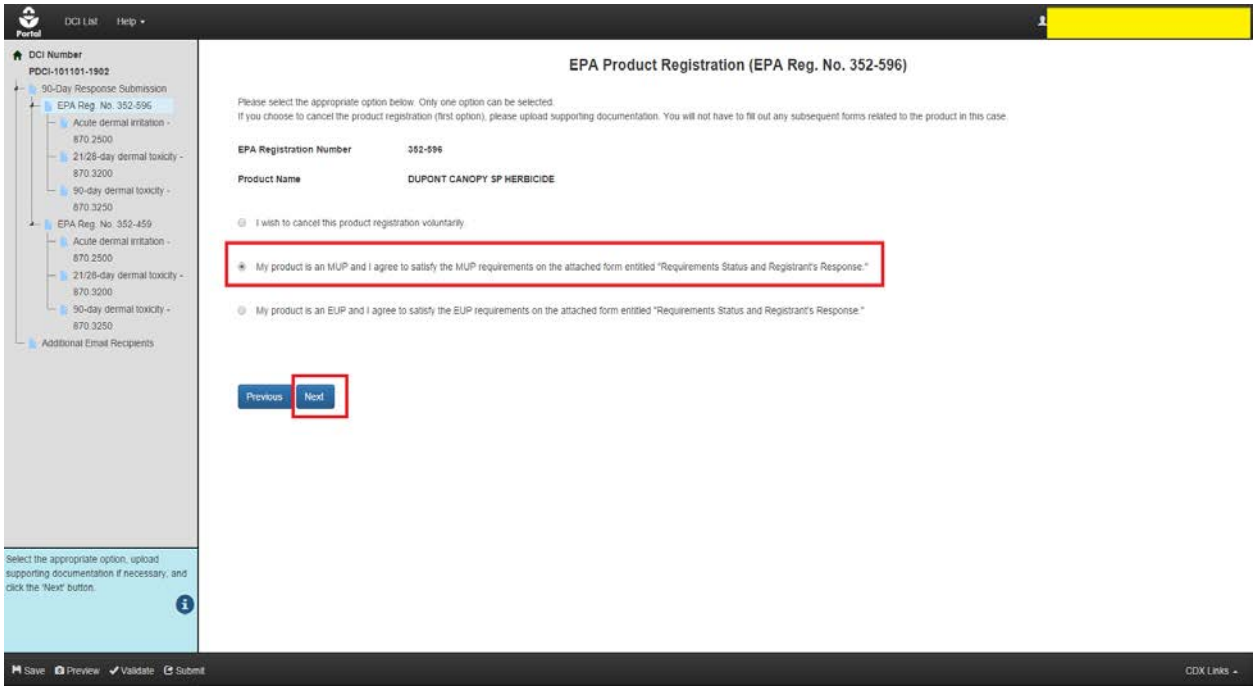


Exhibit 12-27: MUP Option

Navigation: After selecting this option, click the 'Next' button to respond to the guidelines within the DCI as seen below in Exhibit 12-27.

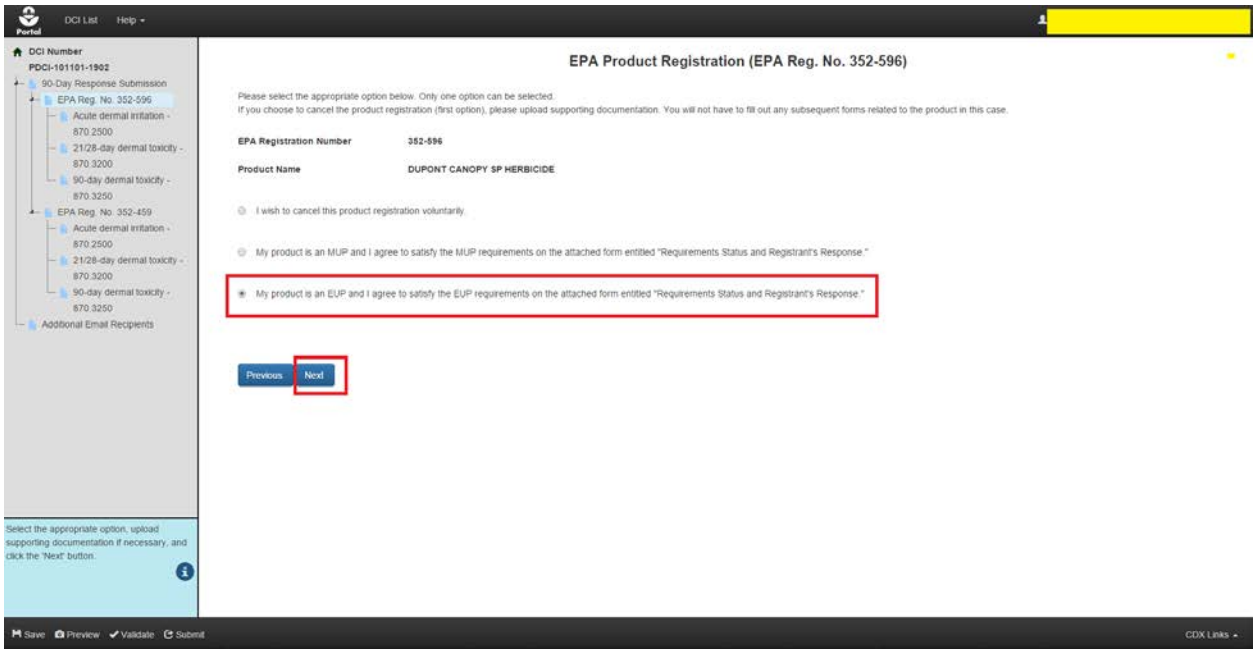


Exhibit 12-28: EUP Option

Navigation: After selecting this option, click the 'Next' button to respond to the guidelines within the DCI.

12.5.3 PDCI Requirements Status and Registrant's Response Screen

This screen contains information about a Guideline Number within the DCI. On this screen, you may choose a response from the 'Registrant Response' dropdown. After selecting a response, additional fields or a document upload section may appear so that you can submit data to support your response. You may also enter comments about the response into the 'Comments' text box. You must respond to all guidelines before submitting the 90-Day Response.

The following information is displayed on the 'Requirements Status and Registrant's Response' screen:

- **GuideLine Number:** The Guideline Number associated with the DCI. This field is not editable.
- **Study Title**: The study associated with the guideline. This field is not editable.
- **Target Submission Date:** The targeted date for submission. This field is not editable.
- **Protocol:** The protocol for the guideline. This field is not editable.
- **Use Pattern:** The use pattern for the guideline. This field is not editable.
- **Test Substance:** The test substance for the guideline. This field is not editable.
- **Time Frame (month):** The time frame for the guideline. This field is not editable.

You may select a response for the guideline via the 'Registrant Response' drop down. You may also copy a response to all guidelines under that EPA Product Registration Number by clicking the blue icon next to the 'Registrant Response' drop down and clicking 'OK' in the pop-up window. Please note that this will only copy the response to the guidelines grouped under that particular EPA Product Registration Number. This will ensure that all guidelines under a specific registration number have the selected response applied to them. You can later change the response for the affected guidelines if you wish. See Exhibit 12-15 in the GDCI section above for reference.

The possible responses for 'Registrant Response' are:

- **Developing Data:** Selecting this response indicates that you will provide study data at a later date. There is no document upload or data required as part of 90-Day Response submission for this response. If you choose 'Developing Data,' you can click 'Next' to proceed to the next guideline.
- **Agreement to Cost Share:** This response requires at least one 'General Correspondence' document upload. When selecting a response that requires a file upload, there are two radio buttons available. The 'Add New Document' radio button should be used when you want to upload a new document to the response. Click the 'Add New Document' radio button. The document types are as follows:
    - Form
        - Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data.
    - Correspondence
        - General Correspondences

Select the ‘Correspondence’ document type and the ‘General Correspondences’ subtype. Enter any comments if necessary. Upload a document via the ‘Browse…’ button. Click the ‘Save’ button. The uploaded document will appear in the documents table in the center of the screen. You may delete an uploaded document by clicking the red ‘Delete’ icon in the ‘Action(s)’ column. After uploading a document, you will not be able to change your ‘Registrant Response’ selection. You will have to delete all uploaded documents before you can change your response. See

Exhibit 12-16 in the GDCI section above for an example. Exhibit 12-17 and Exhibit 12-18 above also detail the ‘Use Previously Uploaded Document’ radio button.

- **Offer to Cost Share:** This response requires at least one ‘General Correspondence’ and one ‘Form 8570-32 (Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data)’ document upload. This response has the same document types as ‘Agreement to Cost Share.’ Upload the necessary documents and click the ‘Next’ button to proceed to the next guideline.
- **Submitting Existing Data:** This response allows you to upload study documents. It features the standard file upload feature, but also allows you to enter an MRID for your study via the ‘MRID’ field. For assistance with generating a root MRID, please refer to **Section 4**. The document types are as follows:
    - Study
        - Data Entry Spreadsheet Template (DEST)
        - Data Waiver Request
        - Protocol
        - Study
        - Study Profile
        - Supplemental Study Data
        - Transmittal Document
        - Water Monitoring Data

Upload all necessary documents and click the ‘Next’ button to proceed to the next guideline. See Exhibit 12-19 in the GDCI section above for reference.

Note: The MRIDs you enter will be validated during submission or when you press the ‘Validate’ button within the Application Footer.

- **Upgrading a Study:** This response allows you to upload study documents. It features the standard file upload feature, but also allows you to enter an MRID for your study via the ‘MRID’ field. For assistance with generating a root MRID, please refer to **Section 4**. This response has the same document types and features as the ‘Submitting Existing Data’ response.
- **Citing a Study:** This response allows you to cite studies. It features an ‘MRID Number’ field so that you may enter the MRID of the studies you are citing. You can click the ‘Cite an additional MRID Number’ link to cite multiple studies. You can also delete MRIDs by

clicking the red ‘Delete’ icon next to the MRID Number. See Exhibit 12-20 in the GDCI section above for reference.

- **Waiver Request:** This response features the standard file upload feature. The document type and subtype are as follows:
    - Correspondence
        - Waiver Request

Upload the necessary documents and click the ‘Next’ button to proceed to the next guideline.

- **Not Applicable:** This response features the standard file upload feature. The document type and subtype is the same as the ‘Waiver Request’ response. This response also features an ‘MRID’ field so that you may enter an MRID. Upload the necessary documents and click the ‘Next’ button to proceed to the next guideline.

12.5.4 Additional Email Recipients and GDCI Submission Process

After all guidelines have been responded to, you may indicate additional email recipients on the ‘Additional Email Recipients’ screen. This screen allows you to indicate additional email addresses to which DCI notification emails will be sent. By default, these emails are only sent to the PSP account that performs the submissions. These emails will inform the recipients when 90-Day Responses and Data Submissions are submitted to OPP.

Click the ‘Add a new email address’ link. An ‘Email Address’ text field will appear. Enter the email address of the desired recipient. If you would like to add more than one email address, click the 'Add a new email address’ link as many times as necessary. You can use the red ‘x’ icon in order to delete entered addresses.

Once you are finished entering email addresses, click the ‘Submit’ button to begin the submission process. Press ‘OK’ in the pop-up that appears. See Exhibit 12-21 in the GDCI section above for reference.

Please refer to **Section 10** for assistance with the submission process. After you have successfully submitted the DCI, you will be navigated back to the ‘DCI List’ screen. Your submitted DCI will have a status of ‘In Transmission.’ You will be able to submit data once your DCI status changes to ‘Successfully Transmitted to OPP.’ See Exhibit 12-22 in the GDCI section above for reference.

In addition, you will receive an email stating that your 90-Day Response Submission was successfully transmitted to OPP. An example of this email is seen below in Exhibit 12-23.

12.6 Submit Data

The ‘Submit Data’ feature of PSP allows you to submit additional documents after you have submitted a 90-Day Response. These additional documents will support previous responses and help satisfy guidelines. You may submit data at any point after submitting a 90-Day Response. The ‘Submit Data’ feature functions the same for both GDCIs and PDCIs.

Navigate to the ‘DCI List’ screen. Before you can submit data, the status of your 90-Day Response submission must be ‘Successfully Transmitted to OPP.’ Click the ‘Submit Data’ link in the ‘Data Submission’ column. See Exhibit 12-29 below for reference.

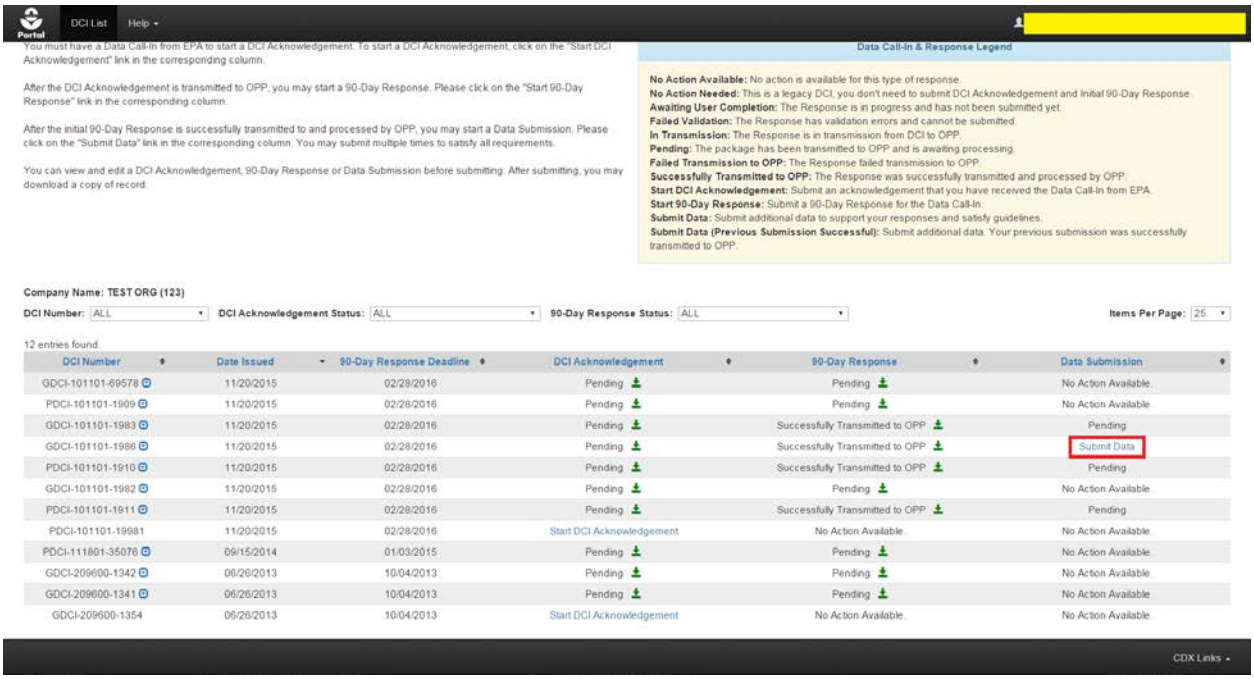


Exhibit 12-29: 'Submit Data' Link

Navigation: Click the 'Submit Data' link.

After clicking the 'Submit Data' link, you will be navigated to the 'Enter Passphrase' screen. Enter the passphrase that was used to encrypt your 90-Day Response submission. Refer to **Section 8.1** above if you need assistance with navigating this screen.

Important: If you forget the passphrase to your DCI, you will be unable to access it. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company. The same passphrase must be used throughout the life of the DCI. Your data submission will require the same passphrase that was used to encrypt your 90-Day Response submission.

After entering the correct passphrase, you will be navigated to the 'Data Submission' screen. As seen in Exhibit 12-30 below, this is the same screen you were first navigated to when starting the 90-Day Response. Notice that your previous response to the first EPA Product Registration Number is saved; the guidelines are crossed out in the navigation tree.

