Pesticide Submissions Portal (PSP) User Guide

Environmental Protection Agency

Office of Pesticide Programs

August 13, 2021

EPA ICR Nos. 0597.13, 0161.15, 1204.14, 0276.17, 0278.14, 0227.21, 0227.22, 2288.03, and 2311.14

OMB Control Nos. 2070-0024, 2070-0027, 2070-0039, 2070-0040, 2070-0044, 2070-0060, 2070-0162, 2070-0174, and 2070-0182

EPA No. EPA 705-G-2021-3739

Table of Contents

List of Exhibits

1   Introduction

The United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) developed the Pesticide Submission Portal (PSP) and its associated applications to allow applicants and registrants to electronically submit pesticide data to EPA.

Applications for pesticide registration can be submitted, including forms, studies, and draft product labeling. 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 paper applications. As electronic submissions are easily reproducible, EPA will accept electronic applications containing one copy of all the required elements.

EPA encourages electronic submission of the following items:

- Product Registration – Section 3
    - New pesticide active ingredients
    - New pesticide products containing already-registered pesticide active ingredients
    - Amendments to registered pesticide products.
    - FIFRA 6(a)(2) study submissions
    - Gold Seal Letter Requests
    - Final Printed Labeling (FPL)
    - Pet Spot-On Enhanced Reporting
- Experimental Use Permit – Section 5
- Food Tolerance Petitions
- Distributor Products
- Notifications
- Inert Ingredient Requests
- Pre-Applications
- Foreign Purchaser Acknowledgment Statements (FPAS)

In addition to preparing registration action packages, users may also respond to both Generic Product-Specific Data Call-Ins (GDCIs and PDCIs); respond to data requests by forming or using an existing consortium; and submit registration review items, including labels and non-DCI data.

1.1   Purpose

This document provides instructions on how to use PSP and its associated applications. 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)

- Prepare and submit registration action packages to EPA for processing

- Upload and submit batch registration action packages in the e-Submission XML format

- Upload, modify, and submit registration action packages created with e-Dossier Builder

- Respond to GDCIs and PDCIs by submitting Acknowledgements, 90-Day Responses, and Data Submissions

- Respond to data requests by forming or using an existing consortium

- Make data submissions that are not in response to a GDCI Notice

- Submit requested draft labels for registered products in response to interim or final registration review decision

- Make FPAS submissions; including Annual Summaries

2   System Requirements

The following items are required to use the PSP applications:

- Internet access
- An e-mail account
- A vendor supported web browser with Java Script enabled and pop-up blockers disabled
- A vendor supported version of Adobe Acrobat Reader
- A CDX account with an active PSP Program Service role

2.1   Supported Browsers

For optimal performance, Google Chrome is recommended to access the PSP applications. However, vendor supported versions of the following browsers may also be used:

- Google Chrome
- Mozilla Firefox
- Microsoft Internet Explorer (IE) or Edge
- Safari

2.2   Screen Resolution

Screen resolution should be set to 1024 x 768 or greater.

3   Live Application Support

Real-time application support is available by contacting the CDX Help Desk (CDXHD) using one of the following options:

- **By Telephone:**

  Person-to-person telephone support is available from 8:00 am to 6:00 pm eastern standard time/eastern daylight time (EST/EDT). Call the CDXHD at its toll-free line, (888) 890-1995 or +1 (970) 494-5500 for international callers.

- **By Email:**

  Send an email to helpdesk@epacdx.net with "Technical Support" in the 'Subject' line.

- **By Chat:**

  Select the 'Chat with the CDX Help Desk' link on the CDX 'Contact Us' screen to generate a web form to enter information regarding a help request.

- **By Contact Form:**

  Enter information in the text fields under the 'Contact Form' section of the CDX 'Contact Us' screen.

4 Pesticide Submission Portal General Functionalities

This section describes general PSP functionalities that are common across all underlying PSP applications. This includes the following topics:

- PSP roles for registrants
- Accessing PSP from CDX
- Navigating the PSP 'Home' screen
- The functions available in all PSP applications' navigation tree, application header, and application footer
- Creating and entering submission passphrases
- Globally validating submission contents prior to sending to EPA
- Completing the submission process

4.1 PSP Registrant Roles

Registrants can access PSP using two roles - Primary Submitter or Authorized Agent. Primary Submitters can view all packages and DCIs created for a company, sponsor and maintain Authorized Agent users' access to PSP, and prepare and make submissions using any of the PSP applications.

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.

Authorized Agents can only see packages they created and are unable to sponsor other users' access to PSP. Authorized Agents may prepare and make submissions using any of the PSP applications.

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

4.2 Access the Pesticide Submission Portal

To access PSP, first navigate to the CDX 'Home' screen.

Exhibit 4-1 shows a screen capture of the CDX 'Home' screen:

Exhibit 4-1: CDX 'Home' Screen – Login

Navigation: Enter valid values into the 'User ID' and 'Password' fields and select the 'Log In' button.

The 'MyCDX' screen displays once a user successfully logs into CDX. This screen contains a list of associated program services under the 'Services' header. If registered for the PSP program service, 'PSP: Pesticide Submission Portal (Company Number Requests)' will be listed. A program service's status is visible by scrolling over the icons in the 'Status' column. Roles within a program service are accessed by selecting the blue, underlined link in the 'Role' column. The currently available registrant roles for PSP are 'Primary Submitter' and 'Authorized Agent.'

Exhibit 4-2 shows a screen capture of the 'My CDX' screen:
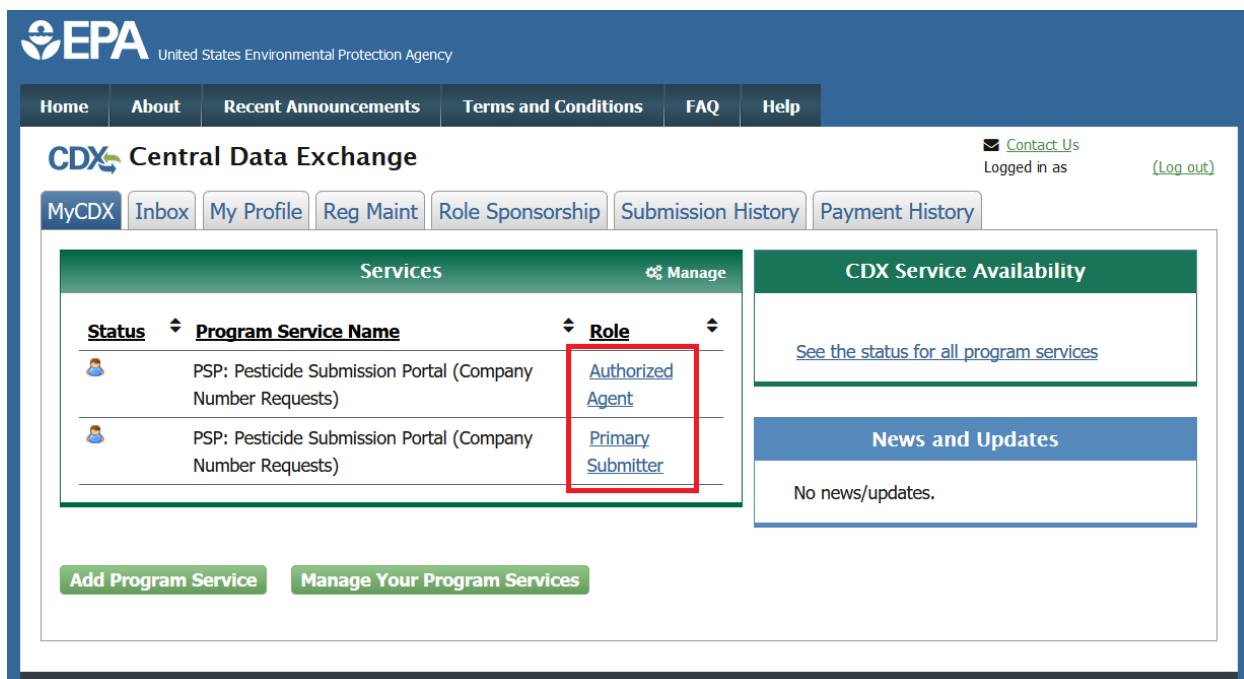
Exhibit 4-2: 'MyCDX' Screen – PSP Program Services

Navigation: Select a blue role link under the 'Role' column to enter PSP as the selected role.

When a role is associated with multiple organizations, selecting the role link on the 'MyCDX' screen generates the 'Application Profile Settings' pop-up. The user navigates directly into PSP when a role is associated with only one organization.

Exhibit 4-3 shows a screen capture of the 'Application Profile Settings' pop-up window:
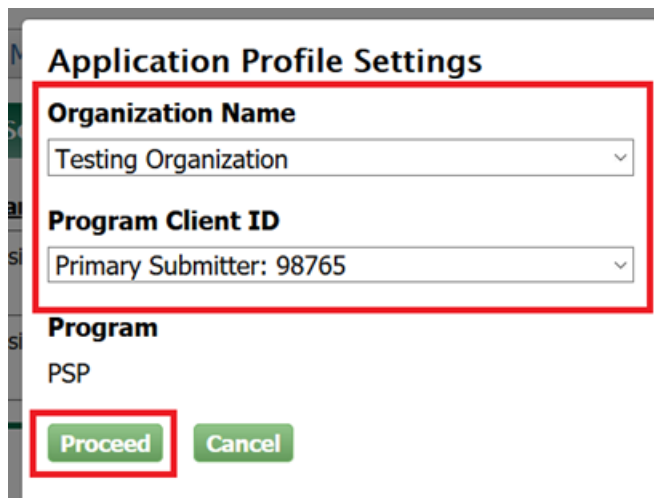
Exhibit 4-3: CDX 'Application Profile Settings' Pop-up

Navigation: Select an organization and company role/number and then select the 'Proceed' button to enter the PSP application.

4.3 Pesticide Submission Portal 'Home' Screen

The PSP 'Home' screen is the initial screen within PSP and it provides access to the various underlying PSP applications and functions available within the portal. The screen is separated into three panels:

- The **'Submissions and Tools'** panel provides guided access to all submission applications and is logically divided into regulatory sections for 'Registration Actions,' Registration Review,' 'Reregistration,' and 'Pre-Submission Tools.' Selecting these sections displays additional information for the options available under each regulatory section. For information on how to locate a specific submission type, navigate to the corresponding section of this user guide.

- The **'PSP Alerts'** panel displays information pertinent to PSP including outage, maintenance, and OPP programmatic notifications.

- The **'View Recent Packages'** panel displays the five (5) most recently modified registration packages for the user and organization displayed in the application header. Note that non-registration package submissions (e.g., DCI Responses) and registration packages for organizations other than the one displayed in the application header will not display.

Exhibit 4-4 shows a screen capture of the PSP 'Home' screen:
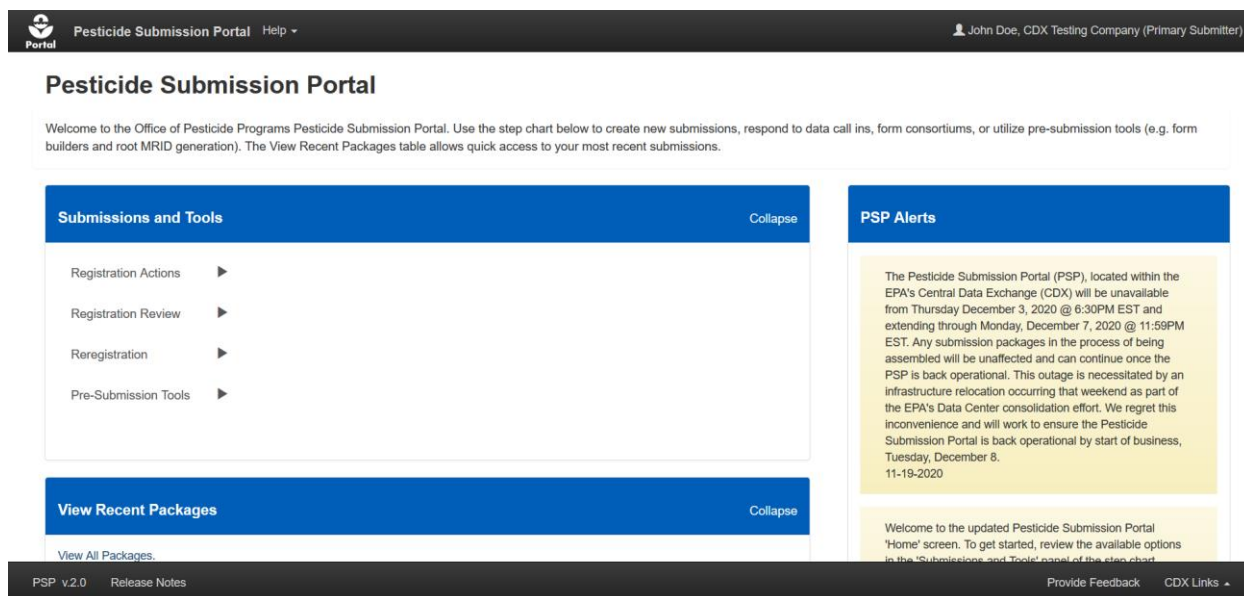
Exhibit 4-4: Pesticide Submission Portal 'Home' Screen

4.4   Pesticide Submission Portal Header

The PSP header, first displayed on the PSP 'Home' screen, displays throughout all PSP applications and contains the following useful navigation tools and information:

- The 'Portal' icon displayed on the left side of the header navigates the user to the PSP 'Home' screen from any of the PSP application screens when selected.

- Selecting the 'Help' link displays application resources including user guides, answers to frequently asked questions, and contact information for the CDXHD.

- The logged in user's name, organization, and role display as a link on the right side of the header to assist CDX users who have registered for multiple organizations and roles identify the role/organization combination with which they accessed PSP. Selecting the link will log the user out of both the PSP application and CDX.

Exhibit 4-5 shows a screen capture of the PSP application header:

Exhibit 4-5: Application Header

4.5   Pesticide Submission Portal Footer

The PSP footer, first displayed on the PSP 'Home' screen, displays throughout all PSP applications and dynamically presents the below functionalities based on the displayed screen:

- The PSP version number and 'Release Notes' link, displayed when on a PSP screen, provides a history of recent PSP releases and their contents.
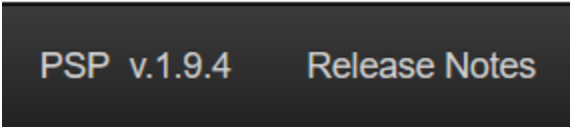
Exhibit 4-6: Application Footer Release Number and Notes

- **Provide Feedback:** The feedback functionality allows users to share their PSP application experience directly with the PSP project team. Select the 'Provide Feedback' link to launch the feedback pop-up and provide application feedback. **Important**: Contact the CDXHD for immediate assistance while working within PSP.
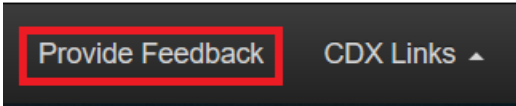
Exhibit 4-7: Application Footer Provide Feedback

Exhibit 4-8: Application Footer Provide Feedback Pop-Up

- **Help Links:** The 'CDX Links' menu in the application footer provides convenient access to the following CDX resources:

  - CDX 'Home' screen

  - 'MyCDX' screen

  - EPA Homepage

  - CDX 'Terms and Conditions' screen

  - CDX 'Privacy and Security Notice' screen
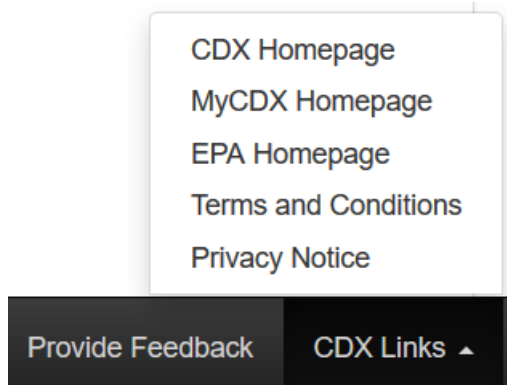
Exhibit 4-9: Application Footer 'CDX Links'

- **Save:** While on a submission screen, select the 'Save' icon to save all entered data on the current screen. The 'Save' function does not validate entered data.
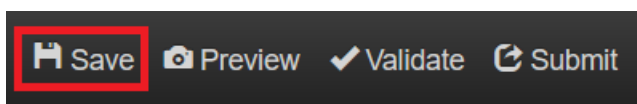
Exhibit 4-10: Application Footer 'Save' Icon

- **Preview:** While on a submission screen, select the 'Preview' icon to generate and display an in-progress PDF representation of the submission.
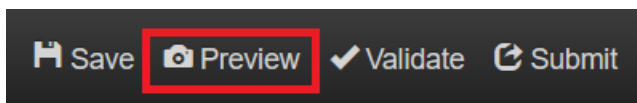
Exhibit 4-11: Application Footer 'Preview' Icon

- **Validate:** While on a submission screen, select the 'Validate' icon to check the current submission for errors and generate a comprehensive pop-up window report. Refer to **Section 4.8.2** for additional information about global validation.
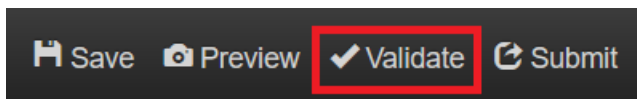
Exhibit 4-12: Application Footer 'Validate' Icon

- **Submit:** While on a submission screen, select the 'Submit' icon to begin the submission process and navigate to the 'Submitter Information' screen. Consult **Section 4.9** for guidance on the submission process.
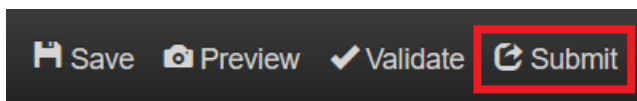
Exhibit 4-13: Application Footer 'Submit' Icon

4.6   Navigation Tree

The navigation tree is located on the left side of each screen within the PSP submission applications. The bottom portion of the navigation tree contains contextually based tips for the

displayed screen and provides guidance throughout the submission creation process. The navigation tree has the following functions:

- **Collapse and Expand folders:** Each submission section falls under a collapsible folder within the navigation tree. To collapse an expanded folder, select the folder title link to hide that section of the navigation tree. Select the folder title link for a collapsed folder to expand that section of the navigation tree.

- **Navigate between screens:** Navigation between the various screens within a submission is possible by selecting a screen title link to navigate to the desired screen.

  Important: All information entered on a screen must be saved before navigating to another screen via the navigation tree or entered information will be lost. A prompt displays when a link in the navigation tree is selected stating, "Are you sure you want to leave the current page? Any unsaved changes will be lost." Selecting the 'OK' button navigates the application to the requested screen without saving any changes on the current screen. Selecting the 'Cancel' button closes the prompt without navigating away from the current screen.

Exhibit 4-14 shows a screen capture of the navigation tree:

Exhibit 4-14: PSP Navigation Tree

4.7   Passphrases

PSP requires that submissions have an associated passphrase. A passphrase protects a submission by limiting access to only those users who have the passphrase and acting as an encryption key for submission data both at rest in CDX and during submission from CDX to OPP.

4.7.1   Create Passphrase Screen

A passphrase must have at least eight (8) characters; may contain a combination of letters, numbers, and spaces; and must **not** contain special characters (e.g., +, and *).

Important: The user who creates a submission is responsible for remembering the passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a package if the passphrase is lost or forgotten**. A new submission will need to be created when a passphrase is lost or forgotten. OPP suggests that each organization use the same passphrase for all submissions. A shared passphrase ensures that someone from the same organization can retrieve and/or complete the submission when the package creator is unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

Exhibit 4-15 shows a screen capture of the 'Create Passphrase' screen:
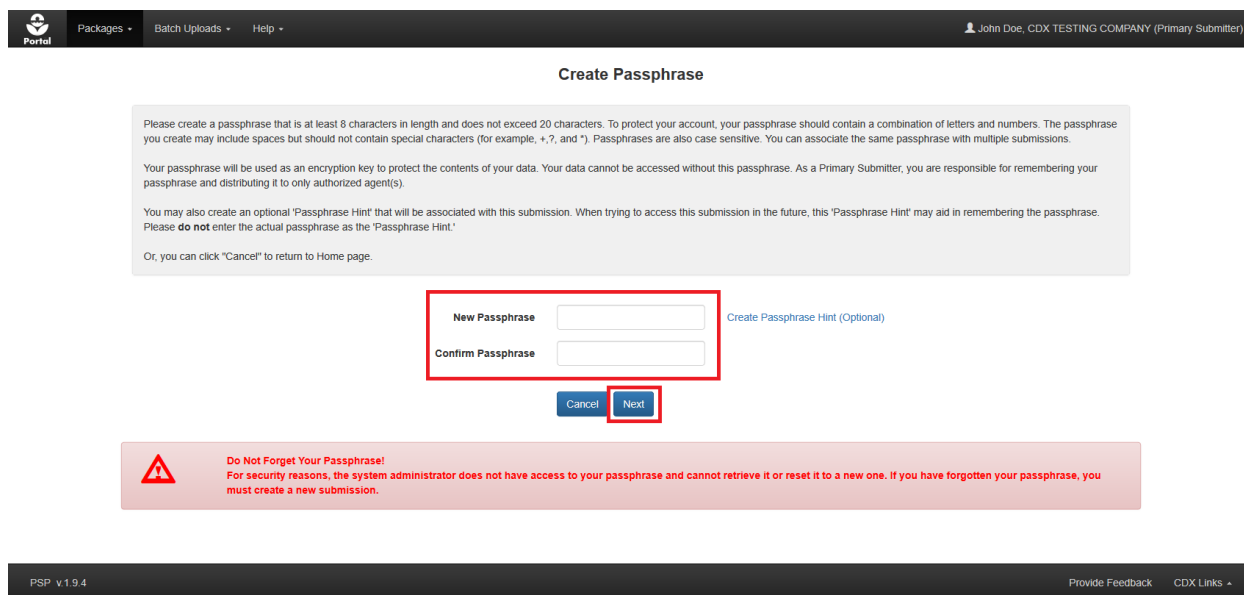
Exhibit 4-15: PSP 'Create Passphrase' Screen

Navigation: Create a passphrase and select the 'Next' button to navigate to the first screen within the selected submission type. For a PSP package, the first screen is the 'Package Info' screen. Refer to **Section 6.2** for additional information on the 'Package Info' screen.

4.7.1.1   Passphrase Hint

A passphrase hint is an optional reminder that can be associated with a submission via the 'Create Passphrase' screen and is intended to reduce forgotten passphrases. It is highly discouraged to use the same passphrase and passphrase hint as the hint is not encrypted and may be available to users that should not have package access. Only one passphrase hint may be set per submission and cannot be changed once set.

Exhibit 4-16 shows a screen capture of the passphrase hint link on the 'Create Passphrase' screen:
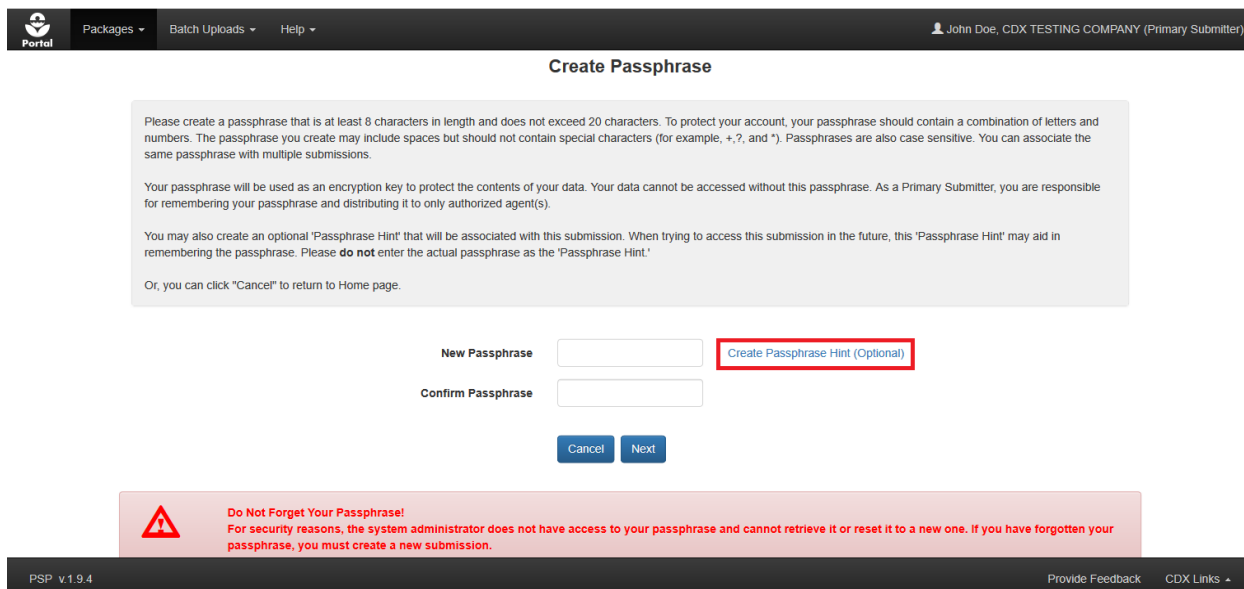
Exhibit 4-16: 'Create Passphrase' Screen – 'Create Passphrase Hint' Link

Navigation: Select the 'Create Passphrase Hint (Optional)' link next to the 'New Passphrase' field to launch the 'Create Passphrase Hint' pop-up.

Exhibit 4-17 shows a screen capture of 'Create Passphrase Hint' pop-up:
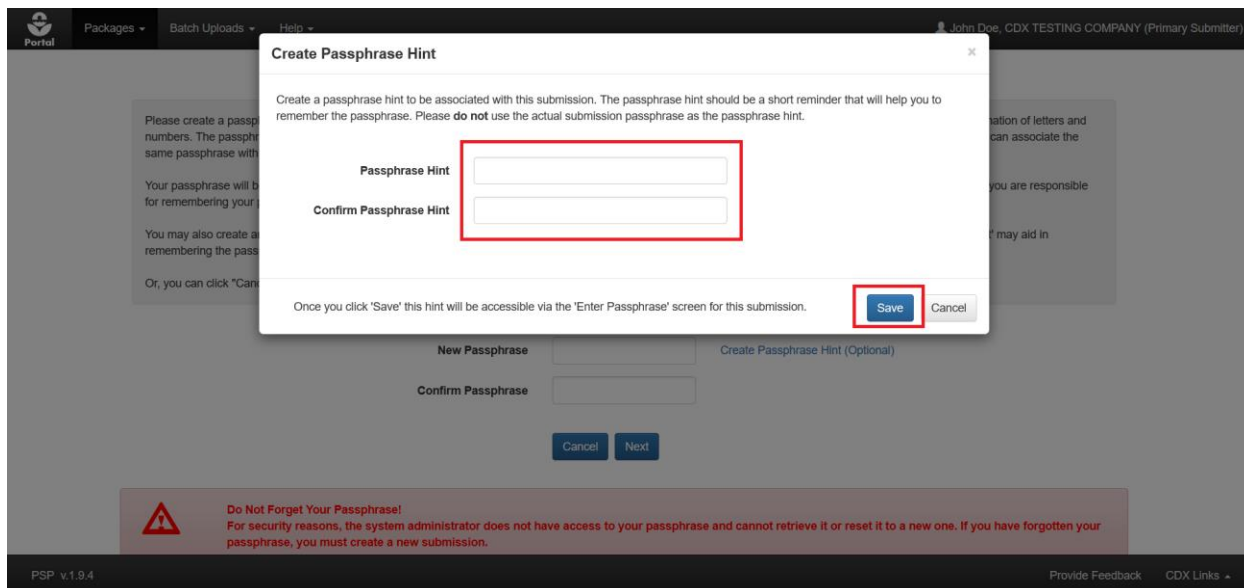
Exhibit 4-17: 'Create Passphrase Hint' Pop-Up

Navigation: Enter a short hint into the 'Passphrase Hint' field. Enter the same text into the 'Confirm Passphrase Hint' field. Select the 'Save' button.

A passphrase hint can be viewed on screens that require the passphrase to be entered, such as when accessing a submission via the 'Enter Passphrase' screen or when accessing a submission copy of record via the 'CROMERR' screen.

Exhibit 4-18 shows a screen capture of the 'View Passphrase Hint' link on the 'Create Passphrase' screen:
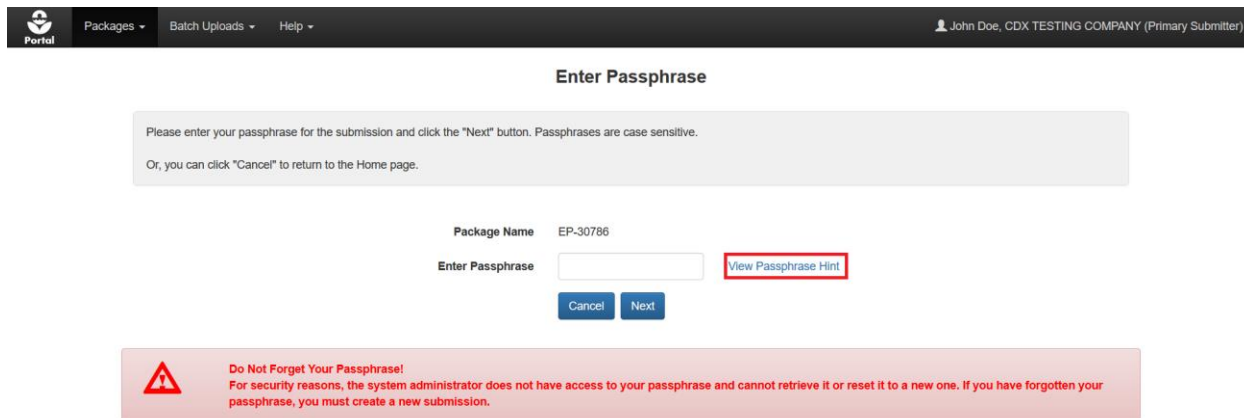
Exhibit 4-18: 'Enter Passphrase' Screen - 'View Passphrase Hint' Link

Navigation: Select the 'View Passphrase Hint' link to display the 'View Passphrase Hint' pop-up.

Exhibit 4-19 shows a screen capture of the 'View Passphrase Hint' link on the 'CROMERR' screen:
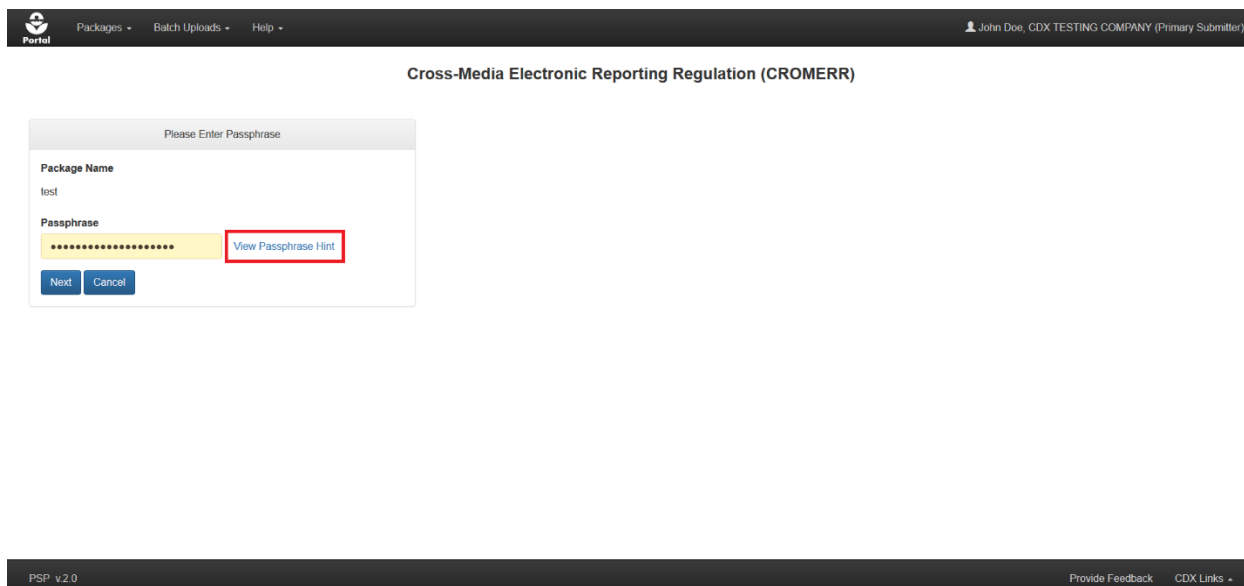
Exhibit 4-19: 'CROMERR' Screen - 'View Passphrase Hint' Link

Navigation: Select the 'View Passphrase Hint' link on the 'CROMERR' screen.

Exhibit 4-20 shows a screen capture of the 'View Passphrase Hint' pop up:
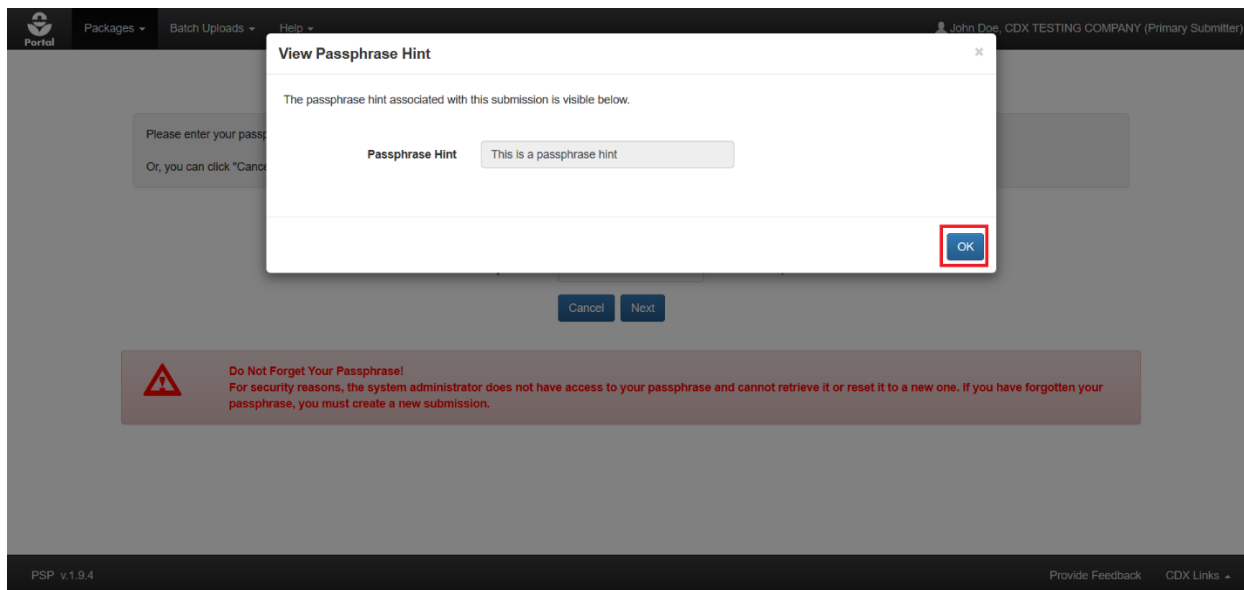
Exhibit 4-20: 'View Passphrase Hint' Pop-Up

Navigation: Review the passphrase hint and select the 'OK' button to close the pop-up.

4.7.2 Enter Passphrase Screen

To access an in-progress package, the passphrase that was used to encrypt that package must first be entered on the 'Enter Passphrase' screen

Exhibit 4-21 shows a screen capture of the 'Enter Passphrase' screen:
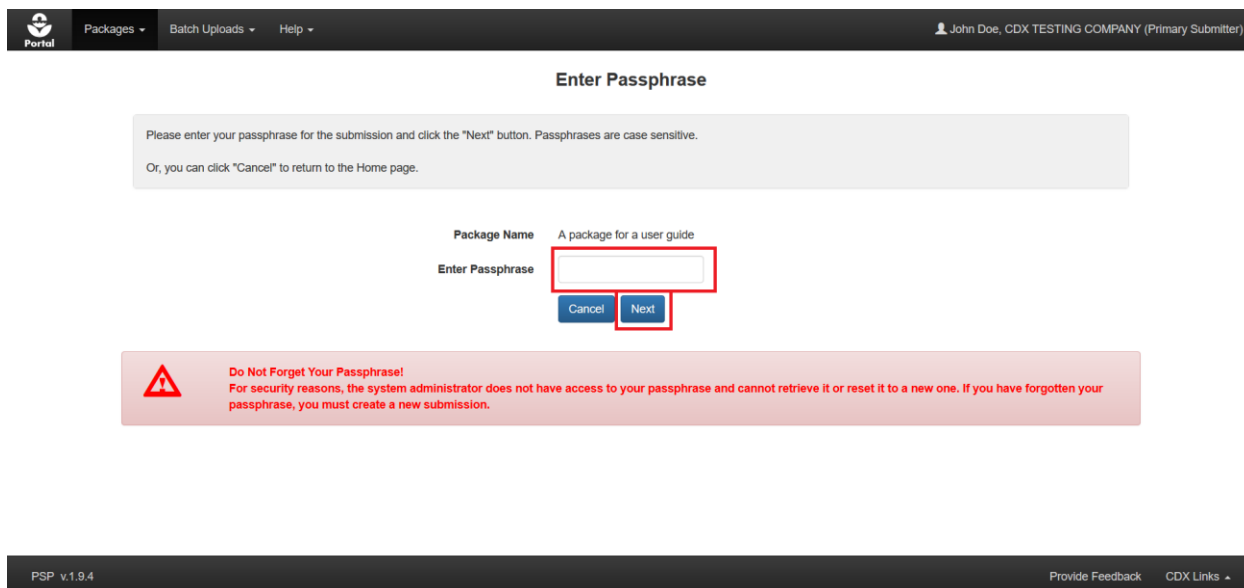
Exhibit 4-21: 'Enter Passphrase' Screen

Navigation: Enter the passphrase originally used to create a submission and select the 'Next' button to navigate to the first screen in the selected submission.

4.8 Validation

To ensure that the data and documents entered into a PSP submission are accurate and complete, the various PSP applications apply a two-part validation scheme that indicates errors while a user works on a submission and prevents incomplete submissions from being sent to EPA.

4.8.1 On-Screen Validation

Each screen in the PSP applications that contains a 'Next' navigation button will run on-screen validation on the displayed data when a user selects the 'Next' button. If no validation errors are present, the application will display the next screen as requested. However, if validation errors are present, error messages will display on the screen and must be corrected prior to navigation.

To navigate away from a screen that contains validation errors without correcting them, select a link in the application's navigation tree or select the 'Mark for Registrant Review' checkbox prior to selecting the 'Next' button. All errors and selected 'Mark for Registrant Review' checkboxes must be cleared before submission to EPA is permitted.