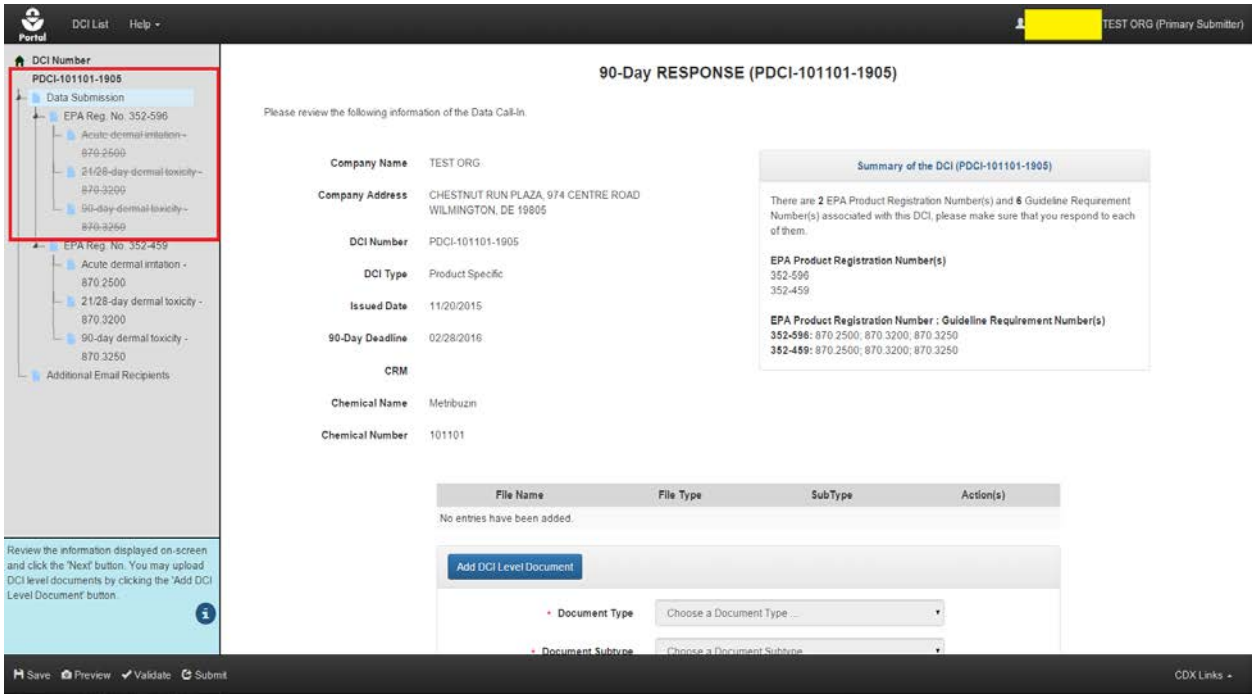


Exhibit 12-30: Data Submission Screen

Navigation: Add additional DCI Level Documents if desired by clicking the 'Add DCI Level Document' button. Proceed to the next set of guidelines to submit additional documents.

The 'Data Submission' portion of PSP allows you to re-enter your 90-Day Response and upload additional documents to satisfy guidelines. All previously entered data will be displayed. However, you will not be able to change any of your responses as seen in Exhibit 12-31 below. Any previously submitted documents will have a status of 'Previously Submitted' in the 'Action(s)' column. For assistance with uploading documents to a response, please refer to **Section 12.4.3** for GDCIs and **Section 12.5.3** for PDCIs.

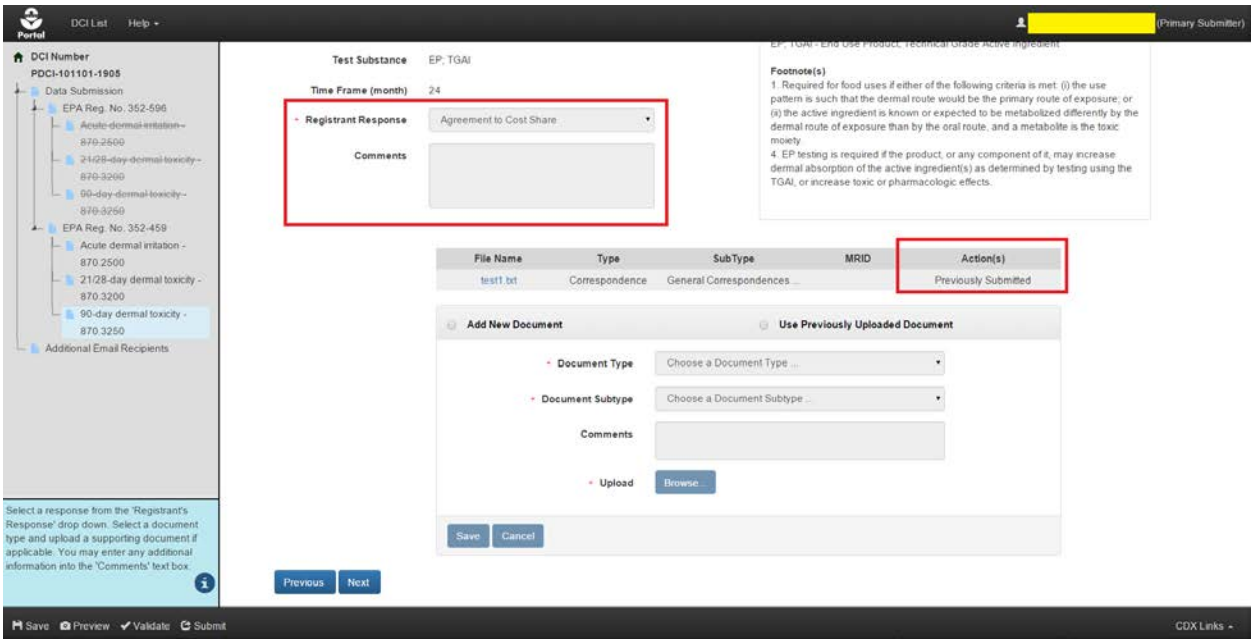


Exhibit 12-31: Data Submissions

Navigation: Upload any additional documents and click the ‘Next’ button.

The submission process for a Data Submission is the same as the 90-Day Response. Please refer to **Section 10** for assistance with the PSP submission process. When you successfully submit a Data Submission, the 90-Day Response copy of record is updated on the ‘DCI List’ screen. The copy of record is additive, it will show all the documents submitted as part of the 90-Day Response or subsequent Data Submissions. Please refer to **Section 12.7** for assistance with accessing the copy of record. You can make another data submission after your previous data submission successfully transfers to OPP. However, you will not be able to submit additional data until the status changes to ‘Submit Data (Previous Submission Successful).’ You can submit data as many times as is necessary to satisfy all guidelines. See Exhibit 12-32 below.

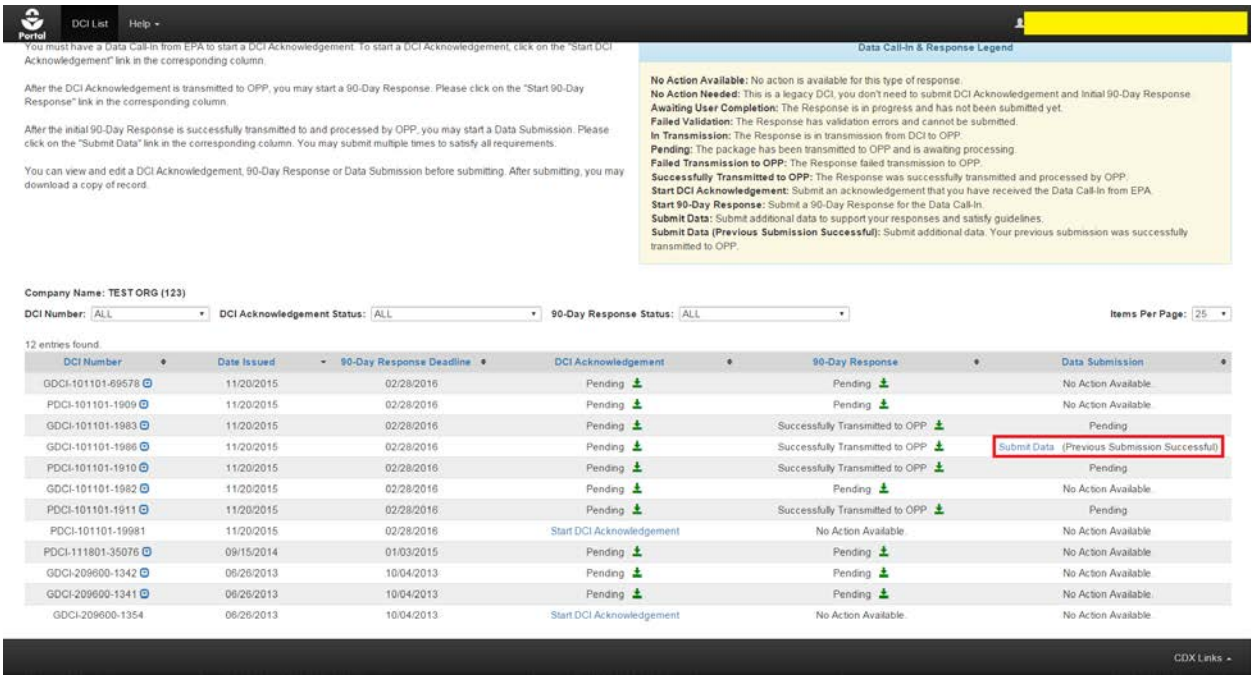


Exhibit 12-32: Submit Data (Previous Submission Successful)

Navigation: Click the 'Submit Data (Previous Submission Successful)' link to start another data submission. You can do this as many times as necessary until all guidelines are satisfied.

12.7 DCI Copy of Record

Once you submit a DCI Acknowledgement or 90-Day Response, you will have the ability to download a copy of record. To download a copy of record, click the green 'Copy of Record' icon in either the 'DCI Acknowledgement' or '90-Day Response' column on the 'DCI List' screen. See Exhibit 12-33 below for reference.

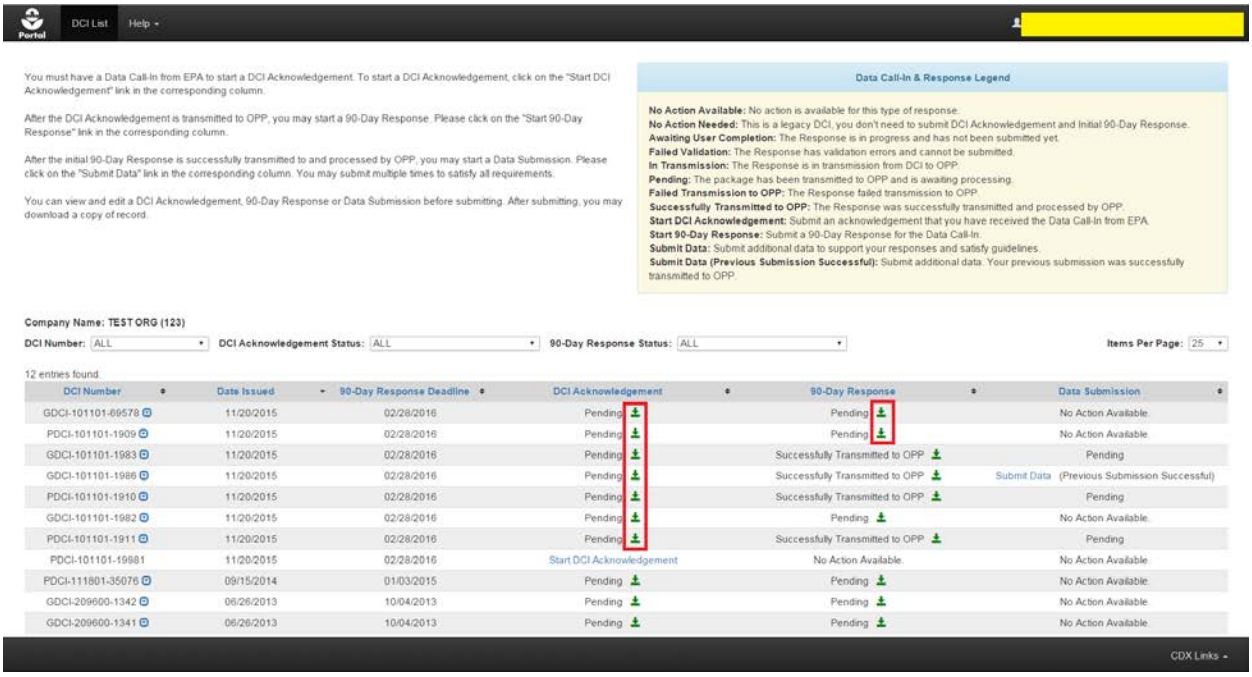


Exhibit 12-33: 'Copy of Record' Icons

Navigation: Click the green 'Copy of Record' icon in the 'DCI Acknowledgement or '90-Day Response' column.

After clicking the 'Copy of Record' icon, you will be navigated to the 'Cross-Media Electronic Reporting Regulation (CROMERR)' screen. You will have to enter the passphrase used to encrypt the submission, your CDX password, and the answer to one of your secret questions to see the copy of record. See Exhibit 12-34 below.

Exhibit 12-34: CROMERR Copy of Record Screen

Navigation: Enter the passphrase used to encrypt the submission, your CDX password, and the answer to one of your secret questions. Click the 'Next' button.

Note: Since DCI Acknowledgements do not require a passphrase, you will only have to enter your CDX password and the answer to one of your secret questions.

After entering all the requisite information, you will be navigated to the 'Copy of Record' screen as seen in Exhibit 12-35. Click the green 'Download Document' icon in the 'Action(s)' column to download a copy of record for your submitted documents. You may also download a PDF overview of your submission.

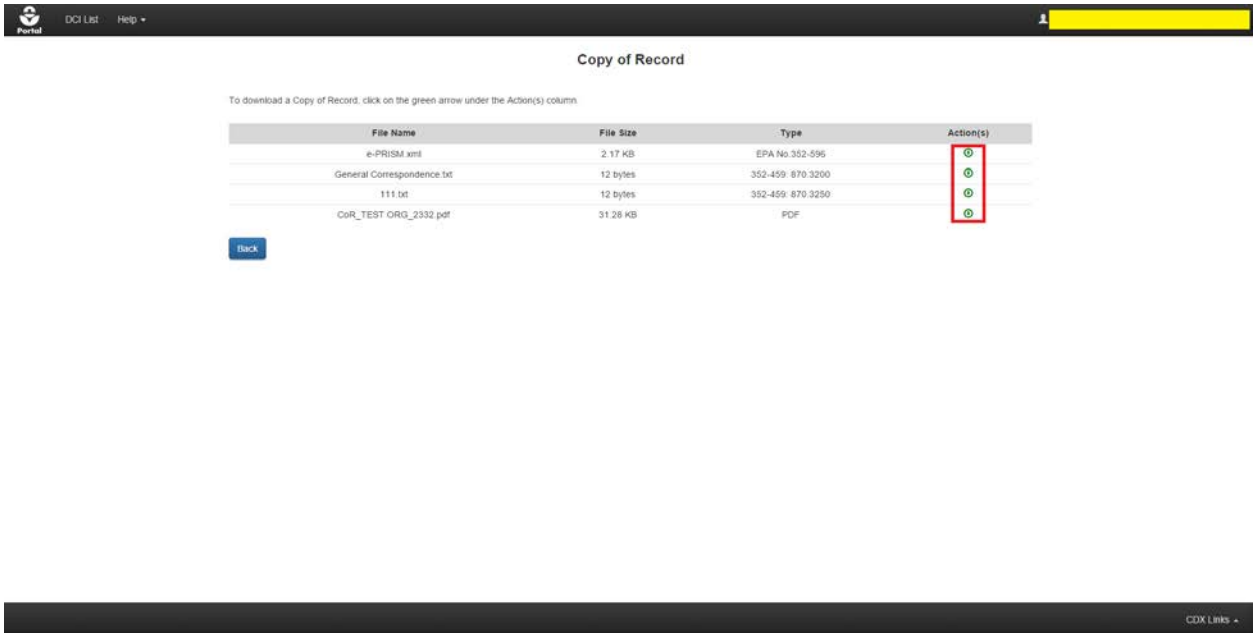


Exhibit 12-35: Copy of Record Screen

Navigation: Click the green 'Download Document' icons to download the associated documents.

12.8 Resubmission of 90-Day Response

Once a 90-Day Response or Data Submission has been successfully transmitted to OPP, users can choose to change their previous 90-Day Response. Users may modify their responses to data requirements, upload additional documents, or change how they want to support their product registration. The 90-Day Response can be changed as often as needed. However, once users commit to changing a 90-Day Response, they will not be able to submit data until the revised 90-Day Response has been successfully transmitted to OPP.

To change a 90-Day Response, click the 'Change 90-Day Response (Previous Submission Successful)' link in the '90-Day Response' column. Exhibit 12-36 below displays a screen capture of the link to change the 90-Day Response.

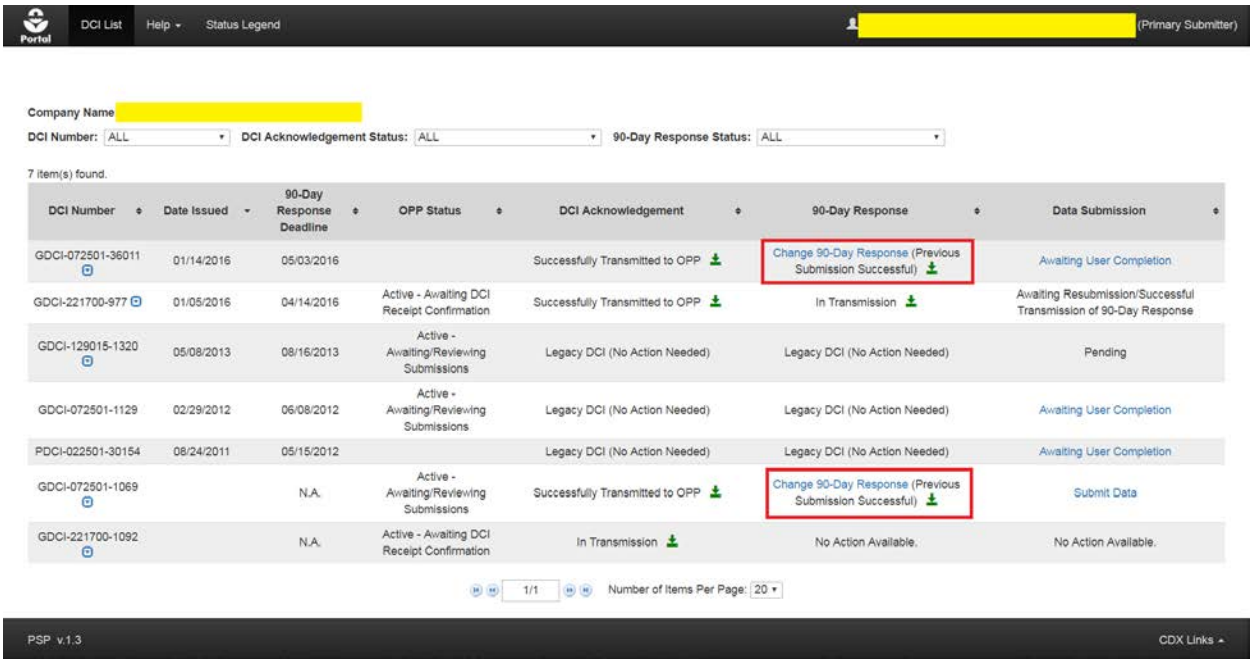


Exhibit 12-36: 'Change 90-Day Response (Previous Submission Successful)' link

Navigation: Click the blue 'Change 90-Day Response (Previous Submission Successful)' link in the '90-Day Response' column.

After clicking the 'Change 90-Day Response (Previous Submission Successful)' link, a pop-up modal will appear with the following language: "Are you sure you want to change your 90-Day Response? If 'OK' is selected, you will not be able to make data submissions until your revised 90-Day response has been successfully transmitted to OPP. Any in-progress data submission information (that has not yet been submitted) will be lost if you choose to change your 90-Day Response. If you would like to retain the copy of record for your original 90-Day Response, please click the 'Copy of Record' icon (green arrow) next to the 90-Day Response before changing your response."

Important: Any in-progress data submission information (not yet submitted) will be lost if you choose to change your 90-Day Response. Additionally, if you would like to retain the original 90-Day Response copy of record, click the green 'Copy of Record' icon in the '90-Day Response' column. Please refer to **Section 12.7** for assistance with accessing and downloading the copy of record.

Exhibit 12-37 below displays a screen capture of the pop-up modal.

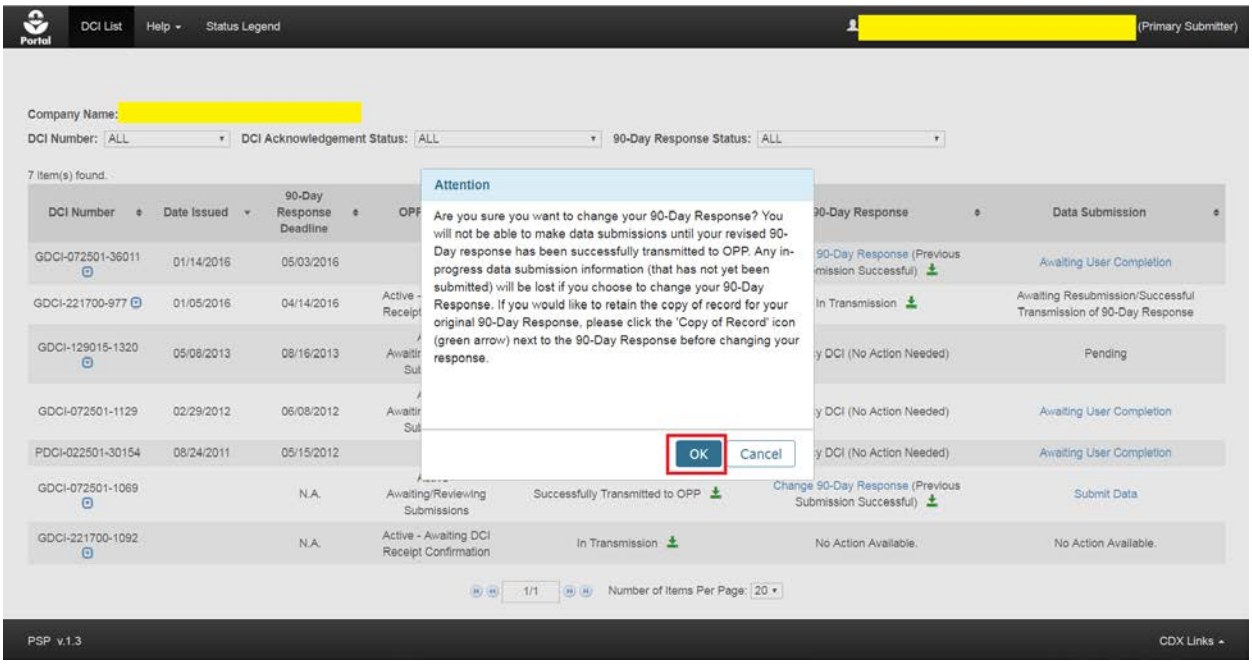


Exhibit 12-37: Change 90-Day Response – Pop-up Modal

Navigation: Click the ‘OK’ button to proceed to the ‘Enter Passphrase’ screen.

After clicking ‘OK’ in the pop-up modal, the user will be navigated to the ‘Enter Passphrase’ screen for the 90-Day Response. After entering the correct passphrase and clicking ‘Next,’ the user will be navigated to the ‘90-Day Response Submission’ screen, seen in Exhibit 12-38 below.

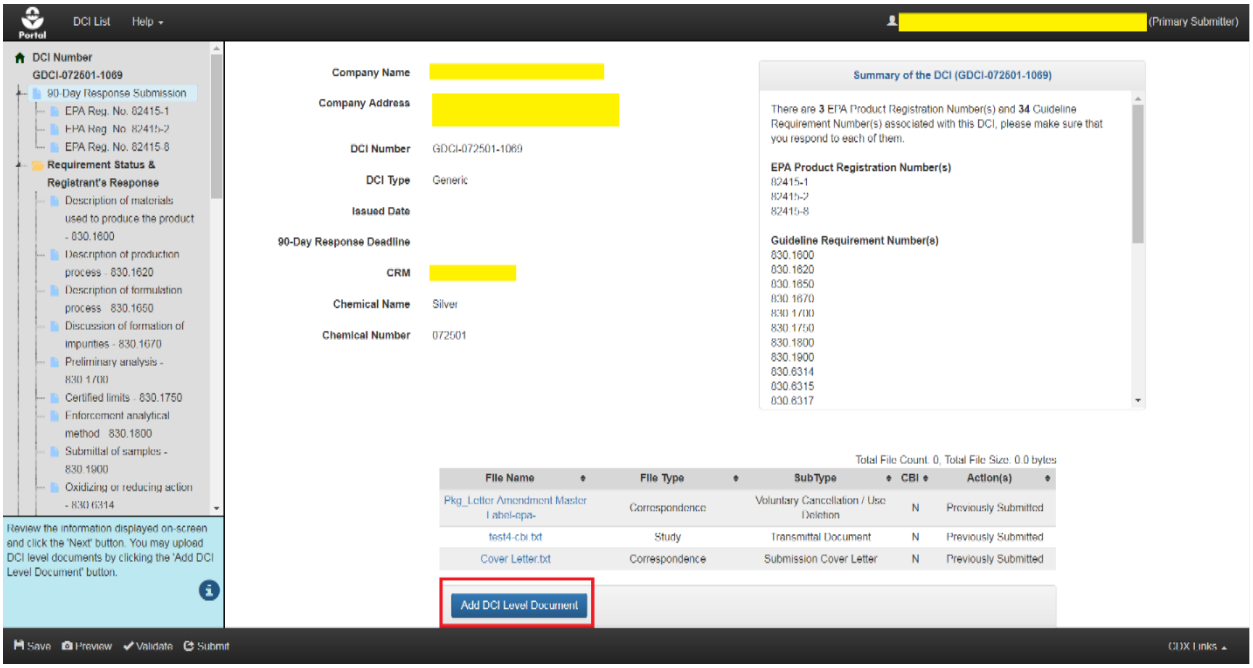


Exhibit 12-38: 90-Day Response Submission Screen

Navigation: Previously submitted files have a status of 'Previously Submitted' in the 'Action(s)' column and cannot be edited. Click the 'Add DCI Level Document' to add more documents to your submission if necessary.

Navigate to one of the 'EPA Product Registration' screens via the navigation tree. You can change your selection on any of these 'EPA Product Registration' screens. When attempting to change your selection, a pop-up modal will appear with the following language: "Are you sure you want to change your selection? Any documents or cited Source EPA Registration Number(s) associated with your previous selection will be lost."

Important: Any previously submitted documents or cited Source EPA registration number(s) associated with your previous selection will be lost if you click 'OK' on the pop-up modal.

See Exhibit 12-39 below for a screen capture of the pop-up modal.

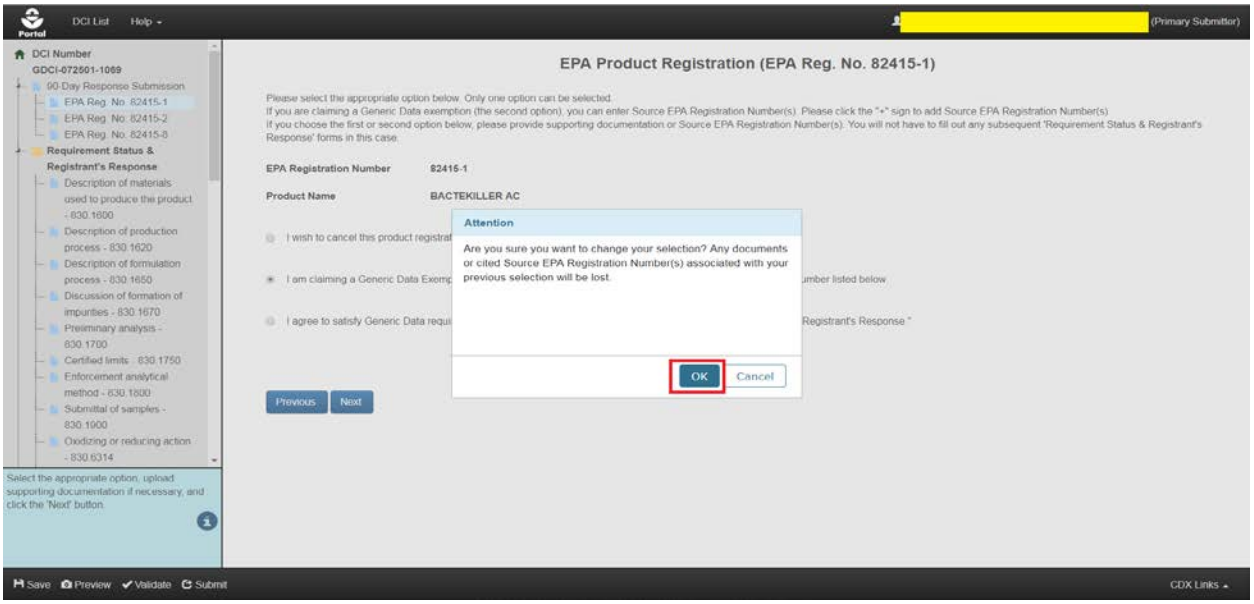


Exhibit 12-39: EPA Product Registration Pop-up Modal

Navigation: If you need to change your selection on the 'EPA Product Registration' screen, click a different radio button and click 'OK' in the resulting pop-up modal.

Navigate to a guideline screen via the navigation tree. On the guideline screens, you may upload additional documents, provide additional data, or change the 'Registrant Response' altogether. Any previously submitted documents will have a status of 'Previously Submitted' in the 'Action(s)' column and will not be editable. You can select a different 'Registrant Response' on the guideline screens by clicking the 'Registrant Response' drop-down and selecting a different response.

When attempting to change the response, a pop-up modal will display with the following language: "If you change the Registrant Response for this guideline, all information associated with this particular guideline, including the documents you submitted as part of previous 90-Day Response Submissions and/or Data Submissions, will be lost. Information associated with other guidelines will remain unaffected. Are you sure you want to proceed?"

Important: All documents/information (including previously submitted documents) associated with the response will be lost when changing the 'Registrant Response.' Information associated with other guidelines will be unaffected.
Exhibit 12-40 below displays a screen capture of the guideline pop-up modal.

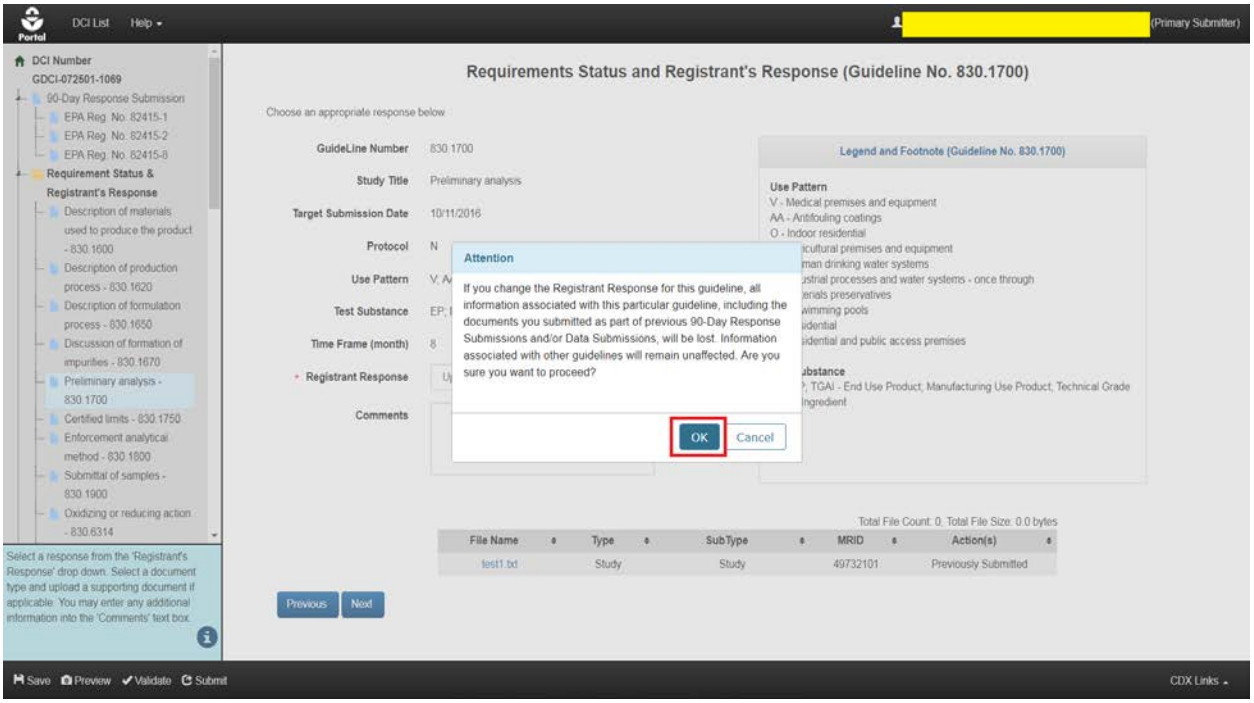


Exhibit 12-40: Guideline Pop-up Modal

Navigation: If you need to change your registrant response for a guideline, select a different option in the 'Registrant Response' drop-down and click 'OK' in the resulting pop-up modal.