Exhibit 4-22 shows a screen capture of the 'Package Info' screen with on-screen validation errors:
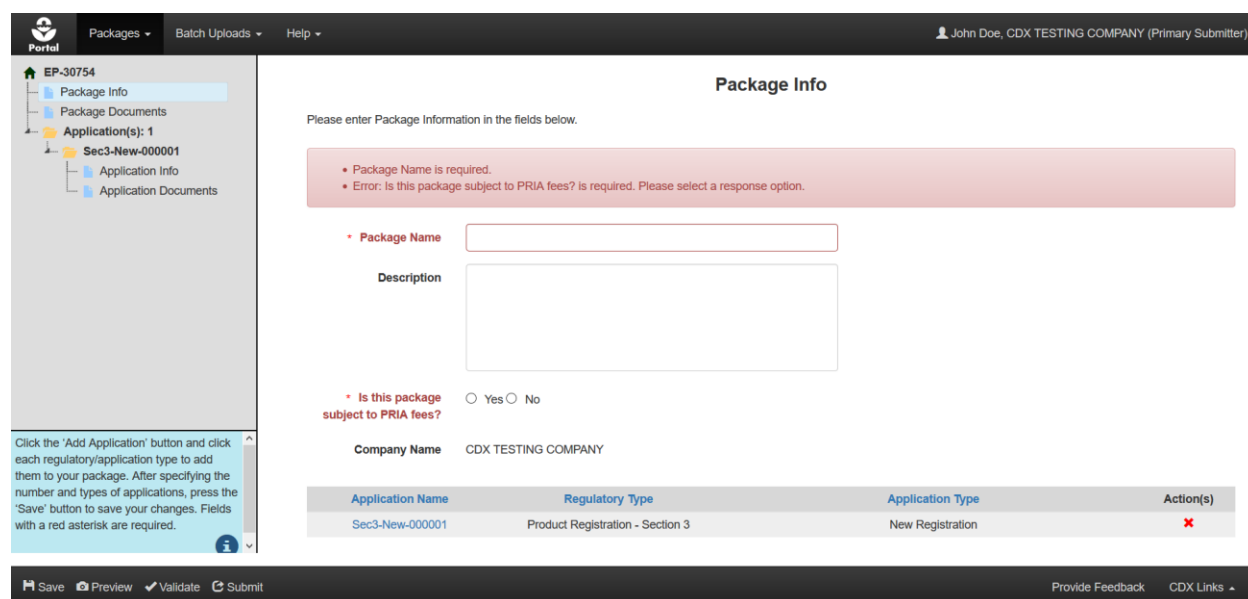
Exhibit 4-22: On-Screen Validation Example

4.8.2 Global Validation

PSP users may perform a validation check on the entirety of a submission at any time by selecting the 'Validate' button in the application footer. Doing so will check each field within the submission for missing and/or invalid data as determined by the submission type and certain metadata when validation is initiated.

The results of a global validation check display in a separate pop-up. Each validation error indicates the screen on which an error occurs as well as the specific error as a link to navigate to the screen to address the error. Once an error is cleared the 'Validate' button may be selected

again to view an updated set of errors. All validation errors must be cleared before a submission can be made.

Note: CDX must be added to the browser's pop-up whitelist for global validation results to properly display.

Exhibit 4-23 shows a screen capture of the global validation pop-up:
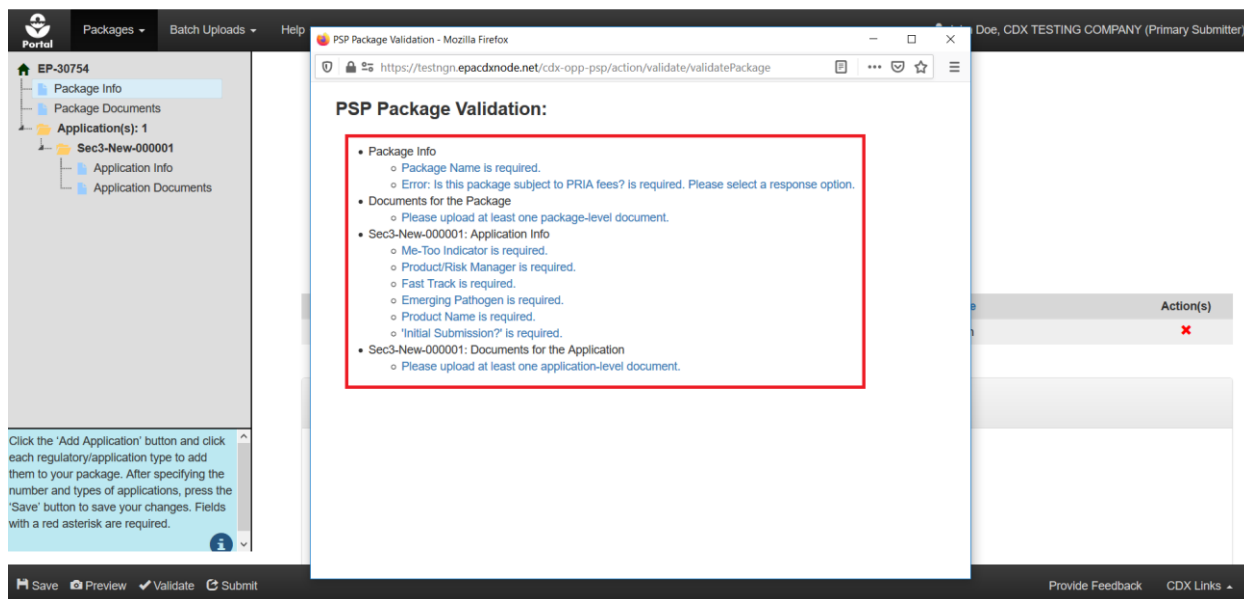
Exhibit 4-23: 'Global Validation' Pop-up

Navigation: Select an error link in the 'Global Validation' pop-up to navigate to the location within the application where the selected error occurs.

4.9 Submit to EPA via CDX

The various applications within PSP allow both Primary Submitters and Authorized Agents to sign and submit forms and packages to EPA. The PSP applications restrict users from making an incomplete submission by applying global validation that must be passed before a submission may be signed and submitted. Refer to **Section 4.8.2** for information on how to run global validation.

Exhibit 4-24 shows a screen capture of the 'Submit' buttons displayed on the 'Documents for the Application' screen:

Exhibit 4-24: PSP 'Documents of the Application' Screen – Submit Buttons

Navigation: To initiate the submission process in any of the PSP applications, select the 'Submit' button located on the last screen within the submission, or select the 'Submit' icon located in the application footer.

4.9.1 Submitter Information Screen

The 'Submitter Information' screen is the first screen in the submission process and it requires the submitter (the currently logged in user) to review their contact information as provided from CDX. This serves as both a check to ensure that the contact information is current in CDX and a reminder for which company the submission will be made.

Exhibit 4-25 shows a screen capture of the 'Submitter Information' screen:

Submitter Information

Company Name	CDX TESTING COMPANY
Company Number	98765
Submitter's Role	Primary Submitter
Prefix	Mr
First Name	John
Last Name	Doe
Phone Number	(888) 555-5345
Email Address	jdoe@cdxtestingco.com
Mailing Address 1	123 Main Street
City	Crystal City
State	VA
Postal Code	22202

[Back] [Validate]

Exhibit 4-25: 'Submitter Information' Screen

Navigation: Select the 'Validate' button to run global validation (the screen will darken and a spinning status wheel will appear). After validation completes, the application navigates to the 'Submission Process: Validate' screen.

4.9.2 Submission Process: Validate Screen

The 'Submission Process: Validate' screen indicates whether a submission meets the minimum validation standards based on its type and certain metadata entered within the submission. If issues are identified during the global validation review, the screen will indicate that validation failed and a pop-up containing a comprehensive list of validation errors will appear. All validation errors must be resolved before a package can be submitted. If the application does not identify any validation errors, the screen will indicate that no issues were found and the user will be able to continue the submission process.

Exhibit 4-26 shows a screen capture of the 'Submission Process: Validate' screen when a submission passes global validation:
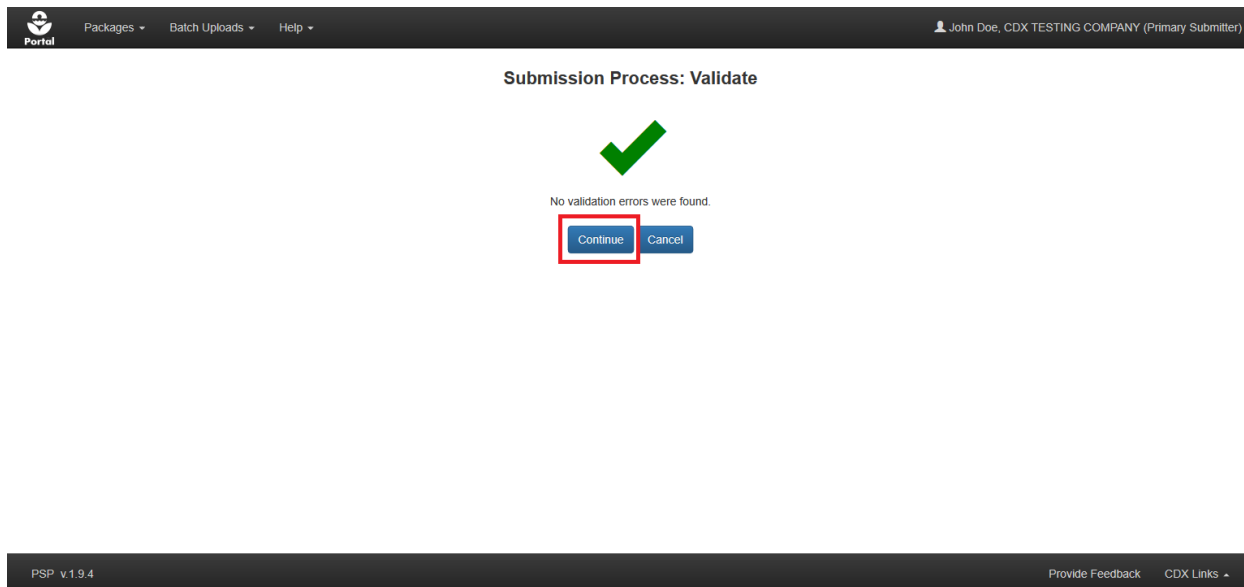
Exhibit 4-26: 'Submission Process: Validate' Screen

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

Exhibit 4-27 shows a screen capture of the 'Submission Process: PDF Generation' screen:
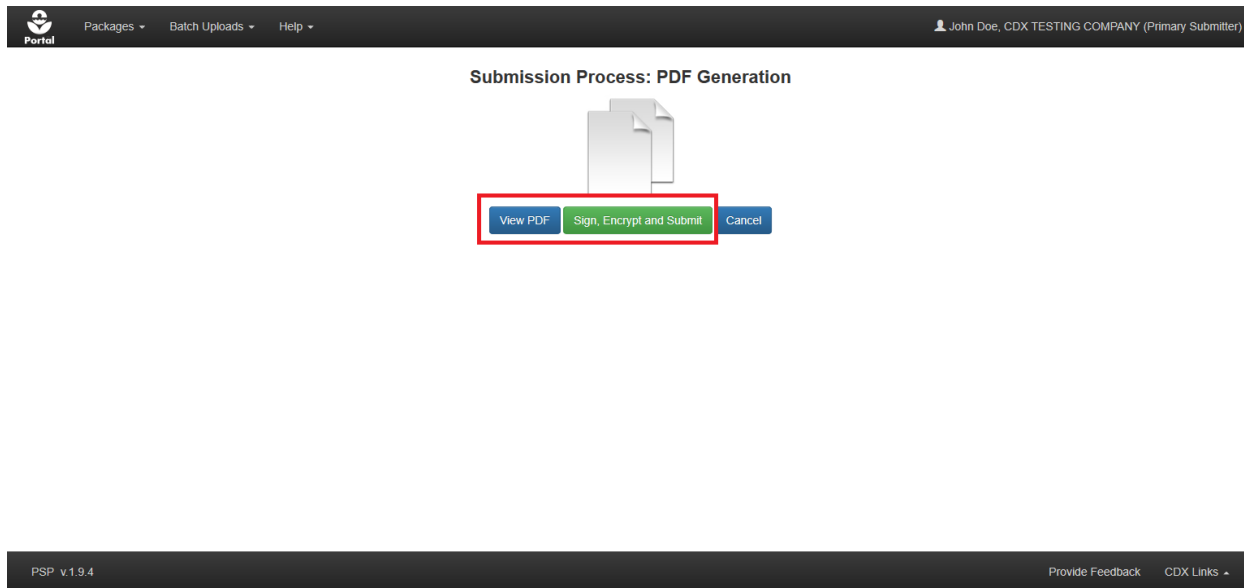
Exhibit 4-27: 'Submission Process: PDF Generation' Screen

Navigation: Select the 'View PDF' button to review a PDF representation of the submission and its contents. After viewing and/or printing the PDF, select the 'Sign, Encrypt, and Submit' button to launch the 'eSignature' widget.

4.9.3 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.

Exhibit 4-28 shows a screen capture of the 'CROMERR eSignature Widget' certification:
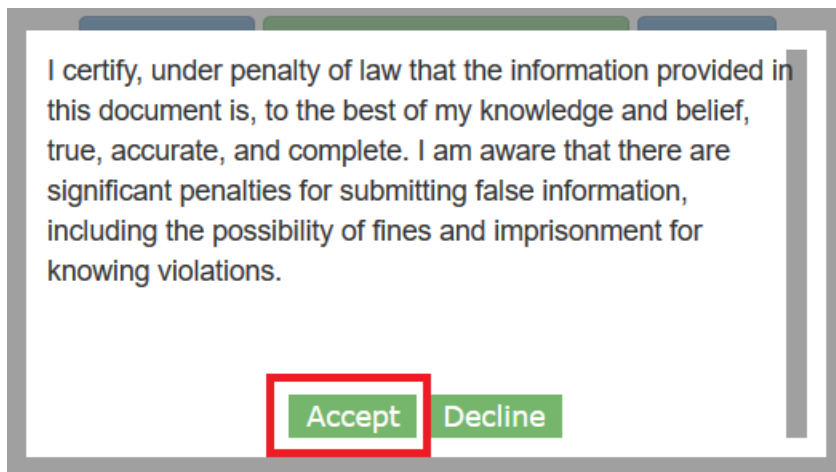
Exhibit 4-28: 'CROMERR eSignature Widget' Certification

Navigation: Review the CROMERR certification terms and, if acceptable, select the 'Accept' button to continue the submission process and sign the submission.

Exhibit 4-29 shows a screen capture of the 'CROMERR eSignature Widget' signature steps:
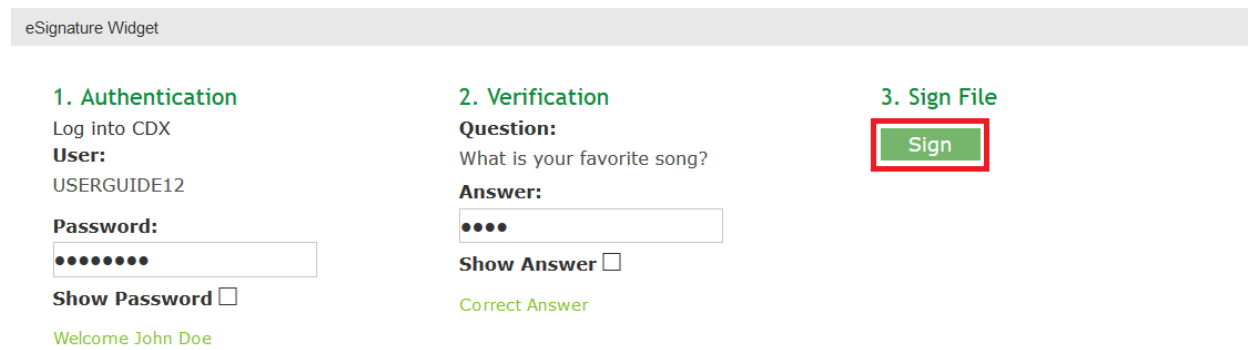
Exhibit 4-29: 'CROMERR eSignature Widget' Signature Steps

Navigation: Enter the logged in user's CDX account password and answer to the displayed '20-5-1' question and then select the 'Sign' button to complete the submission process. The submitter will receive a confirmation email if the submission process successfully completes through to EPA's systems.

5   MRIDs

EPA uses MRID numbers to track and manage information submitted to the pesticide program. An MRID number is a unique, eight-digit number assigned to each study submitted to EPA.

5.1   Generate Root MRIDs

The first six digits of an MRID are referred to as a Root MRID. A Root MRID that was not used in another package submission is necessary to submit studies via the PSP applications.

To generate a Root MRID, access the 'Generate Root MRIDs' screen by selecting the 'Generate Root MRIDs' link under 'Pre-Submission Tools' on the PSP 'Home' screen.

Exhibit 5-1 shows a screen capture of the 'Generate Root MRIDs' screen:

Exhibit 5-1: 'Generate Root MRIDs' Screen

Navigation: Enter the number of Root MRIDs to be created and select the 'Generate Root MRIDs' button; a processing pop-up will display as root MRIDs are generated.

Once system processing completes, all newly generated root MRIDs display on screen and are included in an email sent to the email address associated with the requesting user's CDX account. Root MRIDs are immediately available for use in a submission after generation.

Exhibit 5-2 shows a screen capture of the 'Generate Root MRIDs' screen with generated Root MRIDs:

Exhibit 5-2: 'Generate Root MRIDs' Screen – Review Generated Numbers

Navigation: Select the 'Reset' button to clear the screen to request additional Root MRIDs. Select the 'Back' button to navigate to the PSP 'Home' screen.

Exhibit 5-3 shows a screen capture of the email containing generated Root MRIDs:
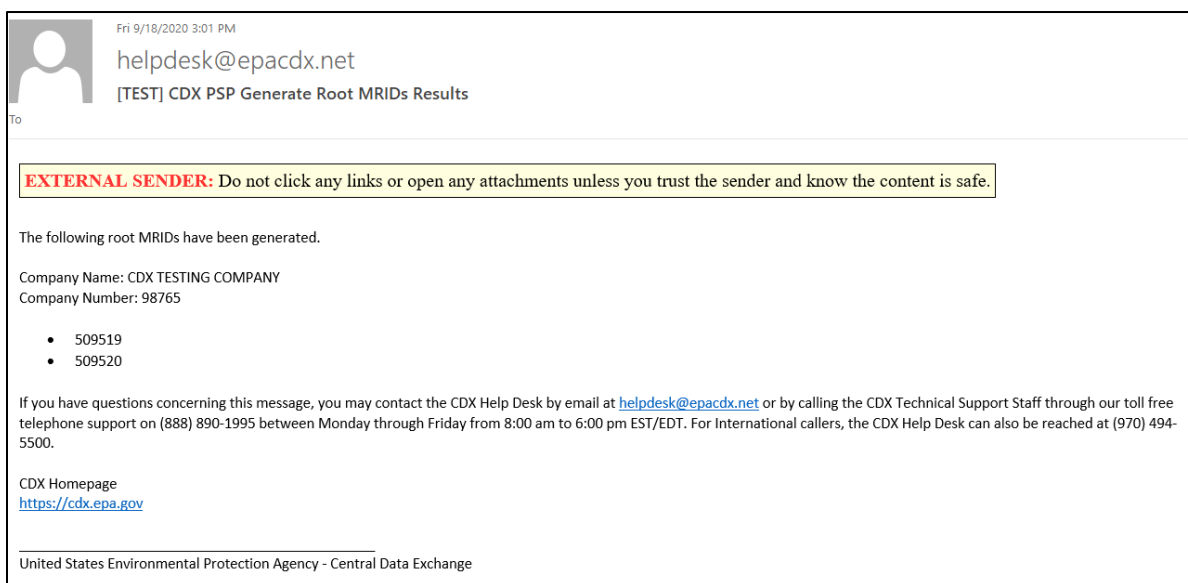
Exhibit 5-3: Root MRID Generation Email

5.2　Adding a Study Document to a PSP Submission

To add a study document to a PSP submission (e.g., registration package or DCI submission), navigate to the appropriate document upload screen (e.g., 'Documents for the Application') after obtaining an unused root MRID.

Please keep the following in mind when using MRID numbers:

- A root MRID can only be used in a single application. Documents within different applications cannot use the same root MRID.

- 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, multiple root MRIDs will be necessary.

- Enter the six-digit root followed by a two-digit sequential number for each uploaded study document.

- 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).

- 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.

Exhibit 5-4 shows a screen capture of the 'Documents for the Application' screen with two saved studies and an additional study in the process of being added:

Exhibit 5-4: 'Documents for the Application' – Documents Table

Navigation: Select the 'Add' button (not pictured) to enter metadata for a document. Choose the 'Study' document type and sub-type, complete all required fields (including the 'Doc MRID' field), and then select the 'Save' button. Saved files display in the table at the top of the screen with the entered MRID value.

![CDX logo]

6 Prepare a Package for Submission Using PSP

This section describes the process to prepare a package for submission using the PSP application. If study documents will be included in a package, refer to **Section 5** for instructions on how to generate Root MRIDs.

6.1 Create Package

The 'Create New Package' link is located in the 'Registration Submission' column on the 'Pesticide Submission Portal' home screen. Selecting this link starts the PSP package creation process.

Exhibit 6-1 shows a screen capture of the 'Create New Package' link on the PSP 'Home' screen:
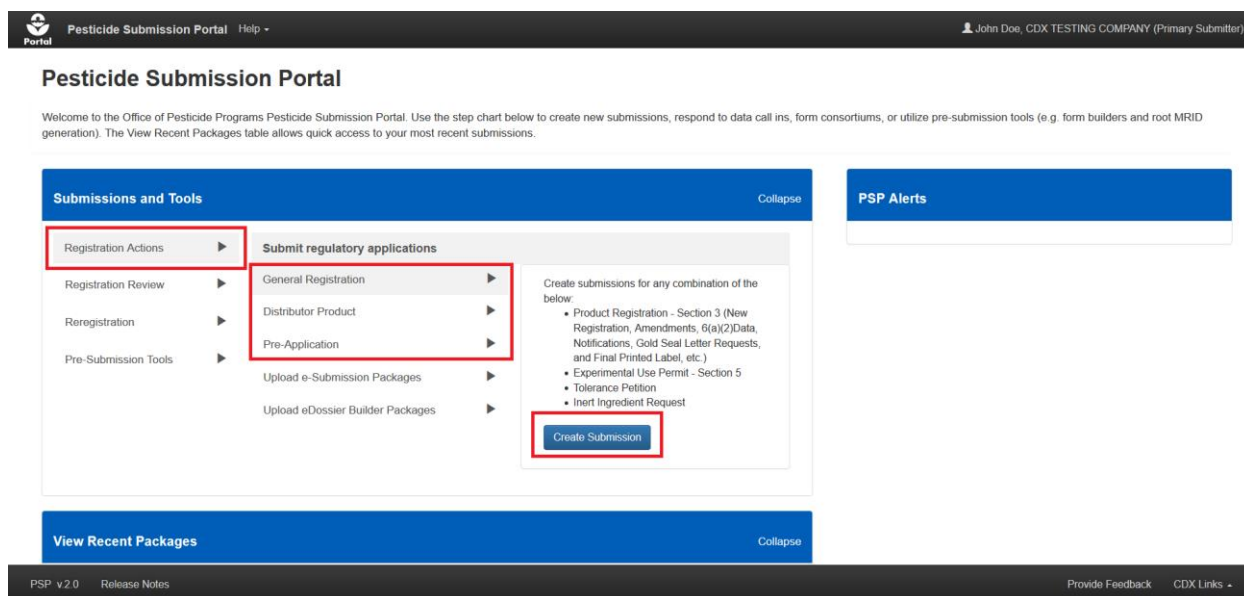
Exhibit 6-1: PSP 'Home' Screen - 'Create New Package' Options

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Actions' option in the first column, then select either the 'General Registration,' 'Distributor Product,' or 'Pre-Application' option in the second column, and finally select the 'Create Submission' button to navigate to the 'Create Passphrase' screen and create a package. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Important: The same passphrase must be used throughout the life of a package. The user who creates a package is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a package if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

![CDX logo]

6.2   Package Information Screen

The 'Package Info' screen collects data about a PSP package and is where underlying applications are added to a package. The following fields are displayed on the 'Package Info' screen with required fields denoted with a red asterisk:

- **Package Name:** Enter a name for the package. This field is required.

- **Description:** Enter a description for the package. This field is optional.

- **Is this PRIA:** Designate if the package is subject to Pesticide Registration Improvement Extension Act (PRIA) fees. This field is optional.

- **Company Name:** The name of the company under which the package will be submitted. This field is not editable and is pre-populated from the logged in user's CDX account.

At least one application must be added to a package and completed prior to package submission. The following regulatory and application types are currently available in the PSP application:

- Distributor Product

    – The application selection for Distributor Products takes place on the 'Application Info' screen. Please see **Section 6.4.1** for guidance on preparing Distributor Product applications.

- Experimental Use Permit – Section 5

    – New

    – Amendment

- Inert Ingredient Request

    – New

- Pre-Application

    – New

- Product Registration – Section 3

    – New Registration

    – Amendment

    – 6(a)(2) Data

    – Notification

    – Gold Seal Letter Request

    – Final Printed Labeling (FPL)

    – Pet Spot-On Enhanced Reporting

- Tolerance Petition

    – New

Exhibit 6-2 shows a screen capture of the 'Package Info' screen as initially displayed:
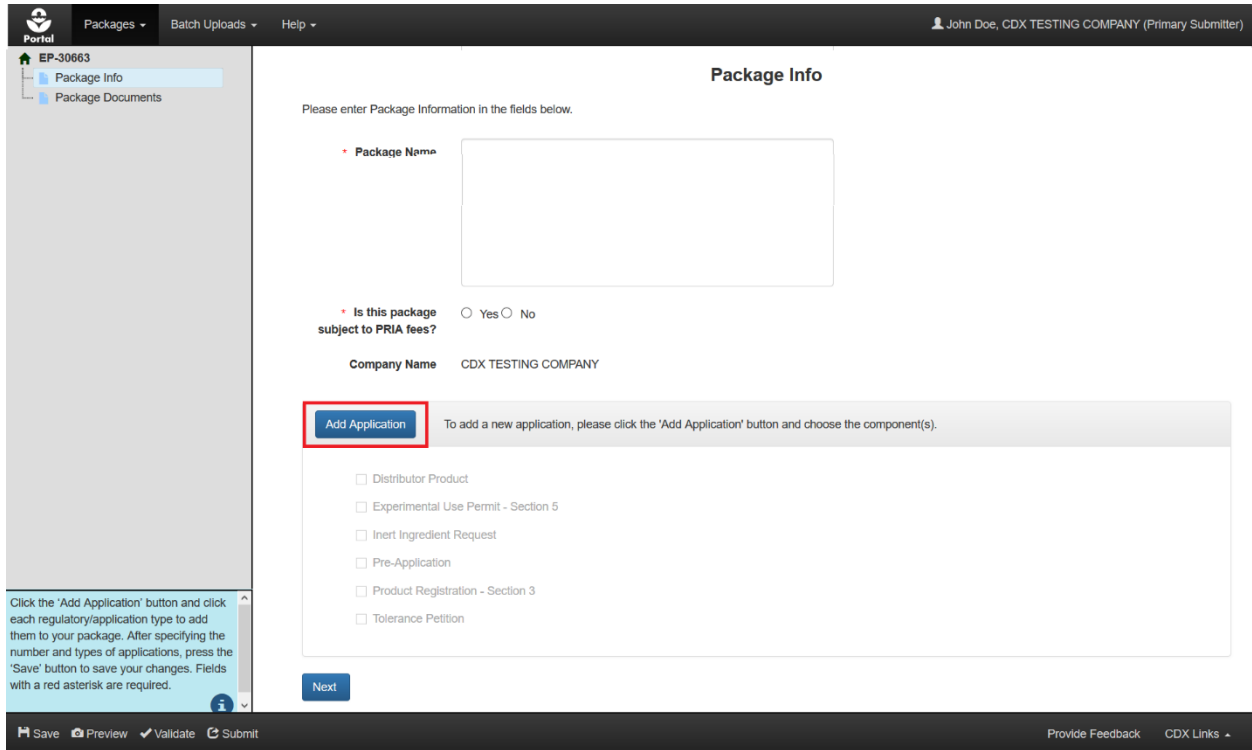
Exhibit 6-2: 'Package Info' Screen

Navigation: Fill out all necessary fields and select the 'Add Application' button.

Exhibit 6-3 shows a screen capture of the 'Add Application(s)' menu on the 'Package Info' screen:
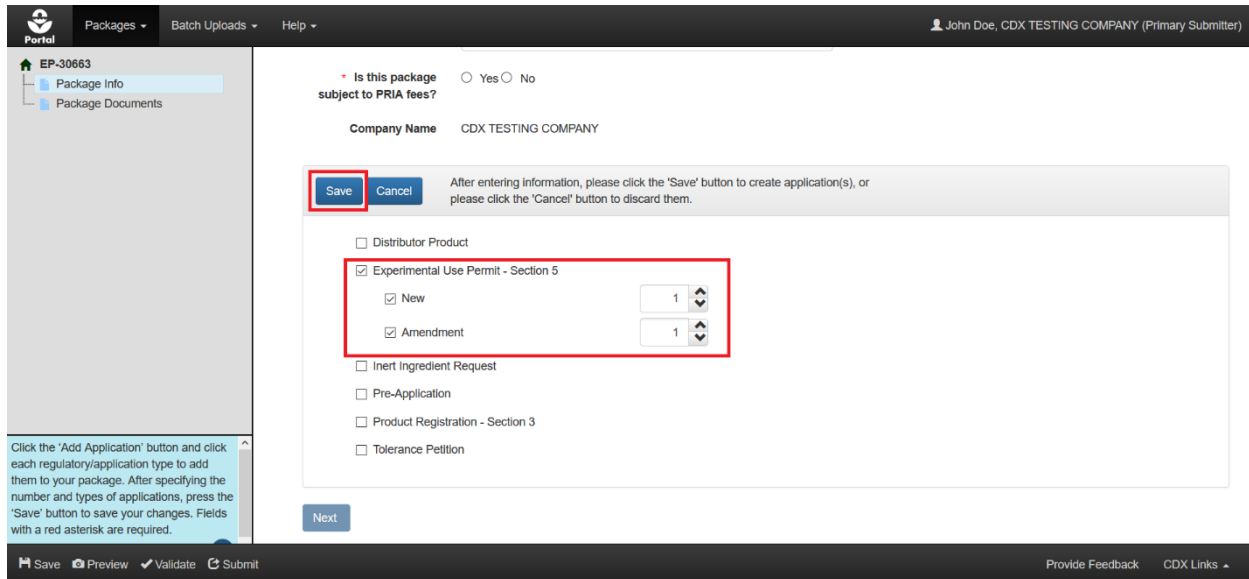
Exhibit 6-3: 'Add Application(s)' Menu on 'Package Info' Screen

Navigation: Check the box adjacent to the necessary regulatory type(s) to reveal the available underlying application type(s). Next, select the corresponding application type(s) checkbox(es) and designate how many of the selected application type(s) will be added to the package – multiple regulatory and application types can be simultaneously added to a package. Finally, select the 'Save' button to add all selections to the package.

Exhibit 6-4 shows a screen capture of the 'Package Info' screen populated with applications:

Exhibit 6-4: 'Package Info' Screen with Applications

Navigation: After an application is added to a package, a table displays detailing each included application and the navigation tree is updated to display each application's screens. To remove an application from a package, select the corresponding 'Delete' icon in the 'Action(s)' column. To navigate directly to an application, select either an 'Application Name' link in the table or the desired screen link in the navigation tree. Alternatively, select the 'Next' button to navigate to the 'Documents for the Package' screen after adding the requisite information for the package.

6.2.1 Adding a Distributor Product Application to a Package

Distributor Product applications are added to a package on the 'Package Info' screen using the below detailed navigation steps.

Exhibit 6-5 shows a screen capture of how add Distributor Product applications to a package on the 'Package Info' screen:

Exhibit 6-5: PSP 'Package Info' Screen - Distributor Product Application

Navigation: Select the 'Add Application' button (not pictured), select the 'Distributor Product' checkbox, indicate the number of Distributor Product applications to add to the package, and finally select the 'Save' button. Once saved, select the Distributor Product application in either the table on the screen or in the navigation tree to navigate to the 'Application Info' screen.

The following fields display on the 'Application Info' screen for a Distributor Product application:

- **Regulatory Type:** The regulatory type of the application. This field is not editable.

- **Basic Product Registration No:** The Basic Product Registration Number for the Distributor Product. It is also known as the Parent Section 3 Number. The system validates that the logged in user's company number matches the entered 'Basic Product Registration No' to ensure submission by the correct organization. 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.

Exhibit 6-6 shows a screen capture of the 'Application Info' screen for a Distributor Product before an 'Application Type' is chosen:
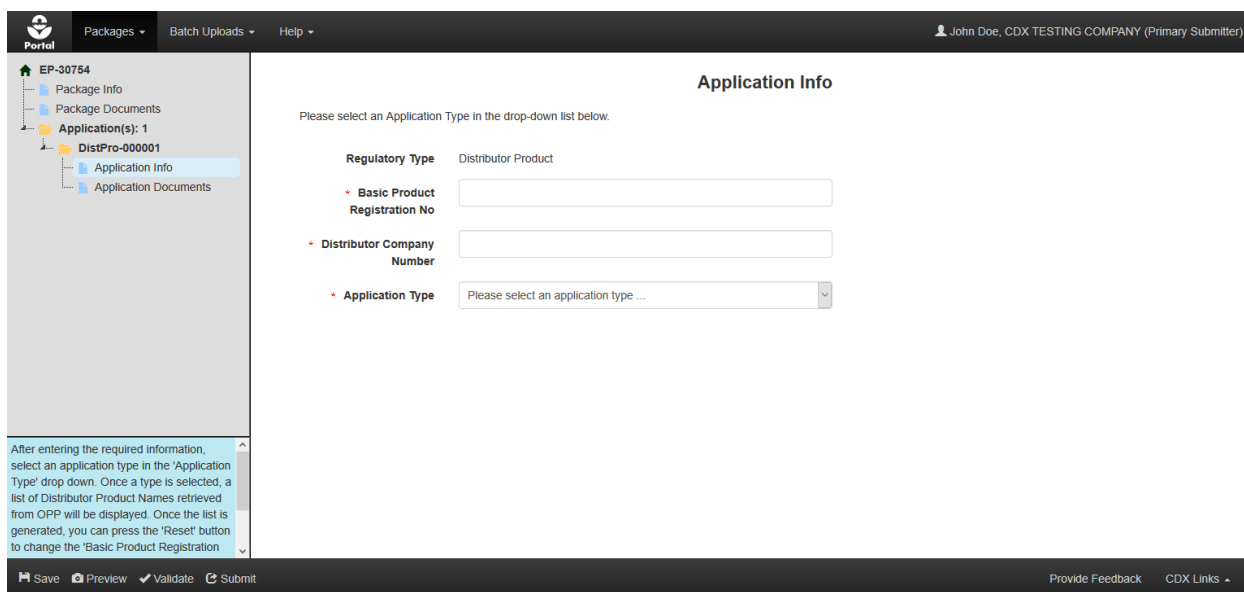
Exhibit 6-6: PSP 'Application Info' Screen – Distributor Product

Navigation: Enter all required information, as noted by the red asterisks, and select a Distributor Product application type from the drop-down menu. Once all information is entered and a Distributor Product application type is chosen, the screen will darken and a spinning status wheel will appear. The screen will then update to display the necessary fields based on the 'Application Type' selection. A list of Distributor Product names will be generated for all Distributor Product application types except for 'New' Distributor Products.

![CDX logo]

6.3　Documents for the Package Screen

Required package-level documents (i.e., files that apply to all package applications) must be uploaded to a package on the 'Documents for the Package' screen. **Important:** At least one package-level document must be uploaded on this screen. Examples of common package-level documents include:

- Submission Cover Letters

- Transmittal Documents

- Payment Receipts

Each 'Document Type' has specific validation rules to ensure data quality, prevent errors, and ensure that requisite document metadata is associated with uploaded files. The following fields dynamically display in the 'Add Document' menu based on the selected 'Document Type:'

- **Package Name:** Displays the package name entered on the 'Package Info' screen. This field is not editable in this location.

- **Document Type:** Select a document type for the uploaded file. This field is required.

- **Document Title –** Only visible when the 'Other' Document Type is selected. Enter a title for the document. This field is optional.

- **Document Upload:** Either drag and drop a file or select the 'browse' link to select a file to upload. Empty, protected, and .exe files are not allowed. Document file names should neither exceed 200 characters, nor be duplicated. This field is required.

- **Document Date:** Specify a date, such as the creation date, to link to a document. This field is optional.

- **Document Group:** Enter a group to which the document is related. This field is optional.

- **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 field is required. 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 a comment for the uploaded document. This field is optional.

Exhibit 6-7 shows a screen capture of the 'Documents for the Package' screen:
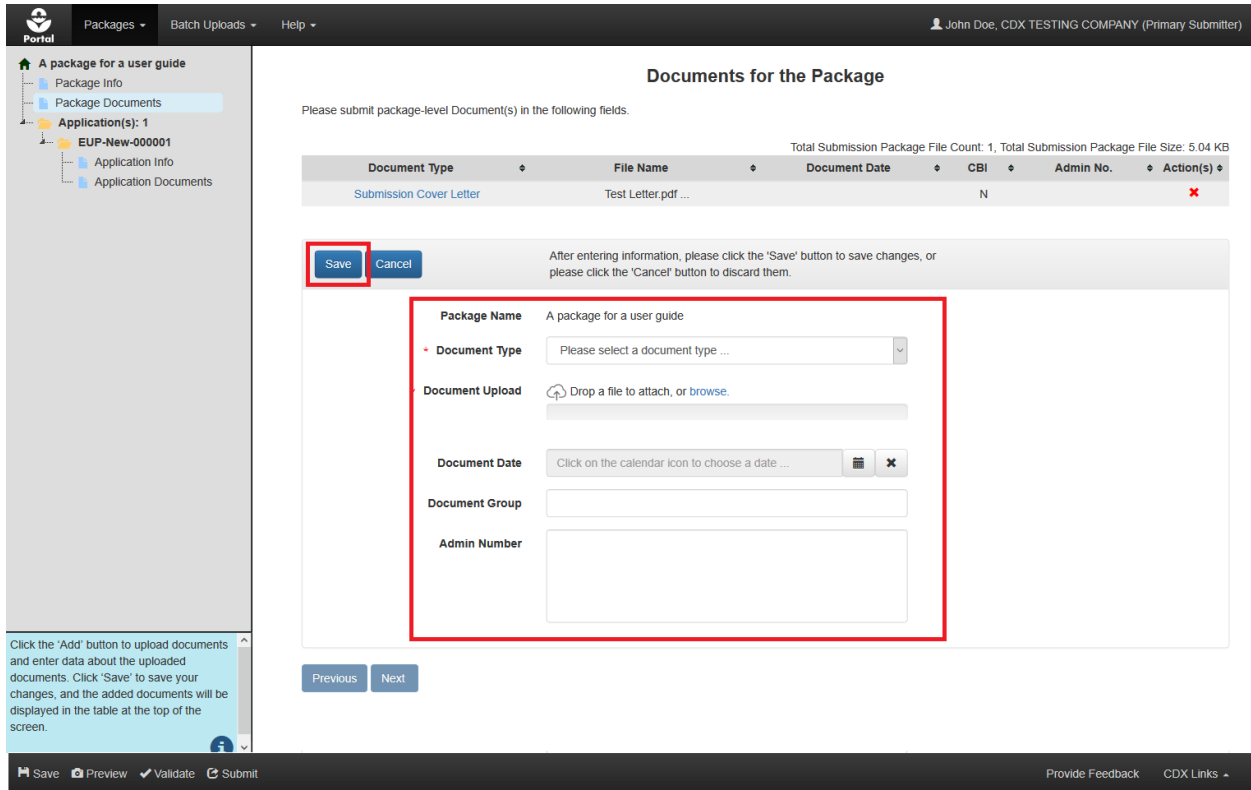
Exhibit 6-7: 'Documents for the Package' Screen – Add Document Menu

Navigation: Select the 'Add' button (not pictured), complete all necessary fields, upload a file, and finally select the 'Save' button to save the file to the package.