After changing all necessary information as part of the 90-Day resubmission, you may submit via the 'Submit' button in the application footer. For assistance with the submission process, please refer to **Section 10.**

After submitting the 90-Day Response resubmission, you will be navigated to the 'DCI List' screen. The newly submitted 90-Day Response will have a status of 'In Transmission' and the status in the 'Data Submission' column will be 'Awaiting Resubmission/Successful Transmission of 90-Day Response.'

Note: You will not be able to submit data or change the 90-Day Response until the 90-Day Response resubmission has been successfully transmitted to OPP. Once it has been successfully transmitted to OPP, its status will change to 'Change 90-Day Response (Previous Submission Successful)' and you will have the opportunity to either submit data or change the 90-Day Response again. The copy of record will reflect the most recent 90-Day Response submission.

Exhibit 12-41 below displays a screen capture of a newly submitted 90-Day resubmission on the 'DCI List' screen.

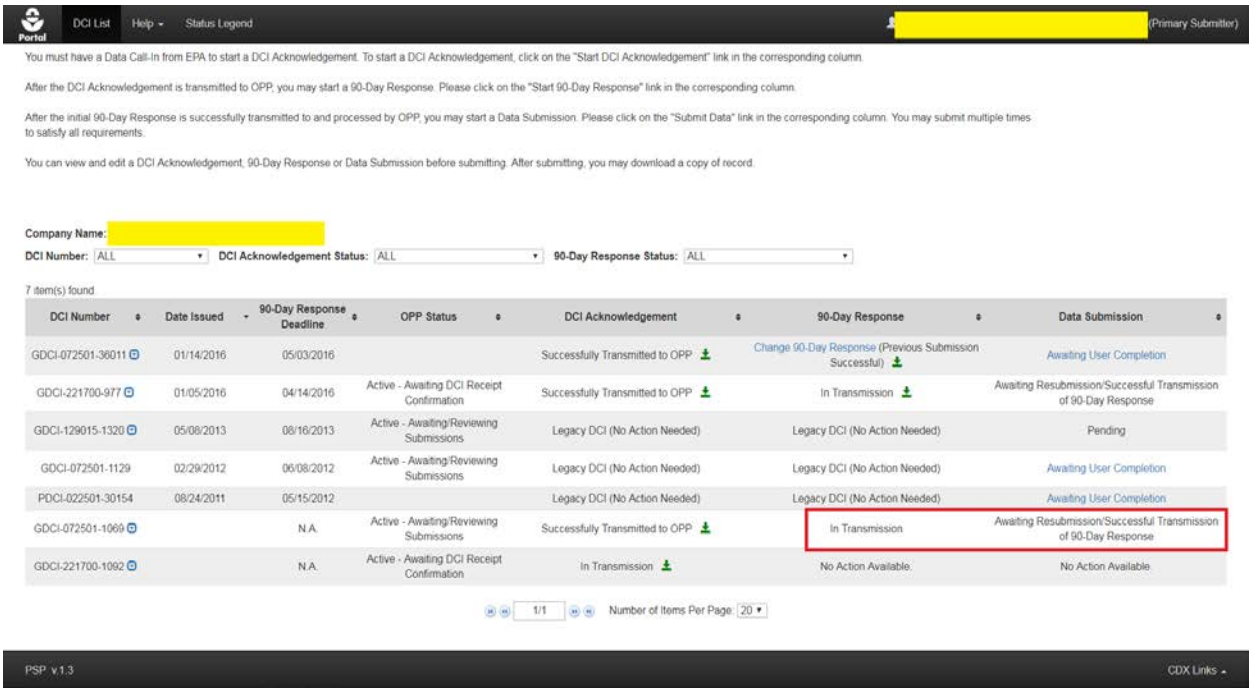
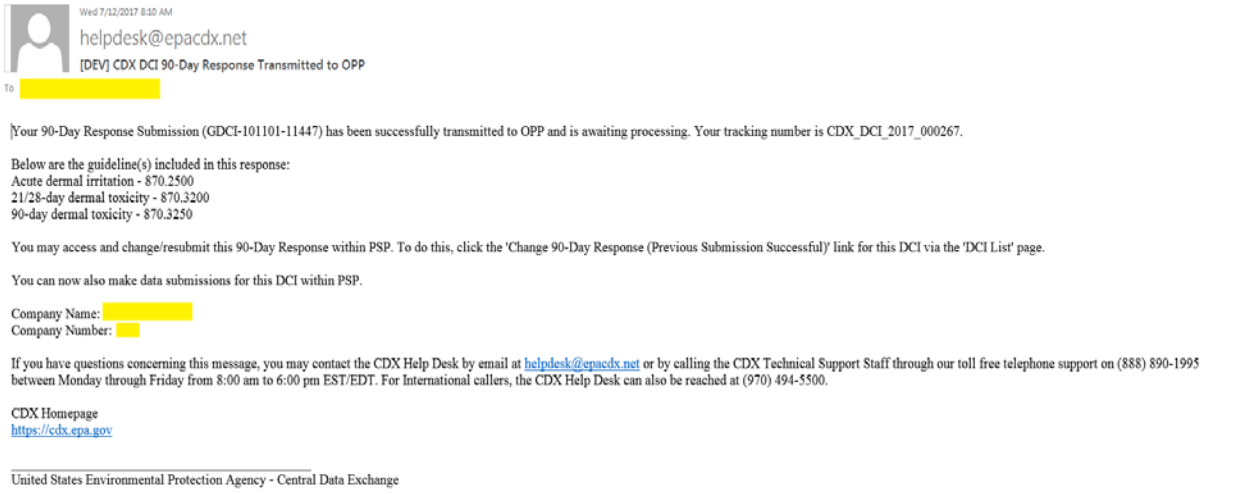


Exhibit 12-41: DCI List Screen – 90-Day Resubmission

Navigation: Confirm the status of the newly submitted 90-Day resubmission.

A notification email will be sent to you once the 90-Day Response resubmission has been successfully transmitted to OPP, seen in Exhibit 12-42 below.


Wed 7/12/2017 8:10 AM
helpdesk@epacdx.net
[DEV] CDX DCI 90-Day Response Transmitted to OPP
To

Your 90-Day Response Submission (GDCI-101101-11447) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_DCI_2017_000267.

Below are the guideline(s) included in this response:
Acute dermal irritation - 870.2500
21/28-day dermal toxicity - 870.3200
90-day dermal toxicity - 870.3250

You may access and change/resubmit this 90-Day Response within PSP. To do this, click the 'Change 90-Day Response (Previous Submission Successful)' link for this DCI via the 'DCI List' page.

You can now also make data submissions for this DCI within PSP.

Company Name:
Company Number:

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

Exhibit 12-42: 90-Day Response Resubmission Notification Email

13 Voluntary Data Submissions

This section describes the process to prepare a package for a voluntary data submission (non-DCI) through PSP. Users may cite MRID numbers and submit documents not related to specific Data Call-Ins. As elsewhere in PSP, voluntary data submissions (VDS) feature real-time validations, status updates, and email notifications to ensure a streamlined experience. Voluntary data submissions will be associated with a specific registration review case number.

Note: Voluntary data submission visibility is based off company number. That is, all users (both Primary Submitter and Authorized Agent) associated with the same company number will be able to share and see the same submissions.

To access voluntary data submissions, click on the 'Voluntary Submission' icon on the PSP 'Home' screen. Upon clicking the link, you will be navigated to the 'Voluntary Data Submission List' screen. Exhibit 13-1 below displays the 'Voluntary Submission' link on the PSP 'Home' screen.

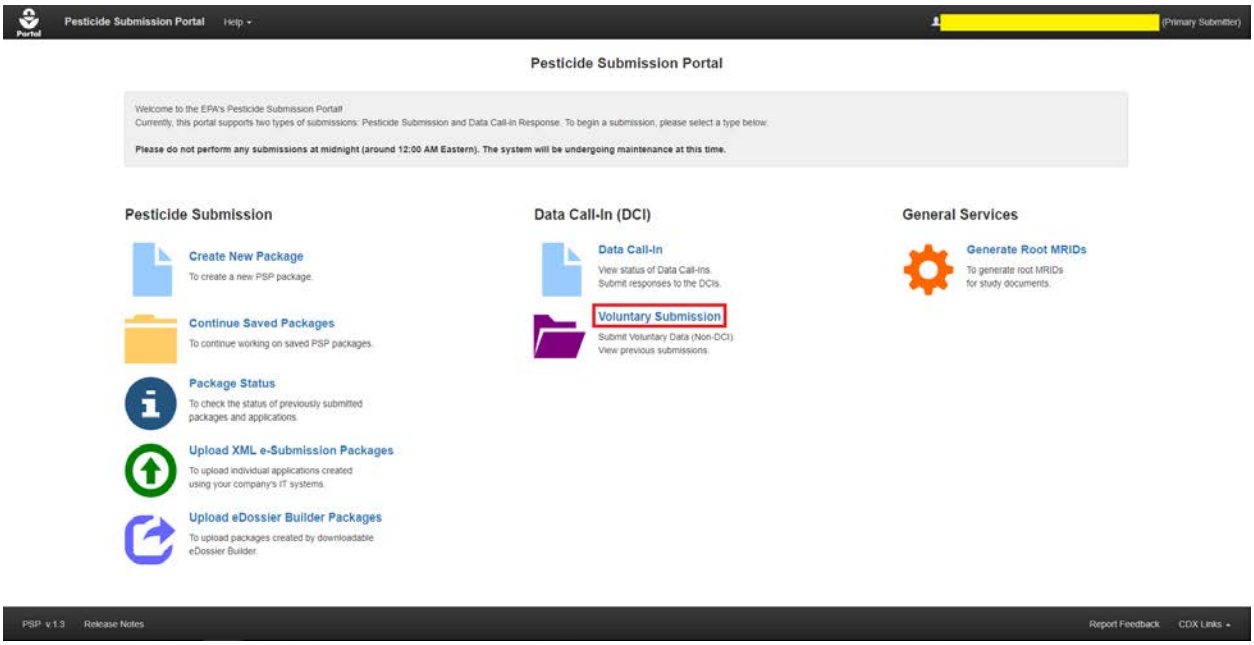


Exhibit 13-1: Voluntary Submission Link

Navigation: Click the 'Voluntary Submission' link on the PSP 'Home' screen.

13.1 Voluntary Data Submission List Screen

The 'Voluntary Data Submission List' screen allows you to see the details and statuses of voluntary data submissions. Both in-progress and submitted voluntary data submissions are visible via this screen. You may go back to the 'Home' screen by clicking the 'Portal' link at the top left of the screen. Once a voluntary data submission has been submitted, a 'Show Detail' icon will appear next to the 'VDS ID.' This icon will reveal the tracking number associated with the submission and any submitted files. Additionally, the copy of record for submitted voluntary data submissions can be accessed via the green arrow icon in the 'Action(s)' column. In-progress voluntary data submissions can be removed via the red 'x' icon within the 'Action(s)' column.

The various columns on this screen are sortable. The entries on this screen can also be filtered using the drop-down filters available above the list. Using the filters and sorting feature will allow you to manage and customize your displayed list of voluntary data submissions. To find a specific entry on this screen, use the 'Filter Results' text box. Exhibit 13-2 below displays the 'Voluntary Data Submission List' screen.

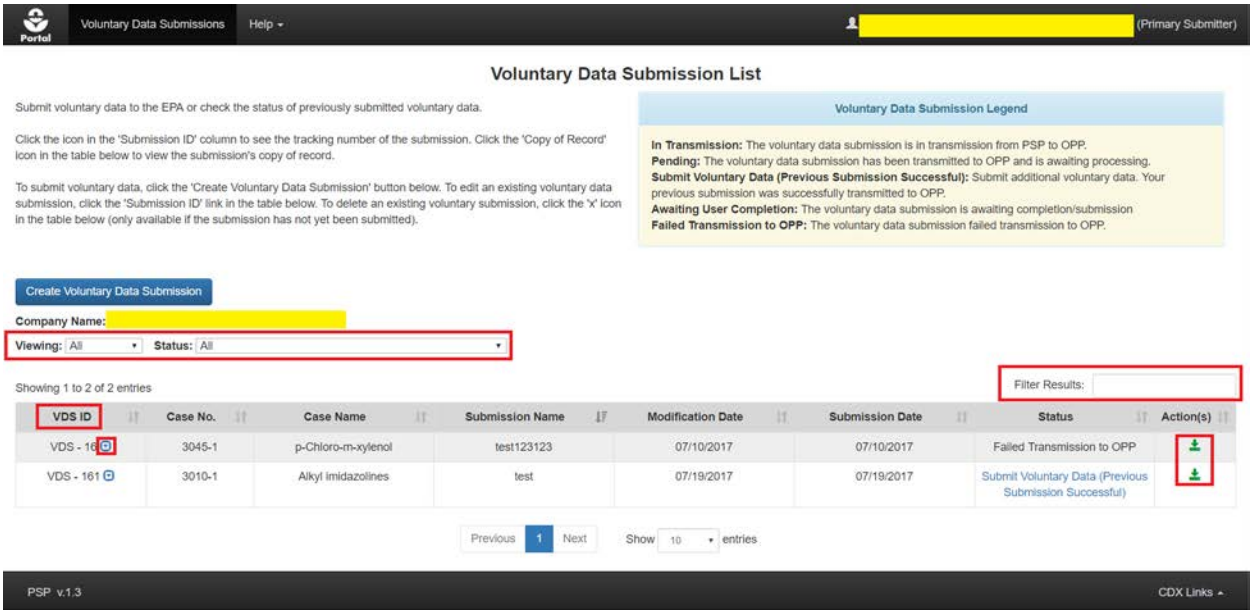


Exhibit 13-2: Voluntary Data Submission List Screen

13.2 Create and Prepare a Voluntary Data Submission

To create a voluntary data submission, click the 'Create Voluntary Data Submission' button on the 'Voluntary Data Submission List' screen, seen below in Exhibit 13-3.

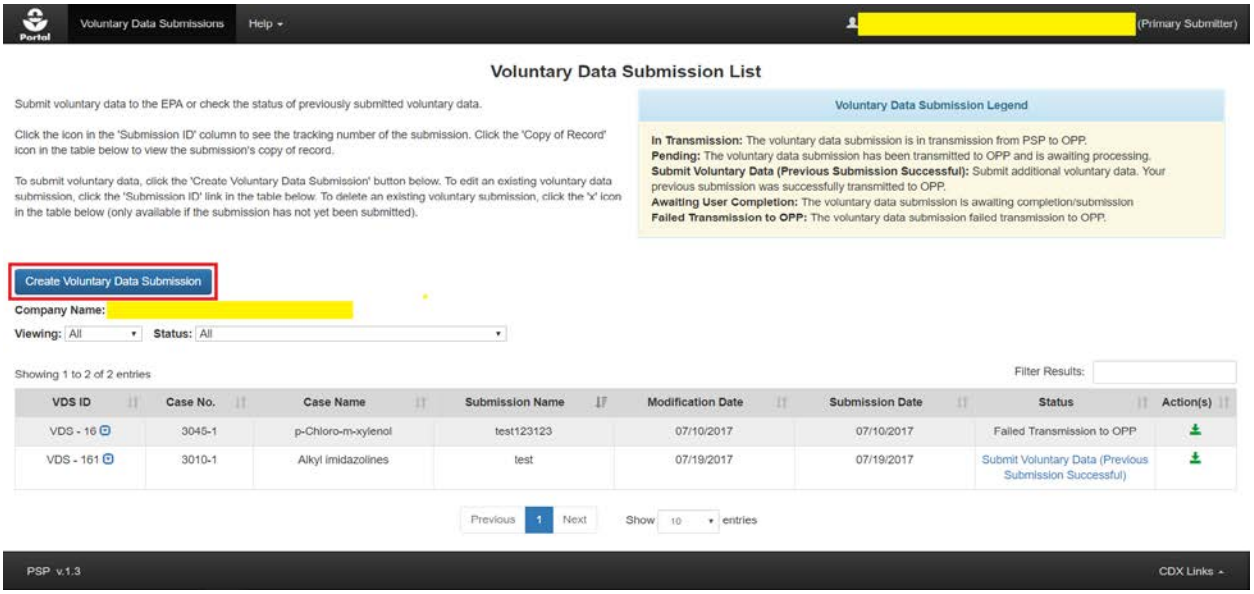


Exhibit 13-3: Voluntary Data Submission List Screen – Create Button

Navigation: Click the 'Create Voluntary Data Submission' button on the 'Voluntary Data Submission List' screen.