Exhibit 6-8 shows a screen capture of the 'Documents for the Package' screen with an uploaded file:
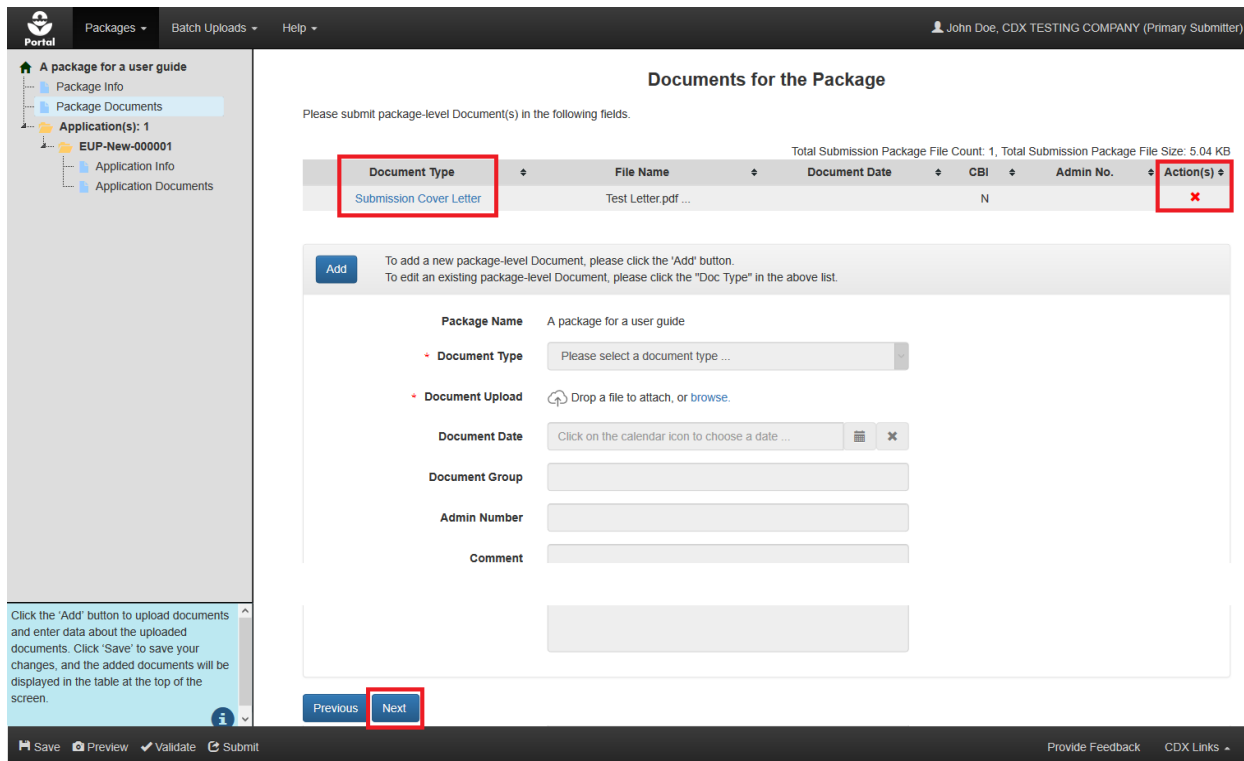
Exhibit 6-8: 'Documents for the Package' Screen with Attached Documents

Navigation: Saved documents display in a table at the top of the 'Documents for the Package' screen and can be edited by selecting a 'Document Type' link or deleted by selecting the corresponding 'Delete icon. Additional documents can be added to the package by selecting the 'Add' button. After uploading all necessary documents, select the 'Next' button to navigate to the 'Application Info' screen for the first application in the package.

6.4   Application Info Screen

The 'Application Info' screen captures information about an application included in a package. The fields on this screen dynamically display based on the application type selected on the 'Package Info' screen (i.e., the below described fields will not display for every application type). The following fields may display on the 'Application Info' screen:

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. This field is required.

- **Description:** Enter a description for the application. The copy icon next to the 'Description' field copies the package level 'Description' as entered on the 'Package Info' screen. This field is optional.

- **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.

- **Initial Submission:** Select whether the application is an initial submission. This field is required.

- **Admin Number:** Enter the Admin Number, Registration Number, or SLN number. This field is required when displayed. Please refer to **Appendix B – Admin Number** for more information about Admin Numbers.

- **Product Name:** Enter the name of the product. This field is required when displayed.

- **Ingredient Name:** Enter the name of the ingredient. This field is required when displayed.

- **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 a 'Product/Risk Manager' from the drop-down menu. The available options display based on the chosen application type. This field is required when displayed.

- **Me-Too Indicator:** Enter a final Me-Too Indicator. This field is required when displayed.

- **Petition Type:** Enter a final Petition Type. This field is required when displayed.

- **Fast Track:** Enter a final Fast Track Indicator. This field is required when displayed.

- **Emerging Pathogen:** Indicate whether the product is for use against an emerging pathogen (e.g. SARS-CoV-2). This field is required when displayed.

- **Remarks:** Provide questions, notes, or other remarks. This field is optional.

- **Mark for Review:** This checkbox is used to flag a screen for future consideration. Selecting the checkbox changes the screen link display to red in the navigation tree and necessitates that the checkbox be unselected to pass global validation.

Exhibit 6-9 shows a screen capture of the 'Application Info' screen:
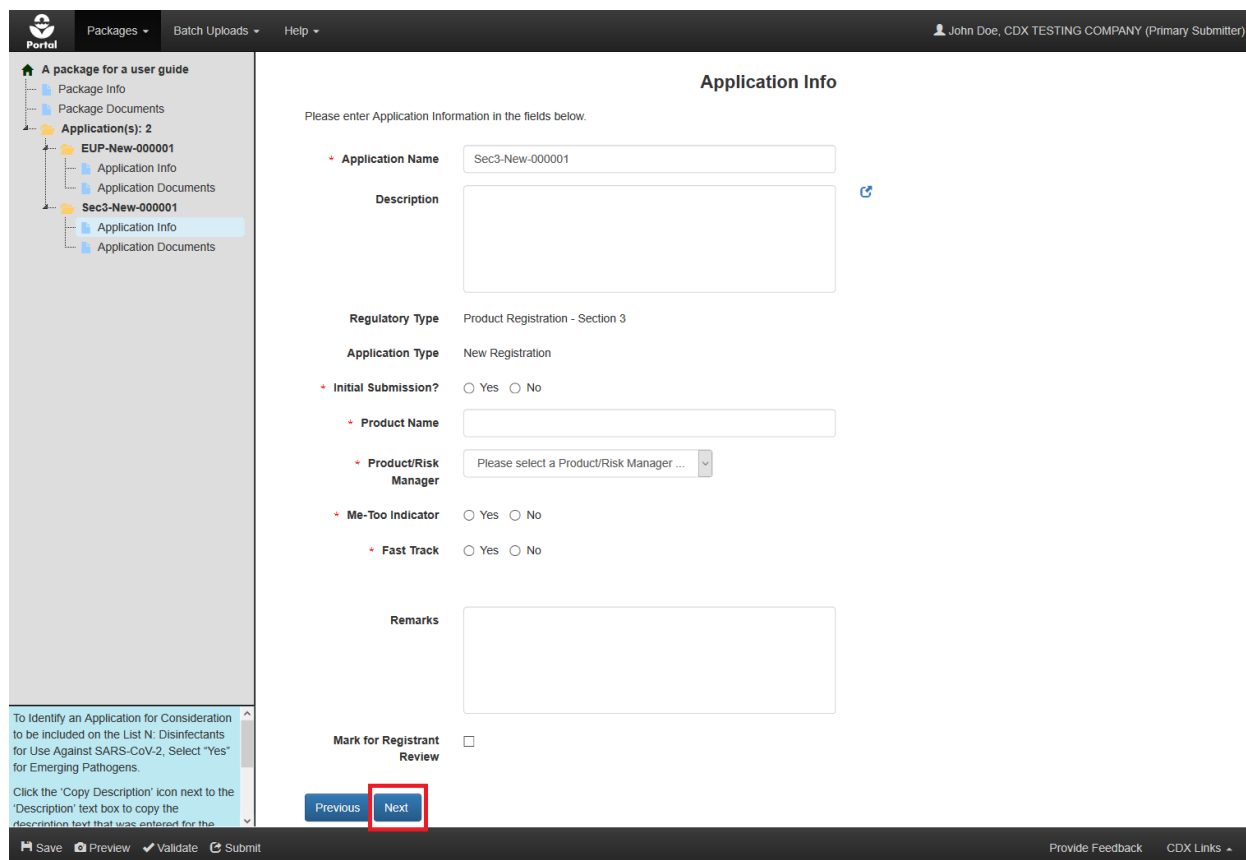
Exhibit 6-9: PSP 'Application Info' Screen

Navigation: Enter all required information, as designated by a red asterisk, and select the 'Next' button to navigate to the 'Documents for the Application' screen for the application.

6.4.1   Distributor Product Applications

This section describes how to prepare the five types of Distributor Product applications supported by PSP. The five types of actions that can be taken in a Distributor Product application are:

- Create a 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

6.4.1.1   Request a New Distributor Product

The following additional fields display after a user chooses the 'New Distributor Product' option:

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. 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 6-10 shows a screen capture of the 'Application Info' screen for a Distributor Product after selecting 'New Distributor Product' application type from the drop-down menu:

Exhibit 6-10: PSP 'Application Info' Screen - New Distributor Product

Navigation: Enter values in the 'Basic Product Registration No' and 'Distributor Company Number' fields, choose 'New Distributor Product' from the 'Application Type' drop-down menu, enter information in remaining required fields, as designated by a red asterisk, and finally select the 'Next' button.

![CDX logo]

6.4.1.2   Add an Alternate Distributor Product Name to an Existing Distributor Product

The following additional fields display after a user chooses the 'Add Alternate Distributor Name to an Existing Distributor Product' option and system processing completes:

- The option to use either a new or existing, inactive Distributor Product Name

- A table of existing Distributor Product Names and their statuses

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. This field is required.

- **Distributor Product Name:** The name of the Distributor Product. This field is required.

Exhibit 6-11 shows a screen capture of how to enter a new Distributor Product Name on the 'Application Info' screen:

Exhibit 6-11: PSP 'Application Info' Screen - Add New Alternate Distributor Product Name

Navigation: Enter values in the 'Basic Product Registration No' and 'Distributor Company Number' fields, choose 'Add Alternate Distributor Name to an Existing Distributor Product' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Then select the 'Use New Distributor Product Name' radio button, enter a new Distributor Product name in the 'Distributor Product Name' field, and finally select the 'Next' button.

Exhibit 6-12 shows a screen capture of how to select an existing, inactive Distributor Product Name on the 'Application Info' screen:
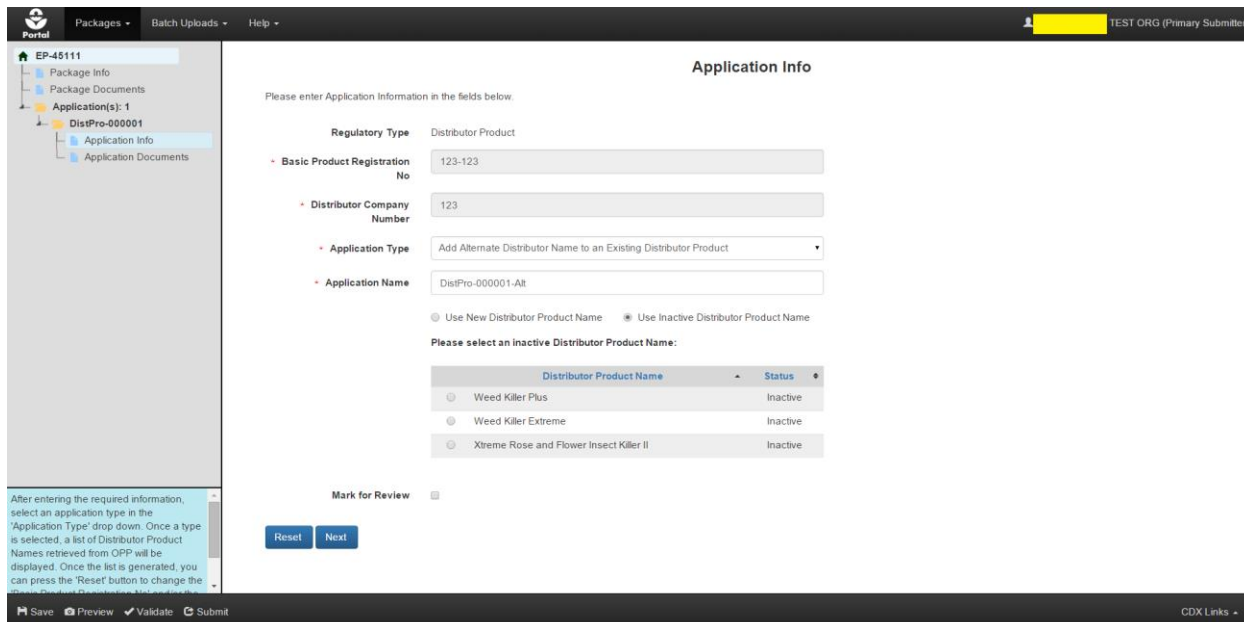
Exhibit 6-12: PSP 'Application Info' Screen – Submit Inactive Alternate Distributor Product Name

Navigation: Enter values in the 'Basic Product Registration No' and 'Distributor Company Number' fields, choose 'Add Alternate Distributor Name to an Existing Distributor Product' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Then select the 'Use Inactive Distributor Product Name' radio button, select the radio button next to the existing name to be used, and finally select the 'Next' button.

6.4.1.3   Cancel a Distributor Product

The following additional fields display after a user chooses the 'Cancel a Distributor Product (Including All Distributor Product Names for This Product)' option and system processing completes:

- Text stating that, "These Distributor Product Names will be deleted together with the Distributor Product:"

- A table of existing Distributor Product Names and their statuses

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. This field is required.

Exhibit 6-13 shows a screen capture of how cancel a Distributor Product on the 'Application Info' screen:

Exhibit 6-13: PSP 'Application Info' Screen – Cancel Distributor Product

Navigation: Enter the 'Basic Product Registration No' and 'Distributor Company Number,' choose 'Cancel a Distributor Product (Including All Distributor Product Names for This Product)' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Then review the list of Distributor Product Names for accuracy and finally select the 'Next' button.
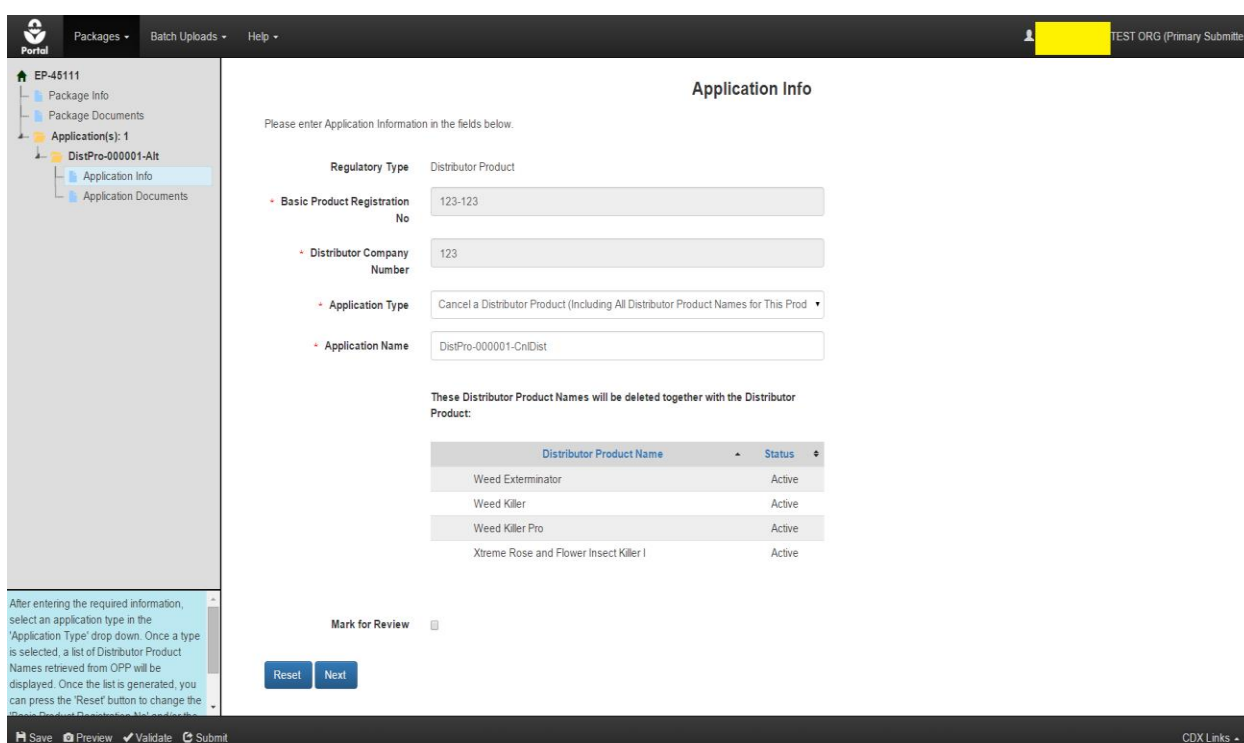
![CDX logo]

6.4.1.4 Cancel a Single Distributor Product Name

The following additional fields display after a user chooses the 'Cancel a Single Distributor Product Name' option and system processing completes:

- Text stating, "Please select an active Distributor Product Name you would like to cancel:"

- A table of active Distributor Product Names

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. This field is required.

Exhibit 6-14 shows a screen capture of how to cancel an individual Distributor Product Name on the 'Application Info' screen:

Exhibit 6-14: PSP 'Application Info' Screen- Cancel Single Distributor Product Name
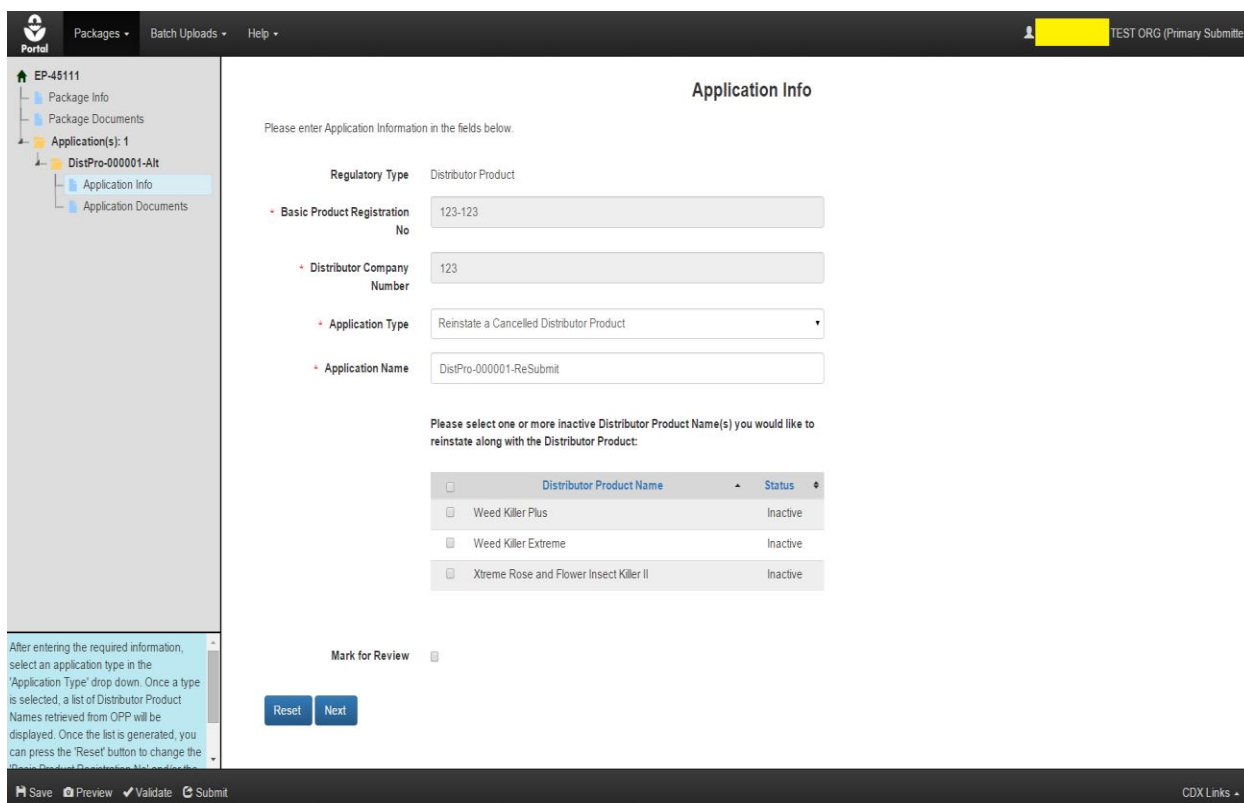
Navigation: Enter the 'Basic Product Registration No' and 'Distributor Company Number,' choose 'Cancel a Single Distributor Product Name' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Then select the radio button next to the active Distributor Product Name to be canceled and finally select the 'Next' button.

![CDX logo]

6.4.1.5 Reinstate a Cancelled Distributor Product

To reinstate a previously created Distributor Product that was cancelled, enter the 'Basic Product Registration No' and 'Distributor Company Number,' choose 'Reinstate a Cancelled Distributor Product' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Once processing completes the following items display:

- Text stating, "Please select one or more inactive Distributor Product Name(s) you would like to reinstate along with the Distributor Product:"

- A table of inactive Distributor Product Names

- **Application Name:** Enter a name for the application. The system assigns a default name that can be updated. This field is required.

Exhibit 6-15 shows a screen capture of how to reinstate a previously cancelled Distributor Product on the 'Application Info' screen:

Exhibit 6-15: PSP 'Application Info' Screen - Reinstate a Cancelled Distributor Product

Navigation: Enter the 'Basic Product Registration No' and 'Distributor Company Number,' choose 'Reinstate a Cancelled Distributor Product' from the 'Application Type' drop-down menu, and wait for the system to complete processing. Then check the box(es) next to the inactive Distributor Product(s) and finally select the 'Next' button.

![CDX logo]

6.5   Documents for the Application Screen

Documents for a specific application within a package must be uploaded on the 'Documents for the Application' screen. The screen dynamically updates, based on the application type, to ensure that an application contains all the requisite documents and accompanying metadata prior to submission. Examples of common application-level documents include forms, labels, and studies.

Each 'Document Type' has specific validation rules to ensure data quality, prevent errors, and ensure that requisite document metadata is associated with uploaded files. The following fields dynamically display in the 'Add Document' menu based on the selected 'Document Type':

- **Package Name:** Displays the package name entered on the 'Package Info' screen. This field is not editable in this location.

- **Application Name:** Displays the application name entered on the 'Application Info' screen. This field is not editable in this location.

- **Document Type:** Select a document type for the uploaded file. This field is required.

- **Document Sub-Type:** Select a document sub-type for the uploaded file. Available sub-types are based on the selected document type. This field is required.

- **Document Upload:** Either drag and drop a file or select the 'browse' link to select a file to upload. Empty, protected, and .exe files are not allowed. Document file names should neither exceed 200 characters, nor be duplicated. This field is required.

- **Document Title:** Enter the title of the document. This field is optional.

- **Document Author:** Enter the name(s) of the person(s) who authored the document. Use commas to separate the names if there are multiple authors. This field is optional.

- **Document Date:** Enter a date, such as the creation date, to be linked to the document. This field can be either required or optional based on the selected document type and document sub-type.

- **Document Group:** Enter a group to which the document is related. This field is optional.

- **Contains CBI?:** Indicates whether the document contains CBI. This field is required. 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 field is required.

- **Doc MRID:** A MRID Number associated with a particular application cannot be reused with any other application or package and is validated to ensure validity. This field is required for study documents. Please refer to **Section 5** for information about how to generate and use MRIDs.

- **Lab Report Number:** Enter the internal identification number for a study used by the lab that produced the study. This field is optional.

- **Guideline Number:** Enter the "Guideline Number" associated with a study. This field is optional.

- **Comment:** Add a comment for the uploaded document. This field is optional.

Exhibit 6-16 shows a screen capture of the 'Documents for the Application' screen:

Exhibit 6-16: 'Documents for the Application' Screen

Navigation: Select the 'Add' button (not pictured), complete all necessary fields, upload a file, and then select the 'Save' button to save the file to the application.

Exhibit 6-17 shows a screen capture of the 'Documents for the Application' screen with uploaded files:
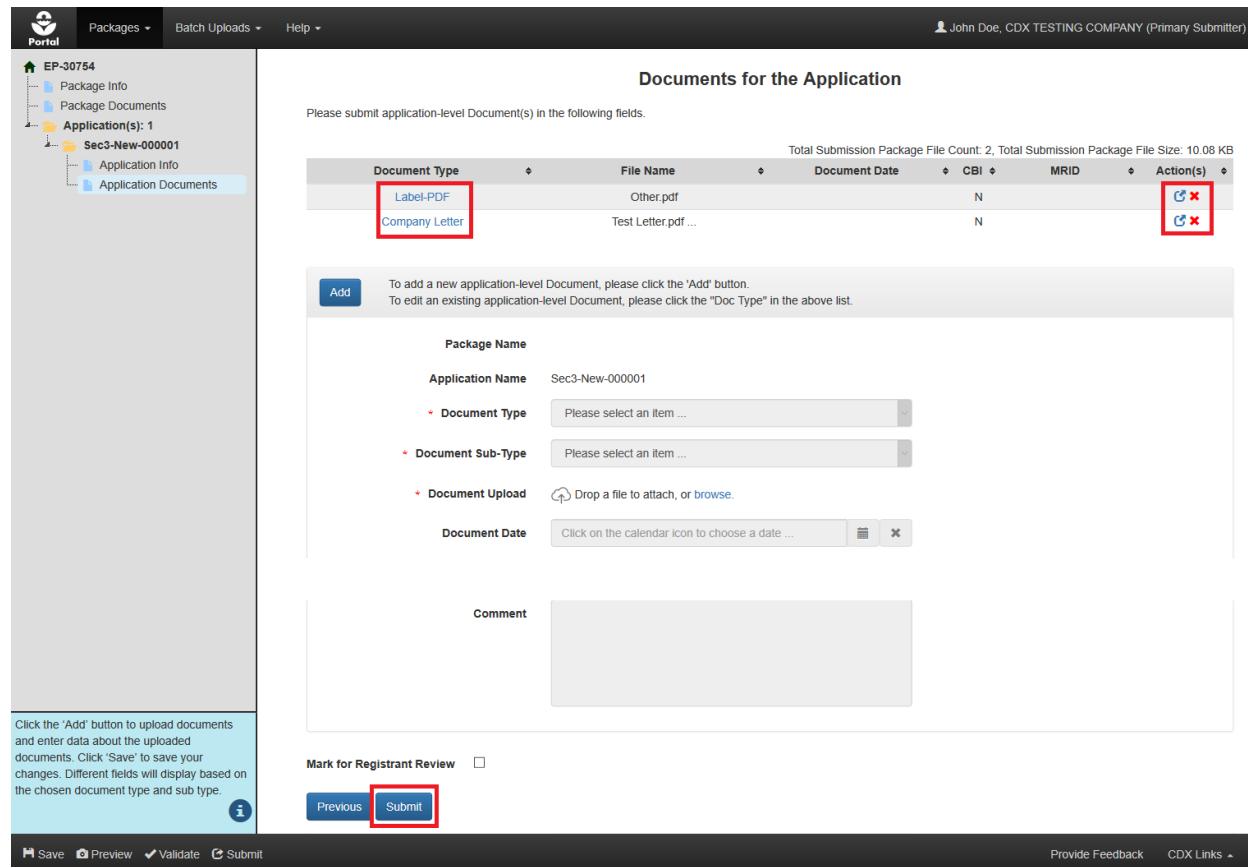
Exhibit 6-17: PSP 'Documents for the Application' - Documents Table

Navigation: Saved documents display in a table at the top of the 'Documents for the Application' screen and can be edited by selecting a 'Document Type' link or deleted by selecting the corresponding 'Delete icon. Additional documents can be added to the application by selecting the 'Add' button. After uploading all necessary documents, select the 'Next' button to navigate to the next application. If no additional applications follow this screen, select the 'Submit' button to begin the submission process. See **Section 4.9** for additional information about submitting packages.

6.5.1   Using Electronic Confidential Statement of Formula (eCSF) and OPP Electronic Label (OPPEL) Files

Important: The eCSF and OPPEL PSP builder applications are only available to pilot users at this time.

The eCSF and OPPEL PSP builder applications allow users to prepare electronic versions of 8570-4: Confidential Statement of Formula forms and labels, respectively. Submission of electronic versions of these items provides efficiencies to both registrants and EPA reviewers that allow for faster creation, review, and approval.

Note: The eCSF and OPPEL file types are available on the 'Documents for the Application' screen for all application/regulatory types within a PSP registration package, except for Distributor Products and Gold Seal Letter Requests.

Exhibit 6-18 shows a screen capture of how to upload an eCSF file on the 'Documents for the Application' screen:
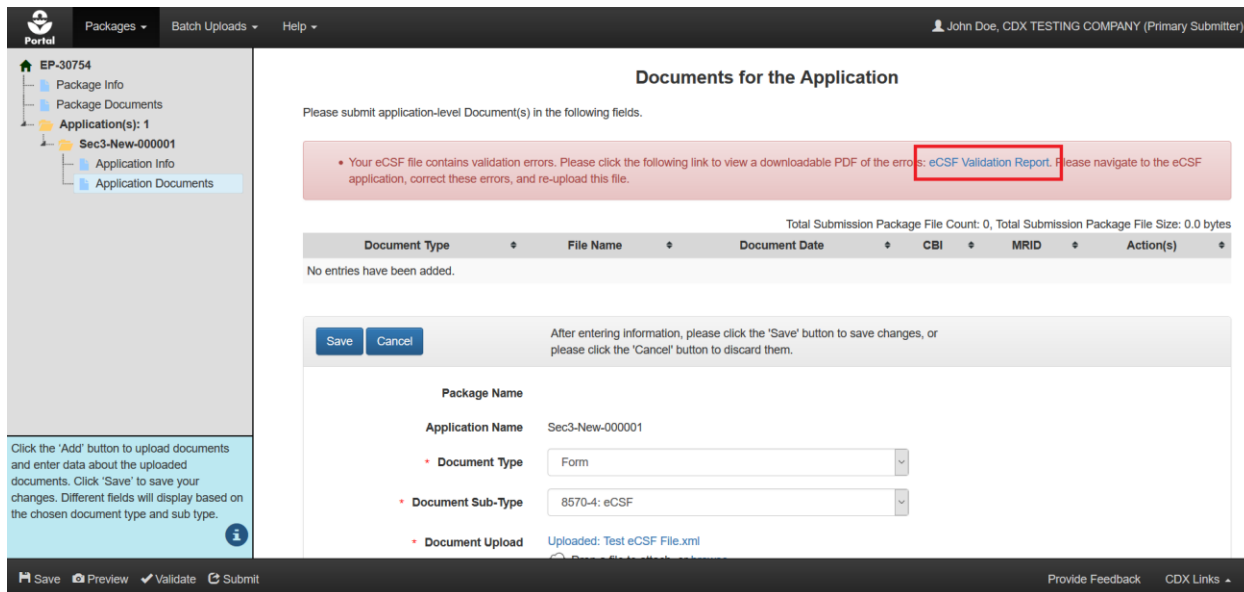

Exhibit 6-18: 'Documents for the Application' Screen – Upload eCSF File

Navigation: Select the 'Add' button (not pictured), select 'Form' from the 'Document Type' drop-down menu, select '8570-4: eCSF' from the 'Document Sub-Type' drop-down menu, upload an eCSF file, indicate whether the eCSF file contains CBI, and finally select the 'Save' button to save the file to the application.

The application performs a validation check on the uploaded file when the 'Save' button is selected and if the uploaded file is determined to not be in the correct eCSF format and/or contain validation errors, it will not save to the documents table and a corresponding error message will display.
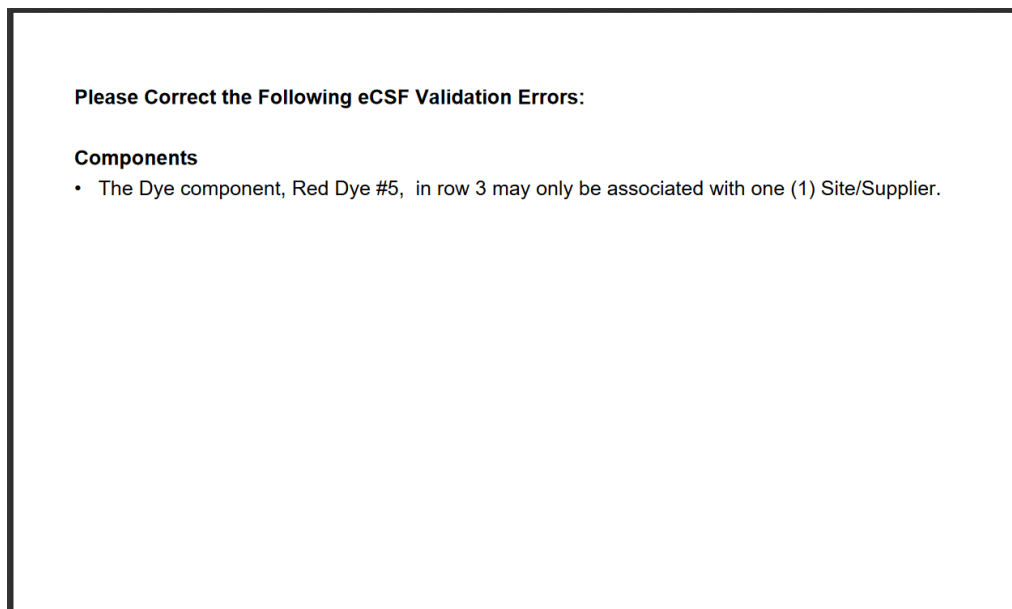
Exhibit 6-19 shows a screen capture of a validation error message for an uploaded eCSF file:

Exhibit 6-19: 'Documents for the Application' Screen – eCSF File Validation Error Report Link

Navigation: Select the 'eCSF Validation Report' link to access a report detailing the validation errors present within the uploaded eCSF file. An eCSF file cannot be saved to a package when it contains validation errors.
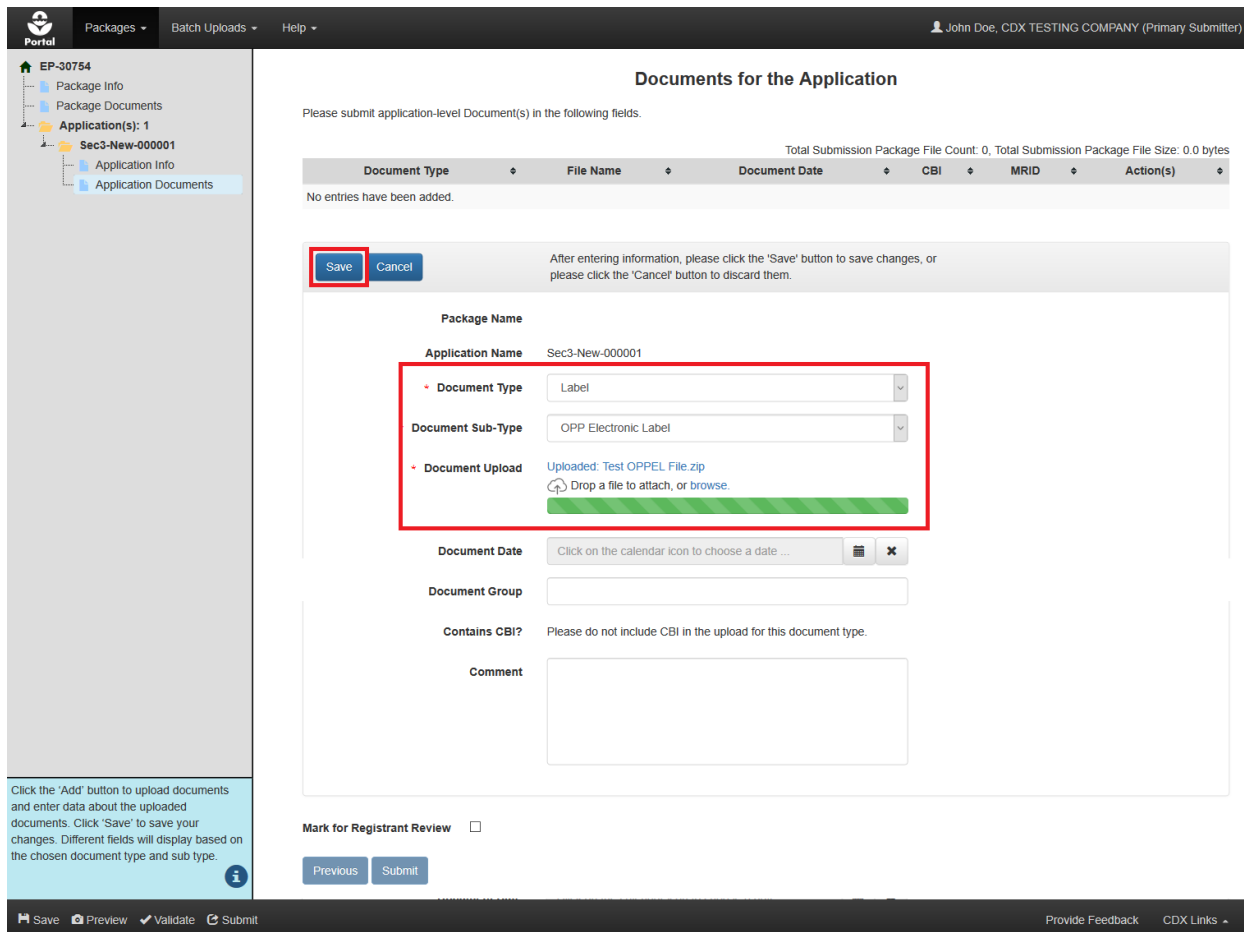
Exhibit 6-20 shows a screen capture of an eCSF Validation Report for an eCSF file:

Exhibit 6-20: eCSF File Validation Report

Exhibit 6-21 shows a screen capture of how to upload an OPPEL file on the 'Documents for the Application' screen:
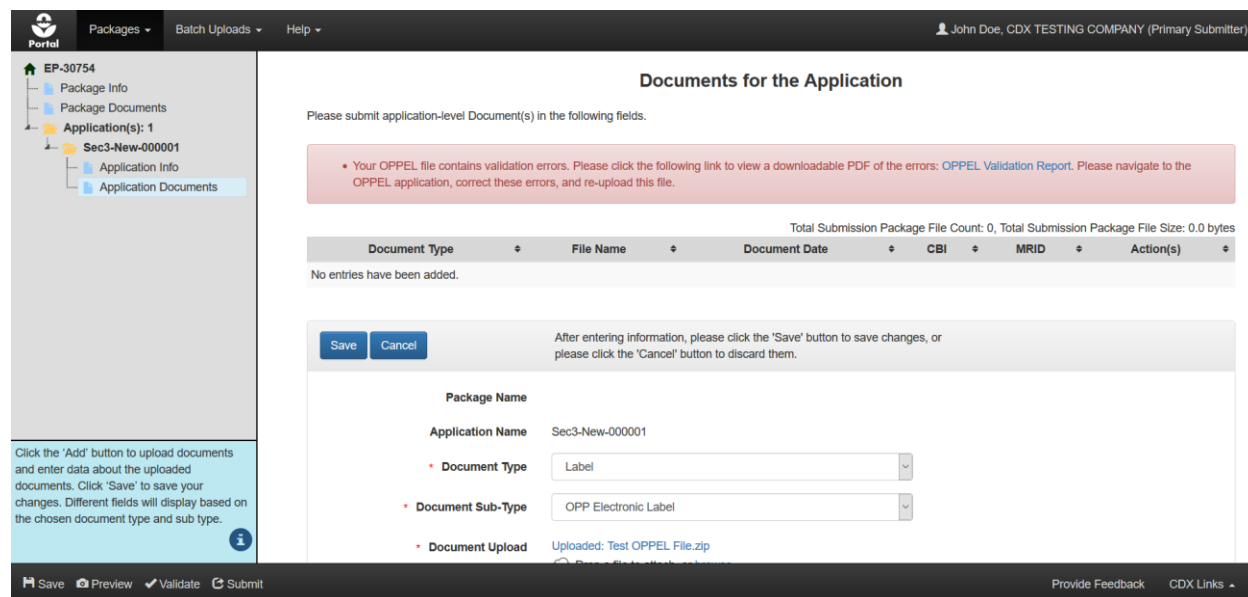

Exhibit 6-21: 'Documents for the Application' Screen – Upload OPPEL File

Navigation: Select the 'Add' button (not pictured), select 'Label' from the 'Document Type' drop-down menu, select 'OPP Electronic Label' from the 'Document Sub-Type' drop-down menu, upload an OPPEL .zip file, and finally select the 'Save' button to save the file to the application.