After clicking the 'Create Voluntary Data Submission' button, you will be navigated to the 'Create Passphrase' screen.

A passphrase protects your submission from unauthorized disclosure while it is being prepared and encrypts your voluntary data submission. To associate a passphrase with the submission, enter a passphrase that is at least 8 characters long. To protect your submission, your passphrase should contain a combination of letters and numbers. The passphrase you create may include spaces, but should **not** contain special characters (for example, +, and *). You can associate the same passphrase with multiple submissions.

You are responsible for remembering the passphrase and distributing it to only authorized persons for the submission

Important: If you forget the passphrase, you will be unable to access the submission. If you lose or forget the passphrase, you must create a new voluntary data submission and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one. To prevent losing access to submissions, OPP suggests that each company agree upon and use the same passphrase for all submissions. A shared passphrase also allows users within the same company to perform submissions for others if needed. If the original creator of a submission (either completed or in draft) is unavailable for whatever reason, the shared passphrase ensures that someone from the same company can retrieve and/or complete the submission. OPP will be unable to retrieve or unlock the submission for the company.

Exhibit 13-4 below displays a screen capture of the 'Create Passphrase' screen.

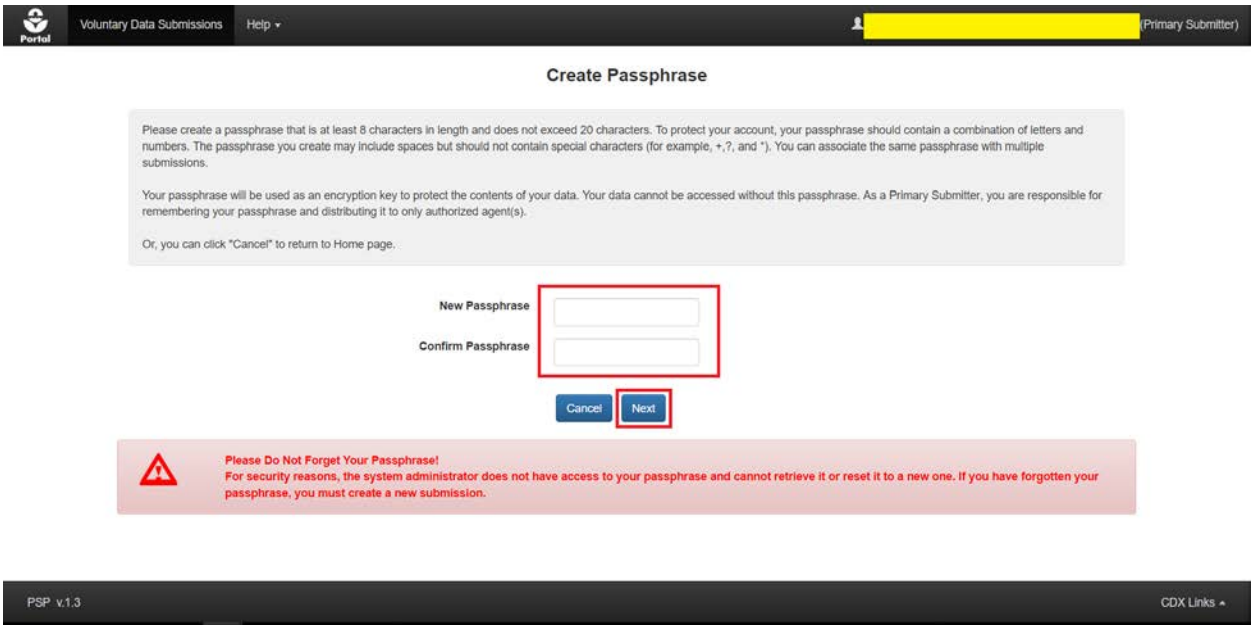


Exhibit 13-4: Create Passphrase Screen

Navigation: Create a passphrase and click the 'Next' button to navigate to the 'Voluntary Data Submission' screen.

After creating a passphrase, you will be navigated to the 'Voluntary Data Submission' screen. The 'Voluntary Data Submission' screen allows you to prepare all necessary information for your voluntary data submission. All fields marked with a red asterisk are required. The following fields are displayed on the 'Voluntary Data Submission' screen:

- **Submission Name:** Enter a name for the voluntary data submission. This is a required field.
- **Case Number:** Indicate the registration review case number that the submission relates to. This is a required field.
- **Registration Review Cycle:** Indicate the registration review cycle for the entered case number. This field will auto-populate and will not be editable if a case number only belongs to one registration review cycle. This is a required field.
- **Case Name:** The corresponding name for the entered case number. This field is not editable and will auto-populate when a valid case number is entered into the 'Case Number' field.
- **Reason for Submitting:** Please explain the reason for the voluntary data submission. This is a required field.
- **Cite Studies:** Select the check box if you are citing one or more studies as part of the submission. You can cite additional MRIDs by clicking the 'Cite an additional MRID Number' link. You can remove all cited MRIDs by unchecking the 'Cite Studies' check box. If the 'Cite Studies' check box is checked, at least one MRID will be required. Otherwise, this field is not required.
- **Company Name:** The name of the company for which you are submitting. This field is not editable and is pulled from CDX.

Exhibit 13-5 below displays a screen capture of the ‘Voluntary Data Submission’ screen with data entered for the fields listed above.

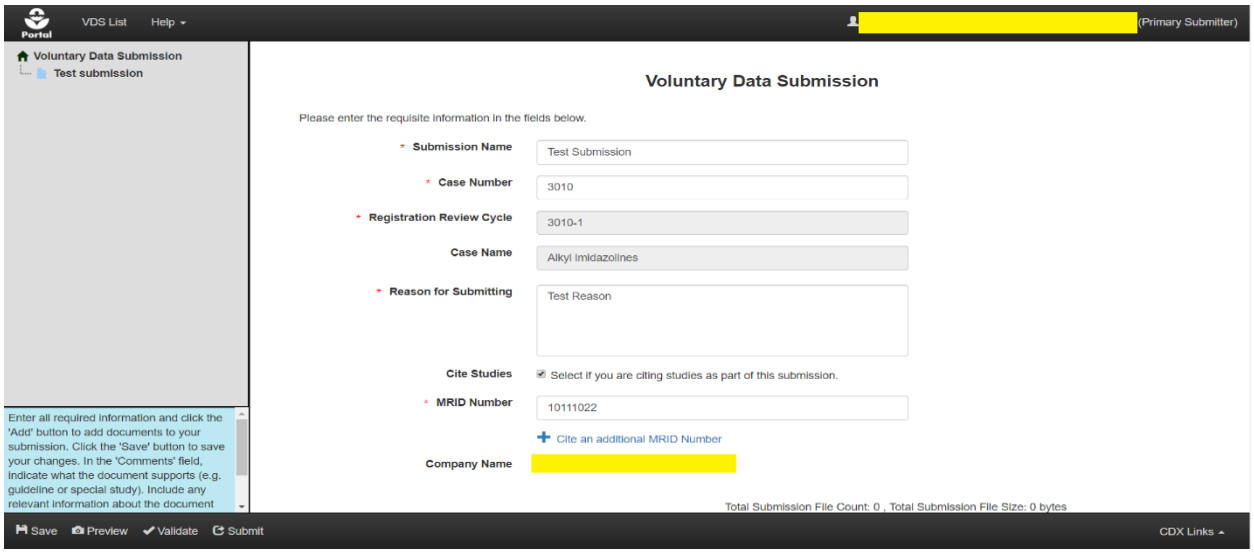


Exhibit 13-5: Voluntary Data Submission Screen

Navigation: Enter data into the fields displayed.

After entering data into the fields on the ‘Voluntary Data Submission’ screen, users will be required to upload at least one document.

To upload documents to your voluntary data submission, click the ‘Add’ button within the document upload section of the ‘Voluntary Data Submission’ screen. The following fields are displayed within the document upload section of the ‘Voluntary Data Submission’ screen:

- **Document Type:** Select the document type for the uploaded file. This is a required field.
- **Document Subtype:** Select the document sub-type for the uploaded file. Available sub-types are based on the document type chosen. This is a required field.
- **Document Upload:** Click the ‘Browse…’ button and select a file to upload. Empty files, duplicate file names, .zip, and .exe files are not allowed into the system. Document file names should not exceed 255 characters. This is a required field.
- **Comments:** Indicate what the document supports (e.g. guideline or special study). Include any relevant information about the document upload. This is an optional field.
- **MRID Number:** The master record identification number associated with the study. Please refer to **Section 4** for information about how to generate root MRIDs. A basic validation, ensuring that the MRID is an eight-digit number, is performed on this field. The MRID is also validated against OPP’s system at submission. This is a required field for study documents.
- **Is this CBI?:** Indicate whether the document contains confidential business information (CBI). For study documents, users can specify the type of CBI via a dropdown selection. This is a required field.

Exhibit 13-6 below displays a screen capture of the document upload section on the 'Voluntary Data Submission' screen.

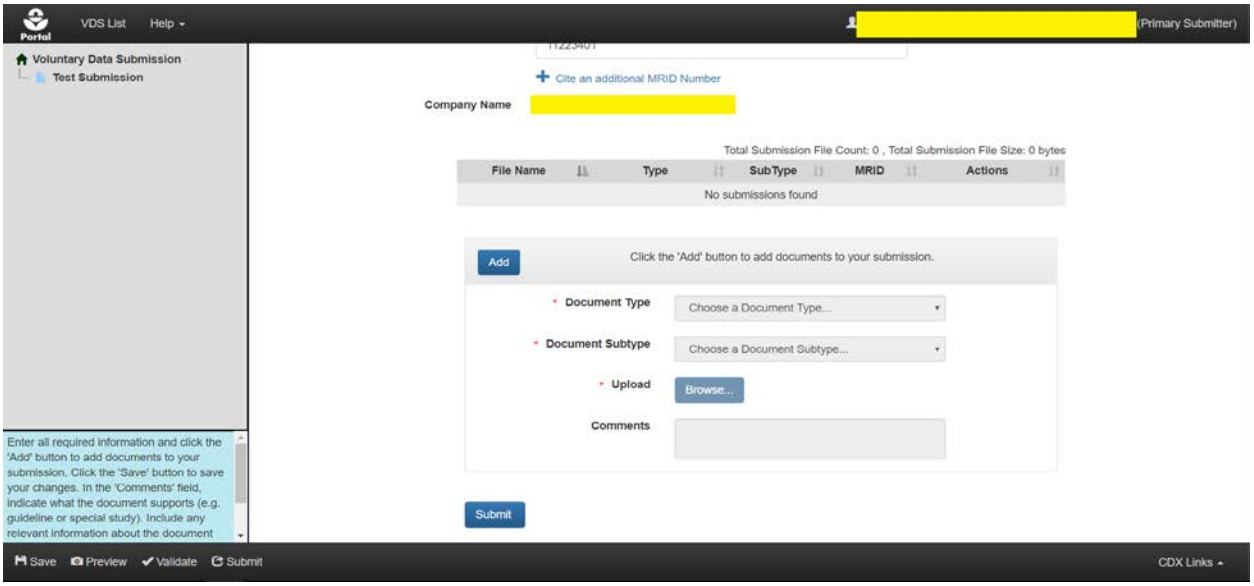


Exhibit 13-6: Voluntary Data Submission Screen – Document Upload Section

Navigation: Click the 'Add' button to enter information and upload documents. After clicking the 'Add' button, the fields become editable. Different fields will display based upon the chosen document type and sub-type. Fill out all necessary fields and click the 'Browse…' button to select and upload a document. Click the 'Save' button to save your changes.

Exhibit 13-7 below displays a screen capture of the document upload table on the 'Voluntary Data Submission Screen.'

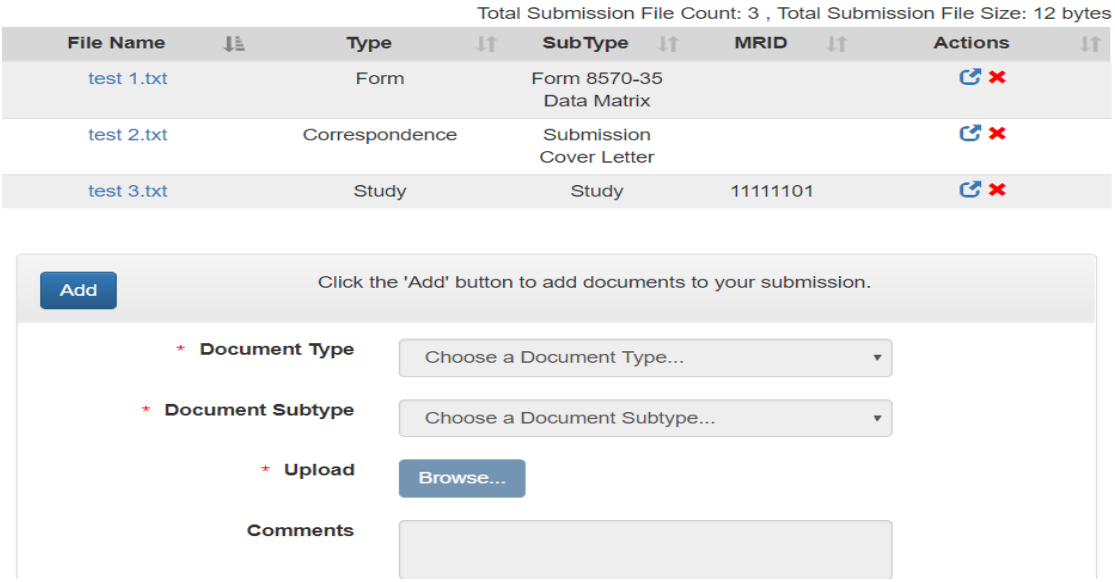


Exhibit 13-7: Voluntary Data Submission Screen – Document Upload Table

Navigation: After clicking the 'Save' button, the uploaded document is displayed in a table above the document upload section. You can click the red 'x' icon in the 'Actions' column of this table to remove any uploaded documents. You can also click the blue 'Copy Metadata'

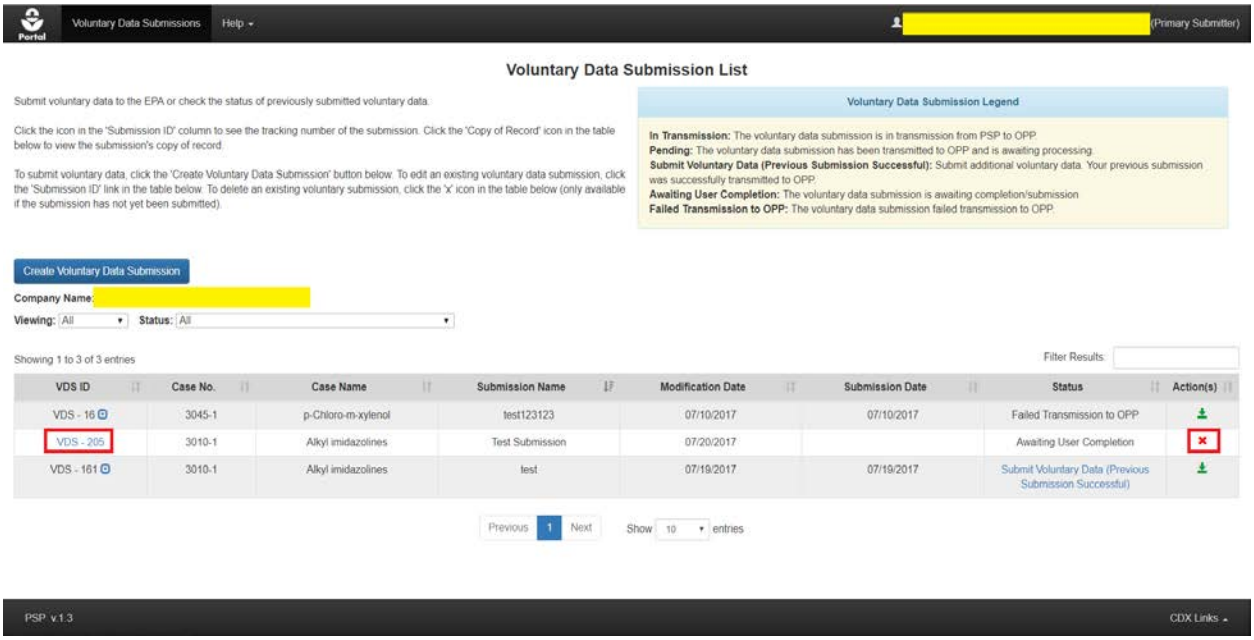
button in the ‘Actions’ column to copy the metadata of the document into a new document entry. To edit the details of a specific document, click the file name of the document in the ‘File Name’ column. You may add as many documents as needed by clicking the ‘Add’ button.

13.3 Continue Working on Saved Voluntary Data Submissions

You can return to a saved voluntary data submission at any time via the ‘Voluntary Data Submission List’ screen.

Any previously saved voluntary data submissions will appear on this screen with a status of ‘Awaiting User Completion.’ You may access these in-progress submissions by clicking the blue link in the ‘VDS ID’ column. After clicking the blue link, you will be navigated to the ‘Enter Passphrase’ screen for the submission. You will be required to enter the correct passphrase before being granted access to the submission.

You may also delete any in-progress submissions (that have not yet been submitted), by clicking the ‘Delete’ icon in the ‘Action(s)’ column. Exhibit 13-8 below displays a screen capture of the



‘Voluntary Data Submission List’ screen with an in-progress submission.

Exhibit 13-8: Voluntary Data Submission List Screen – In-Progress Submission

Navigation: Click the blue link in the ‘VDS ID’ column to navigate to the ‘Enter Passphrase’ screen for the selected submission. After entering the passphrase, you can continue editing the submission. You can remove the submission by clicking the ‘Remove’ icon in the ‘Action(s)’ column.

To continue editing the submission, you must first enter the passphrase that was used to encrypt it. The ‘Enter Passphrase’ screen allows you to enter the passphrase associated with the submission. Exhibit 13-9 below displays a screen capture of the ‘Enter Passphrase’ screen.

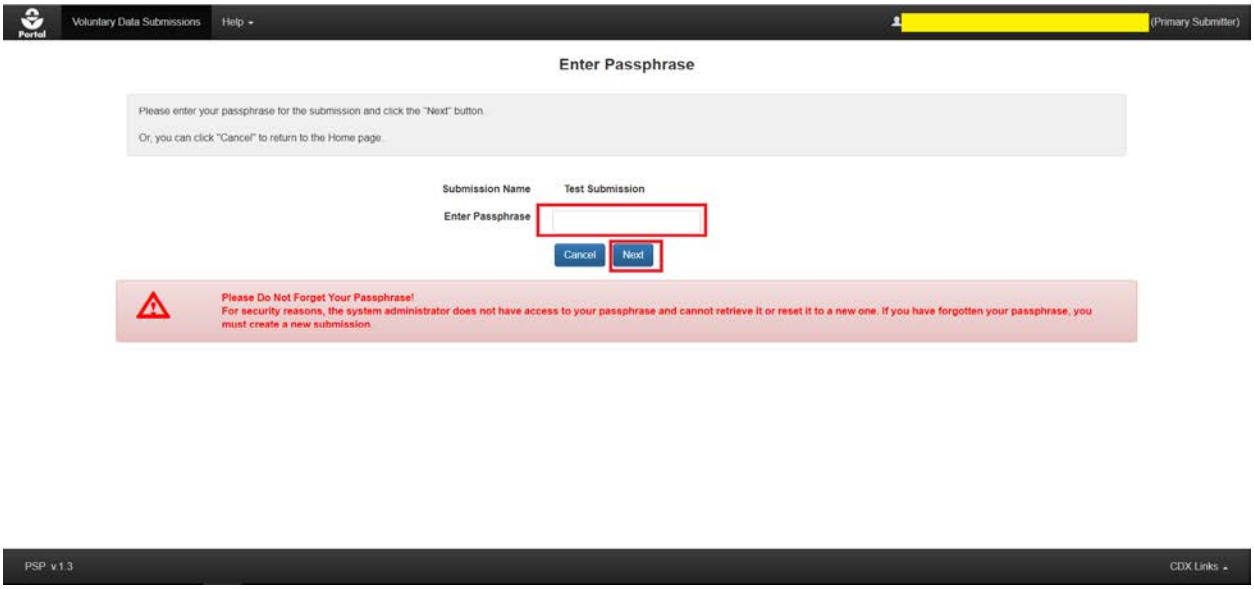


Exhibit 13-9: Enter Passphrase Screen

Navigation: Enter the passphrase that you originally associated with the submission and click the ‘Next’ button.

After entering the correct passphrase and clicking ‘Next,’ you will be navigated to the ‘Voluntary Data Submission’ screen, where you will see all previously entered information.

13.4 Submit Voluntary Data Submission

Both Primary Submitters and Authorized Agents have the ability to submit voluntary data submissions. Once you complete all required information and pass validation, the system will allow you to submit.

To begin the submission process, click the ‘Submit’ icon located in the application footer to access the ‘Submitter Information’ screen. The system requires you to review your contact information provided during CDX registration.

Exhibit 13-10 below displays a screen capture of the ‘Submitter Information’ screen.

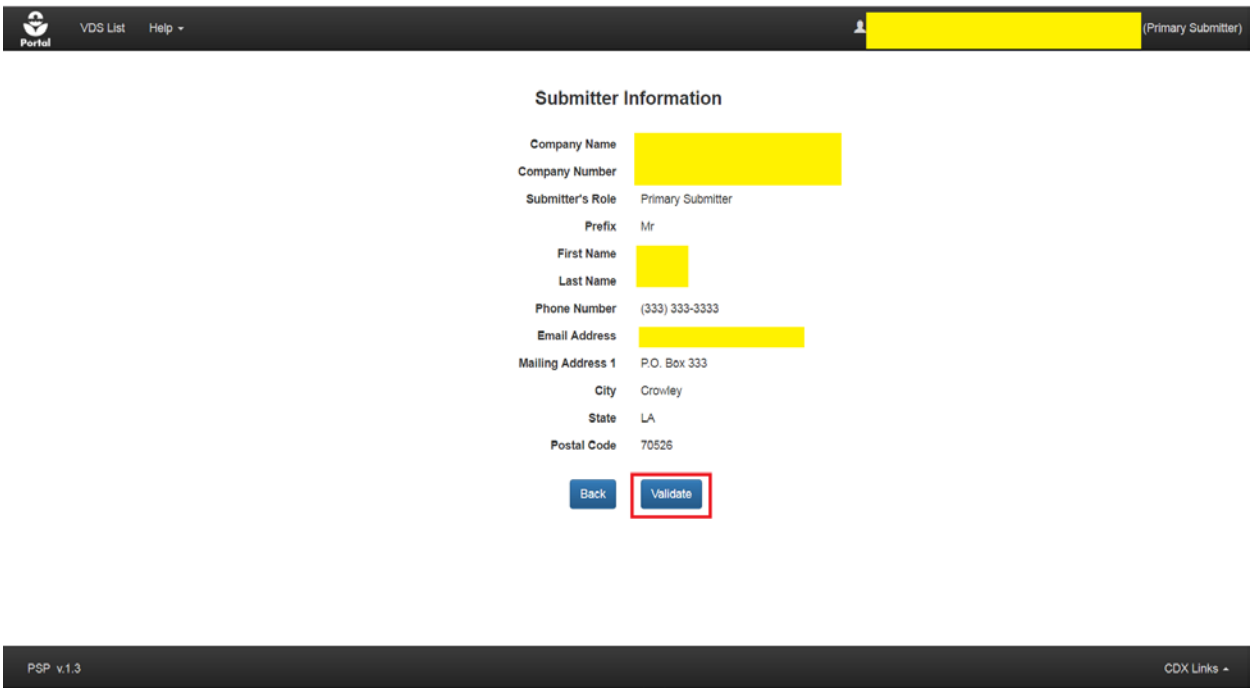


Exhibit 13-10: Submitter Information Screen

Navigation: Click the 'Validate' button. After clicking the button, a spinning status wheel will appear while your submission is checked for validation errors and viruses. After the validation process completes, you will be navigated to the 'Submission Process: Validate' screen.

The 'Submission Process: Validate' screen notifies you if your package contains validation errors. If validation errors are found within your package, the screen will display a red 'X' icon and text on the screen will read: "Validation errors were found." A pop-up window containing a list of validation errors will also appear. All validation errors must be resolved before voluntary data can be successfully submitted. For more information about validation, please refer to **Section 9**. If your voluntary data submission passes validation, the screen will display a green 'Checkmark' icon and text on the screen will read: "No validation errors were found."

Exhibit 13-11 below displays the screen capture for when no validation errors are found.

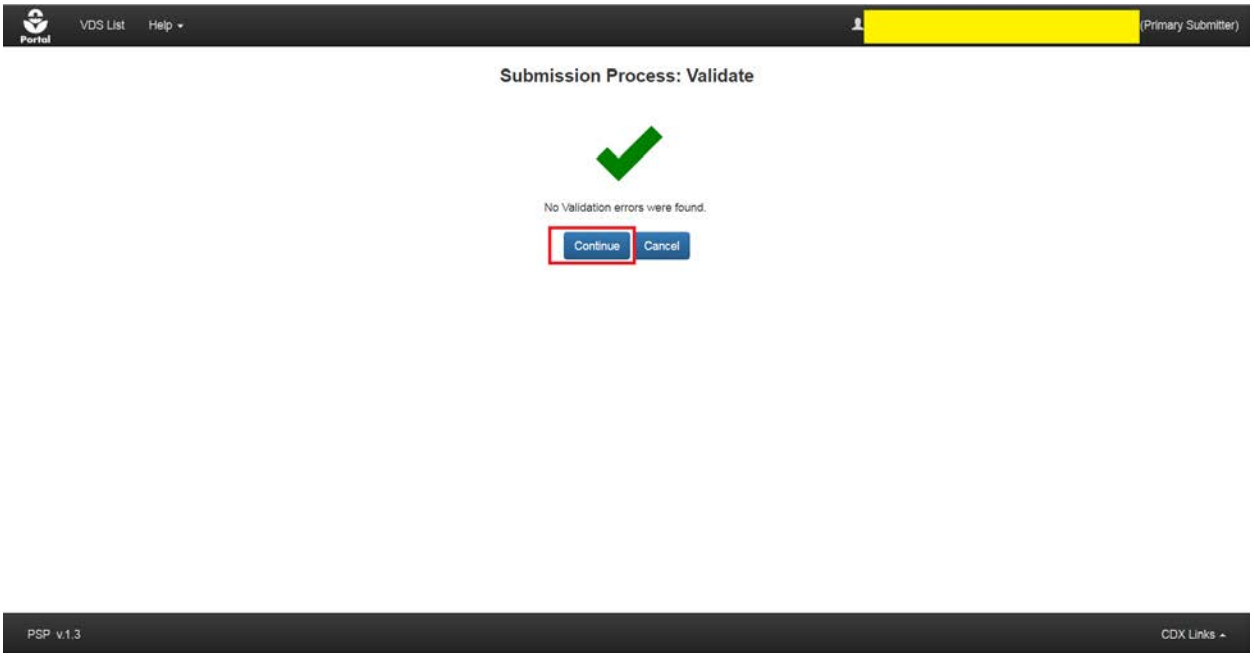


Exhibit 13-11: Validation Passed

Navigation: Click the ‘Continue’ button to proceed to the ‘Submission Process: PDF Generation’ screen.

Exhibit 13-12 below displays a screen capture of the ‘Submission Process: PDF Generation’ screen.

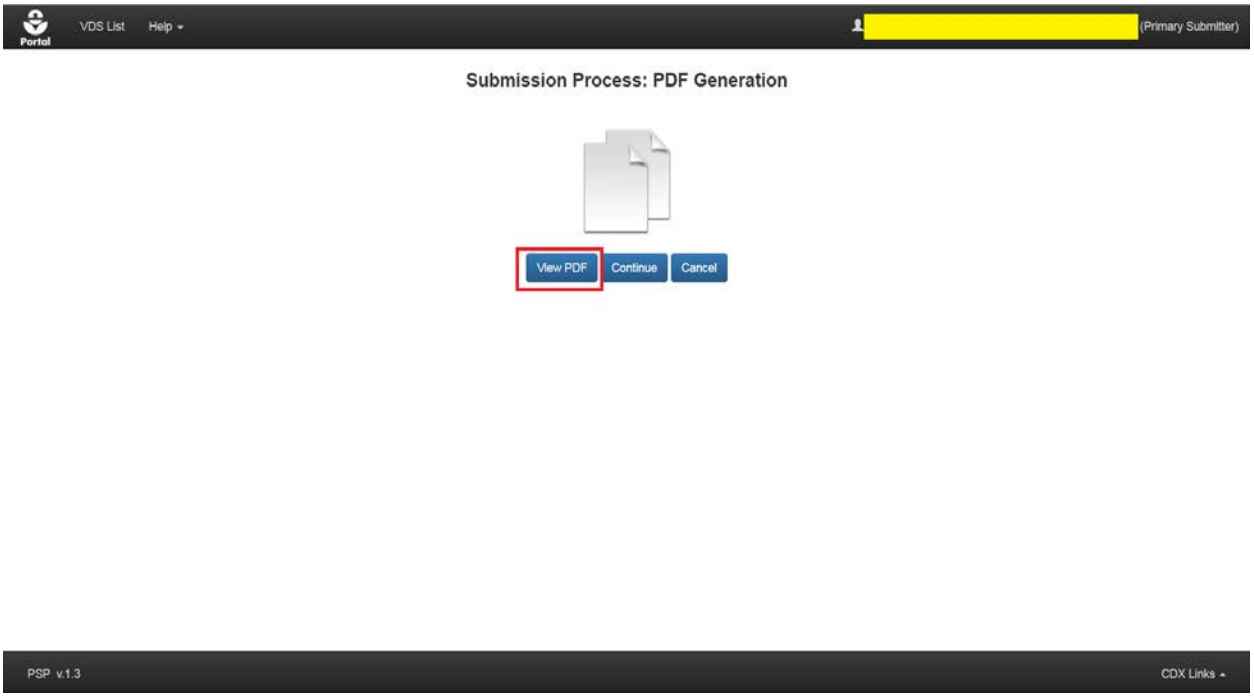


Exhibit 13-12: PDF Generation

Navigation: Click the ‘View PDF’ button to see a PDF representation of your package and its contents. After viewing and/or printing the PDF, you can click the ‘Continue’ button to proceed

to the eSignature widget containing the Cross-Media Electronic Reporting Rule (CROMERR) questions.

EPA's Cross-Media Electronic Reporting Rule (CROMERR) provides the legal framework for electronic reporting under EPA's regulatory programs. CROMERR sets performance-based, technology-neutral system standards and provides a streamlined, uniform process for Agency review and approval of electronic reporting. The CROMERR program ensures the enforceability of regulatory information collected electronically by EPA and EPA's state, tribal, and local government partners.

Via the e-Signature widget, you will enter your CDX credentials, answer a 20-5-1 question associated with your CDX account, and certify your submission. For additional information about the 20-5-1 questions, please refer to the CDX PSP Registration User Guide. If your package is successfully submitted, you will receive a 'Success' confirmation. You will also receive an email from the CDX Help Desk once your package has been successfully transmitted to OPP.

Exhibit 13-13 and Exhibit 13-14 below display a screen capture of the electronic signing process for voluntary data submissions.