The application performs a validation check on the uploaded file when the 'Save' button is selected and if the uploaded .zip file is determined to not be in the correct OPPEL format and/or contain validation errors, it will not save to the documents table and a corresponding error message will display.

Exhibit 6-22 shows a screen capture of a validation error message for an uploaded OPPEL file:

Exhibit 6-22: 'Documents for the Application' Screen – OPPEL File Validation Error Report Link

Navigation: Select the 'OPPEL Validation Report' link to access a report detailing the validation errors present within the uploaded OPPEL .zip file. An OPPEL file cannot be saved to a package when it contains validation errors.

Exhibit 6-23 shows a screen capture of an OPPEL Validation Report for an OPPEL .zip file:
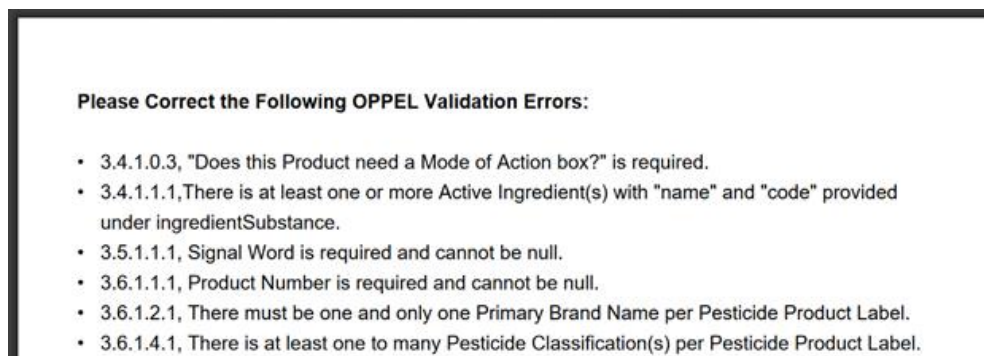
Exhibit 6-23: OPPEL File Validation Report

6.6   Access Registration Action Packages

Both in progress (i.e., packages with the 'Awaiting User Completion' status) and submitted packages can be accessed via the 'View Recent Packages' table on the PSP 'Home' screen.

Exhibit 6-24 shows a screen capture of the 'Pesticide Registration Packages' screen:

Exhibit 6-24: 'Pesticide Registration Packages' Screen

Navigation: Select the blue link in the 'Package ID' column to navigate to the 'Enter Passphrase' screen and access the selected in progress package to edit Please refer to **Section 4.7.2** for additional information about entering a passphrase. To delete a package, select the corresponding 'Remove' icon in the 'Action(s)' column.

6.6.1　Check Package Status and Download Copy of Record

The 'Pesticide Registration Packages' screen details the status of submitted packages, lists submitted application tracking numbers, and makes package copies of record available for download. The screen can be filtered by using the 'Submission Type' and 'Submission Status' drop-down menus.

To access a submitted package's copy of record data, the passphrase used to encrypt the package, the logged in user's CDX password, and the logged in user's answer to a 20-5-1 secret question must be entered.

Exhibit 6-25 shows a screen capture of the various functions available on the 'Pesticide Registration Packages' screen:

Exhibit 6-25: PSP 'Package Status' Screen

Navigation: Select the 'Show Detail' button next to the application number to display the application tracking numbers in a submitted package. Select the 'Copy of Record' icon in the 'Actions' column to download a package's copy of record.

Exhibit 6-26 shows a screen capture of the 'Cross-Media Electronic Reporting Regulation (CROMERR)' screen that displays when the 'Copy of Record' icon is selected:

Exhibit 6-26: PSP 'Copy of Record' Download Process – CROMERR

Navigation: Enter the correct data into the displayed fields and select the 'Next' buttons to proceed to the 'Copy of Record' screen.

6.6.1.1 'Copy of Record' Screen

The 'Copy of Record' screen makes a package's copy of record as well as copies of files within a package available for download.

Exhibit 6-27 shows a screen capture of the 'Copy of Record' screen:
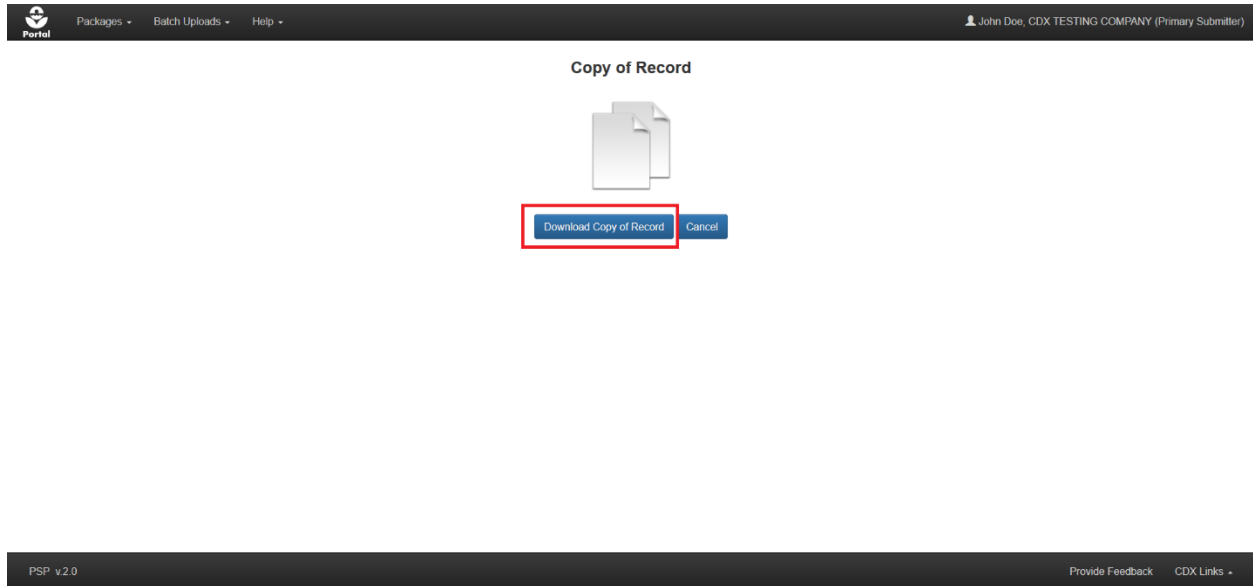
Exhibit 6-27: PSP 'Copy of Record' Screen

Navigation: Select the 'Download Copy of Record' button to download copies of the materials within a package.

![CDX logo]

7 Batch Upload Packages

The PSP application's batch upload functionality allows users to upload packages using the e-Submission XML format or created using the legacy e-Dossier Builder application.

7.1 Upload e-Submission Packages

PSP allows for the upload and submission of packages using the e-Submission XML format. This allows registrants to create XML files using their IT systems and quickly submit them to OPP.

7.1.1 Navigating the PSP Home Screen

The PSP 'Home' screen is the initial screen within PSP and provides access to the various underlying PSP applications and functions available within the portal, including e-Submission XML file upload.

Exhibit 7-1 shows a screen capture of how to navigate the PSP 'Home' screen to upload an e-Submission XML file:
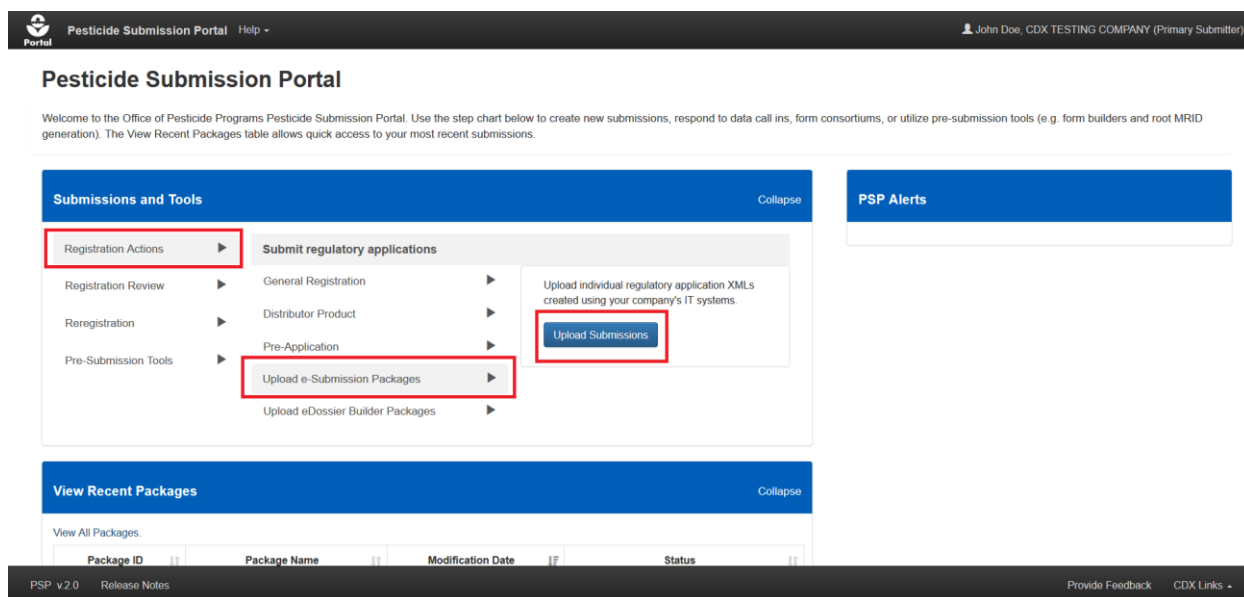
Exhibit 7-1: Pesticide Submission Portal - 'Upload XML e-Submission Packages' Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Actions' option in the first column, next select the 'Upload e-Submission Packages' option in the second column, and finally select the 'Upload Submissions' button.

7.1.2 Upload XML e-Submission Packages Screen

The 'Upload e-Submission Packages' screen is used to locate, upload, and process packages in the e-Submission XML format. Note that the screen will provide a link to the 'Upload eDossier Builder Packages' screen should an eDossier package file be mistakenly uploaded. Please keep the following items in mind when creating an e-Submission package:

- The e-Submission XML file in a package .ZIP file must have the "e-PRISM" prefix as the first part of the file name.

- Document file names within a package .ZIP file cannot exceed 200 characters and should not include special characters.

- Package .ZIP files cannot include more than 400 files.

- Package .ZIP files cannot be larger than 700mb.

Exhibit 7-2 shows a screen capture of how to upload an e-Submission package:
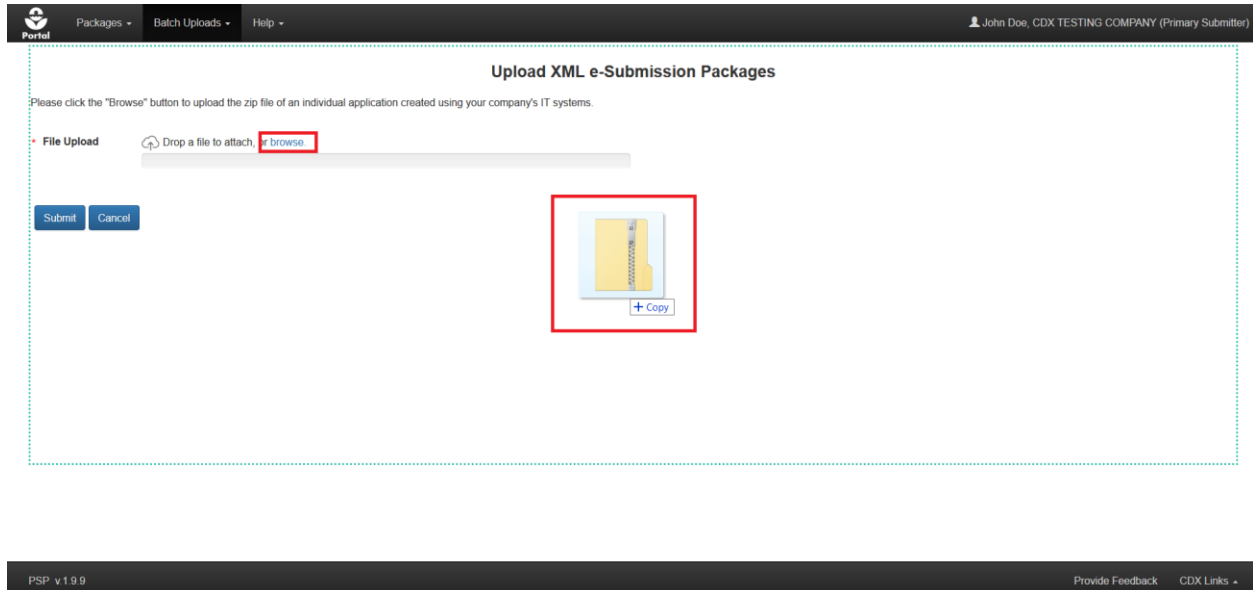
Exhibit 7-2: PSP 'Upload XML e-Submission Packages' Screen – File Upload

Navigation: Select the 'browse' link to search the local machine for a file or drag and drop an e-Submission package file onto the screen to initiate upload.

Exhibit 7-3 shows a screen capture of an uploaded e-Submission file on the 'Upload XML e-Submission Packages' screen:
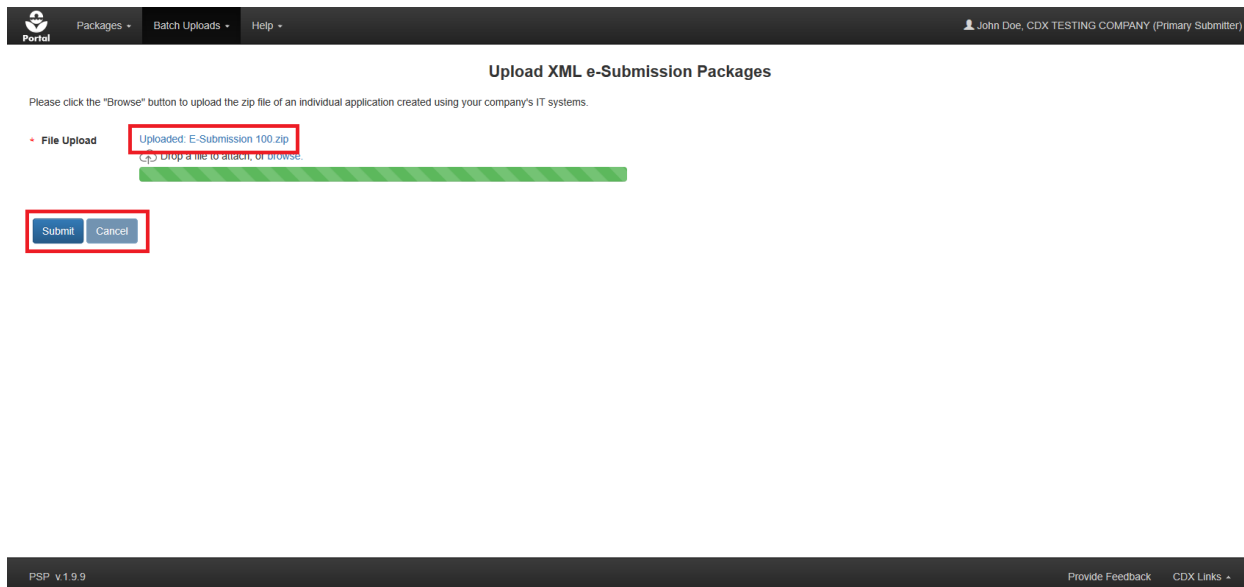
Exhibit 7-3: PSP 'Upload XML e-Submission Packages' Screen – Submit File

Navigation: Wait for the file name to display (upload processing is incomplete until the file name displays) and then select the 'Submit' button to navigate to the 'Create Passphrase' screen. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Once a passphrase is created the submission process will initiate. Please refer to **Section 4.9** for assistance with the submission process.

Important: The same passphrase must be used throughout a package's life. The user who creates a package is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

7.2   Upload eDossier Builder Packages

PSP also allows for the upload and submission of packages created using the legacy eDossier Builder application.

7.2.1   Home Screen

The PSP 'Home' screen is the initial screen within PSP and it provides access to the various underlying PSP applications and functions available within the portal, including eDossier Builder file upload.

Exhibit 7-4 shows a screen capture of how to navigate the PSP 'Home' screen to upload an eDossier Builder file:
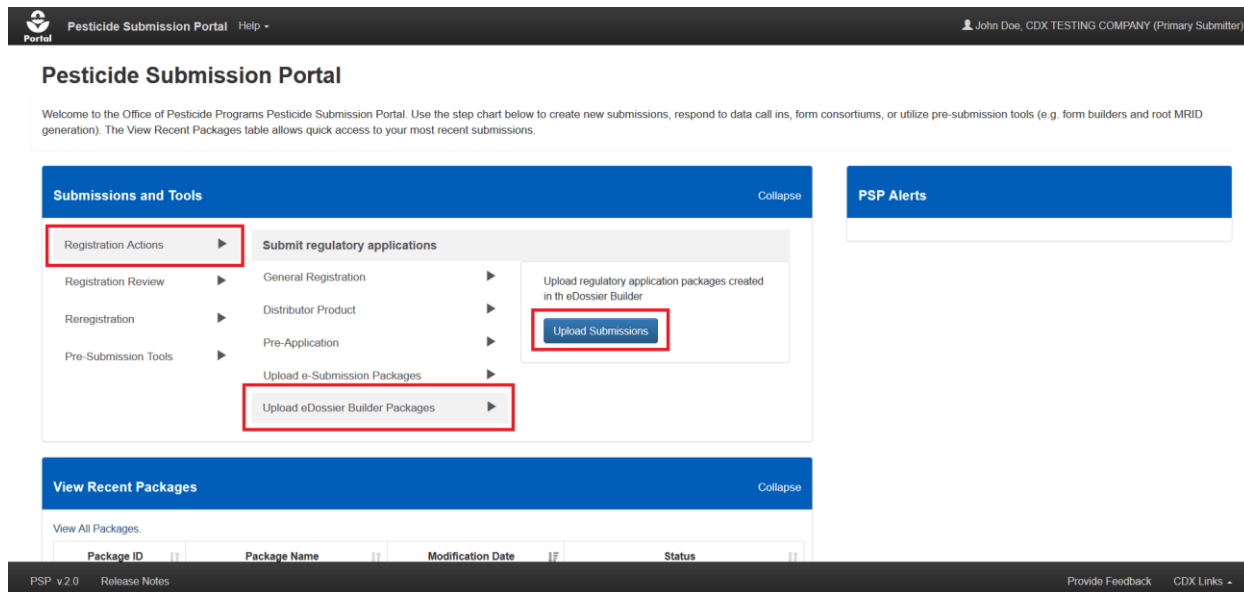
Exhibit 7-4: Pesticide Submission Portal - 'Upload eDossier Builder Packages' Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Actions' option in the first column, next select the 'Upload eDossier Builder Packages' option in the second column, and finally select the 'Upload Submissions' button.

7.2.2   Upload eDossier Builder Packages Screen

The 'Upload eDossier Builder Packages' screen is used to locate, upload, and process packages created using the legacy eDossier Builder application. Note that the screen will provide a link to the 'Upload XML e-Submission Packages' screen should an e-Submission package file be mistakenly uploaded. Please keep the following items in mind when submitting an eDossier Builder package:

- The package file should contain the 'main.xml' file that the eDossier Builder automatically creates upon package finalization.

- Document file names cannot exceed 200 characters and should not include special characters.

- Packages should not include more than 400 files.

- Package files cannot be larger than 700mb.

Exhibit 7-5 shows a screen capture of how to upload an eDossier Builder package:
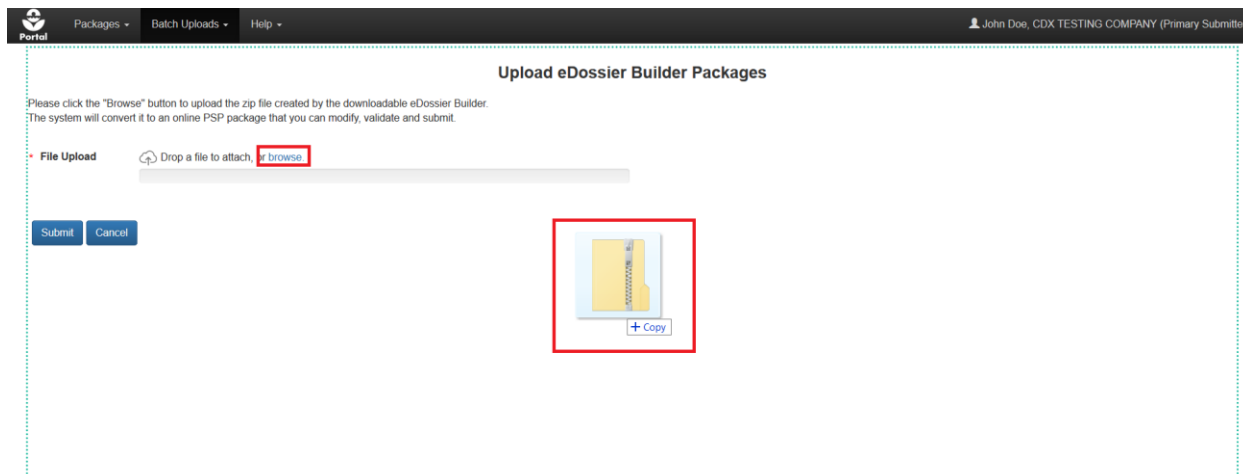
Exhibit 7-5: PSP 'Upload eDossier Builder Packages' Screen – Upload File

Navigation: Select the 'browse' link to search the local machine for a file or drag and drop an e-Submission package file onto the screen to initiate upload.

Exhibit 7-6 shows a screen capture of an uploaded eDossier Builder file on the 'Upload eDossier Builder Packages' screen:
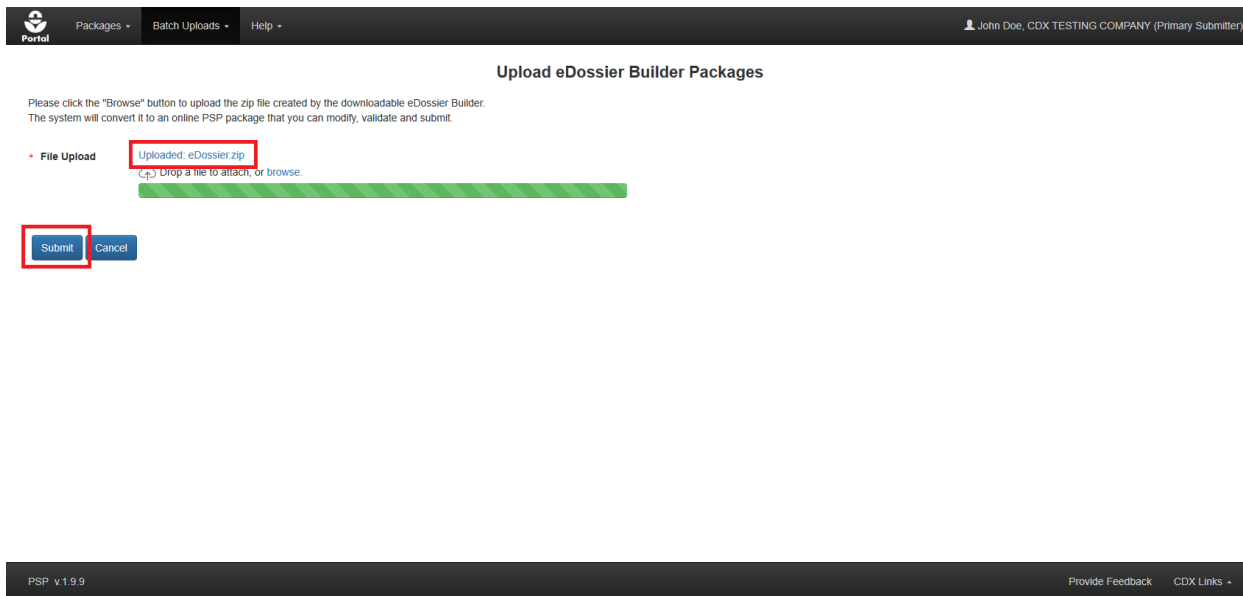
Exhibit 7-6: PSP 'Upload eDossier Builder Packages' Screen – Submit File

Navigation: Wait for the file name to display (upload processing is incomplete until the file name displays) and then select the 'Submit' button to navigate to the 'Create Passphrase' screen. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Once a passphrase is created, the application navigates to the 'Package Info' screen to complete the package. Please refer to **Section 6.2** for additional information about the 'Package Info' screen.

Important: The same passphrase must be used throughout a package's life. The user who creates a package is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

8   Respond to Data Call-Ins (DCIs)

OPP periodically issues data call-in requests for both chemicals (GDCIs) and specific products (PDCIs) as part of its registration program. PSP supports both data call-in types by allowing registrants to review DCI requirements and make supporting submissions; including DCI Acknowledgements, 90-Day Responses, and Data Submissions.

Note: OPP will send a notification email to registrants when a DCI is assigned and available in PSP.

Exhibit 8-1 shows a screen capture of how to access a list of GDCIs assigned to the registrant from the PSP 'Home' screen:
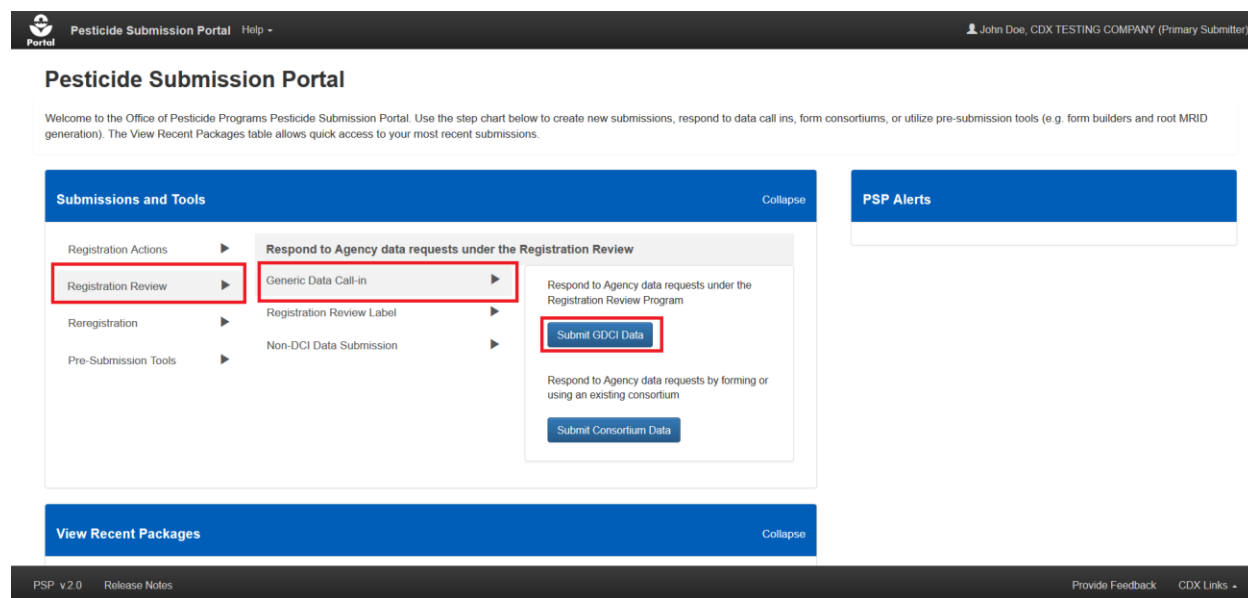
Exhibit 8-1: Pesticide Submission Portal – 'Generic Data Call-In' Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Review' option in the first column, next select the 'Generic Data Call-In' option in the second column, and finally select the 'Submit GDCI Data' button.

Exhibit 8-2 shows a screen capture of how to access a list of PDCIs assigned to the registrant from the PSP 'Home' screen:
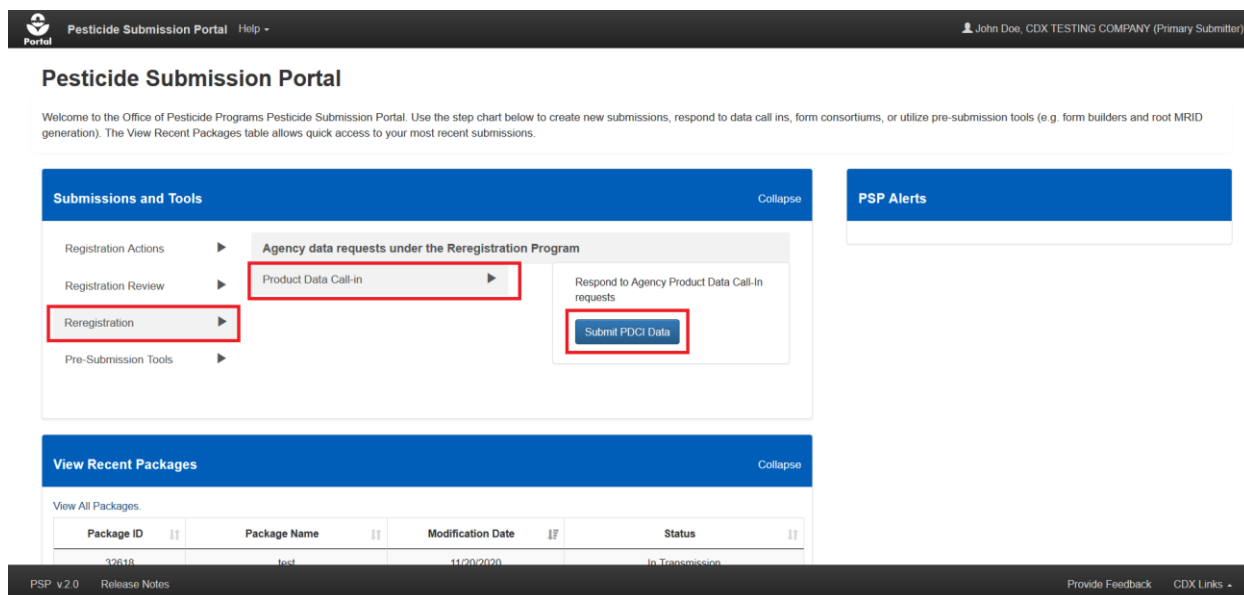
**Exhibit 8-2: Pesticide Submission Portal – 'Product Data Call-In' Option**

Navigation: In the 'Submissions and Tools' panel, select the 'Reregistration' option in the first column, next select the 'Product Data Call-In' option in the second column, and finally select the 'Submit PDCI Data' button.

8.1   DCI List Screen

The 'DCI List' screen displays all DCIs assigned to a registrant as well as their associated details and statuses. The DCI table has the following features that update the table view to assist registrants locate DCIs and obtain up-to-date submission information:

- The 'DCI Number,' 'DCI Acknowledgement Status,' and '90-Day Response' filters narrow displayed results to the selected option(s)

- Each column is sortable to cluster similar DCIs and submissions

- DCIs with completed submissions display a 'Show Detail' icon next to the DCI number that reveals the tracking numbers associated with the DCI

- Completed Data Submissions can be viewed by selecting the blue "i" icon in the 'Data Submission' column

- The statuses in the 'DCI Acknowledgement,' '90-Day Response,' and 'Data Submission' columns indicate where in the process a DCI currently is. A complete listing of all statuses is available in the application header under 'Status Legend.'

Exhibit 8-3 shows a screen capture of the 'DCI List' screen:

Exhibit 8-3: 'DCI List' Screen

Exhibit 8-4 shows a screen capture of the 'DCI Status Legend' pop-up:

DCI Status Legend

No Action Available: No action is available for this type of response.
No Action Needed: This is a legacy DCI, you don't need to submit a DCI Acknowledgement or 90-Day Response.
Awaiting User Completion: The Response is in progress and has not been submitted yet.
Failed Validation: The Response has validation errors and cannot be submitted.
In Transmission: The Response is in transmission from CDX to OPP.
Pending: The package has been transmitted to OPP and is awaiting processing.
Failed Transmission to OPP: The Response failed transmission to OPP.
Successfully Transmitted to OPP: The Response was successfully transmitted and processed by OPP.
Start DCI Acknowledgement: Submit an acknowledgement that you have received the Data Call-In from EPA.
Start 90-Day Response: Submit a 90-Day Response for the Data Call-In.
Submit Data: Submit additional data to support your responses and satisfy guidelines.
Submit Data (Previous Submission Successful): Submit additional data. Your previous submission was successfully transmitted to OPP.
Change 90-Day Response (Previous Submission Successful): Change your 90-Day Response. Your previous 90-Day Response was successfully transmitted to OPP. If you choose to change any of the responses to the guidelines, you will lose any previously submitted data for that particular response.
Awaiting Resubmission/Successful Transmission of 90-Day Response: You cannot submit data until your revised 90-Day Response has been submitted and successfully transmitted to OPP.
Awaiting Successful Transmission of Data Submission: You cannot change your 90-Day Response until your Data Submission has been submitted and successfully transmitted to OPP.

OK

Exhibit 8-4: 'DCI Status Legend' Pop-Up

Navigation: Select the 'Status Legend' button in the application header to open the 'DCI Status Legend' pop-up. Select the 'OK' button to close the pop-up.

![CDX logo]

8.2 DCI Acknowledgement

The DCI Acknowledgement is a single screen form used to confirm that an organization received a DCI request from OPP and will submit the requested data. Note that the DCI Acknowledgement form is the same for both GDCIs and PDCIs.

Exhibit 8-5 shows a screen capture of the 'Start DCI Acknowledgement' link on the 'DCI List' screen:

Exhibit 8-5: 'DCI List' Screen - 'Start DCI Acknowledgement' Link

Navigation: To acknowledge receipt of a DCI, select the 'Start DCI Acknowledgement' link for the correct 'DCI Number.'

Exhibit 8-6 shows a screen capture of the 'DCI Acknowledgement' screen:

Exhibit 8-6: 'DCI Acknowledgment' Screen

Navigation: Check the first checkbox to acknowledge receipt of the DCI, check the second checkbox to indicate if the acknowledgement is being made by an agent on behalf of the listed company, and finally select the 'Submit' button to begin the submission process. Please refer to **Section 4.9** for additional information about the submission process.

Exhibit 8-7 shows a screen capture of the notification email from the CDX Help Desk indicating that a DCI Acknowledgement was successfully transmitted to OPP:

Exhibit 8-7: DCI Successful Transmission Email Notification

8.3   DCI 90-Day Response

The 90-Day Response is used to review and respond to studies/guidelines as outlined in a DCI. After indicating intent to satisfy a DCI's data requirements, the application affords the opportunity to respond to each guideline and provide additional documents/data.

The 90-Day Response is similar for GDCIs and PDCIs. However, GDCIs contain a single list of guidelines (regardless of the number of EPA Registration Numbers) and PDCIs contain a list of guidelines for each EPA Registration Number to allow for differing responses per number. For a GDCI, guidelines responses are not required if the selection to cancel or claim a generic data exemption is made for all EPA Registration Numbers.

A 90-Day Response cannot be started until the corresponding DCI Acknowledgement's status changes to 'Pending.' When the status of a DCI Acknowledgement submission changes to 'Pending,' the 'Start 90-Day Response' link will appear in the '90-Day Response' column.

Exhibit 8-8 shows a screen capture of the 'DCI List' screen with a 'Pending' DCI Acknowledgement, available DCI Acknowledgement copy of record, and active 'Start 90-Day Response' link:

Exhibit 8-8: 'DCI List' Screen - 'Start 90-Day Response' Link

Navigation: Select a 'Start 90-Day Response' link under the '90-Day Response' column to generate a new 90-Day Response form for the 'DCI Number' and navigate to the 'Create Passphrase' screen. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Important: The same passphrase must be used throughout the life of a DCI's 90-Day Response. The user who creates a submission is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

8.3.1   90-Day Response Submission Screen

The '90-Day Response Submission' screen is the first screen within a 90-Day Response and is accessed by either creating or entering a passphrase for a new or existing submission, respectively. This screen displays summary information about the DCI and provides a place to upload DCI-level documents that apply to the entire form. Note that the '90-Day Response Submission' screen is the same for both GDCIs and PDCIs.

The following fields display 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 Response 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.

- **DCI Summary Table:** Displays the EPA Product Registration Numbers and Guideline Requirement Numbers associated with the DCI.

Certain documents may be uploaded at the DCI level and applied to the entire submission using this screen. For example, 90-Day Reponses that contain a study document must have a Transmittal Document uploaded on this screen. Please note that document file names cannot exceed 200 characters. The document upload section allows for the upload of the following document types applicable to the entire submission:

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

- Study
    - Transmittal Document

Exhibit 8-9 shows a screen capture of the '90-Day Response' screen for a GDCI:

Exhibit 8-9: DCI '90-Day Response' Screen – GDCI Example

Exhibit 8-10 shows a screen capture of the '90-Day Response' screen for a PDCI:

Exhibit 8-10: DCI '90-Day Response' Screen – PDCI Example

Navigation: Review the displayed information, upload any necessary DCI level documents by selectin the 'Add DCI Level Document' button and populating all required fields, and finally select the 'Next' button to navigate to the 'EPA Product Registration' screen.

8.3.2 EPA Product Registration Screen

The 'EPA Product Registration' screen contains basic information about an EPA registered pesticide product and provides response options for a registered product included in a DCI

request. Note that the response options differ for GDCI and PDCI requests and are detailed in the subsequent two sections. However, the following information is displayed on the 'EPA Product Registration' screen for both GDCIs and PDCIs:

- **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.

8.3.2.1   GDCI Response Options

The following response options are available for GDCI requests and are demonstrated in the following screen captures:

- **I wish to cancel this product registration voluntarily:** Select this option to voluntarily cancel the product registration and upload a required, supporting document.

- **I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below:** Select this option to indicate that the product's active ingredient is sourced from another EPA registered product and enter the requisite source registration number(s).

- **I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response":** Select this option to agree to provide the data requested in the listed DCI. Supporting information is not required when this option is chosen.

Exhibit 8-11 shows a screen capture of the voluntary cancellation response option:
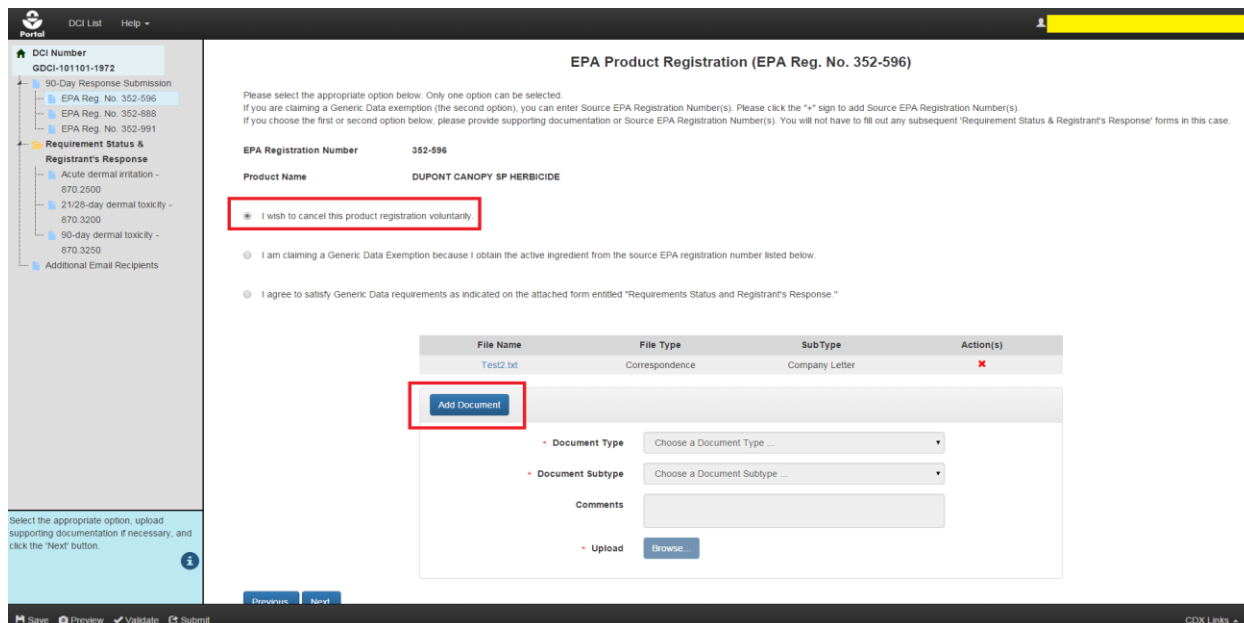
Exhibit 8-11: GDCI 'EPA Product Registration' Screen - Voluntary Cancellation

Navigation: Select the 'I wish to cancel this product registration voluntarily' radio button, upload a required, supporting document by selecting the 'Add Document' button, and finally select the 'Next' button to navigate to either the next 'EPA Product Registration' screen for the DCI or the 'Requirement Status & Registrant's Response' screen if no additional 'EPA Product Registration' screens are required.

Exhibit 8-12 shows a screen capture of the generic data exemption response option:

Exhibit 8-12: GDCI 'EPA Product Registration' Screen – Generic Data Exemption Claim

Navigation: Select the generic data exemption radio button, enter all required 'Source EPA Registration Numbers,' and finally select the 'Next' button to navigate to either the next 'EPA Product Registration' screen for the DCI or the 'Requirement Status & Registrant's Response' screen if no additional 'EPA Product Registration' screens are required.

Note: All entered 'Source EPA Registration Numbers' are validated during submission or by selecting the 'Validate' button in the application footer.

Exhibit 8-13 shows a screen capture of the satisfy generic data requirements response option:
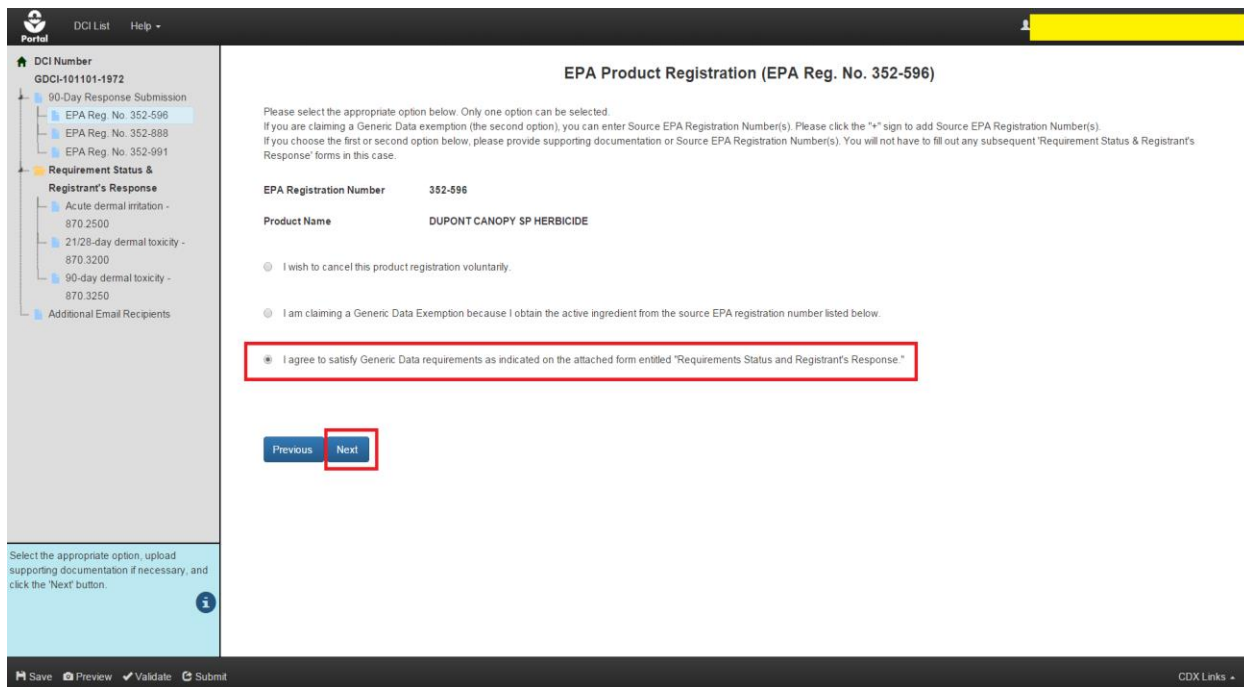
Exhibit 8-13: GDCI 'EPA Product Registration' Screen – Satisfy Generic Data

Navigation: Select the agree to satisfy data requirements radio button and then select the 'Next' button to navigate to either the next 'EPA Product Registration' screen for the DCI or the 'Requirement Status & Registrant's Response' screen if no additional 'EPA Product Registration' screens are required.

Guideline responses are not required if voluntarily cancellation or generic data exemption claim (first and second radio buttons) responses are entered for all listed EPA Product Registration Numbers. In this case, each guideline will display in a gray strikethrough font in the navigation tree and red text will appear at the top of each guideline screen.

Exhibit 8-14 shows a screen capture of the 'Requirements Status and Registrant's Response' screen when voluntarily cancellation or generic data exemption claim responses are recorded for all EPA Product Registration Numbers:
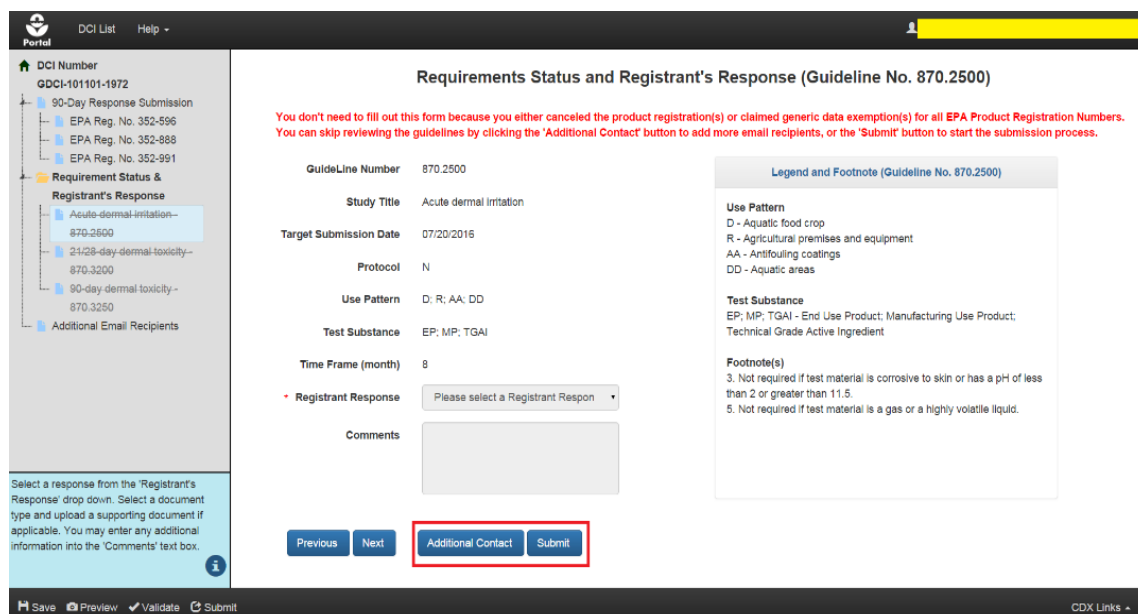
Exhibit 8-14: GDCI 'Requirements Status and Registrant's Response' Screen

8.3.2.2   PDCI Response Options

The following response options are available for PDCI requests and are demonstrated in the following screen captures:

- **I wish to cancel this product registration voluntarily:** Select this option to voluntarily cancel the product registration and upload a required, supporting document.

- **My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response":** Select this option to agree to provide the MUP requirements in the listed DCI. Supporting information is not required when this option is chosen.

- **My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response":** Select this option to agree to provide the EUP requirements in the listed DCI. Supporting information is not required when this option is chosen.

Exhibit 8-15 shows a screen capture of the voluntary cancellation response option:
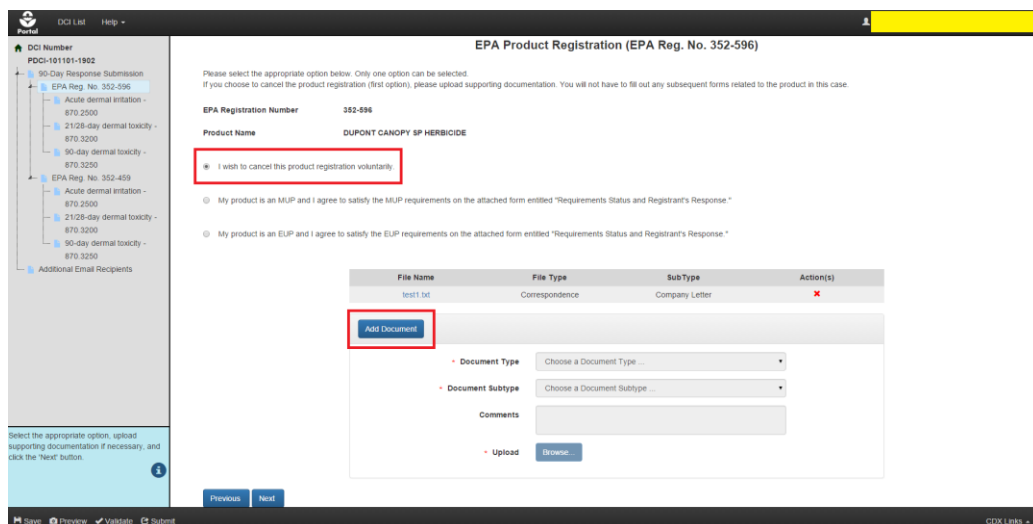
Exhibit 8-15: PDCI 'EPA Product Registration' Screen – Voluntary Cancellation

Navigation: Select the 'I wish to cancel this product registration voluntarily' radio button, upload a required, supporting document by selecting the 'Add Document' button, and finally select the 'Next' button the 'Requirement Status & Registrant's Response' screen.

Exhibit 8-16 shows a screen capture of the agree to satisfy MUP requirements response option:
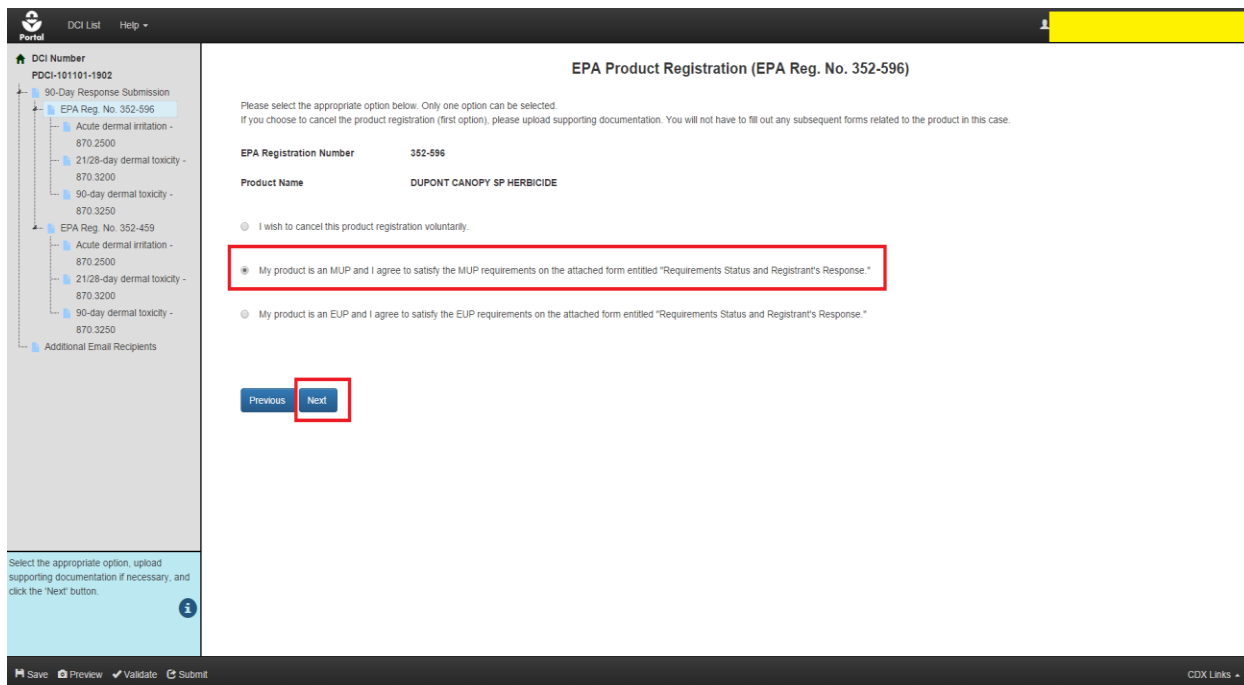
Exhibit 8-16: PDCI 'EPA Product Registration' Screen – Satisfy MUP Requirements

Navigation: Select the 'My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."' radio button and then select the 'Next' button the 'Requirement Status & Registrant's Response' screen.

Exhibit 8-17 shows a screen capture of the agree to satisfy EUP requirements response option:
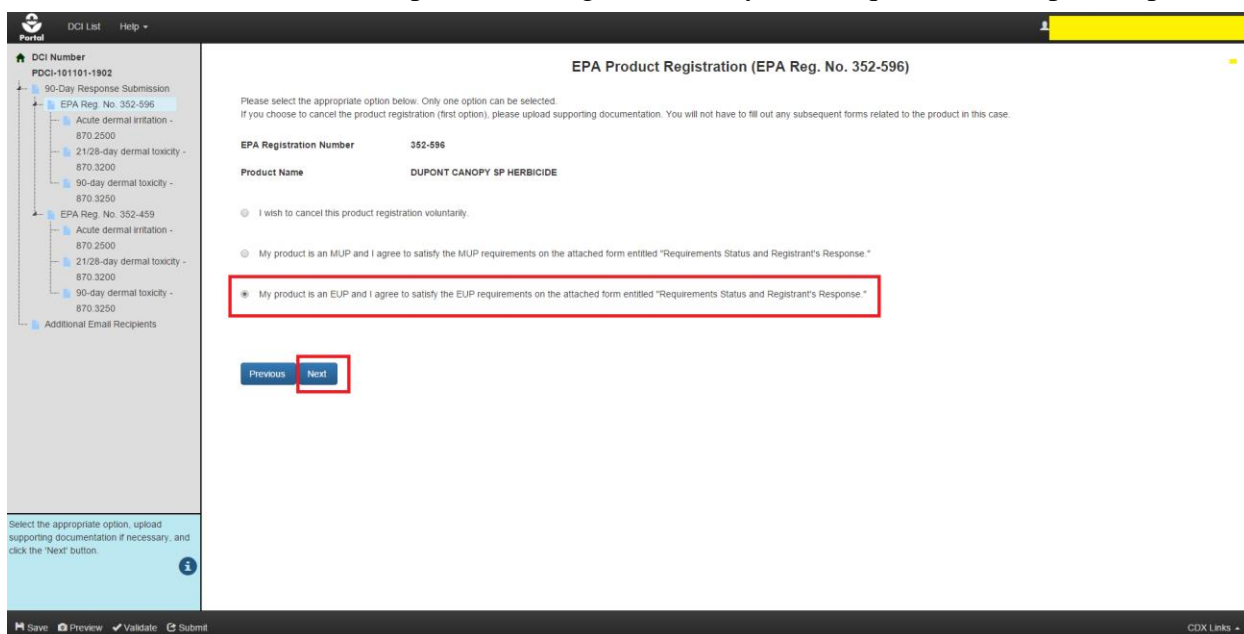
Exhibit 8-17: PDCI 'EPA Product Registration' Screen – Satisfy EUP Requirements

Navigation: Select the 'My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."' radio button and then select the 'Next' button the 'Requirement Status & Registrant's Response' screen.

Guideline responses are not required when the voluntarily cancellation response is selected for the listed EPA Product Registration Number. In this case, each guideline will display in a gray strikethrough font in the navigation tree and red text will appear at the top of each guideline screen.

Exhibit 8-18 shows a screen capture of the 'Requirements Status and Registrant's Response' screen when the voluntarily cancellation response is recorded:
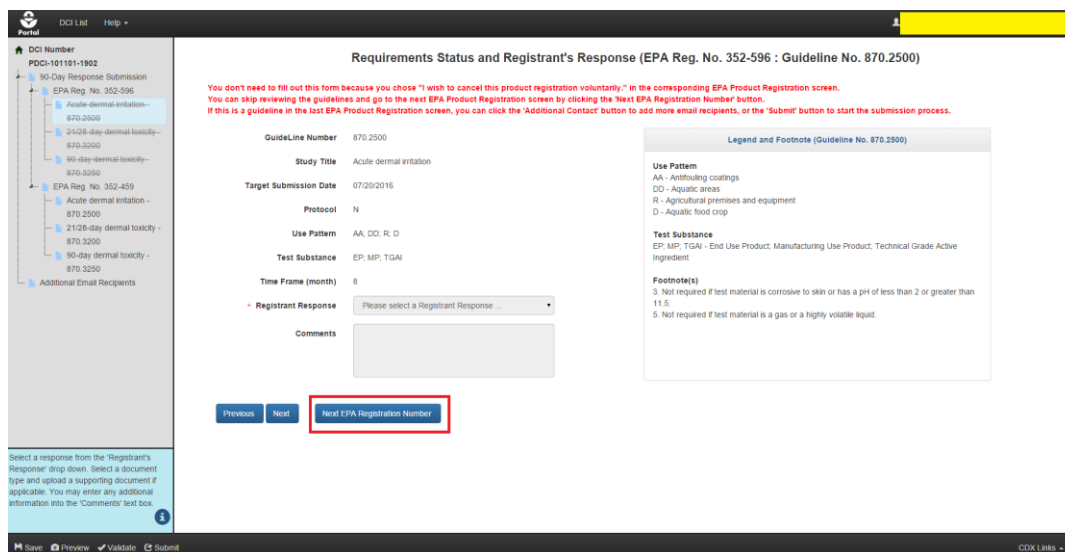
Exhibit 8-18: PDCI 'Requirements Status and Registrant's Response' Screen – Voluntary Cancellation

8.3.3 Requirements Status and Registrant's Response Screen

The 'Requirements Status and Registrant's Response' screen displays relevant 'Guideline Number' information, collects a response to listed guideline requirements, and allows for the inclusion of data and/or documents to support the selected response. All guidelines included within a 90-Day Response must have a response and contain the required supporting data/documents prior to submission.

The following information is displayed on the 'Requirements Status and Registrant's Response' screen for both GDCI and PDCI requests:

- **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:**

- **Registrant Response:** Each guideline listed in a DCI must have a registrant response. A response can either be directly chosen from the drop-down menu or copied from another guideline. Copied responses can be individually updated later on, if needed. The available responses are:

- **Developing Data:** Select this response to indicate that study data will be provided at a later date. There are no data and/or document required for this response.

- **Agreement to Cost Share:** Select this response when an agreement to cost share was reached for a guideline. This response requires at least one 'General Correspondence' document upload.

- **Offer to Cost Share:** This response indicates an offer to cost share for a guideline and 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.

- **Submitting Existing Data:** Use this response to indicate that existing study data will be submitted to fulfill a guidelines requirements.

- **Upgrading a Study:** Select this response to submit upgraded study data to fulfill a guidelines requirements.

- **Citing a Study:** Utilize this response to cite studies that were previously submitted to EPA to fulfill a guidelines requirements.

- **Deleting Uses (GDCI Only):** This response indicates a willingness to delete uses for the EPA registered product listed in a GDCI. This response requires at least one draft label document upload and an entry in the 'Comment' field.

- **Low Volume/Minor Use Waiver Request (GDCI Only):** Select this response to request a 'Low Volume/Minor Use Waiver' for a guideline. This response requires at least one 'Waiver Request' document upload.

- **Waiver Request:** Select this response to request a waiver for a guideline. This response requires at least one 'Waiver Request' document upload.

- **Not Applicable (PDCI Only):** Select this response to indicate that a guideline is not applicable. This response requires at least one 'Waiver Request' document upload or an entry in the 'Comment' field.

Exhibit 8-19 shows a screen capture of the 'Requirements Status and Registrant's Response' screen copy response functionality:
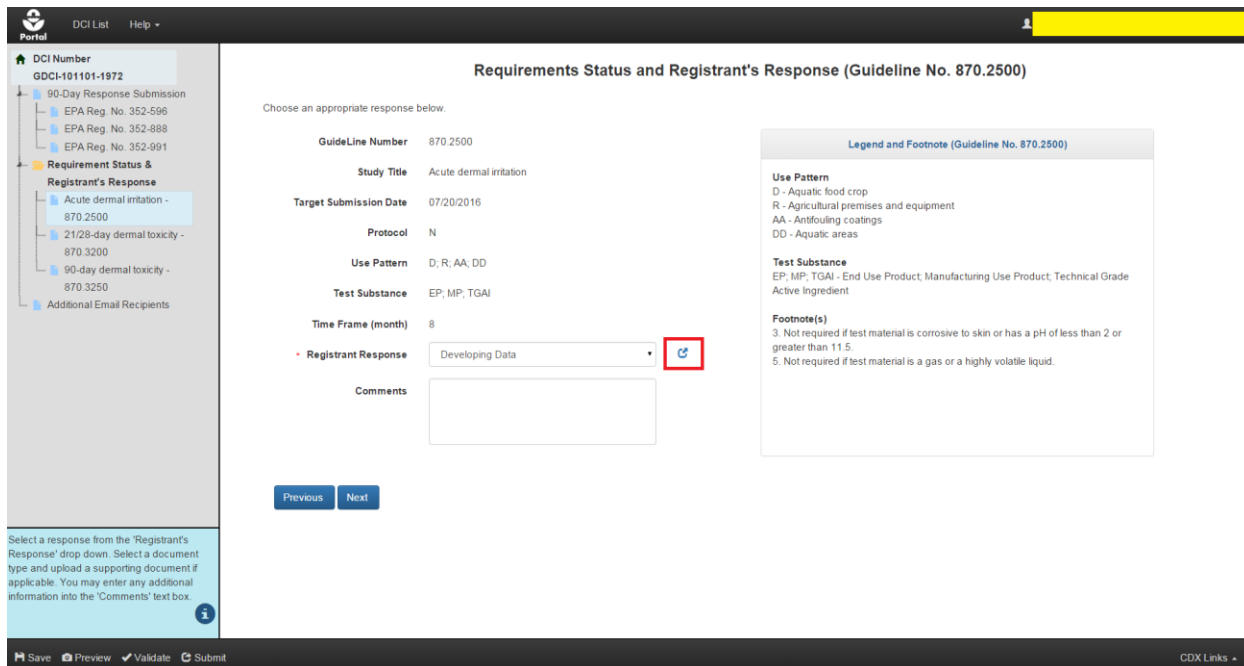
Exhibit 8-19: 'Requirements Status and Registrant's Response' Screen – Copy Response

Navigation: Make a selection from the 'Registrant Response' drop-down menu and select the blue icon next to the drop down-down menu to copy a response to all guidelines within a DCI (GDCI) or EPA Product Registration Number (PDCI).

Exhibit 8-20 shows a screen capture of the 'Requirements Status and Registrant's Response' screen with an uploaded file:
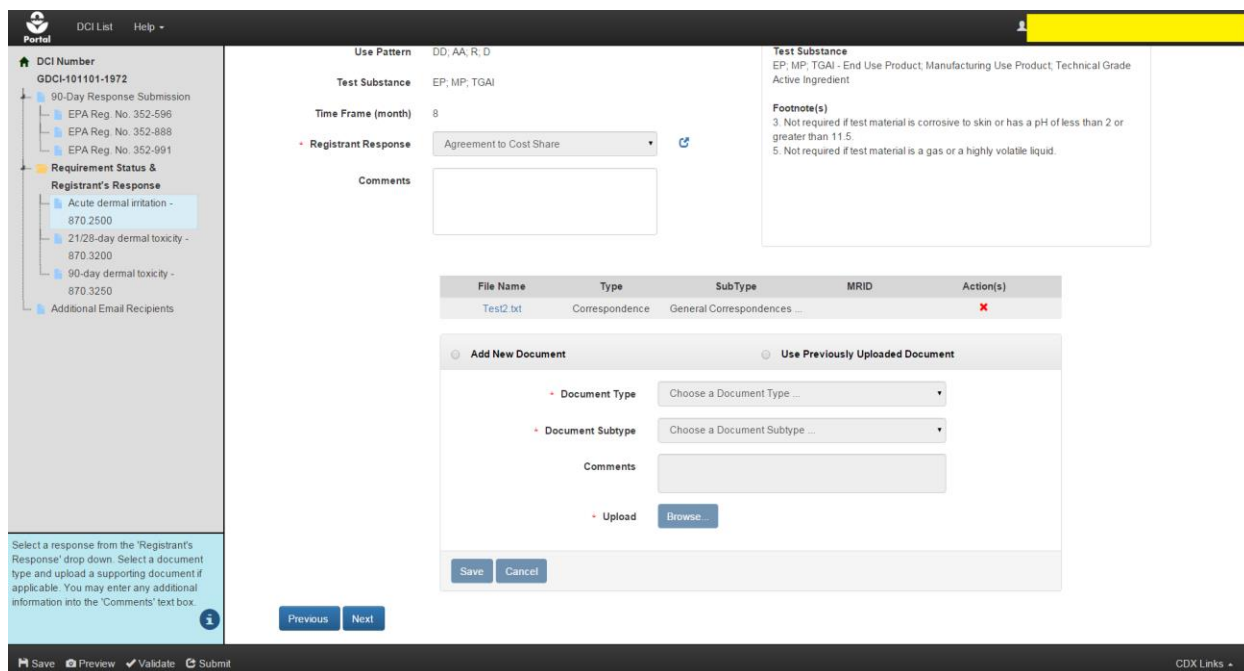
Exhibit 8-20: 'Requirements Status and Registrant's Response' Screen – Add New Document

Navigation: Select the 'Add New Document' radio button, select a document type and subtype, populate required fields, upload a document, and then select the 'Save' button. The uploaded document will appear in the documents table in the center of the screen. To delete an uploaded document, select a red 'Delete' icon in the 'Action(s)' column. Note that uploaded documents will be deleted for a guideline if the 'Registrant Response' selection is changed.

The 'Use Previously Uploaded Document' radio button allows documents uploaded on another guideline with a matching response to be reused for the current guideline without uploading the file again.

Exhibit 8-21 shows a screen capture of the 'Previously Uploaded Document' functionality on the 'Requirements Status and Registrant's Response' screen:

Exhibit 8-21: 'Requirements Status and Registrant's Response' Screen – Use Previously Uploaded Document

Navigation: Select the 'Use Previously Uploaded Document' radio button, select the appropriate document from the 'Uploaded Documents' drop-down menu (if available), and then select the 'Reuse' button. The referenced document will appear in the documents table. To remove a reference to an uploaded document select the yellow icon in the 'Action(s)' column.

Exhibit 8-22 shows a screen capture of how to upload a study on the 'Requirements Status and Registrant's Response' screen:
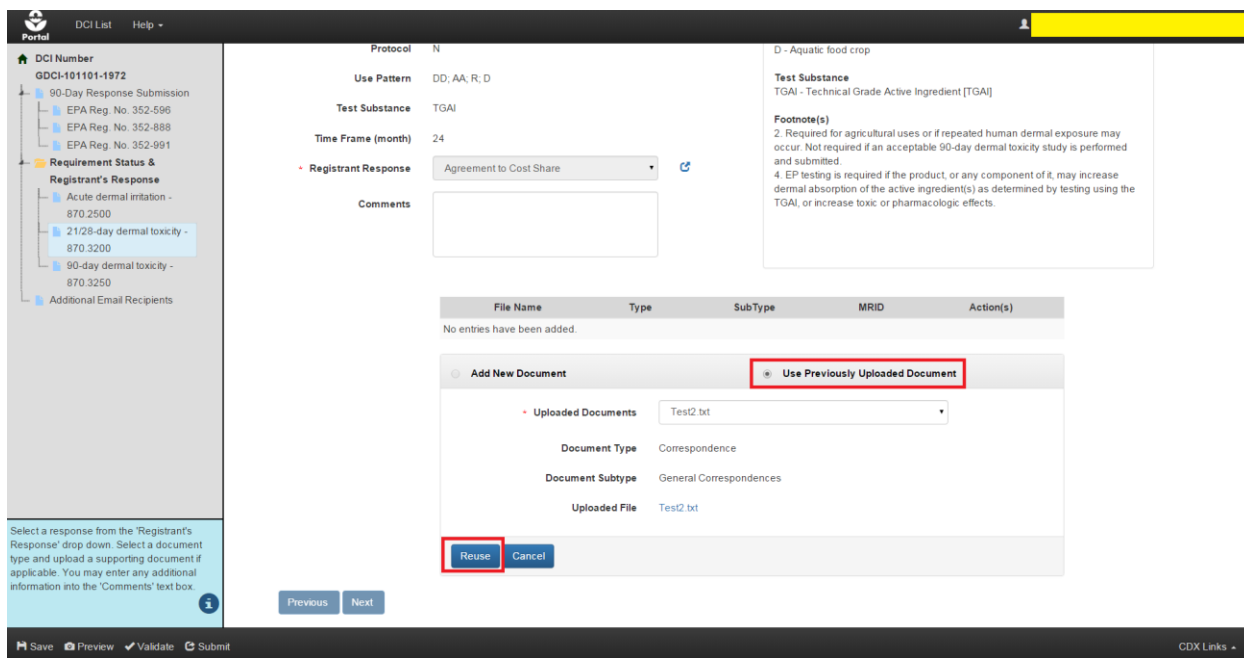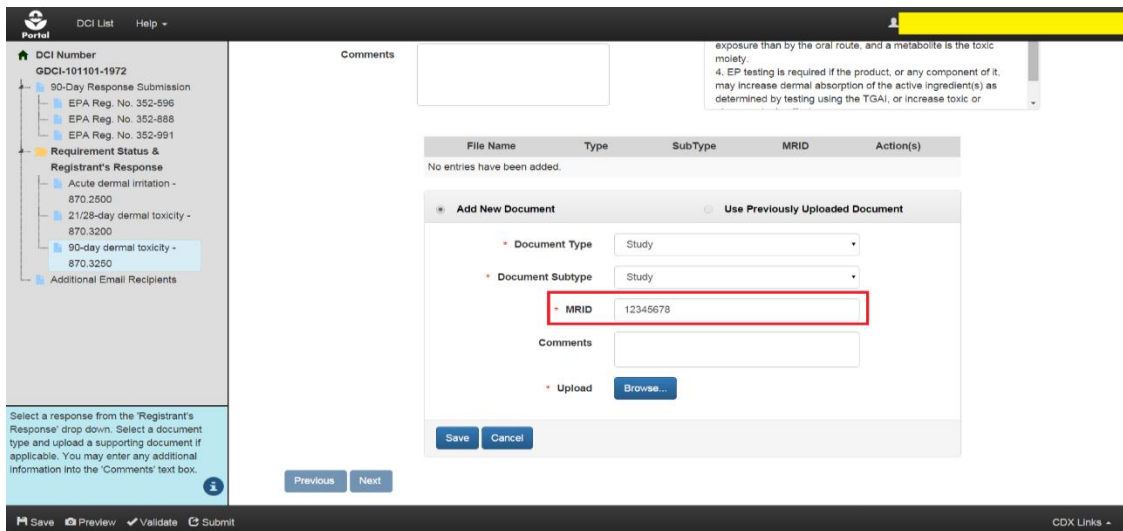

Exhibit 8-22: 'Requirements Status and Registrant's Response' Screen – Study Upload

Navigation: Select the 'Add New Document' radio button, select 'Study' for both document type and document subtype, enter a valid MRID, upload a document, and finally select the 'Save' button. MRIDs are validated upon submission or when the 'Validate' button is selected from the application footer. Refer to **Section 5** for additional information about MRIDs.

Exhibit 8-23 shows a screen capture of how to cite studies on the 'Requirements Status and Registrant's Response' screen:


Exhibit 8-23: 'Requirements Status and Registrant's Response' Screen – Cite Studies

Navigation: Enter the MRID of a previously submitted study. To cite additional studies, select the 'Cite an additional MRID Number' link. Select the 'Next' button to proceed to the next guideline.

8.3.4   Additional Email Recipients Screen and Submission Process

The 'Additional Email Recipients' screen allows the submitter of a 90-Day Response to indicate additional email addresses to which DCI notification emails will be sent. By default, notification emails are only sent to the CDX account that performs the submissions. These emails inform recipients when 90-Day Responses and Data Submissions are submitted to OPP.
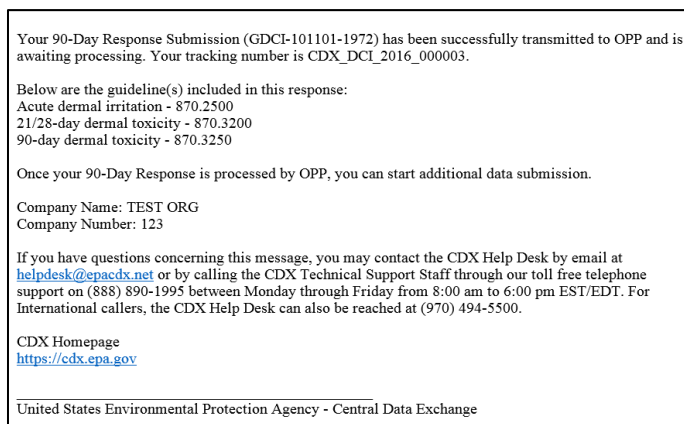
Exhibit 8-24 shows a screen capture of the 'Additional Email Recipients' screen:
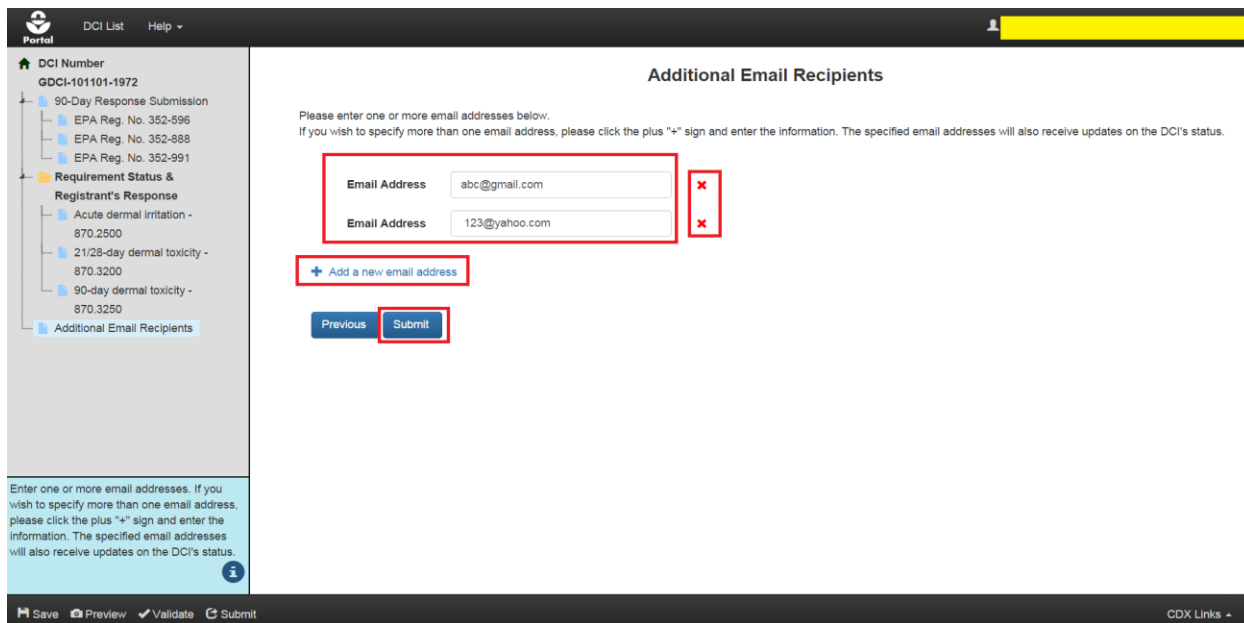
Exhibit 8-24: 'Additional Email Recipients' Screen

Navigation: Enter a valid email address in the 'Email Address' field. Select the 'Add a new email address' link to generate 'Email Address' fields for additional recipients. Once finished entering email addresses, select the 'Submit' button to begin the submission process. Please refer to **Section 4.9** for assistance with the submission process.

Exhibit 8-25 shows a screen capture of the 'Additional Email Recipients' screen:

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 8-25: DCI 90-Day Response Successful Transmission Notification Email

![CDX logo]

8.3.5   90-Day Response Resubmission

A previously submitted and processed 90-Day Response can be amended and resubmitted to OPP as often as necessary when a DCI does not have a Data Submission with the 'Pending' status. Amendments allow for modifications to previous data requirements responses, additional document uploads, and/or changes to product registration support. Note that a Data Submission cannot be made until an amended 90-Day Response successfully transmits to OPP.

Important: In-progress, un-submitted Data Submissions are deleted when a 90-Day Response amendment is initiated.

Exhibit 8-26 shows a screen capture of the link to change a 90-Day Response:

Exhibit 8-26: 'DCI List' Screen - 'Change 90-Day Response' Link

Navigation: Select the blue 'Change 90-Day Response' link in the '90-Day Response' column. After selecting the 'Change 90-Day Response' link, a pop-up displays indicating that in-progress Data Submissions will be deleted and that new Data Submissions cannot be made until the amended 90-Day Response is submitted.

Exhibit 8-27 shows a screen capture of the 'Change 90-Day Response Confirmation' pop-up:

Attention

Are you sure you want to change your 90-Day Response? 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.

OK   Cancel

Exhibit 8-27: DCI 'Change 90-Day Response Confirmation' Pop-Up

Navigation: Select the 'OK' button to proceed to the 'Enter Passphrase' screen. For additional information on the 'Enter Passphrase' screen refer to **Section 4.7.2**. After entering the correct passphrase, the '90-Day Response Submission' screen will display.