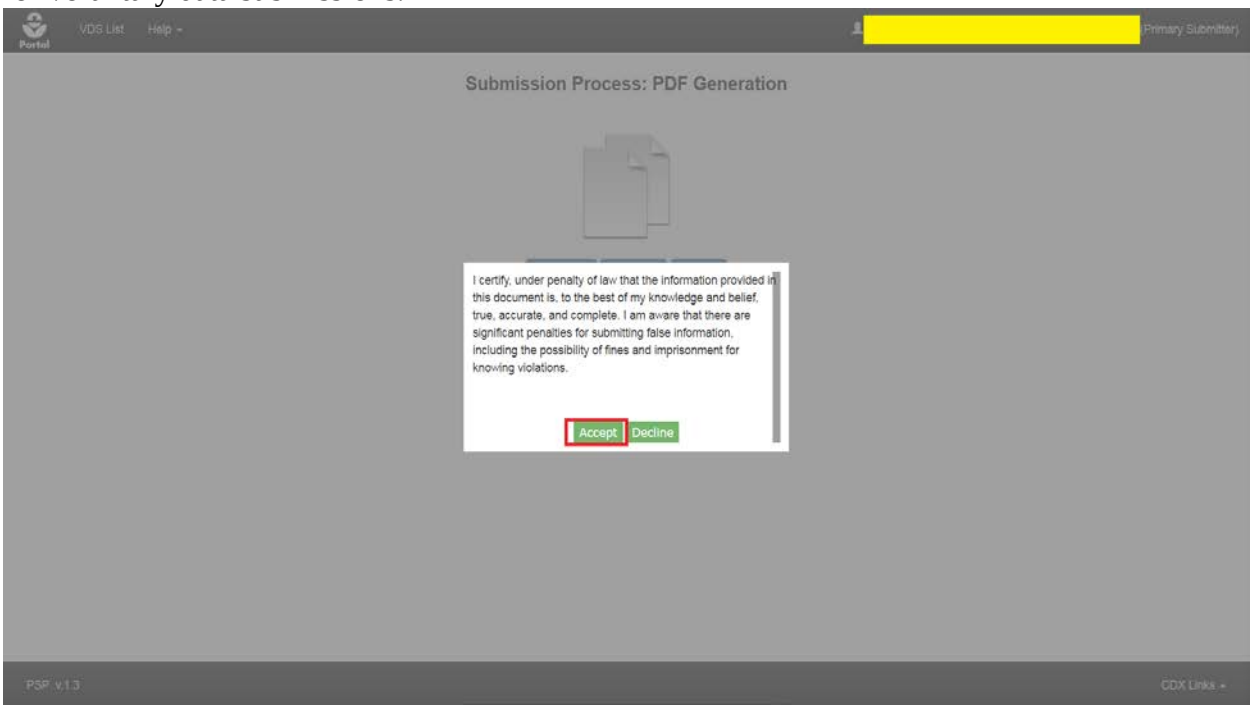


Exhibit 13-13: Accept Button

Navigation: Click the 'Accept' button to confirm and proceed to the eSignature Widget.

After clicking ‘Accept,’ you will be required to provide your CDX password, answer a secret question, and electronically sign the file via the ‘Sign’ button.

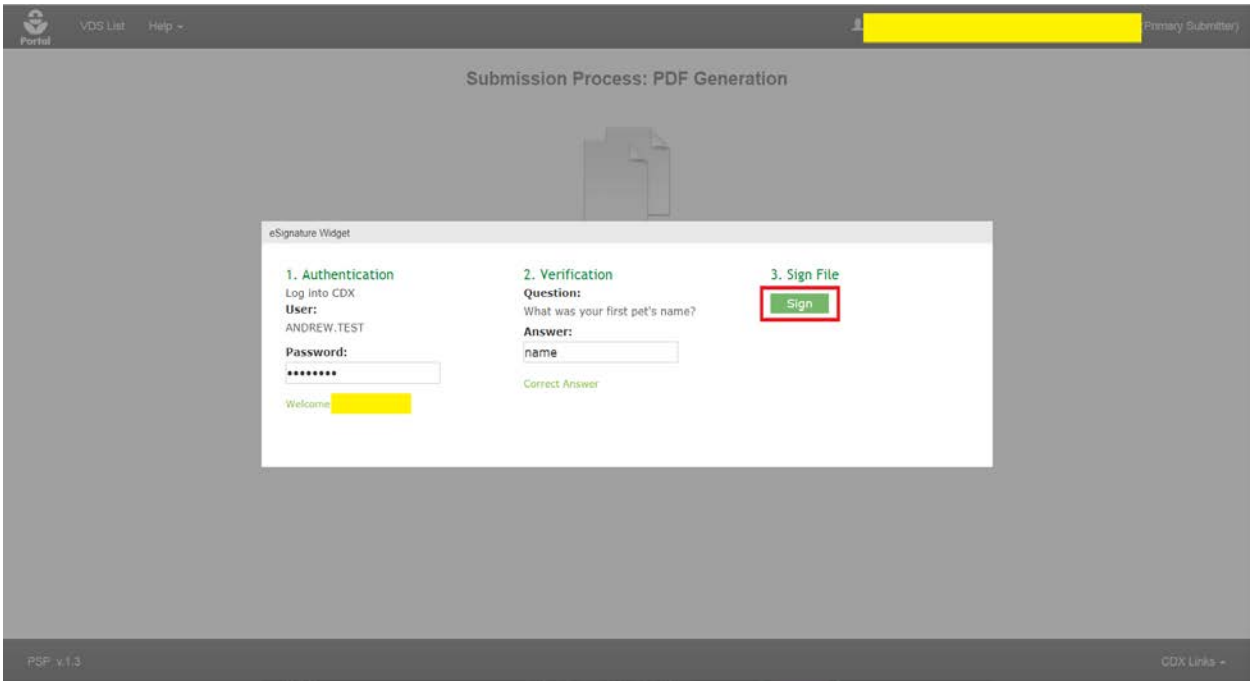


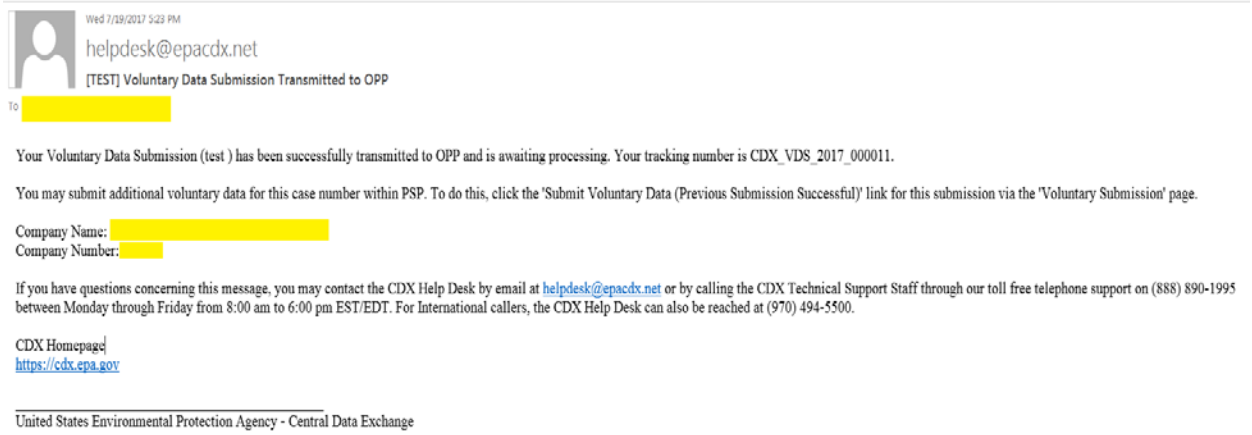
Exhibit 13-14: eSignature Widget

Navigation: Enter your CDX password, answer the secret question, and click the ‘Sign’ button.

After clicking ‘Sign,’ you will be navigated to the ‘Voluntary Data Submission List’ screen, where your newly submitted voluntary data submission will appear with a status of ‘In Transmission.’

Once your voluntary data submission has been successfully transmitted to OPP, the status will transition to ‘Submit Voluntary Data (Previous Submission Successful).’ A notification email will also be sent once your submission reaches this status. For assistance with submitting additional voluntary data please refer to **Section 13.6**.

Exhibit 13-15 below displays a screen capture of a sample voluntary data submission email notification.



Wed 7/19/2017 5:23 PM

helpdesk@epacdx.net

[TEST] Voluntary Data Submission Transmitted to OPP

To [redacted]

Your Voluntary Data Submission (test) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_VDS_2017_000011.

You may submit additional voluntary data for this case number within PSP. To do this, click the 'Submit Voluntary Data (Previous Submission Successful)' link for this submission via the 'Voluntary Submission' page.

Company Name: [redacted]
Company Number: [redacted]

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

Exhibit 13-15: Voluntary Data Submission Notification Email

13.5 Voluntary Data Submission Tracking Number and Copy of Record

You can check the details of submitted packages via the 'Voluntary Data Submission List' screen. You can view the copy of record for your submission, as well as check the tracking number and submitted files. To access the tracking number and submitted files, click the 'Show Detail' icon in the 'VDS ID' column.

Exhibit 13-16 below displays a screen capture of the tracking number and submitted files.

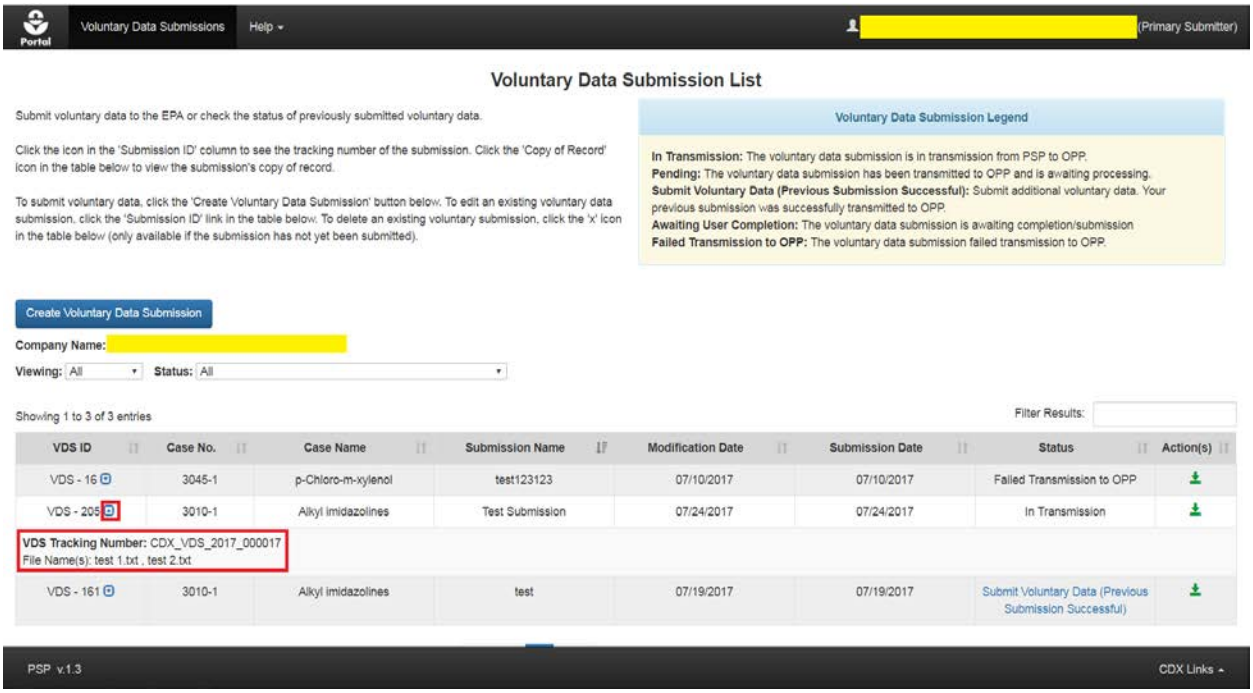


Exhibit 13-16: Tracking Number and Submitted Files

Navigation: Click the 'Show Detail' icon to view the tracking number and files submitted.

To access the copy of record, click the green ‘Copy of Record’ icon in the ‘Action(s)’ column. You will have to enter the passphrase used to encrypt the submission, your CDX password, and the answer to a secret question to see the copy of record.

Exhibit 13-17 below displays a screen capture of the copy of record icon.

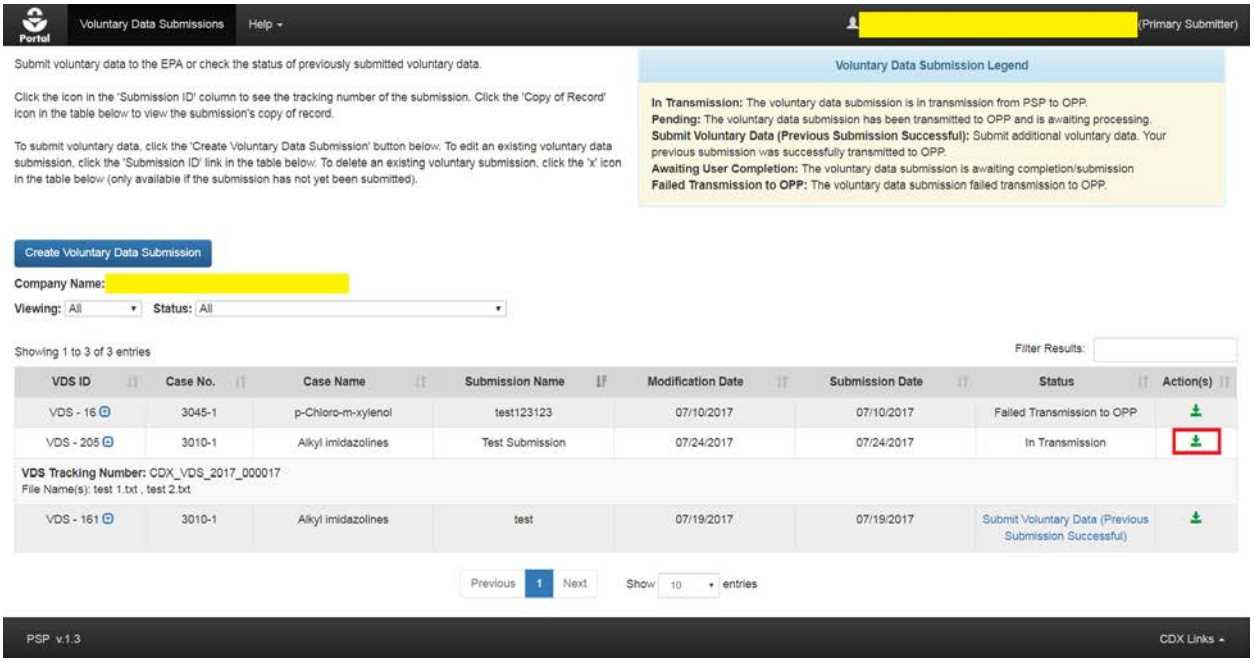


Exhibit 13-17: Copy of Record Icon

Navigation: Click the green ‘Copy of Record’ icon in the ‘Action(s)’ column.

Exhibit 13-18 below displays a screen capture of the process of accessing the copy of record.

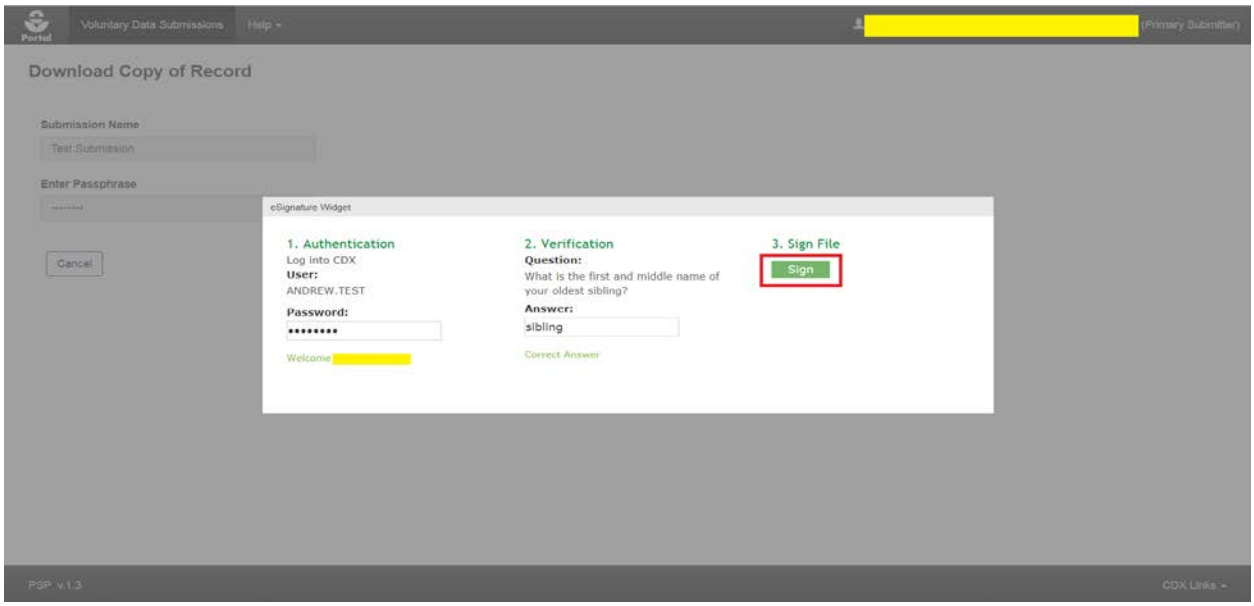


Exhibit 13-18: Copy of Record Process

Navigation: Enter the passphrase for the submission and click the ‘Continue’ button. Click ‘Accept’ on the resulting pop-up message. Within the eSignature Widget, enter your CDX password, answer the secret question, and click the ‘Sign’ button. After clicking ‘Sign,’ the copy of record, along with the files submitted will appear inside a table on-screen.