Exhibit 8-28 shows a screen capture of the '90-Day Response' screen for an amended 90-Day Response form:

Exhibit 8-28: DCI '90-Day Response' Screen for Amended Form

Navigation: Previously submitted files have a status of 'Previously Submitted' in the 'Action(s)' column and cannot be edited. Select the 'Add DCI Level Document' to add documents to a submission as necessary. Navigate to an 'EPA Product Registration' screen to change the response for an EPA Registration Number.
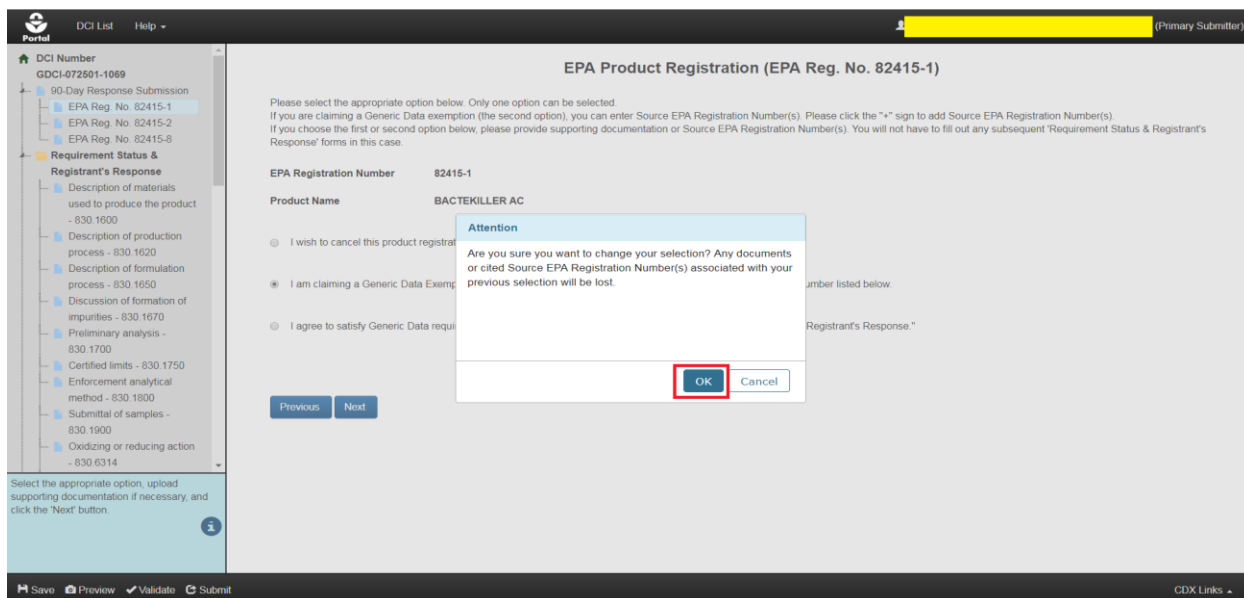
Use the 'EPA Product Registration' screen(s) to make changes to selections for an EPA Registration Number.

Important: Previously submitted documents or cited Source EPA registration number(s) associated with a previous selection are removed when the 'OK' button is selected in the pop-up.

Exhibit 8-29 shows a screen capture of the 'EPA Product Registration' screen for an amended 90-Day Response:


Exhibit 8-29: DCI 'EPA Product Registration' Screen – Change Selection Pop-Up

Navigation: To change a selection on the 'EPA Product Registration' screen, select a different response radio button. A pop-up will display asking for confirmation of the selection, select the 'OK' button. Use the navigation tree to access the screens for guidelines that need updates.

The 'Requirements and Registrant's Response' screen(s) may be used to upload additional documents, provide additional data, and/or change a 'Registrant Response' for a guideline. Previously submitted documents will display a status of 'Previously Submitted' in the 'Action(s)' column and will not be editable.

Important: All documents/information (including previously submitted documents) associated with a guideline response will be lost when the 'Registrant Response' is changed. Information associated with other guidelines will be unaffected.

Exhibit 8-30 shows a screen capture of the 'Requirements and Registrant's Response' screen for an amended 90-Day Response:
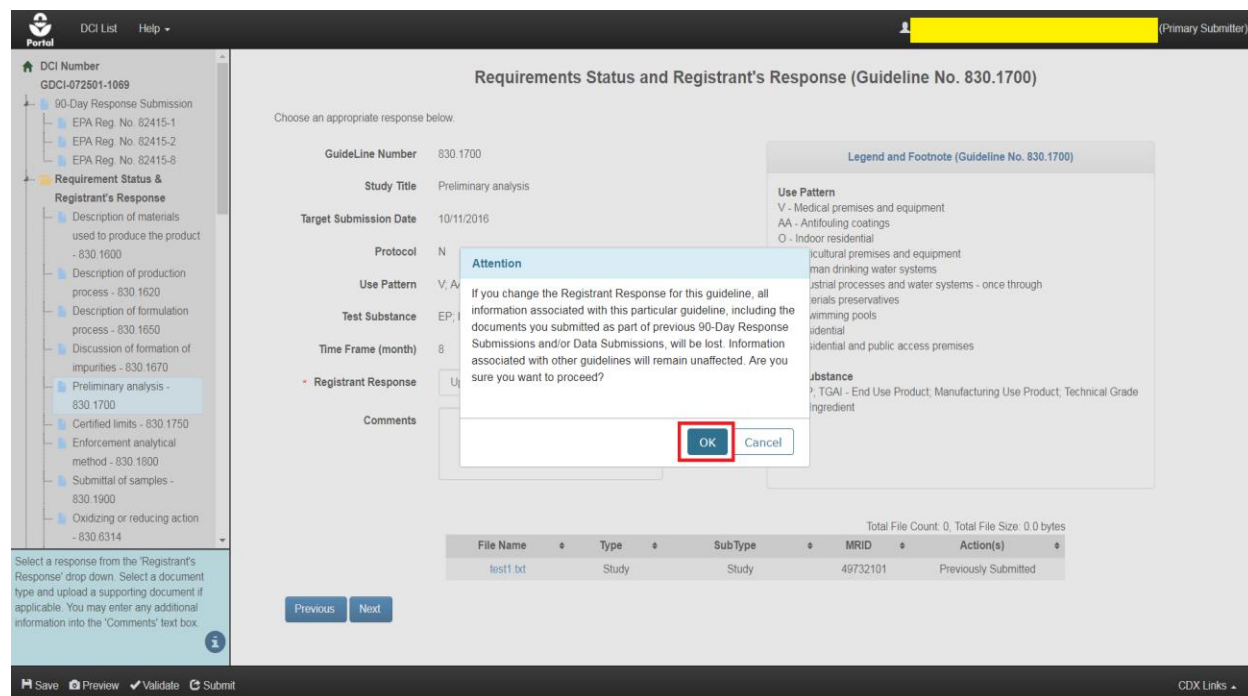
Exhibit 8-30: DCI 'Requirements and Registrant's Response' Screen – Change Selection Pop-Up

Navigation: To change a selection on the 'Requirements and Registrant's Response' screen, select a different option from the 'Registrant Response' drop-down menu. A pop-up will display asking for confirmation of the selection, select the 'OK' button. After making all necessary changes, select the 'Submit' button in the application footer. For assistance with the submission process, please refer to **Section 4.9**.

On the 'DCI List' screen, a newly submitted 90-Day Response resubmission will have a status of 'In Transmission' and the 'Data Submission' column will display the 'Awaiting Resubmission/Successful Transmission of 90-Day Response' status. The ability to access Data Submissions and additional 90-Day Response resubmissions for the DCI will remain unavailable until the 90-Day Response status changes to 'Change 90-Day Response (Previous Submission Successful).' The copy of record will reflect the most recent 90-Day Response submission.

Exhibit 8-31 shows a screen capture of a newly submitted 90-Day Response resubmission on the 'DCI List' screen:

Exhibit 8-31: Data Call-In List Screen - 'Awaiting Resubmission' Status

8.4 DCI Data Submission

A DCI Data Submission allows for the submission of additional documents to support previous DCI responses and help satisfy guidelines after a 90-Day Response has been submitted and processed by OPP. Registrants are able to make as many Data Submissions as necessary to satisfy all guidelines. All previously submitted data for a DCI will be displayed when accessing a Data Submission.

A Data Submission form mirrors the screens in a 90-Day Response. Therefore, the EPA Registration Number(s) and underlying guideline screen(s) structure will differ between GDCIs and PDCIs, but the guideline screens themselves will have similar functionality. Please note that, while the screens are the same between the submission types, response options may not be altered within a Data Submission – only additional data may be added.

8.4.1   Create DCI Data Submission

To start a Data Submission, first identify a DCI with a Data Submission status that includes a 'Submit Data' link (i.e., 'Submit Data' or 'Submit Data (Previous Submission Successful')).

Important: A separate passphrase must be created for each Data Submission. However, unlike other DCI submission types, if the passphrase for an in-progress Data Submission is forgotten, a new Data Submission may be created to overwrite the previous in-progress submission.

Exhibit 8-32 shows a screen capture of how to create a Data Submission on the 'DCI List' screen:

Exhibit 8-32: 'DCI List' Screen - 'Submit Data' Link

Navigation: Select the 'Submit Data' link for a DCI that has a 90-Day Response status of 'Change 90-Day Response (Previous Submission Successful)' to navigate to the 'Create Passphrase' screen. Refer to **Section 4.7.1** for assistance navigating the 'Create Passphrase' screen.

Exhibit 8-33 shows a screen capture of how to access the 'Previous Data Submissions' screen from the 'DCI List' screen to create a new Data Submission because a passphrase was forgotten:

Exhibit 8-33: 'DCI List' Screen - 'Show Previous Data Submission(s)' Icon

Navigation: Select the 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' screen.

Exhibit 8-34 shows a screen capture of how to create a Data Submission on the 'Previous Data Submissions' screen because a passphrase was forgotten for an in-progress Data Submission:


Exhibit 8-34: DCI 'Previous Data Submissions Screen

Navigation: Select the 'Create New Data Submission' button to create a passphrase for a new Data Submission. Please note that creating a new data submission will wipe out any in-progress information that has not been previously submitted.

8.4.2 Data Submission Screen

After creating a new passphrase, the application navigates to the 'Data Submission' screen. This screen mirrors the '90-Day Response Submission' screen for the DCI by providing summary information about the DCI and a place to upload DCI-level documents that apply to the entire Data Submission. Note that the 'Data Submission' screen is the same for both GDCIs and PDCIs.

Exhibit 8-35 shows a screen capture of the 'Data Submission' screen:
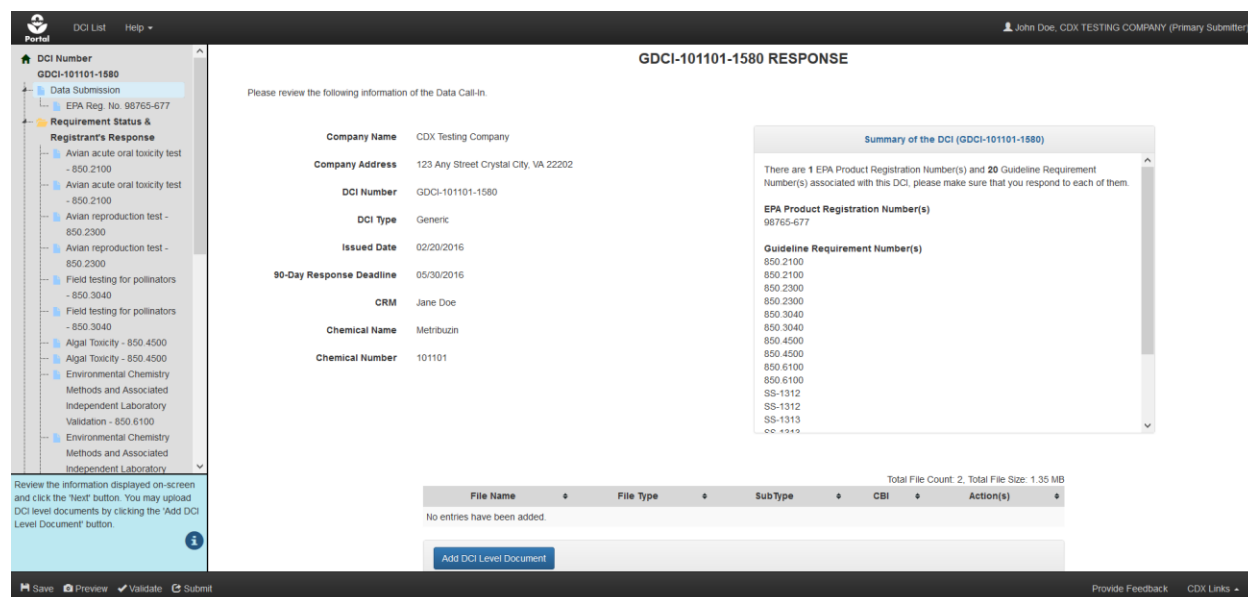
Exhibit 8-35: DCI 'Data Submission' Screen

Navigation: Add additional DCI level documents if desired by selecting the 'Add DCI Level Document' button. Proceed to subsequent screens to add additional documents for specific guidelines.

Once all necessary documents/data have been added to the submission, select the 'Submit' button in the application footer to begin the submission process. Please refer to **Section 4.9** for assistance with the PSP submission process.

Similar to the above 'Data Submission' screen, the remaining screens in a Data Submission (i.e., the 'EPA Product Registration,' 'Requirements Status and Registrant's Response,' and 'Add Additional Email Recipients' screens) only allow for the addition of new documents/data and do not allow the user to make response changes. Previously submitted documents will be listed in the various documents tables and display 'Previously Submitted' in the 'Action(s)' column. Please refer to **Section 8.3** and its subsections for information about how to upload documents on these screens.

8.4.3 Access Previous DCI Data Submissions

Once a Data Submission successfully transmits to OPP, the status will transition to 'Submit Data (Previous Submission Successful)' within the 'Data Submission' column. The data submission will also be archived on the 'Previous Data Submissions' screen alongside any other previous Data Submissions. Additionally, the CoR icon for the most recent Data Submission will appear

within the 'Data Submission' column. Refer to **Section 8.5** for additional information about DCI copies of record.

Exhibit 8-36 shows a screen capture of the 'DCI List' screen containing a Data Submission with the 'Submit Data (Previous Submission Successful)' status:

Exhibit 8-36: 'DCI List' Screen – Show Previous Data Submissions

Navigation: Select the 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' screen.

Exhibit 8-37 shows a screen capture of the previous Data Submission archive on the 'Previous Data Submissions' screen:

Exhibit 8-37: DCI 'Previous Data Submissions' Screen

8.5 DCI Copy of Record

The ability to download a copy of record becomes available on the 'DCI List' screen once a DCI Acknowledgement, 90-Day Response, or Data Submission is successfully submitted to OPP. Note that the copies of record available on the 'DCI List' screen are only for the most recently submitted instance of a given submission.

Exhibit 8-38 shows a screen capture of the copy of record icons on the 'DCI List' screen:

Exhibit 8-38: 'DCI List; Screen - 'Copy of Record' Icon

Navigation: Select a green 'Copy of Record' icon in the 'DCI Acknowledgement,' '90-Day Response,' or 'Data Submission' columns to navigate to the Cross-Media Electronic Reporting Regulation (CROMERR)' screen.

Exhibit 8-39 shows a screen capture of the 'Cross-Media Electronic Reporting Regulation (CROMERR)' screen for a DCI submission:

Exhibit 8-39: DCI 'CROMERR' Screen – Download Copy of Record

Navigation: Enter the passphrase used to encrypt the submission, the logged in user's CDX password, and the answer to one of the logged in user's CDX secret questions. Select the 'Next' button to navigate to the 'Copy of Record' screen.

Note: Since DCI Acknowledgements do not require a passphrase, only the logged in user's CDX password and answer to a secret question are required to access the submission.

Exhibit 8-40 shows a screen capture of the 'Copy of Record' screen for a DCI submission:

Copy of Record

To download a Copy of Record, click on the green arrow under the Action(s) column.

File Name	File Size	Type	Action(s)
e-PRISM.xml	2.17 KB	EPA No.352-596	⊙
General Correspondence.txt	12 bytes	352-459: 870.3200	⊙
111.txt	12 bytes	352-459: 870.3250	⊙
CoR_TEST ORG_2332.pdf	31.28 KB	PDF	⊙

Back
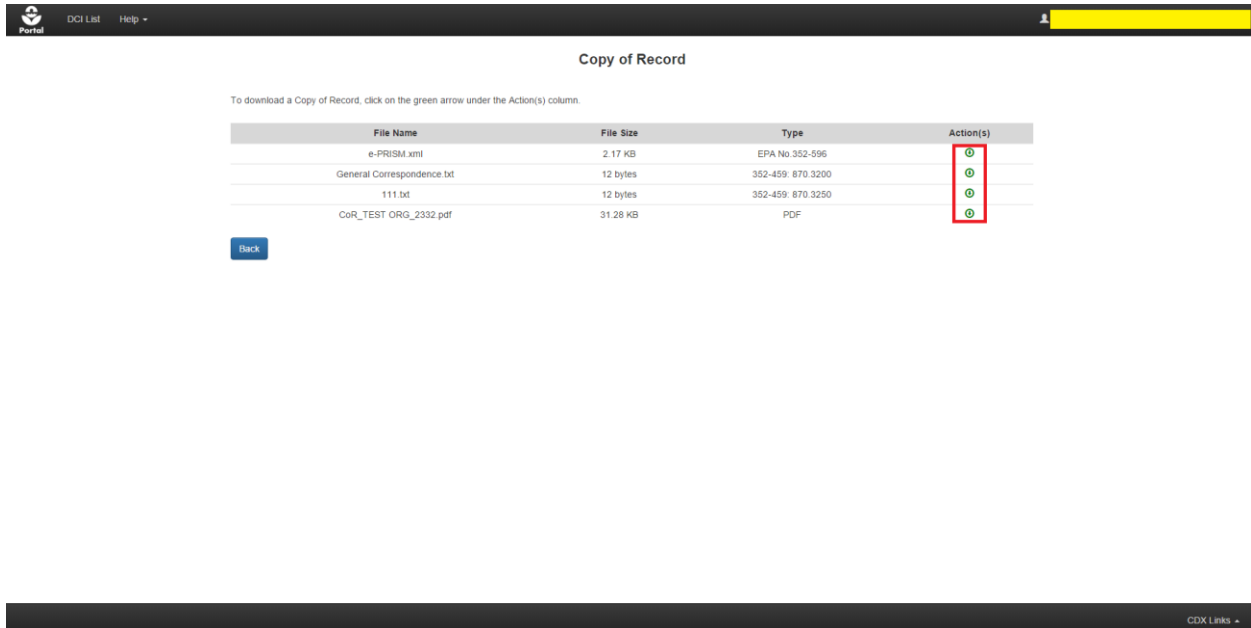
Exhibit 8-40: Data Call-In 'Copy of Record' Screen

Navigation: Select the green 'Download Document' icon in the 'Action(s)' column to download a copy of record for submitted documents.

![CDX logo]

9 Consortium Submissions

This section describes how to form consortia to respond to DCIs within PSP. A consortium consists of two or more companies who agreed to work together to submit data for a specific set of chemicals/DCIs. Consortia are authorized to submit data on behalf of their members.

Users may create new or use previously created consortia to make submissions. The user who creates a consortium is designated as the Consortium Lead and has the sole authority to edit and submit supporting materials. PSP supports transfer of the Consortium Lead role to another company should a Consortium Lead wish to abdicate the role. Similar to other PSP applications, consortium submissions support real-time validations, status updates and submission transparency for all members of the consortium, and email notifications.

Exhibit 9-1 shows a screen capture of how to access consortium submissions from the PSP 'Home' screen:
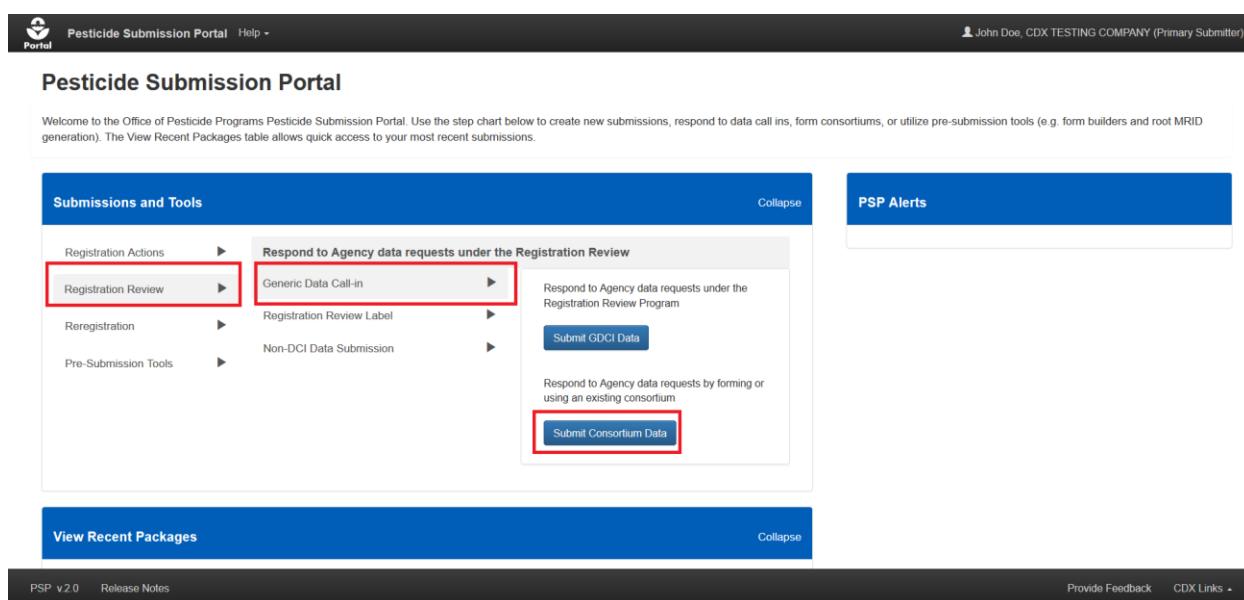
Exhibit 9-1: Pesticide Submission Portal – Consortium Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Review' option in the first column, next select the 'Generic Data Call-In' option in the second column, and finally select the 'Submit Consortium Data' button.

9.1 Consortium List Screen

The 'Consortium List' screen displays the details and statuses for consortium submissions. Both in-progress and submitted consortium submissions are visible via this screen. The consortium application supports two types of submissions: Edit Consortium and Data Submission which are located in eponymous columns on the screen.

Exhibit 9-2 shows a screen capture of how to filter consortia on the 'Consortium List' screen:

Exhibit 9-2: 'Consortium List' Screen – Table Filtering

Navigation: Filter the table to locate specific consortia by using the filter drop-down menus and 'Filter Results' search criteria.

Exhibit 9-3 shows a screen capture of the features in the 'Action(s)' column on the 'Consortium List' screen:

Exhibit 9-3: 'Consortium List' Screen – Table Actions

Navigation: Select a red 'x' icon in the 'Action(s)' column to delete an in-progress consortium submission. Note that a submitted consortia submission cannot be removed once submitted. Consortia with an assigned consortium number may transfer the Consortium Lead role to another user by selecting the 'Transfer Consortium' icon in the 'Action(s)' column. Refer to **Section 9.6** for instructions on how to transfer the Consortium Lead role.

9.2 Consortium Visibility Rules

Consortium visibility is based on company number. If a company is associated to a consortium via a DCI, all users associated with that company in PSP will have read-only access to the consortium. All consortium members (companies associated with a consortium via at least one DCI) can download a non-CBI copy of record for consortium submissions and view the latest statuses for consortium submissions. However, only the Consortium Lead user can edit and make consortium submissions.

Consortium membership can be modified at any time by a Consortium Lead on the 'PC Code(s)' screen. When a Consortium Lead adds or removes DCIs from a consortium, the affected member company's membership is automatically recorded and an updated list of consortia display on the 'Consortium List' screen for all associated PSP users.

A list of DCIs associated with a consortium can be accessed via the 'DCI List' link within the 'DCI Number(s)' column. The list of member companies associated with the consortium can be accessed via the 'View Consortium Members' icon within the 'DCI Number(s)' column. Previous data submissions can be accessed via the 'Show Previous Data Submission(s)' icon in the 'Data Submission' column.

Exhibit 9-4 shows a screen capture of the consortium member view of the 'Consortium List' screen:

Exhibit 9-4: 'Consortium List' Screen – Non-Lead Member View

Navigation: As a consortium member select the yellow 'Download PDF Only' icon in the 'Edit Consortium' or 'Data Submission' columns to download a non-CBI PDF of a submission. Refer to **Section 9.8** for information about downloading copies of record.

9.3 Create a New Consortium

To create a new consortium, select the 'Create New Consortium' button on the 'Consortium List' screen.

Note: The person who creates the consortium will automatically be considered the 'Consortium Lead.' Only the Consortium Lead can edit and make consortium submissions. The Consortium

Lead role can also be transferred to another user if desired. More information about the Consortium Lead role and consortium visibility rules can be found in **Section 9.6**.

Exhibit 9-5 shows a screen capture of how to initiate a new consortium submission on the 'Consortium List' screen:

Exhibit 9-5: 'Consortium List' Screen – 'Create New Consortium' Button

Navigation: Select the 'Create New Consortium' button and then select 'OK' in the resulting pop-up to confirm the selection and navigate to the 'Create Passphrase' screen. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Important: The same passphrase must be used throughout the life of a consortium and cannot be reset or retrieved. If the consortium is transferred, this same passphrase will be needed to access the consortium. The user who creates a submission is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

9.3.1　　Primary Contact Information Screen

The 'Primary Contact Information' screen is the first screen within a consortium submission and is displayed immediately after either creating or entering a submission's passphrase. The 'Primary Contact Information' screen is used to designate a point of contact for a consortium. Some information will be pre-populated from the logged in user's CDX profile but can still be edited. The following fields are displayed on the 'Primary Contact Information' screen:

- **Consortium Name:** The name given to a consortium. This is a required field. **Important:** The consortium name cannot be changed after the first PC Code is saved on the 'PC Code(s)' screen and a consortium number is generated. Please ensure that the entered 'Consortium Name' is correct prior to navigating away from this screen.

- **Company Name:** The name of the company that will serve as the point of contact. This field is required.

- **Company Number:** The company number of the company that will serve as the point of contact. This field is required.

- **Full Name:** The full name of the point of contact. This field is required.

- **Phone Number:** The point of contact's phone number. This field is required.

- **Email Address:** The point of contact's email address. This field is required. The email address specified in this field is the only one that will receive updates about a consortium's submission status.

- **Is this on behalf of a Trade Group?**: Indicate if the consortium submits on behalf of a Trade Group. This field is optional.

- **Mailing Address 1:** The point of contact's mailing address. This field is required.

- **Mailing Address 2:** The second line of the point of contact's mailing address. This field is optional.

- **City:** The point of contact's city. This field is required.

- **County/Parish:** The county/parish of the point of contact. This field is optional.

- **State:** The point of contact's state. This field is required.

- **Postal Code:** The point of contact's postal/zip code. This field is required.

Exhibit 9-6 shows a screen capture of the 'Primary Contact Information' screen:

Exhibit 9-6: Consortium 'Primary Contact Information' Screen

Navigation: Enter data into all required fields and select the 'Next' button to the 'PC Code(s)' screen.

9.3.2 PC Code(s) Screen

The 'PC Code(s)' screen is used to add chemicals and DCIs to a consortium. It also displays any previously added or submitted chemicals. The 'Add PC Code' pop-up on the screen is used to search for and add chemicals and their associated DCI(s) to a consortium.

Note that the first PC Code saved on this screen will be used to generate the consortium number and cannot be removed from a submission once added. Additionally, once a consortium is submitted any underlying PC Codes cannot be removed in a consortium edit submission. DCIs both saved and submitted for a consortium may be removed.

Important: All PSP users registered to companies associated with DCIs added via the 'Add PC Code' pop-up will see the associated Consortium appear on their 'Consortium List' screen. These users will be able to view a consortium's status and download non-CBI PDF copies of record. However, they will not be able to edit, submit, or obtain any submitted files. Consortium Leads can control which companies have this access to the consortium by modifying the list of associated DCIs on this screen.

Exhibit 9-7 shows a screen capture of the 'PC Code(s)' screen:
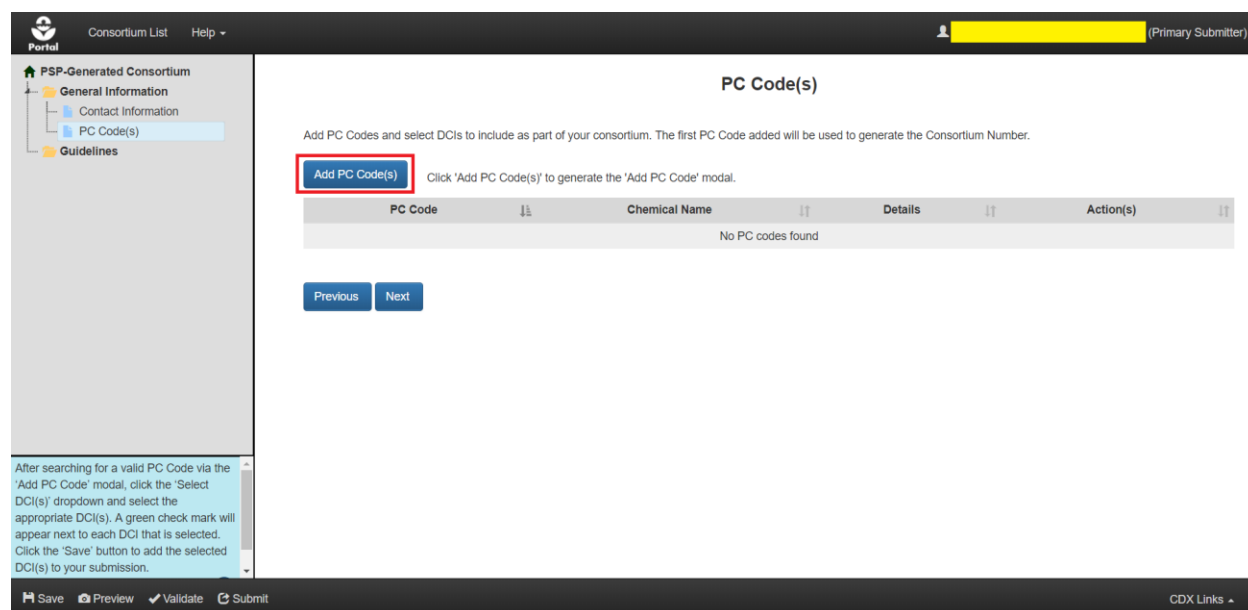
Exhibit 9-7: Consortium 'PC Code(s)' Screen

Navigation: Select the 'Add PC Code(s)' button to launch the 'Add PC Code' pop-up.

The following fields display in the 'Add PC Code' pop-up:

- **PC Code:** The Pesticide Chemical Code of the desired chemical. As numbers are entered into this field it automatically filters to display potential matches. After selecting a PC Code, the 'Chemical Name' field automatically populates with the correct entry. Users can search by either PC Code or chemical name.

- **Chemical Name:** The name of the chemical. As characters are entered into this field it automatically filters to display potential matches. After selecting a Chemical Name, the 'PC Code' field automatically populates with the correct entry. Users can search by either PC Code or chemical name.

- **DCI Number for specified chemical:** The DCIs associated with the selected chemical. This drop-down menu automatically populates with a list of available DCIs associated with the selected chemical. Each DCI is associated with a single company. As DCIs are selected from the drop-down menu, they are added to the pop-up's table.

- **Table that summarizes the added DCIs and has the following columns:**
    - DCI Number
    - Company Name
    - Company Number
    - Chemical Name
    - Status
    - Action(s)

Exhibit 9-8 shows a screen capture of the 'Add PC Code' pop-up populated with a chemical and selected DCIs:
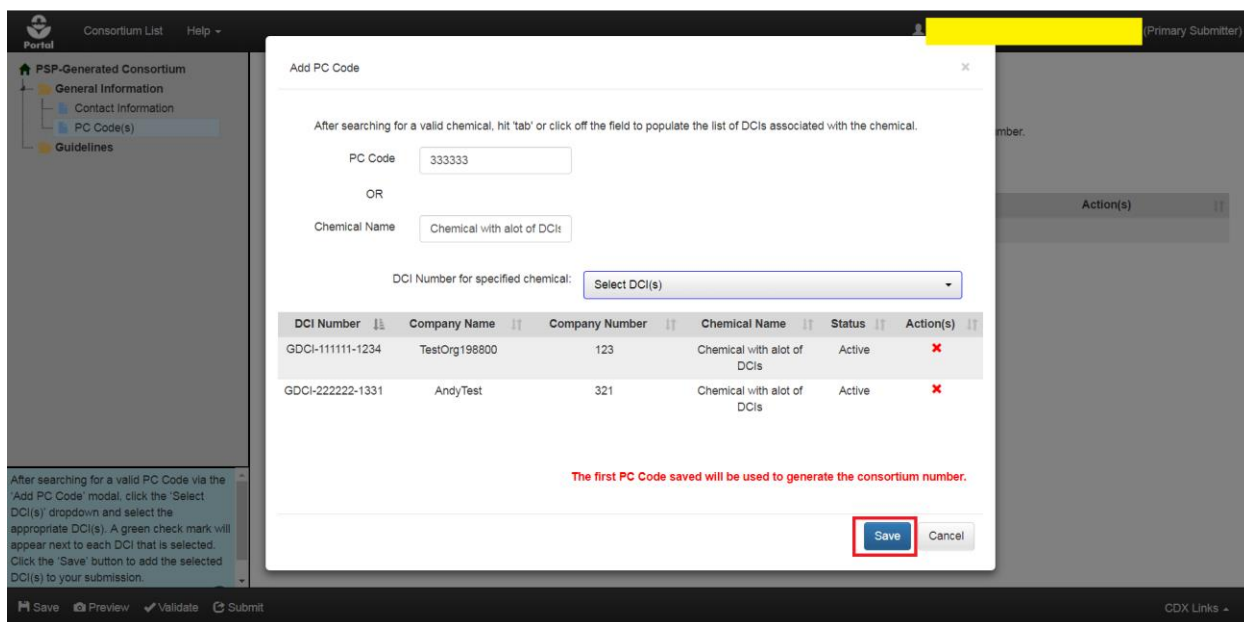
Exhibit 9-8: Consortium 'Add PC Code' Pop-Up

Navigation: Search for a valid chemical, select one or more DCIs from the drop-down menu, and finally select the 'Save' button.

After selecting the 'Save' button, a loading pop-up displays indicating that it will take several minutes for a consortium number to generate. A validation message will display if the consortium name is not unique or if there are errors.

When the consortium number generates, a series of green messages will appear at the top right of the screen and the consortium number will appear in the center of the screen and in the navigation tree. The 'Manage Guidelines' entry will also appear in the navigation tree.

Exhibit 9-9 shows a screen capture of the 'PC Code(s)' screen with a generated consortium number:
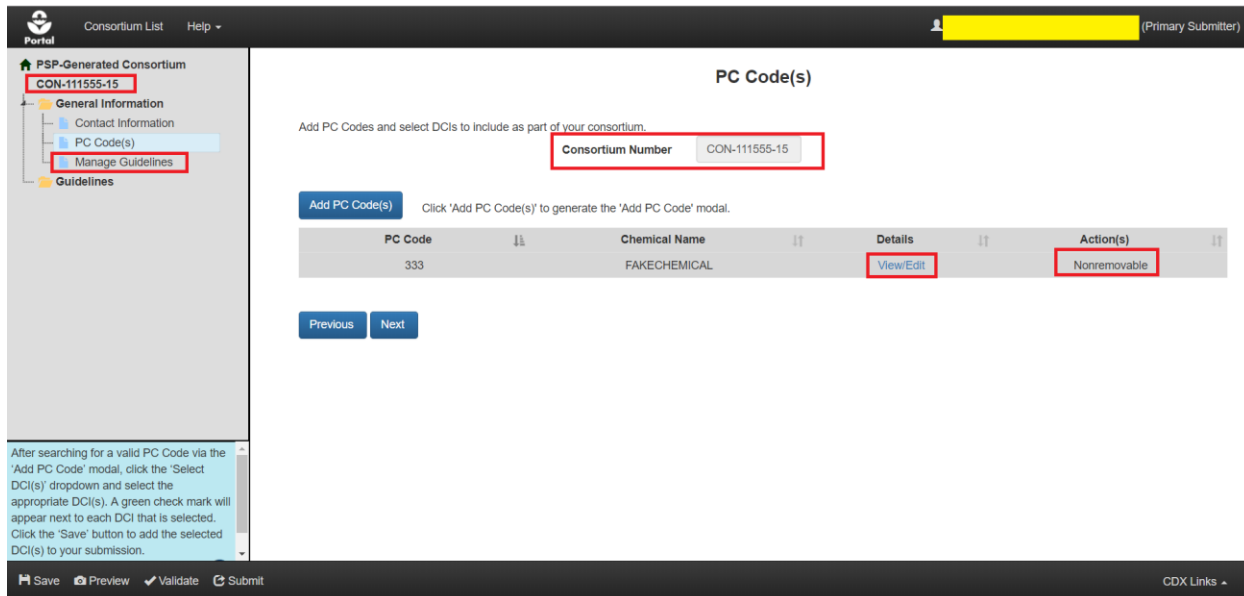
Exhibit 9-9: Consortium 'PC Code(s)' Screen With Consortium Number

Navigation: Confirm the displayed data elements. Select the 'View/Edit' link to view or modify the list of associated DCIs via the 'Edit PC Code' pop-up.

The 'Edit PC Code' pop-up has the same data elements as the 'Add PC Code' pop-up. However, only the DCIs associated with the PC Code may be modified.

Exhibit 9-10 shows a screen capture of the 'Edit PC Code' pop-up:
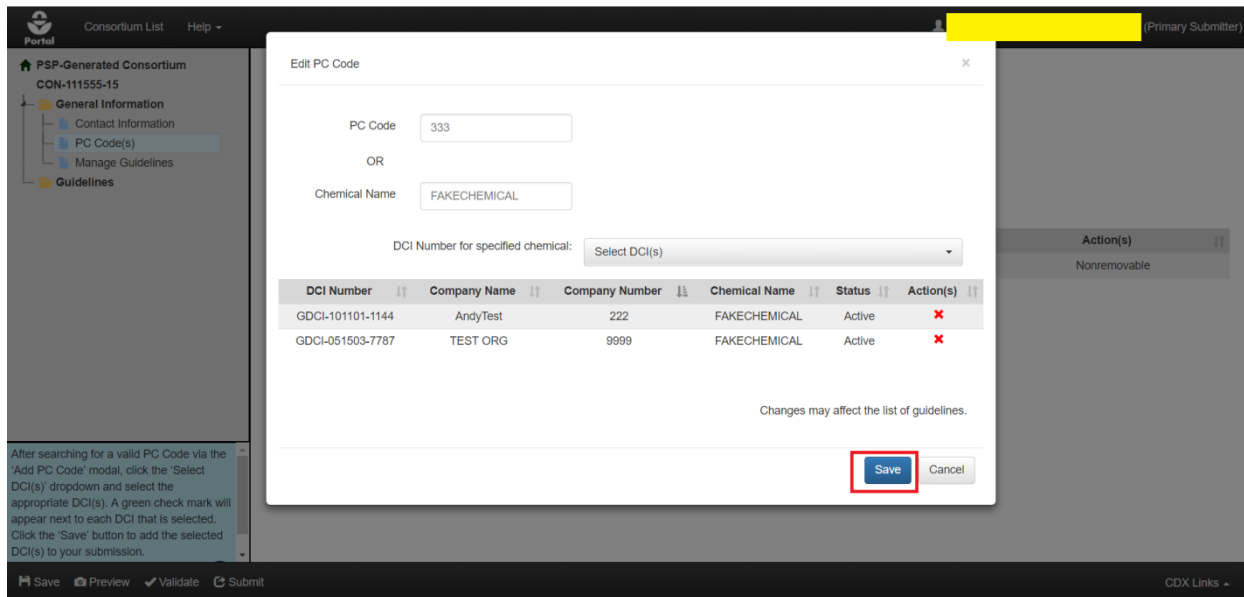
Exhibit 9-10: Consortium 'Edit PC Code' Pop-Up

Navigation: Modify the associated DCIs as desired and then select the 'Save' button.

PC Codes other than the first can be removed via the 'Delete PC Code' pop-up. As previously mentioned, the first saved PC Code is used to generate the consortium ID and cannot be removed.

Exhibit 9-11 shows a screen capture of the 'Delete PC Code' pop-up:
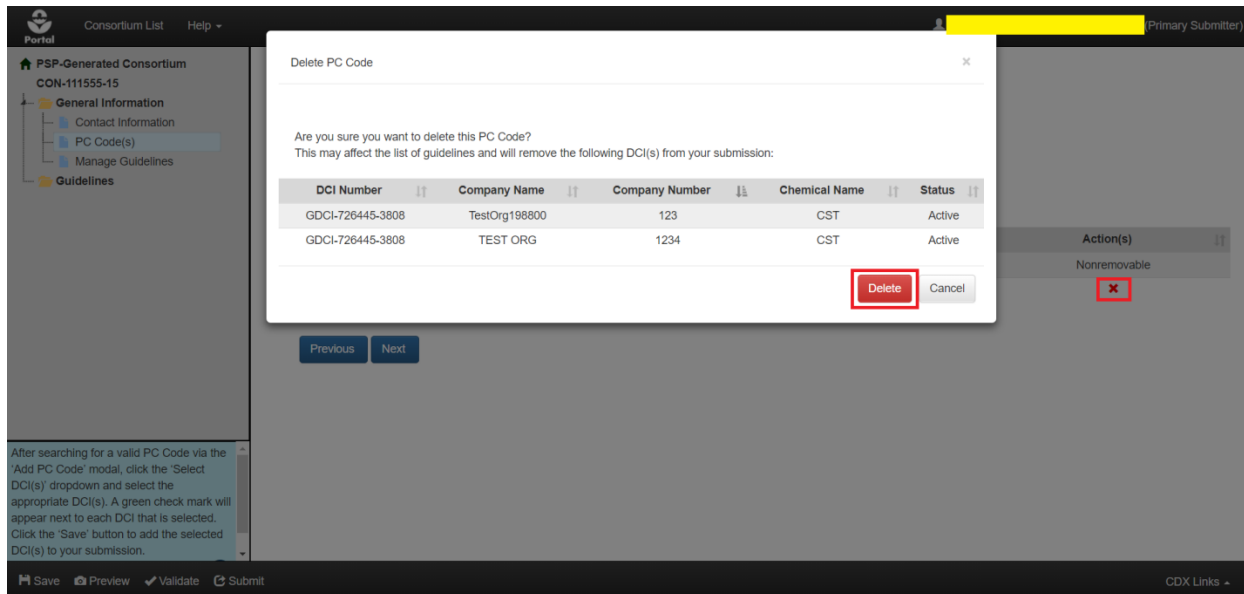
Exhibit 9-11: Consortium 'Delete PC Code' Pop-Up

Navigation: Select a red 'x' icon in the 'Action(s)' column on the 'PC Code(s)' screen for a PC Code. In the 'Delete PC Code' pop-up, review the displayed DCI(s) to be removed and then select the 'Delete' button to confirm the removal.

9.3.3　Manage Guidelines Screen

The 'Manage Guidelines' screen is used to select which guidelines for the PC Codes/ DCIs saved on the 'PC Code(s)' screen a consortium will support. As such, modifying the DCIs associated with a consortium before submission will affect the list of available guidelines.

Important: Guidelines cannot be removed from the consortium once submitted.

Exhibit 9-12 shows a screen capture of how to select guidelines on the 'Manage Guidelines' screen:
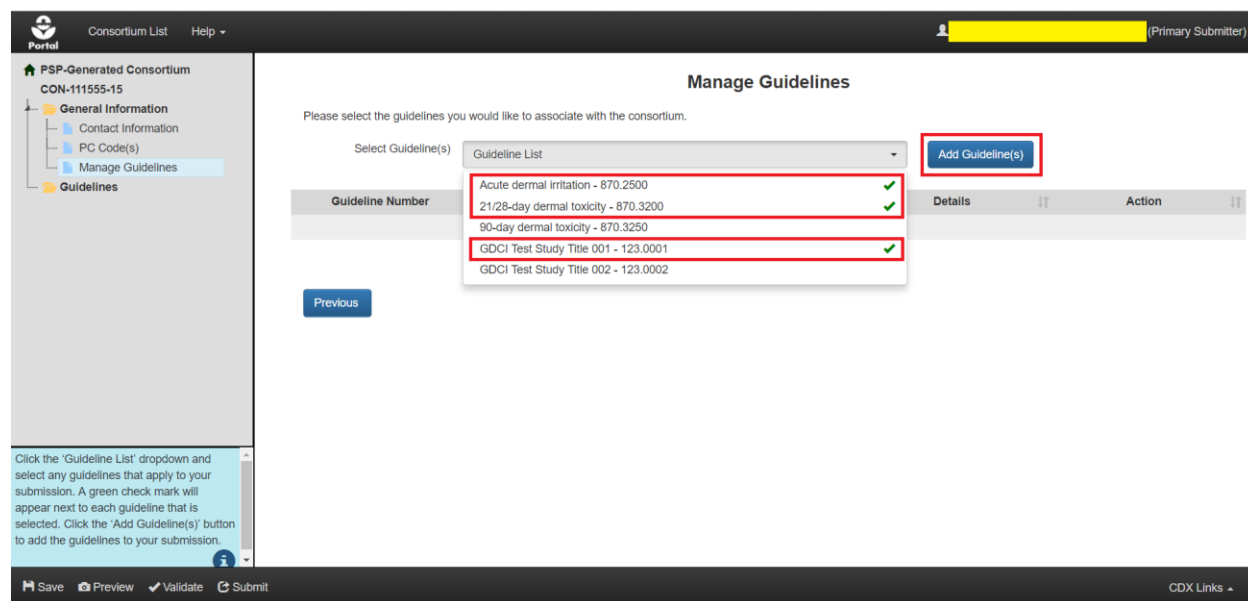
Exhibit 9-12: Consortium 'Manage Guidelines' Screen - Select Guideline(s)

Navigation: Select the 'Select Guideline(s)' drop-down menu to associate guidelines with the submission. Select one or more guidelines within the drop-down menu to select the respective guideline. Selected guidelines will display a green checkmark icon adjacent to the selected guideline. Select the 'Add Guideline(s)' button to add the selected guidelines to the consortium submission.

Exhibit 9-13 shows a screen capture of guidelines added to the 'Manage Guidelines' screen:
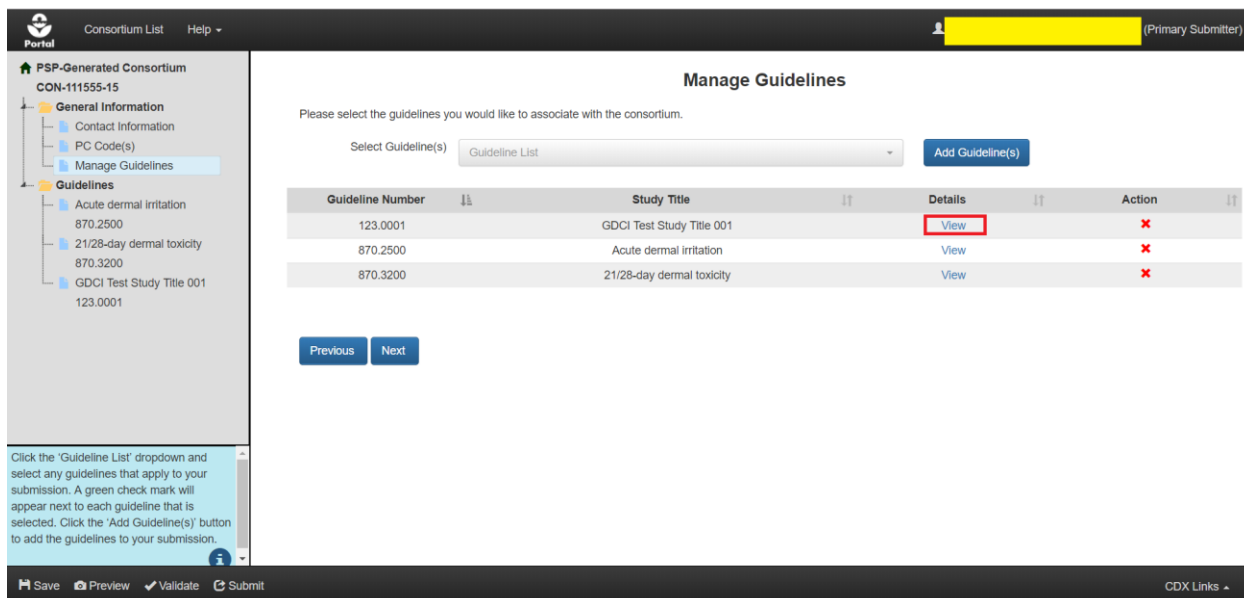
Exhibit 9-13: Consortium 'Manage Guidelines' Screen - Populated

Navigation: To remove a guideline, select the red 'x' icon in the corresponding 'Action' column. Alternatively, select the 'View' link in the 'Details' column to view guideline details.

Exhibit 9-14 shows a screen capture of 'Guideline Details' pop-up:
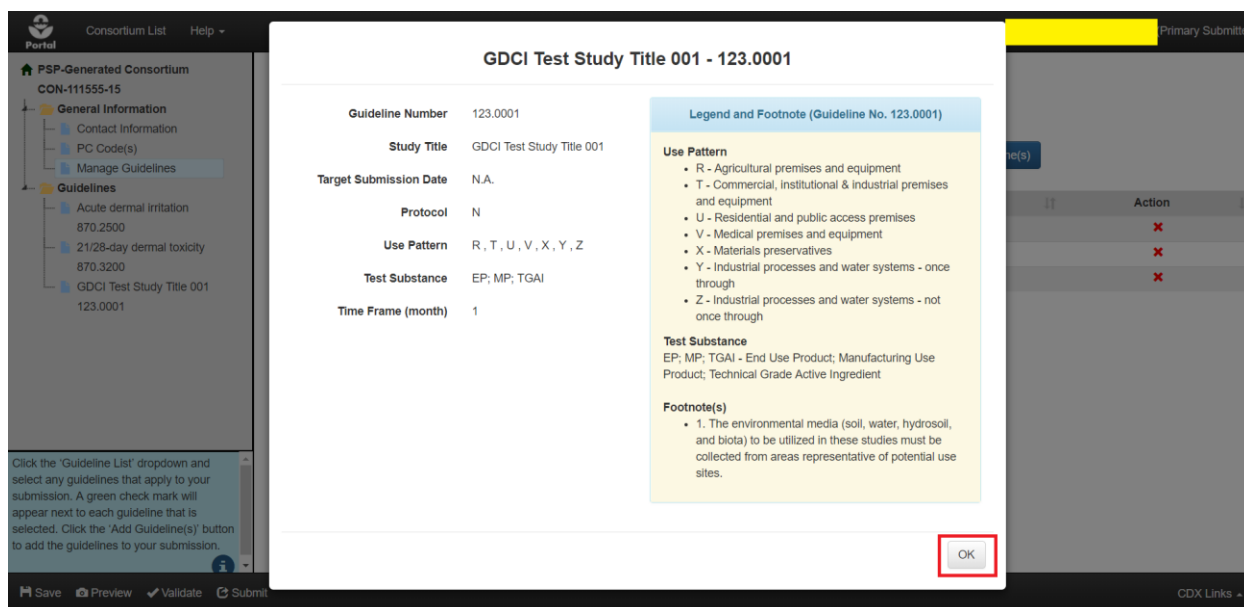
Exhibit 9-14: Consortium 'Guideline Details' Pop-Up

Navigation: Select the 'OK' button after reviewing the guideline's details.

9.3.4　　　Guideline Details Screen(s)

All guidelines added to a consortium are displayed in the navigation tree. Navigating to a 'Guideline Details' screen displays the same information as selecting the guideline's 'View' link on the 'Manage Guidelines' screen. The following fields display on each guideline 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.

Legend & Footnote(s) section: A legend that provides more information about the associated use patterns, test substances, and footnotes.

Exhibit 9-15 shows a screen capture of the 'Guideline' screen and navigation tree:
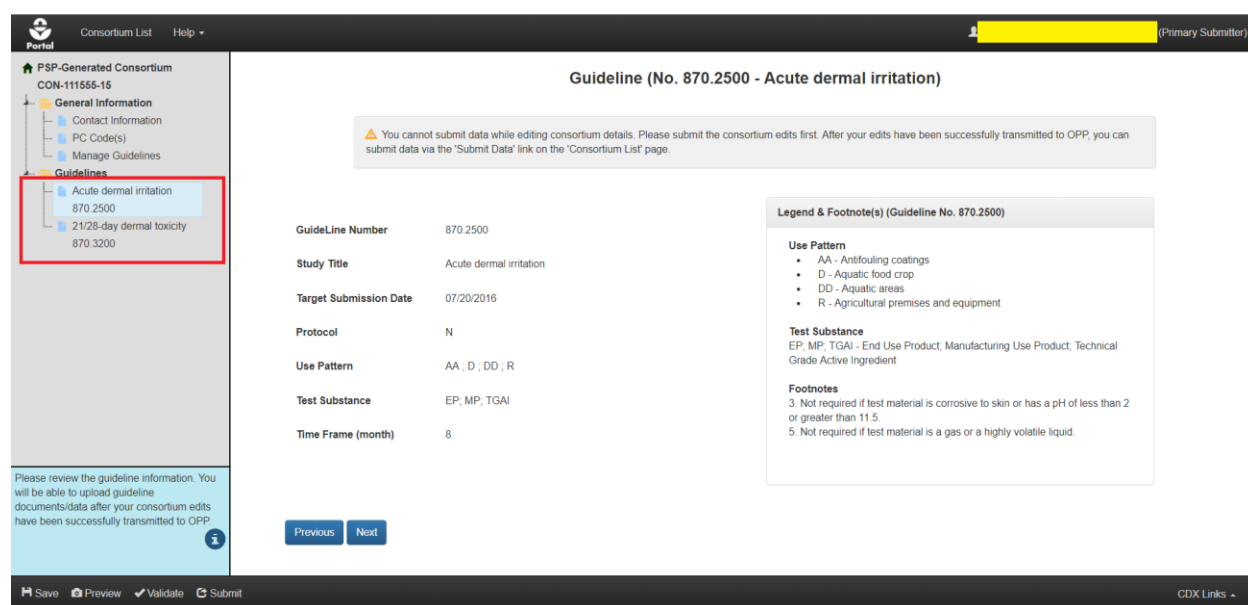
Exhibit 9-15: Consortium 'Guideline' Screen

Navigation: Review each guideline's details as necessary. Once finished reviewing guideline details, select the 'Submit' button to begin the submission process. Please refer to **Section 4.9** for assistance with the submission process.

Once a consortium submission has successfully transmitted to OPP, the consortium's status will transition to 'Edit' in the 'Edit Consortium' column and 'Submit Data' in the 'Data Submission' column, and a notification email be sent to the submitter.

Exhibit 9-16 shows a screen capture of the 'Edit' and 'Submit Data' statuses on the 'Consortium List' screen:

Exhibit 9-16: 'Consortium List' Screen – 'Edit' and 'Submit Data' Statuses

Exhibit 9-17 shows a screen capture of a consortium submission email notification:

Exhibit 9-17: Consortium Successful Transmission Email Notification

9.4 Use an Existing OPP Consortium

Pre-existing consortia (e.g., consortia created by OPP outside of PSP) can also be utilized to make submissions. The user who initiates this process will automatically be considered the 'Consortium Lead' within PSP. As a reminder, only a Consortium Lead can edit and make consortium submissions. The Consortium Lead role can be transferred to another user if necessary. Please refer to **Sections 9.2 and 9.6** for additional information about consortium visibility rules and consortium transfers, respectively.

Exhibit 9-18 shows a screen capture of the 'Use Existing Consortium' button on the 'Consortium List' screen:

Exhibit 9-18: 'Consortium List' Screen – 'Use Exising Consortium' Button

Navigation: Select the 'Use Existing Consortium' button to navigate to the 'Create Passphrase' screen. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Important: The same passphrase must be used throughout the life of a consortium and cannot be reset or retrieved. If the consortium is transferred, this same passphrase will be needed to access the consortium. The user who creates a submission is responsible for remembering its passphrase and only distributing it to authorized persons. **OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

9.4.1   Validate OPP Consortium Screen

After creating a passphrase, the 'Validate OPP Consortium' screen will display. This screen is used to enter the consortium number for a preexisting consortium created by OPP outside of PSP and select the chemical(s) to be included in the consortium.

Exhibit 9-19 shows a screen capture of the 'Validate OPP Consortium' screen:

Exhibit 9-19: Consortium 'Validate OPP Consortium' Screen

Navigation: Enter a valid consortium number (including the "CON" prefix) and then select the 'Validate Number' button.

After a valid consortium number is entered and the 'Validate Number' button is selected, the 'Consortium Summary' pop-up will display and list the consortium's details. If the consortium was formed for multiple chemicals, the ability to select multiple chemicals and associated DCIs is provided.

Important: PC Codes and guidelines already associated with the returned consortium cannot be removed. As with creating new consortia, any submitted PC Codes and guidelines also cannot be removed. Only PC Codes and guidelines added in the current session (before submission) can be removed.

Exhibit 9-20 shows a screen capture of the 'Consortium Summary' pop-up:
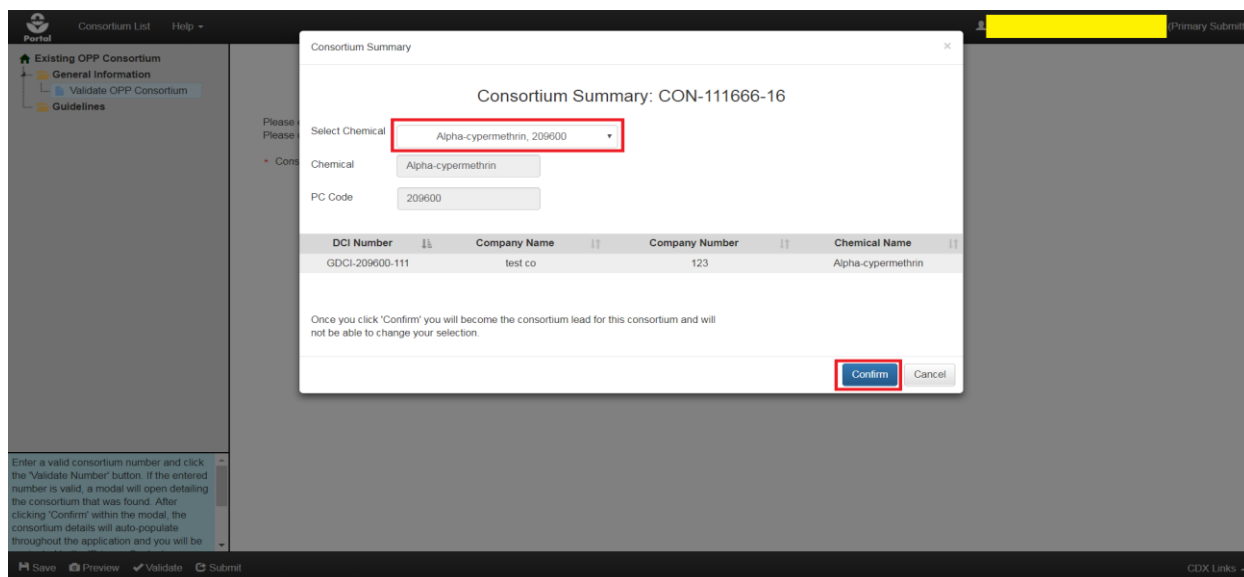
Exhibit 9-20: Consortium 'Consortium Summary' Pop-Up

Navigation: Verify consortium details and then select the 'Confirm' button to navigate to the 'Primary Contact Information' screen.

9.4.2   Primary Contact Information Screen

The 'Primary Contact Information' screen is used to designate a point of contact for a consortium. Some information will be pre-populated based on the information previously provided to OPP, but can still be edited. The following fields are displayed on the 'Primary Contact Information' screen:

- **Consortium Name:** The consortium's name as previously provided to OPP. This field is required and not editable.

- **Company Name:** The name of the company that will serve as the point of contact. This field is required.

- **Company Number:** The company number for the company that will serve as the point of contact. This field is required.

- **Full Name:** The full name of the point of contact. This field is required.

- **Phone Number:** The point of contact's phone number. This field is required.

- **Email Address:** The point of contact's email address. This field is required. The email address specified in this field is the only one that will receive updates about a consortium's submission status.

- **Mailing Address 1:** The point of contact's mailing address. This field is required.

- **Mailing Address 2:** The second line of the point of contact's mailing address. This field is optional.

- **City:** The point of contact's city. This field is required.

- **County/Parish:** The county/parish of the point of contact. This field is optional.

- **State:** The point of contact's state. This field is required.

- **Postal Code:** The point of contact's postal/zip code. This field is required.

Exhibit 9-21 shows a screen capture of the 'Primary Contact Information' screen:

Exhibit 9-21: Consortium 'Primary Contact Information' Screen

Navigation: Enter data into all required fields and then select the 'Next' button to the 'PC Code(s)' screen.

9.4.3   PC Code(s) Screen

The 'PC Code(s)' screen is used to add chemicals and DCIs to a consortium. It also displays any previously added or submitted chemicals. The 'Add PC Code' pop-up on the screen is used to search for and add chemicals and their associated DCI(s) to a consortium.

PC Codes cannot be removed once submitted. Likewise, any PC Codes populated by OPP cannot be removed and will have a status of 'Nonremovable' in the 'Action' column. However, the DCIs associated with the consortium can be modified at any time.

Important: All PSP users registered to companies associated with DCIs added via the 'Add PC Code' pop-up will see the associated Consortium appear on their 'Consortium List' screen. These users will be able to view a consortium's status and download non-CBI PDF copies of record. However, they will not be able to edit, submit, or obtain any submitted files. Consortium Leads can control which companies have this access to the consortium by modifying the list of associated DCIs on this screen.

This screen behaves the same for both the 'create new consortium' and 'use existing consortium' workflows. Please refer to **Section 9.3.2** for assistance navigating the 'PC Code(s)' screen.

9.4.4　Manage Guidelines Screen

The 'Manage Guidelines' screen is used to select which guidelines for the PC Codes/ DCIs saved on the 'PC Code(s)' screen a consortium will support. As such, modifying the DCIs associated with a consortium before submission will affect the list of available guidelines.

Important: Any guidelines associated with the returned consortium cannot be removed. As with creating new consortia, any submitted guidelines also cannot be removed. Only guidelines added in the current session (before submission) can be removed. As seen in the exhibit below, the returned guidelines will have a status of 'Nonremovable' in the 'Action' column.

This screen behaves the same for both the 'create new consortium' and 'use existing consortium' workflows. Please refer to **Section 9.3.3** for assistance navigating the 'Manage Guidelines' screen.

Once the required guidelines have been added, select the 'Submit' button to begin the submission process. Please refer to **Section 4.8.1** for assistance with the submission process.

9.5　Submit Consortium Edits

After a consortium submission has successfully transmitted to OPP, the option to submit additional edits is provided via the 'Edit' status link on the 'Consortium List' screen. Consortium Leads can perform as many consortium 'edit' submissions as necessary throughout a consortium's life.

Important: Consortium Data Submissions cannot be made when a consortium is unlocked for editing until the edits are successfully transmitted to OPP. In-progress, un-submitted Consortium Data Submissions will be deleted when a consortium is unlocked for editing.

Exhibit 9-22 shows a screen capture of the 'Edit' link and pop-up on the 'Consortium List' screen:
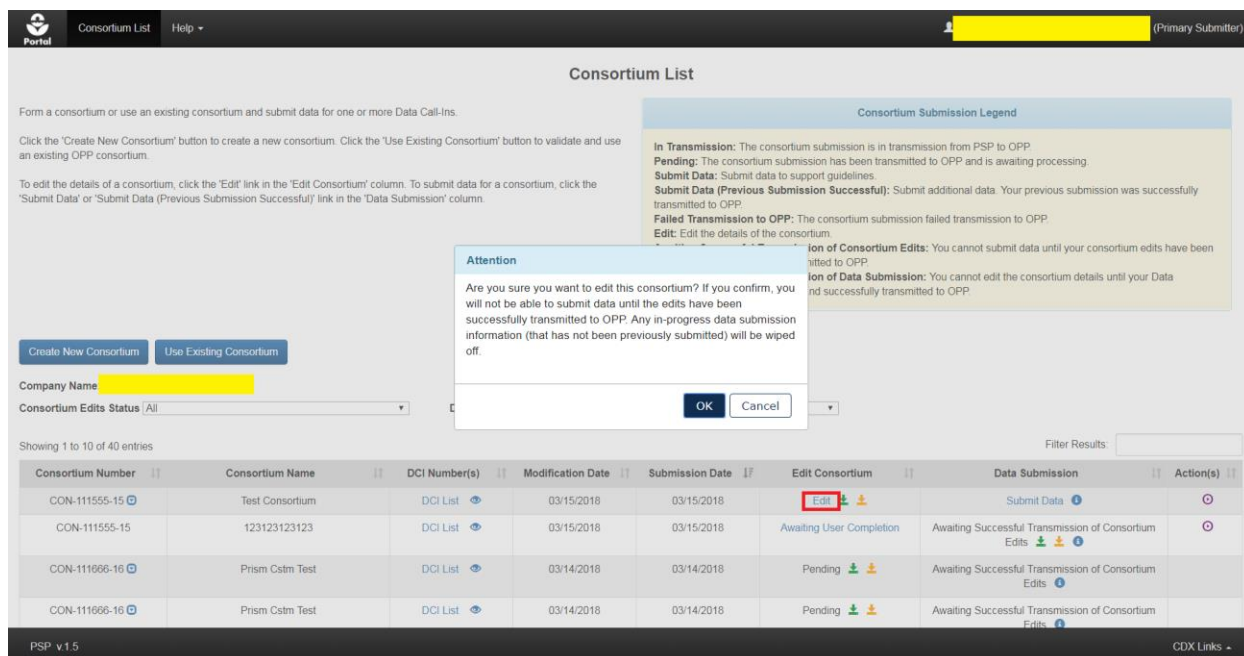
Exhibit 9-22: 'Consortium List' Screen – Edit Consortium Pop-Up

Navigation: Select the 'Edit' link in the 'Edit Consortium' column and then select the 'OK' button in the confirmation pop-up to proceed to the 'Enter Passphrase' screen. For additional information on the 'Enter Passphrase' screen refer to **Section 4.7.2**. After entering the correct passphrase, the 'Validate OPP Consortium' screen or the 'Primary Contact Information' screen (depending on the type of consortium submission) will display.

9.6 Transfer Consortium

Only a Consortium Lead can edit and make consortium submissions within PSP. The user who initiates the consortium creation/validation process within PSP is automatically designated the Consortium Lead. PSP supports transference of the Consortium Lead role to another company/user should the original Consortium Lead choose to abdicate their role.

The 'Transfer Consortium' icon is only available for consortia with a consortium ID and is only visible to a consortium's Consortium Lead. Consortia cannot be transferred when there are in transmission or pending consortium submissions.

![CDX logo]

Exhibit 9-23 shows a screen capture of 'Transfer Consortium' pop-up on the 'Consortium List' screen:
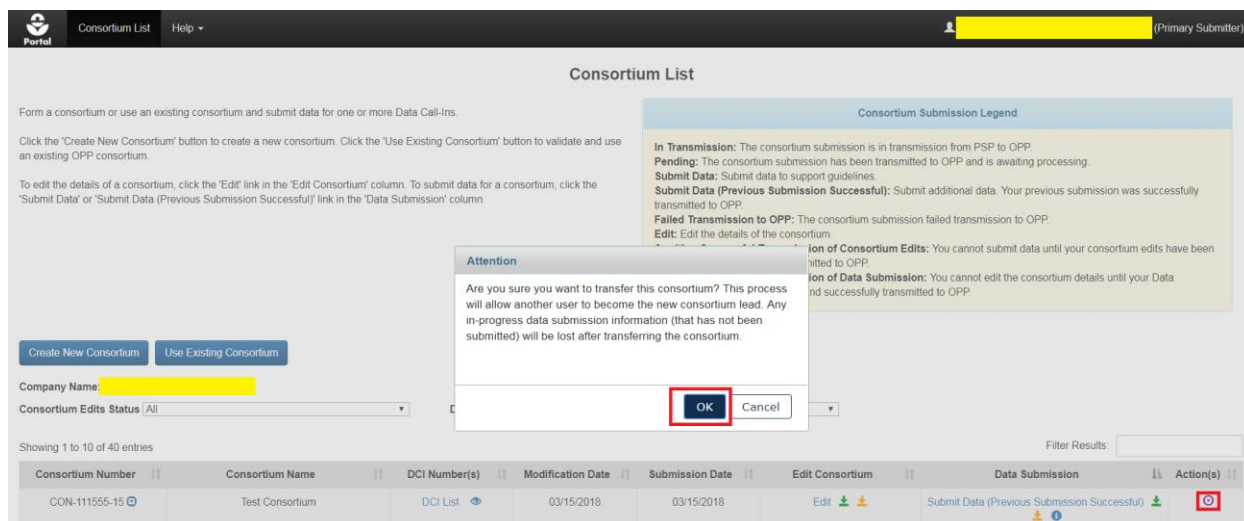
Exhibit 9-23: 'Consortium List' Screen – 'Transfer Consortium' Pop-Up

Navigation: To initiate the transfer process, select the 'Transfer Consortium' icon in the 'Action(s)' column and then select the 'OK' button in the resulting pop-up. The Transfer Consortium' pop-up will then display.

9.6.1   Transfer Consortium Pop-Up

The 'Transfer Consortium' pop-up offers two consortium transfer options:

- **Transfer the 'consortium lead' role only.** Your company will still be associated with the consortium and will retain read-only access. Your company's DCIs attached to the consortium will also remain.

- **Transfer the 'consortium lead' role and remove my company from the consortium.** Your company will no longer be associated with the consortium and will lose the ability to see it within PSP. Your company's DCIs attached to the consortium will also be removed.

Important: If a Consortium Lead selects the first option their company must be associated with at least one consortium DCI to retain read-only access. Additionally, the Consortium Lead role may only transfer to a company that is already associated with at least one DCI within the consortium.

Exhibit 9-24 shows a screen capture of the options available in the 'Transfer Consortium' pop-up:
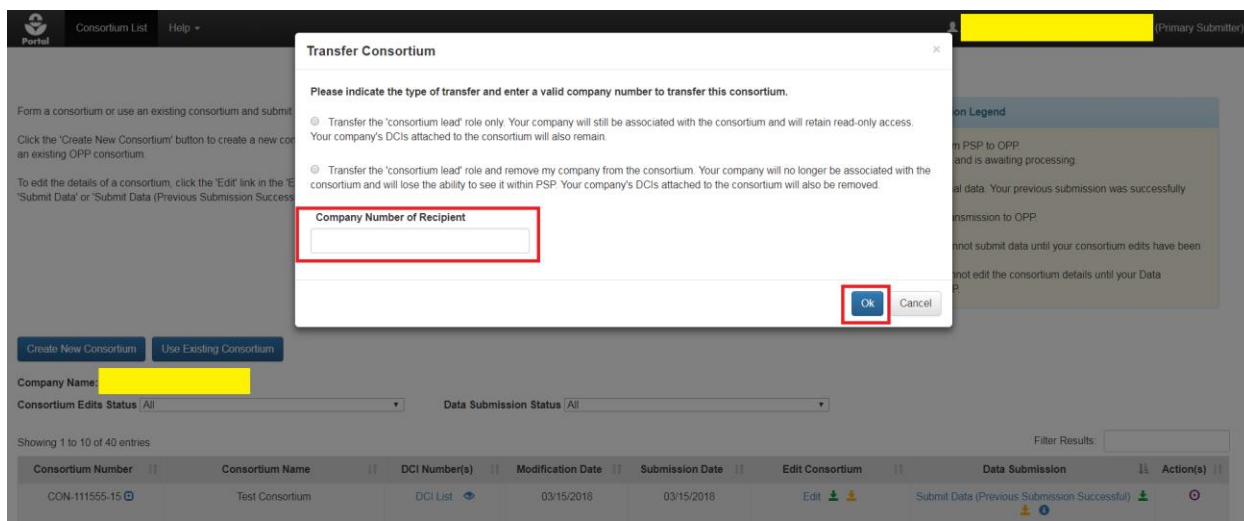
Exhibit 9-24: 'Transfer Consortium' Pop-Up

Navigation: Select the appropriate transfer option, enter the recipient's company number, and finally select the 'OK' button.

9.6.2   Complete Transfer Process

After the initial Consortium Lead successfully initiates the transfer process, the consortium will appear on the 'Consortium List' screen of all users associated with the target company and its status will be set to 'Awaiting User Completion' in the 'Edit Consortium' column. At this point, a user from the target company must claim the Consortium Lead role by unlocking the consortium.

Important: The same passphrase set by the previous Consortium Lead must be used to access/edit the consortium. The user who selects the 'Awaiting User Completion' link and enters the correct passphrase will be automatically designated as the new Consortium Lead.

Exhibit 9-25 shows a screen capture of how the 'Consortium List' screen displays for a user of a transfer target company:
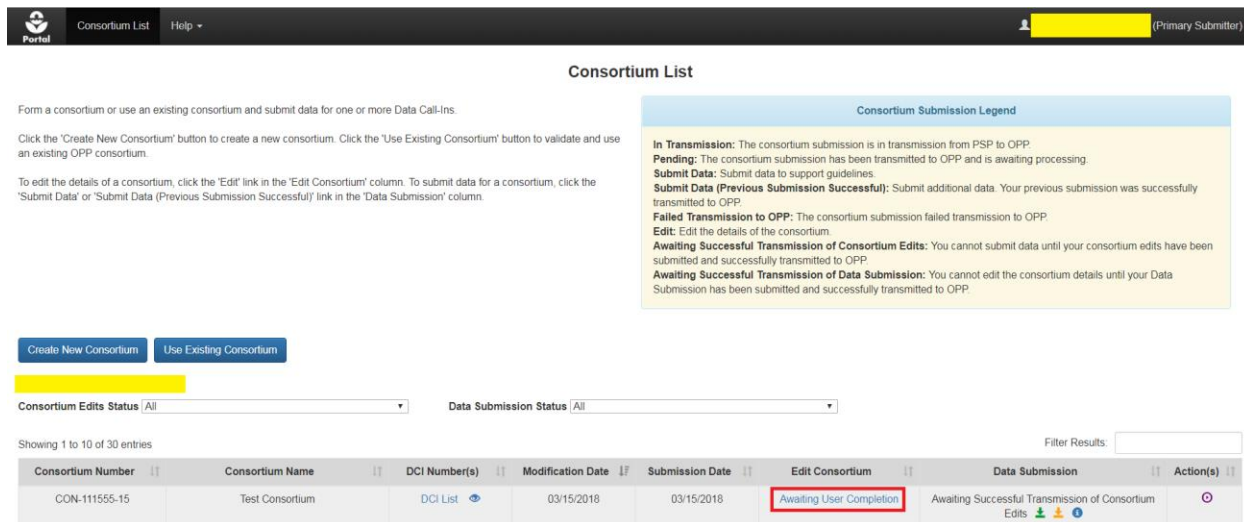
Exhibit 9-25: 'Consortium List' Screen – 'Awaiting User Completion' Link

Navigation: Select the 'Awaiting User Completion' link and enter the correct passphrase. Once the correct passphrase has been entered, the logged in user will become the new Consortium Lead.

After the Consortium Lead role transfer completes, the consortium will follow the visibility rules as detailed in **Section 9.2**.

9.7 Consortium Data Submission

A Consortium Data Submission allows Consortium Leads to submit documents and data to support previous responses. Previously submitted data for a consortium will be displayed when accessing a Data Submission.

After consortium edits are successfully transmitted to OPP, the option to submit data for the consortium's guidelines will become available.

9.7.1 Create Consortium Data Submission

To start a Data Submission, identify a consortium with a Data Submission status that includes a 'Submit Data' link (i.e., 'Submit Data' or 'Submit Data (Previous Submission Successful')).

Important: A separate passphrase must be created for each Data Submission. However, unlike other consortium submissions, if the passphrase for an in-progress Data Submission is forgotten, a new Data Submission may be created to overwrite the previous in-progress submission.

Exhibit 9-26 shows a screen capture of the 'Submit Data' link on the 'Consortium List' screen:
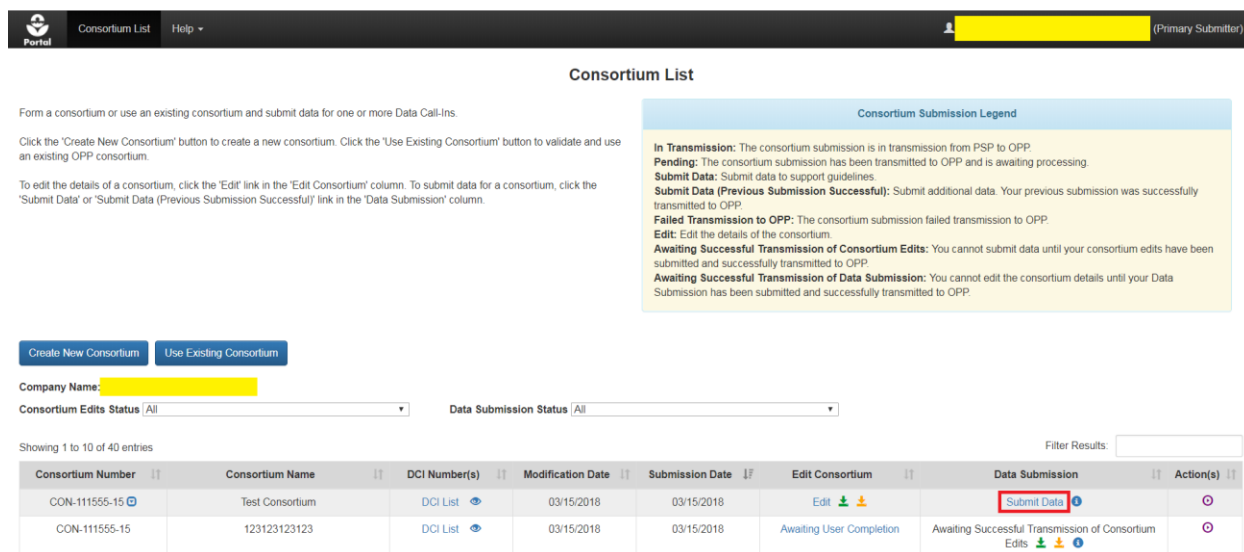
Exhibit 9-26: 'Consortium List' Screen - 'Submit Data' Link

**Navigation:** Select the 'Submit Data' link within the 'Data Submission' column to navigate to the 'Create Passphrase' screen. Refer to **Section 4.7.1** for assistance navigating the 'Create Passphrase' screen.