Exhibit 13-19 below displays a screen capture of the copy of record and submitted files.

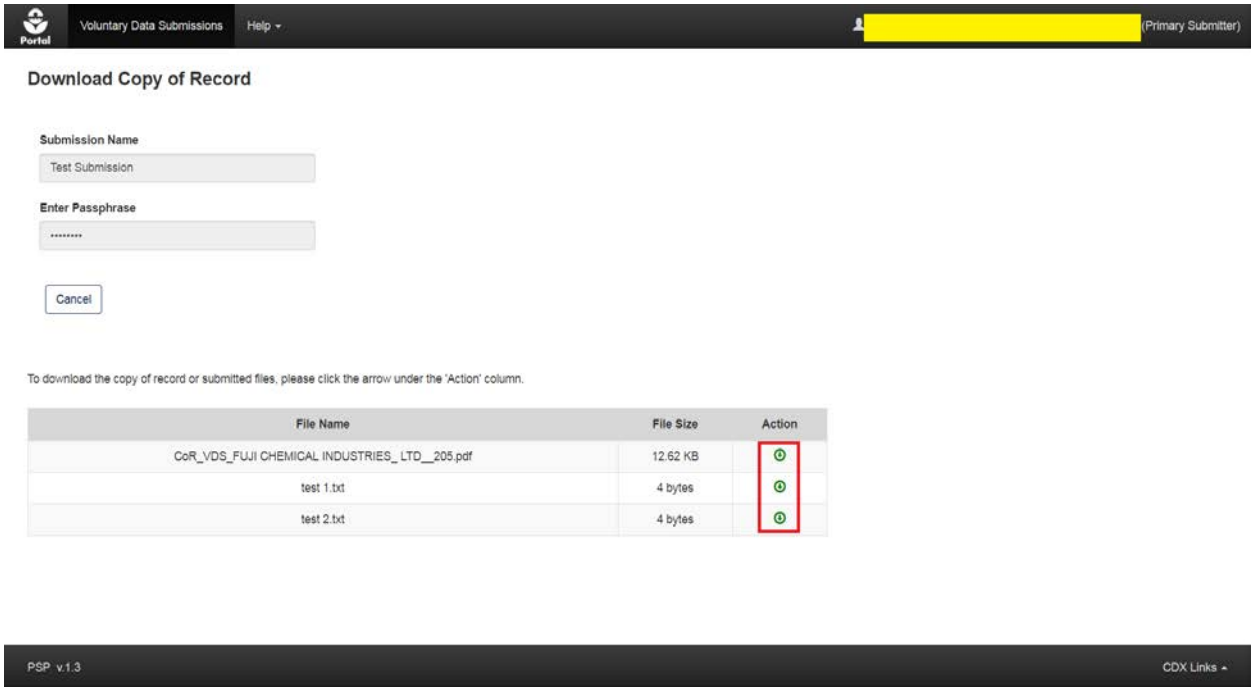


Exhibit 13-19: Copy of Record and Submitted Files

Navigation: Click the green ‘Download Document’ button in the ‘Action’ column to download the copy of record or submitted files.

13.6 Submit Additional Voluntary Data

After a voluntary data submission has been successfully transmitted to OPP, users can submit additional voluntary data for the same case number. To submit additional data for the same case number, click the blue ‘Submit Voluntary Data (Previous Submission Successful)’ link within the ‘Status’ column on the ‘Voluntary Data Submission List’ screen. You may submit additional data as many times as necessary. Exhibit 13-20 below displays a screen capture of the ‘Submit Voluntary Data (Previous Submission Successful)’ link.

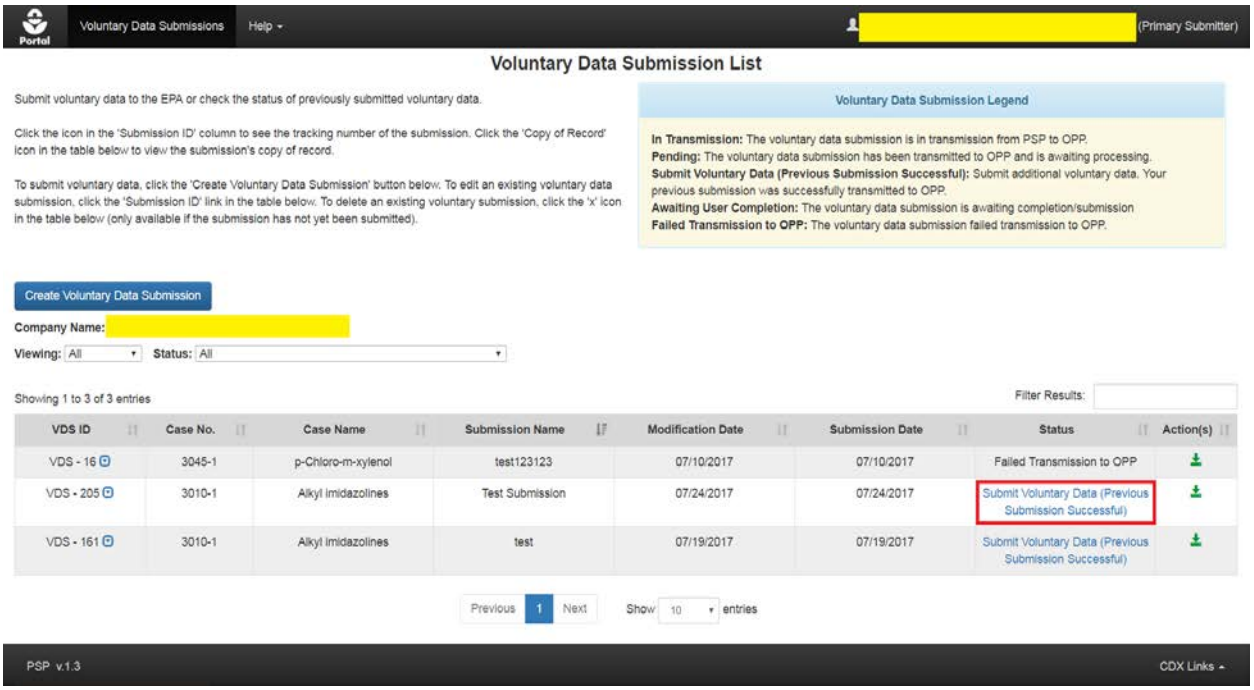


Exhibit 13-20: 'Submit Voluntary Data (Previous Submission Successful)' link

After clicking the 'Submit Voluntary Data (Previous Submission Successful)' link, you will be required to enter the passphrase for the submission on the 'Enter Passphrase' screen. After entering the passphrase and clicking 'Next,' you will be navigated to the 'Voluntary Data Submission' screen.

Exhibit 13-21 below displays a screen capture of the 'Voluntary Data Submission' screen for a previously submitted voluntary data submission.

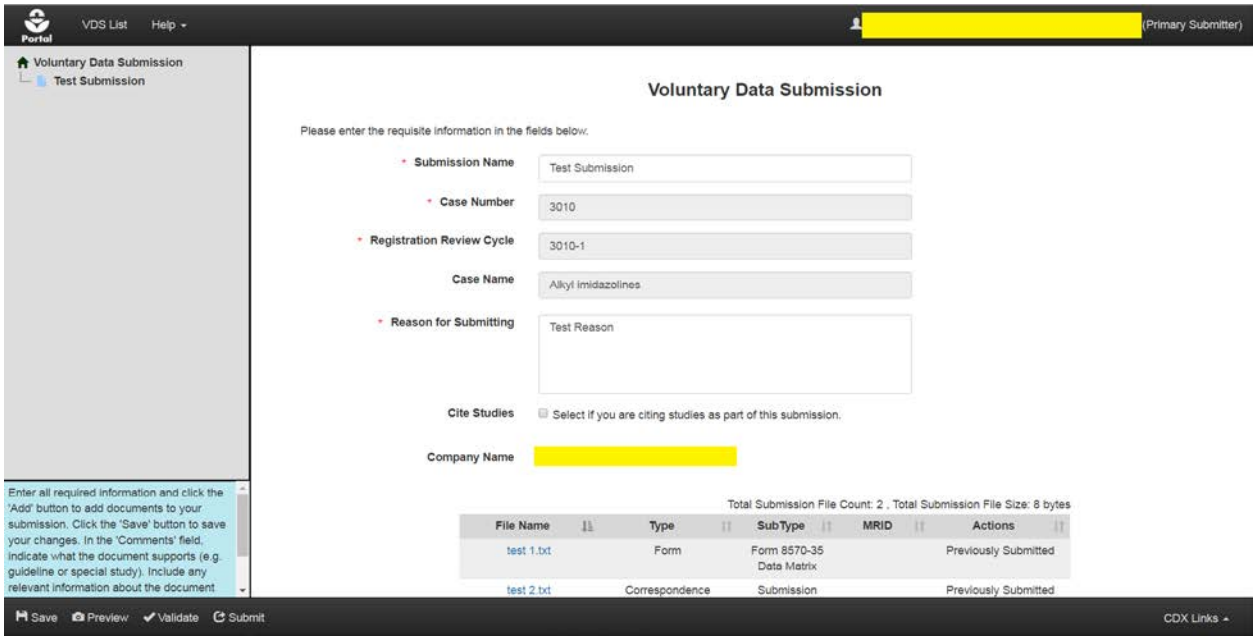


Exhibit 13-21: Voluntary Data Submission Screen

Navigation: The ‘Case Number,’ ‘Registration Review Cycle,’ and ‘Case Name’ fields are read-only and unchangeable. Likewise, previously submitted documents have a status of ‘Previously Submitted’ under the ‘Actions’ column and cannot be edited. You may upload additional documents, cite MRIDs (or remove previously cited MRIDs), change the ‘Reason for Submitting,’ or change the ‘Submission Name.’ You can view the details of previously submitted files by clicking the blue link in the ‘File Name’ column.

Exhibit 13-22 below displays a screen capture of the details of a previously submitted file.

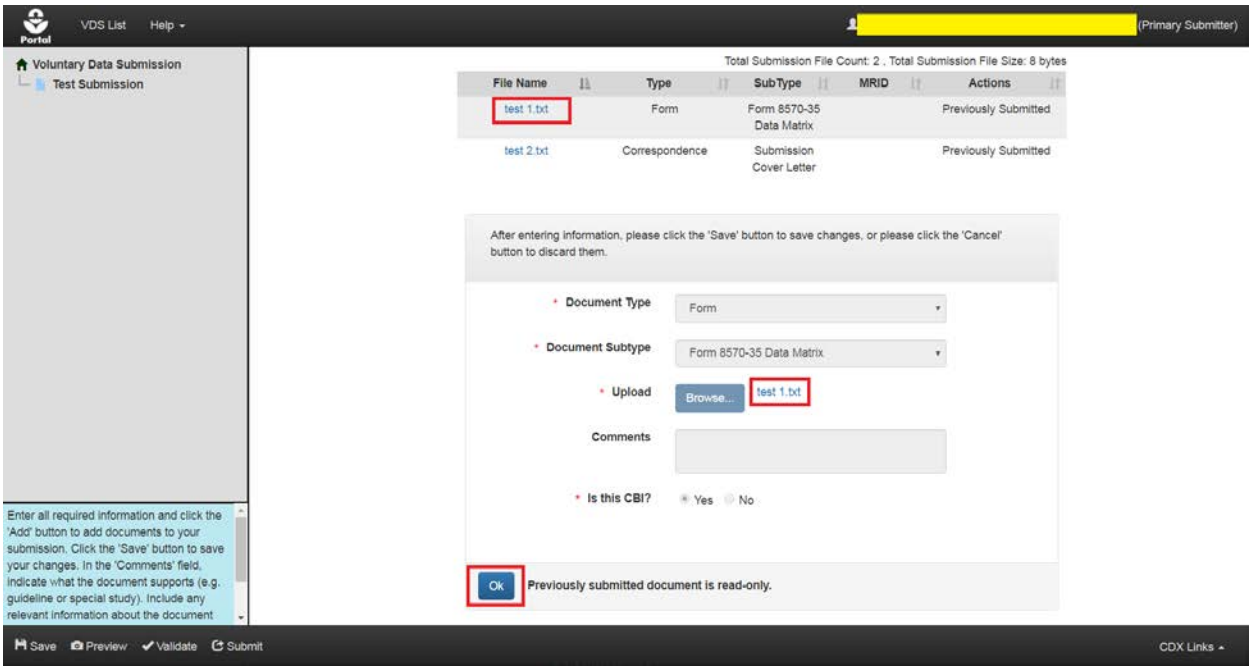


Exhibit 13-22: Previously Submitted File Details

Navigation: After clicking the blue link in the ‘File Name’ column, the details of the previously submitted file will be displayed. Although no information can be edited, you can download the file by clicking the blue link next to the ‘Browse…’ button. Click ‘OK’ to stop viewing the details of the file.

After uploading additional files and/or changing previously entered data, you can submit as normal via the ‘Submit’ button in the application footer. For assistance with submitting a voluntary data submission, please refer to **Section 13.4.**

Once your submission has been successfully transmitted to OPP, you may submit additional voluntary data via the ‘Submit Voluntary Data (Previous Submission Successful)’ link on the ‘Voluntary Data Submission List’ screen. As stated before, you can perform as many additional voluntary data submissions for the same case number as necessary following the steps in this section.

14 Appendix A - Definitions, Acronyms, and Abbreviations

Acronym	Full Name
CBI	Confidential Business Information
CDX	Central Data Exchange
CoR	Copy of Record
CRM	Chemical Review Manager
DCI	Data Call-In
CROMERR	Cross-Media Electronic Reporting Regulation Security System
EPA	Environmental Protection Agency
IT	Information Technology
MRID	Master Record Identification Number
OPP	Office of Pesticide Programs
PDF	Portable Document Format
PRIA	Pesticide Registration Improvement Extension Act
PSP	Pesticide Submission Portal
SLN	Special Local Need
XML	Extensible Markup Language
VDS	Voluntary Data Submission

15 Appendix B – Admin Number Information

Admin Number Information

The EPA Registration Number (Admin Number) is required on all pesticide products. The purpose of an Identification Number is to provide a unique product number for regular registrations, distributor registrations, Special Local Needs registrations, and Experimental Use Permits.

The EPA Registration Number indicates which company holds the registration for the pesticide product, and in which sequence the product was submitted to EPA by the company.

Refer to Exhibit 15-1 below for examples of Admin Numbers. Please note the following:

- CompanyNum = Company Number
- xxSEQxx = Sequence
- Seq = Sequence
- ParentRegNum means = Parent Regulatory Number
- EUP = Experimental Use Permit
- IN = Inert Ingredient Request
- PA = Pre-Application

Regulatory Action	Format	Examples
Product Registration – Section 3	CompanyNum-xxSEQxx	• 55050-1 • 334-165 • 334-ANA (Temporary File Symbol before the product is registered, see Exhibit 15-2)
Distributor Product	ParentRegNum-CompanyNum	• 2155-40-12319 • 3862-140-13103
Experimental Use Permit - Section 5	CompanyNum-EUP-xxSEQxx	• 44544-EUP-2 • 45054-EUP-1
Tolerance Petition	ParentRegNum-CompanyNum	• 3F1383 • 2G1214 • Possible 2nd characters: E,F,G,H,T - based on the Tolerance Petition type
Inert Ingredient Request	As given below 2nd character being E,F,G,H,T based on the tolerance petition type	• IN-10606 • IN-10559
Pre-Application	CompanyNumPASeq	• 2382PA1 • 54022PA16

Exhibit 15-1 Admin Number Examples

R	E	G	U	L	A	T	I	O	N
1	2	3	4	5	6	7	8	9	0

Exhibit 15-2 File Symbol