Exhibit 9-27 shows a screen capture of how to access the 'Previous Data Submissions' pop-up from the 'Consortium List' screen to create a new Data Submission because a passphrase was forgotten:
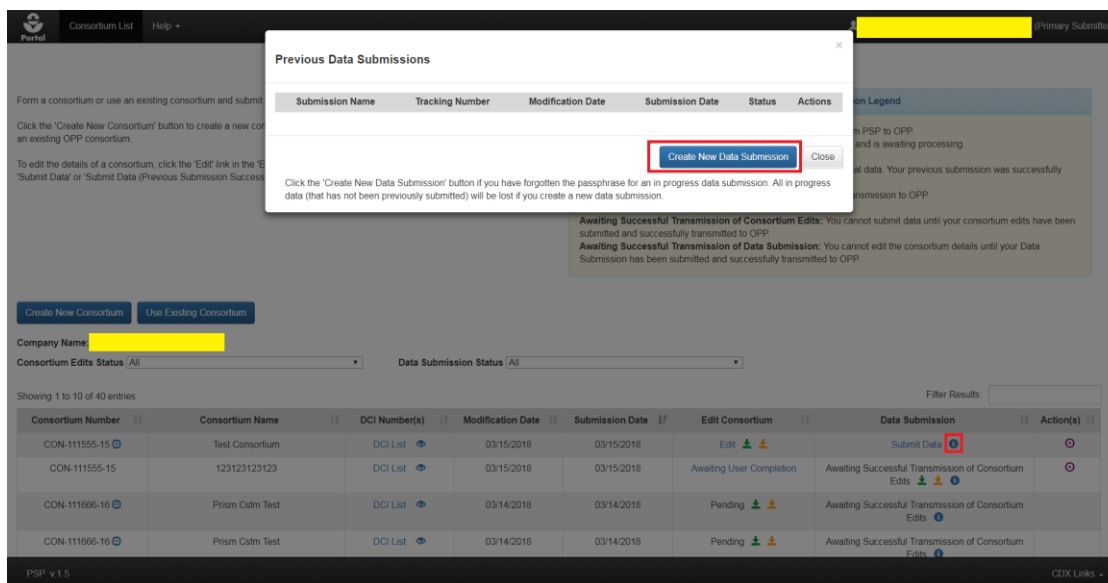
Exhibit 9-27: Consortium 'Previous Data Submissions' Pop-Up

Navigation: Select a 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' pop-up. Select the 'Create New Data Submission' button to create a passphrase for a new Data Submission. Please note that creating a new data submission will permanently delete any un-submitted, in-progress information.

9.7.2   Primary Contact Information Screen

The first screen within a Data Submission is the 'Primary Contact Information' screen. The data on this screen is based on the information submitted as part of the consortium edits and is for informational purposes only. As indicated by the help text at the top of the screen, consortium details cannot be edited while submitting data.

Refer to **Sections 9.3.1** and **9.4.2** for additional information about the 'Primary Contact Information' screen.

Exhibit 9-28 shows a screen capture of the 'Primary Contact Information' screen in a Data Submission:

**Exhibit 9-28: 'Primary Contact Information' Screen**

Navigation: Review the on-screen information and select the 'Next' button.

9.7.3 PC Code(s) Screen

As with the 'Primary Contact Information' screen, the information on the 'PC Code(s)' screen is based on previous consortium edits submission and cannot be edited.

Please refer to **Section 9.3.2** for additional information about the 'PC Code(s)' screen.

Exhibit 9-29 shows a screen capture of the 'PC Code(s)' screen in a Data Submission:
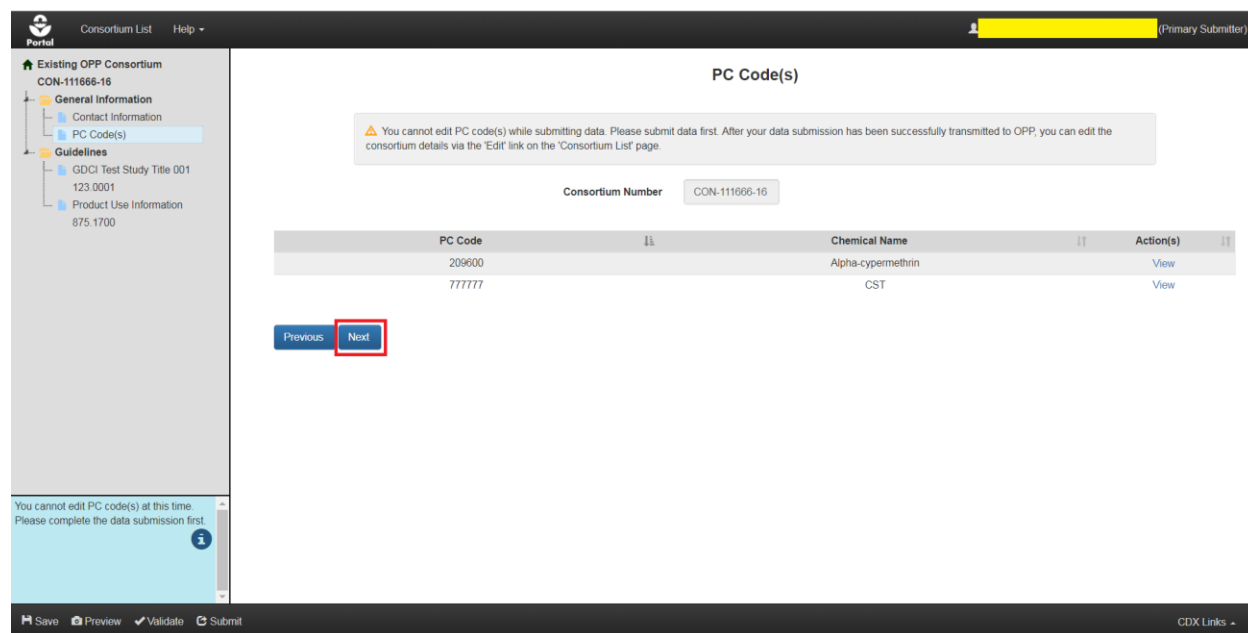
Exhibit 9-29: 'PC Code(s)' Screen

Navigation: Review the on-screen information and then select the 'Next' button.
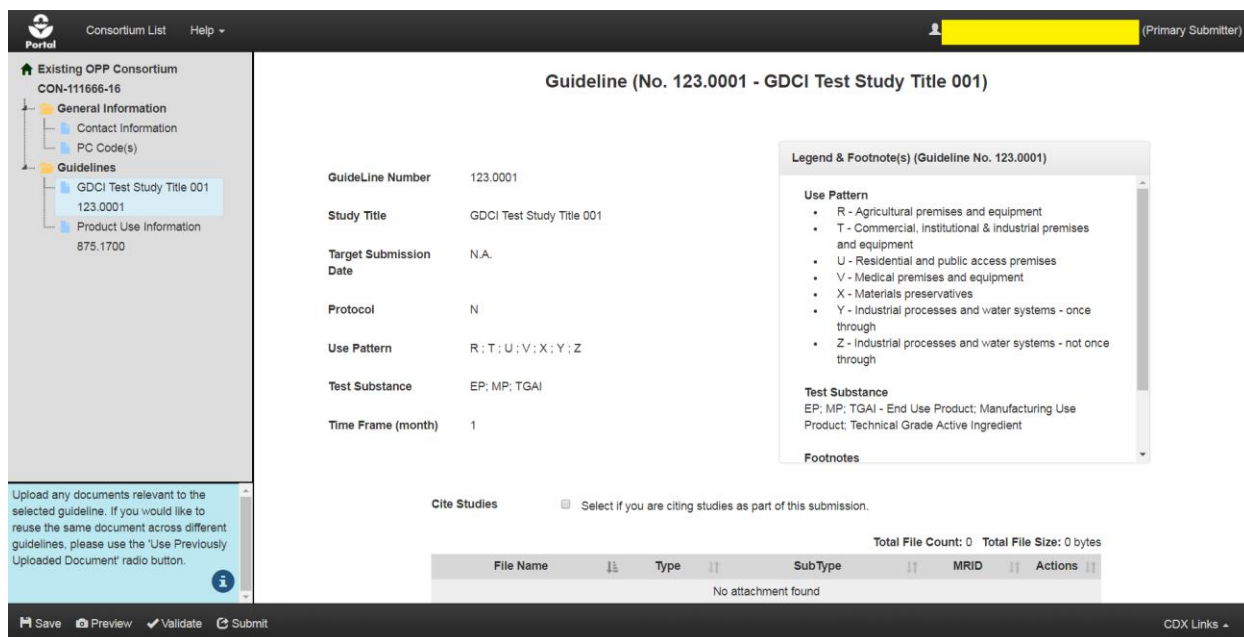
9.7.4 Guideline Details Screen(s)

Each guideline previously added to a consortium has a separate screen to provide the necessary supporting data for that guideline.

The following information/fields are displayed on each guideline 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.

- **Cite Studies:** Select the check box to cite one or more studies as part of the submission. Additional MRIDs can be cited by selecting the 'Cite an additional MRID Number' link. Remove all cited MRIDs by unchecking the 'Cite Studies' check box. This field is optional.

- **Legend & Footnote(s) section:** A legend that provides more information about the associated use patterns, test substances, and footnotes.

**Exhibit 9-30** shows a screen capture of the 'Guideline Details' screen:

Exhibit 9-30: 'Guideline Details' Screen

To upload documents, select the 'Add Document' radio button within the document upload section of the guideline screen. The following fields are displayed within the document upload section of the guideline 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:** Select 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 4.6** 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?:** Indicates 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 9-31 shows a screen capture of the 'Guideline Detail' screen with an uploaded file:
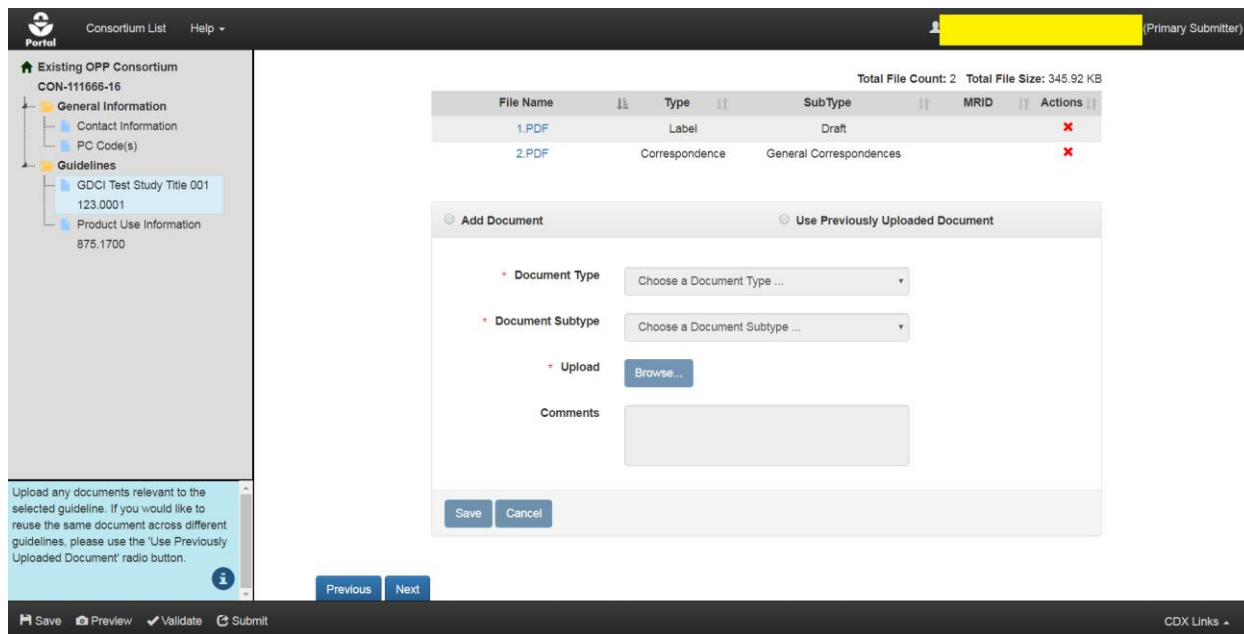

Exhibit 9-31: 'Guideline Detail' Screen – Add New Document

Navigation: Select the 'Add Document' radio button, select a document type and subtype, populate required fields, upload a document, and finally select the 'Save' button. The uploaded document will appear in the documents table in the center of the screen. To delete an uploaded document, select the corresponding red 'Delete' icon in the 'Action(s)' column.

The 'Use Previously Uploaded Document' radio button allows documents uploaded on another guideline to be reused for the current guideline without uploading the file again.

Exhibit 9-32 shows a screen capture of how to associate a previously uploaded document to a guideline on 'Guideline Detail' screen:
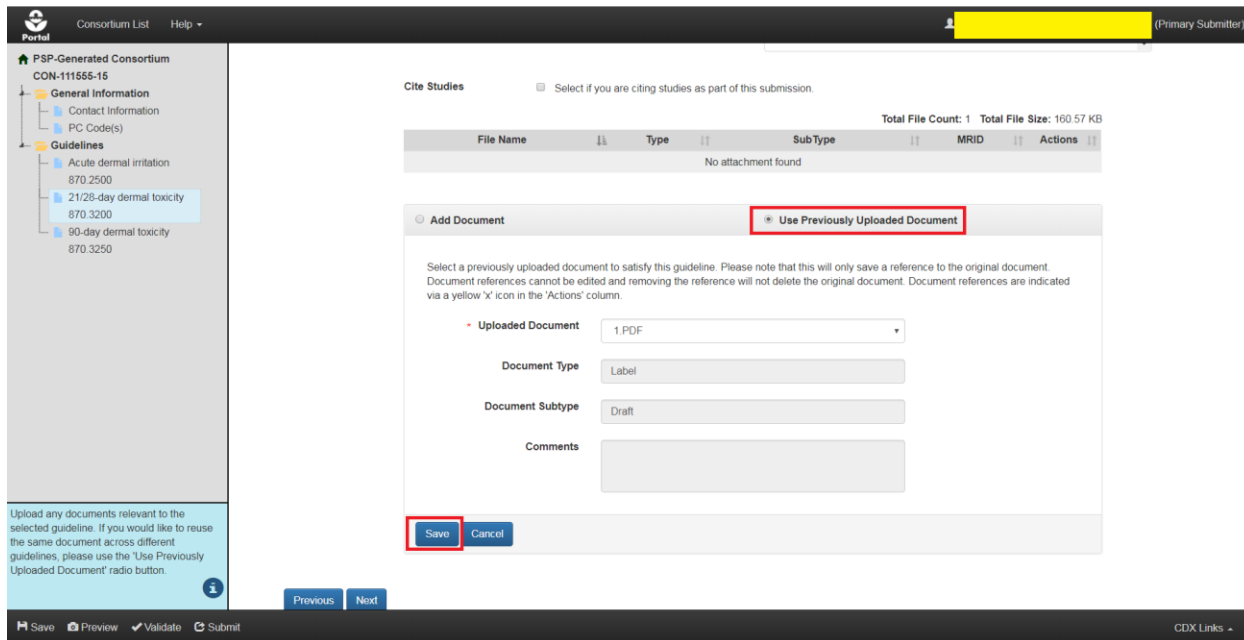
Exhibit 9-32: 'Guideline Details' Screen – Use Previously Uploaded Document

Navigation: Select the 'Use Previously Uploaded Document' radio button, select the appropriate document from the 'Uploaded Documents' drop-down menu (if available), and then select the 'Reuse' button. The referenced document will appear in the documents table. To remove a reference to an uploaded document select the corresponding yellow icon in the 'Action(s)' column.

Once all necessary documents/data have been added to the submission, select the 'Submit' button in the application footer to begin the submission process. Please refer to **Section 4.9** for assistance with the PSP submission process.

Exhibit 9-33 displays a screen capture of a sample data submission email notification:
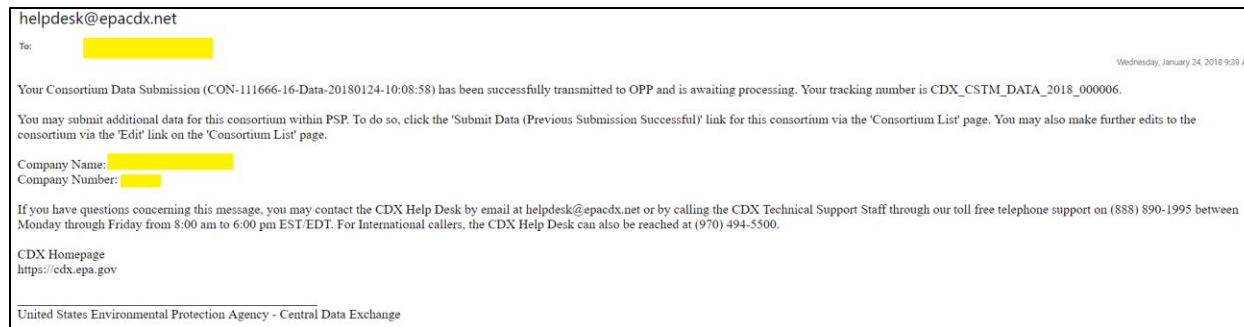
Exhibit 9-33: Consortium Successful Transmission Email Notification

9.7.5 Access Previous Consortium Data Submissions

Once a Data Submission successfully transmits to OPP, the status will transition to 'Submit Data (Previous Submission Successful)' within the 'Data Submission' column. The data submission will also be archived on the 'Previous Data Submissions' pop-up alongside any other previous Data Submissions. Additionally, the CoR icon for the most recent Data Submission will appear within the 'Data Submission' column. Refer to **Section 9.8** for additional information about consortium copies of record.

Exhibit 9-34 shows a screen capture of the 'Consortium List' screen containing a Data Submission with the 'Submit Data (Previous Submission Successful)' status:

Exhibit 9-34: 'Consortium List' Screen – Show Previous Data Submissions

Navigation: Select the 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' pop-up.

Exhibit 9-35 shows a screen capture of the previous Data Submission archive on the 'Previous Data Submissions' pop-up:
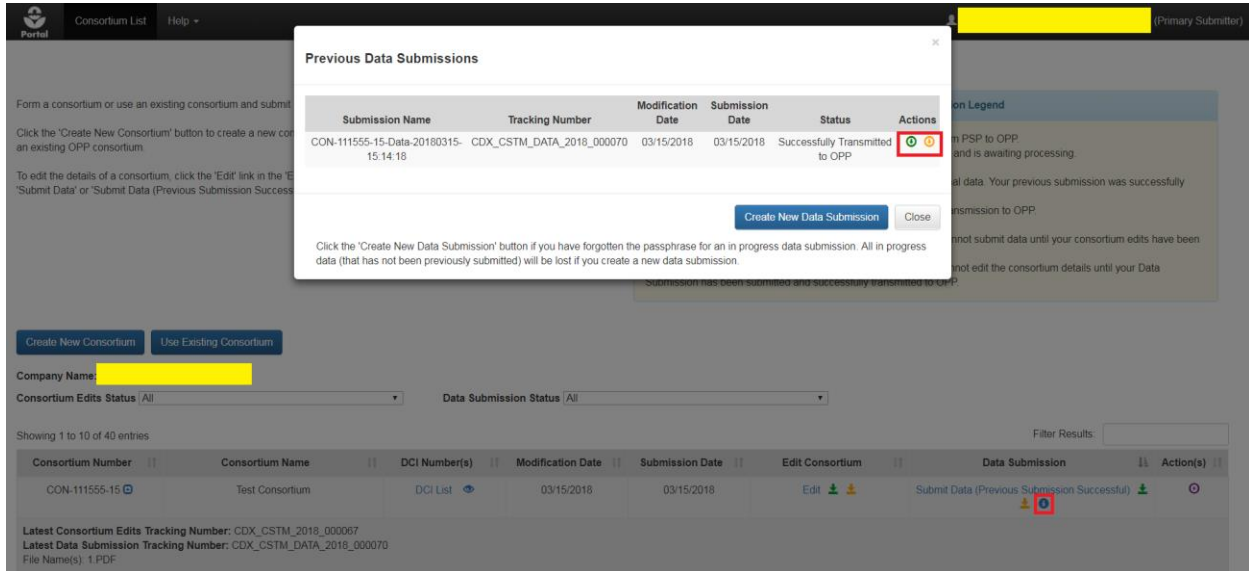
Exhibit 9-35: Consortium 'Previous Data Submissions' Pop-Up

Navigation: Select a download copy of record icon to access either a full copy of record or non-CBI PDF representation of a data submission.

## 9.8   Consortium Tracking Numbers and Copies of Record

The ability to download a copy of record, view a CDX Tracking Number, and view submission documents becomes available on the 'Consortium List' screen once a consortium or data submission is successfully submitted to OPP. Note that the copies of record available on the 'Consortium List' screen are only for the most recently submitted instance of a given submission.

Exhibit 9-36 shows a screen capture of CDX Tracking Numbers and submitted files for a Consortium's submissions:

Exhibit 9-36: 'Consortium List' Screen - 'Show Detail' Icon

Navigation: Select the 'Show Detail' icon to view CDX Tracking Numbers and submitted files for a Consortium submission.

Exhibit 9-37 shows a screen capture of the green 'Full Copy of Record' icons on the 'Consortium List' screen:
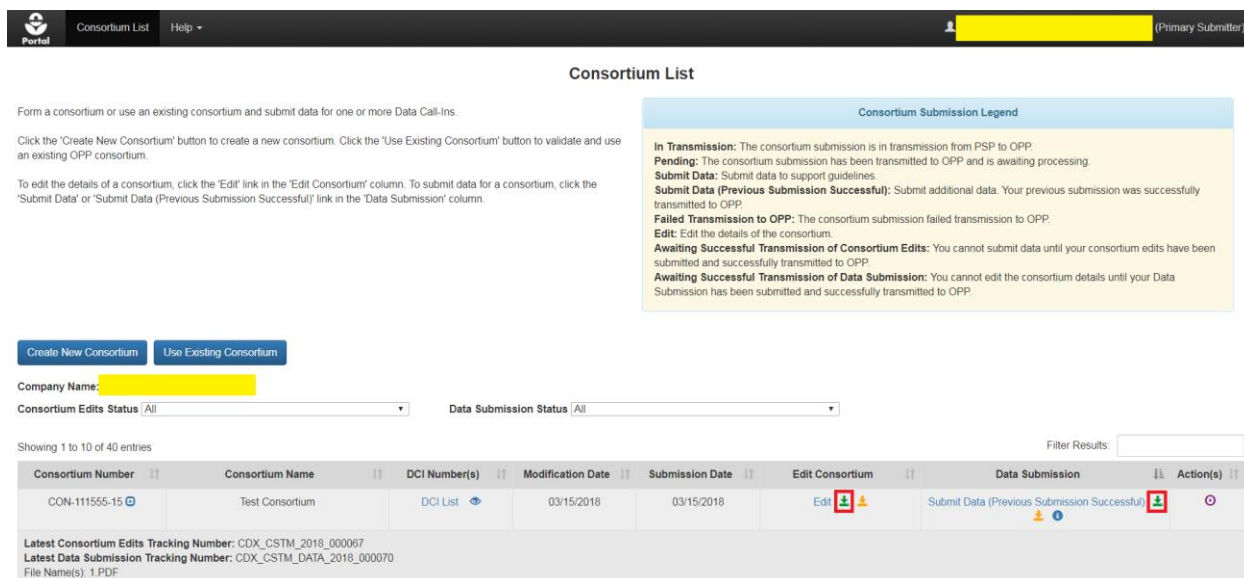
Exhibit 9-37: 'Consortium List' Screen - 'Full Copy of Record' Icons

Navigation: Select the green 'Full Copy of Record' icon in the 'Edit Consortium' or 'Data Submission' column to navigate to the 'Download Copy of Record' screen.

Exhibit 9-38 shows a screen capture of the 'eSignature Widget' pop-up on the 'Download Copy of Record' screen for a consortium submission:
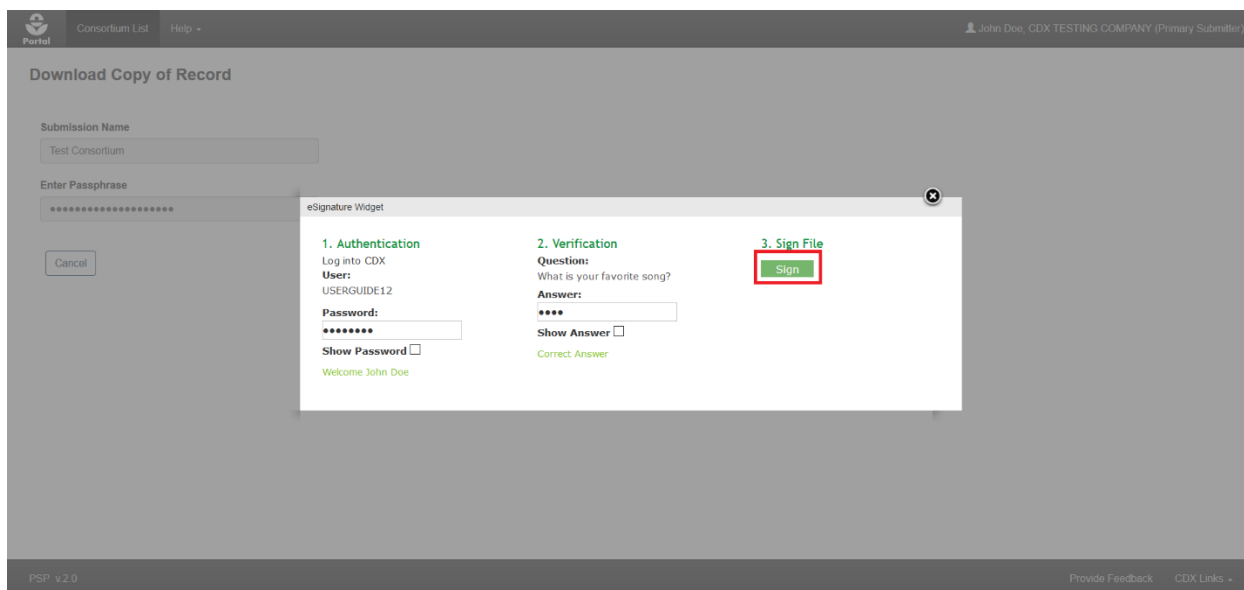
Exhibit 9-38: Consortium 'Download Copy of Record' Screen – 'eSignature Widget' Pop-Up

Navigation: Enter the passphrase for the submission and select the 'Continue' button. Next, select 'Accept' on the resulting pop-up message. Within the 'eSignature Widget' pop-up, enter the logged in user's CDX password and answer to one of the logged in user's CDX secret questions, and finally select the 'Sign' button.

Exhibit 9-39 shows a screen capture of the 'Download Copy of Record' screen for a consortium submission:
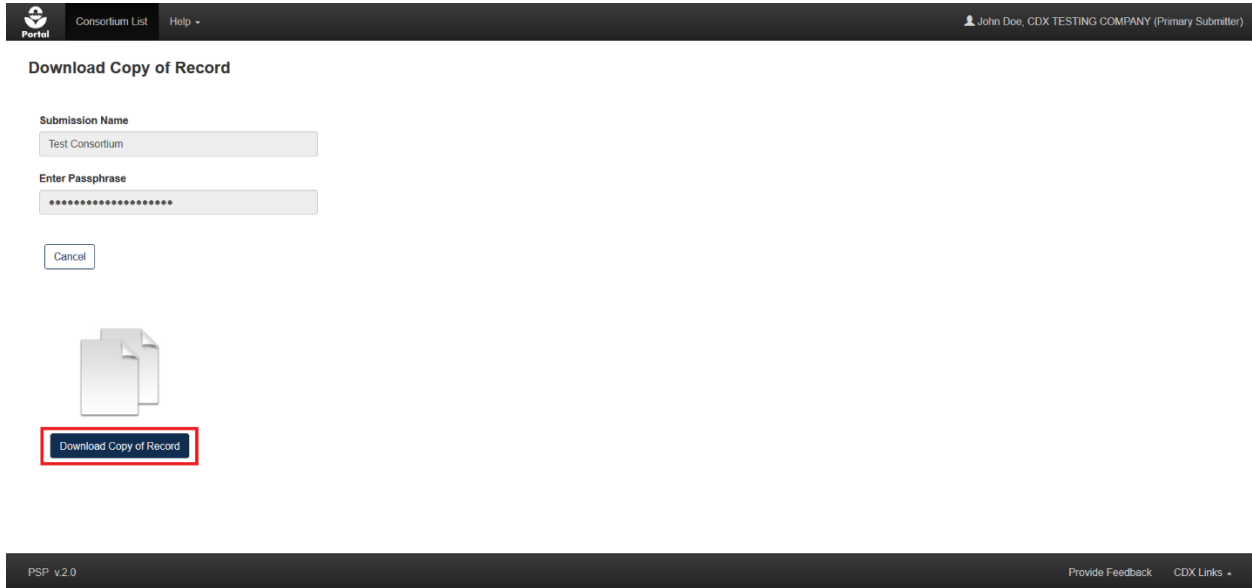
Exhibit 9-39: Consotrium 'Download Copy of Record' Screen

Navigation: Select the 'Download Copy of Record' button to download a zip file containing a PDF representation of the submission and any submitted files.

Non-CBI PDF representations of submissions are also available for download by selecting the yellow 'Download PDF Only' icon in the 'Edit Consortium' or 'Data Submission' columns. Selecting this icon does not require entering credentials since the PDF representation of the submission is non-CBI. This icon allows consortium members to see the details of consortium submissions without granting access to CBI documents.

Exhibit 9-40 shows a screen capture of the yellow 'Download Non-CBI PDF' icons on the 'Consortium List' screen:

Exhibit 9-40: 'Consortium List' Screen - 'Download Non-CBI PDF' Icons

Navigation: Select the yellow 'Download PDF Only' icon in the 'Edit Consortium' or 'Data Submission' column to download a non-CBI PDF representation of the submission.

10   Voluntary Data Submissions

This section describes the process to prepare a voluntary (i.e., non-DCI) data submission associated with a specific registration review case number through PSP. As elsewhere in PSP, voluntary data submissions (VDS) support real-time validations, status updates, and email notifications to ensure a streamlined experience.

Note: Both Primary Submitter and Authorized Agent users associated with a company number will be able to share and see the same submissions.

Exhibit 10-1 shows a screen capture of how to access the 'Voluntary Data Submission' application from the PSP 'Home' screen:
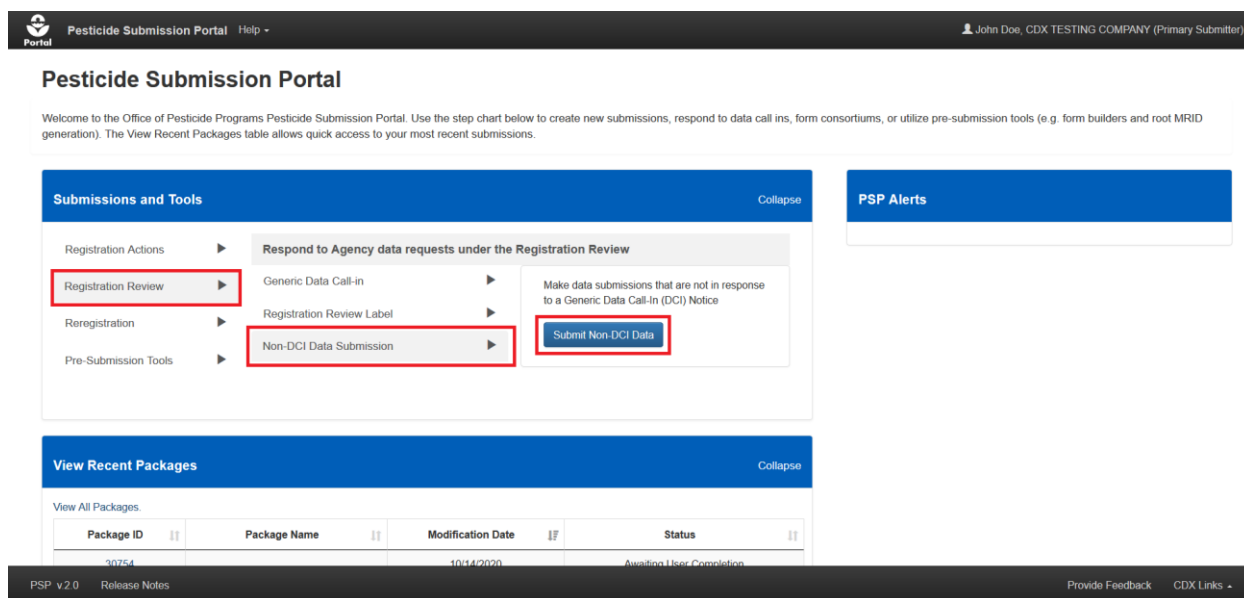
Exhibit 10-1: PSP 'Home' Screen – Non-DCI/Voluntary Data Submission Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Review' option in the first column, next select the 'Non-DCI Data Submission' option in the second column, and finally select the 'Submit Non-DCI Data' button.

10.1   Voluntary Data Submission List Screen

The 'Voluntary Data Submission List' screen displays a company's voluntary data submissions and their associated details and statuses. Both in-progress and submitted voluntary data submissions are visible via this screen. The 'Voluntary Data Submission List' screen has the following features to assist a registrant locate and obtain up-to-date submission information:

- The 'Viewing' and 'Status' filters narrow displayed results to the selected option(s)

- Each column is sortable to cluster similar submissions

- Completed submissions display a 'Show Detail' icon next to the VDS ID number that reveals the tracking numbers associated with the submission

- Completed Data Submissions can be viewed by selecting the blue "i" icon in the 'Status' column

- The 'Status' column indicates at which stage a submission is. A complete listing of all statuses is displayed on the screen

Exhibit 10-2 shows a screen capture of the 'Voluntary Data Submission List' screen:

Exhibit 10-2: 'Voluntary Data Submission List' Screen

10.2   Create and Prepare a Voluntary Data Submission

To create a voluntary data submission, select the 'Create Voluntary Data Submission' button on the 'Voluntary Data Submission List' screen or identify a previously made voluntary data submission with the 'Submit Data (Previous Submission Successful' status.

Important: A separate passphrase must be created for each voluntary data submission. However, unlike other submission types, if the passphrase for an in-progress, previously submitted voluntary data submission is forgotten, a new submission may be created to overwrite the previous in-progress submission.

Exhibit 10-3 shows a screen capture of how to create a voluntary data submission on the 'Voluntary Data Submission List' screen:

Exhibit 10-3: 'Voluntary Data Submission List' Screen – Create Submission

Navigation: Select either the 'Create Voluntary Data Submission' button or the 'Submit Data (Previous Submission Successful)' link to navigate to the 'Create Passphrase' screen and create a new submission. Refer to **Section 4.7.1** for assistance with navigating the 'Create Passphrase' screen.

Exhibit 10-4 shows a screen capture of how to access the 'Previous Data Submissions' screen from the 'Voluntary Data Submission List' screen to create a new submission because a passphrase was forgotten:
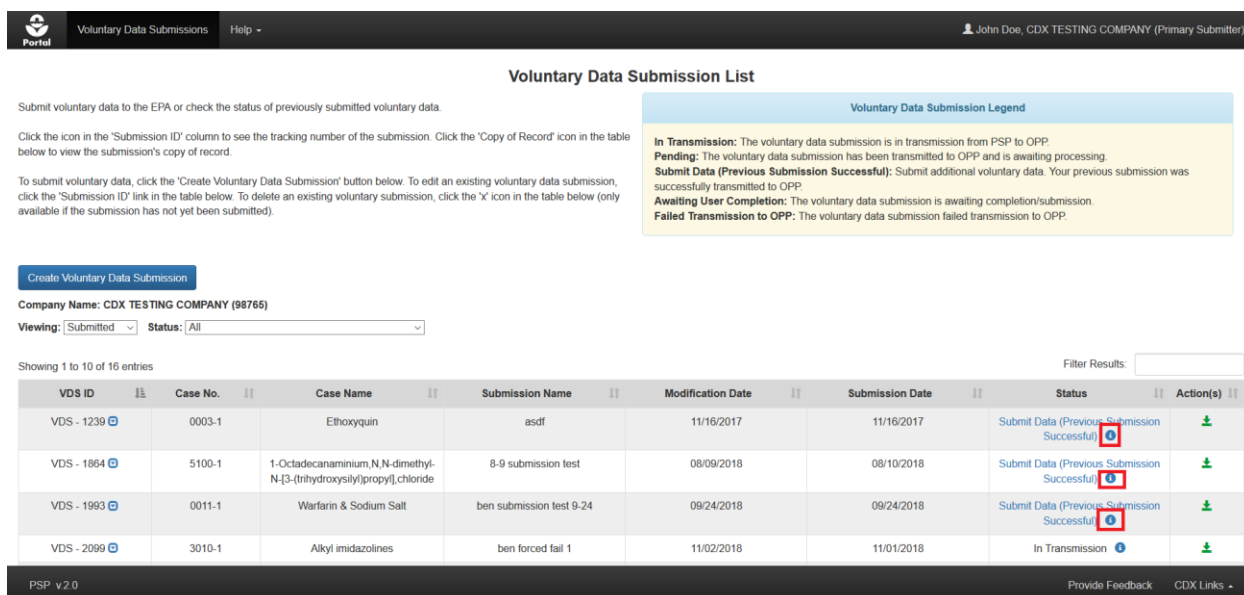
Exhibit 10-4: 'Voluntary Data Submission List' Screen - 'Show Previous Data Submissions' Icon

Navigation: Select the 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' pop-up.

Exhibit 10-5 shows a screen capture of how to create a submission on the 'Previous Data Submissions' pop-up because a passphrase was forgotten for an in-progress Submission:
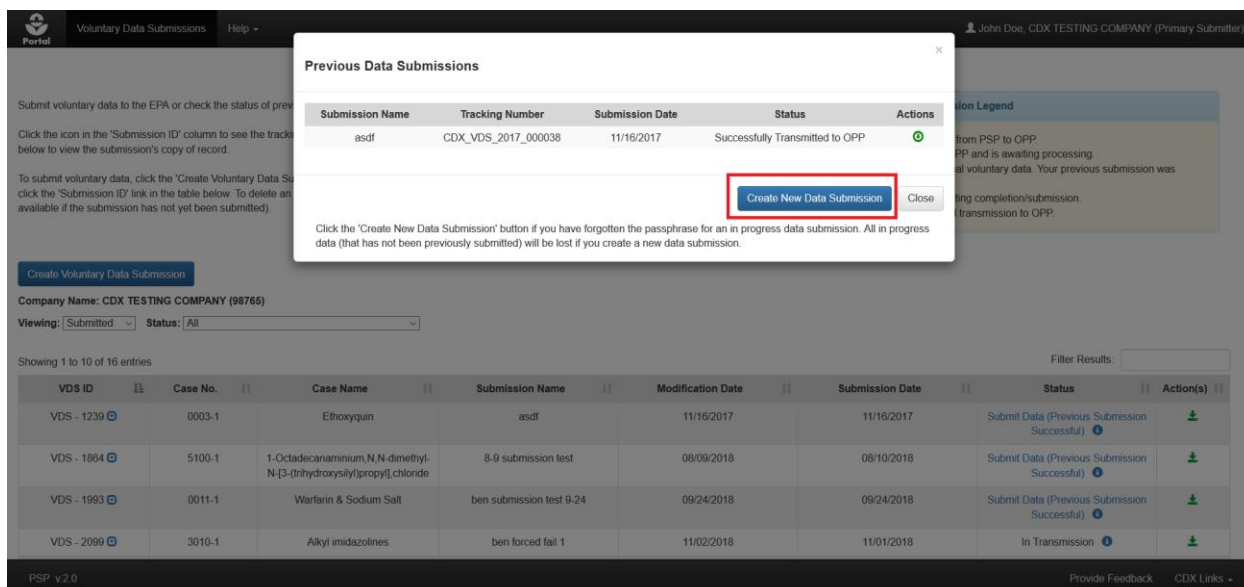
Exhibit 10-5: VDS 'Previous Data Submissions' Pop-Up

Navigation: Select the 'Create New Data Submission' button to create a passphrase for a new Data Submission. Please note that creating a new data submission will permanently delete any un-submitted, in-progress information.

10.2.1   Voluntary Data Submission Screen

After creating or entering a passphrase, the application navigates to the first and only screen within a voluntary data submission, the 'Voluntary Data Submission' screen. This screen allows all necessary information for a submission to be entered to be entered.

The following fields display on the 'Voluntary Data Submission' screen:

- **Submission Name:** Enter a name for the voluntary data submission. This field is required.

- **Case Number:** Indicate the registration review case number for a submission. This field is required.

- **Registration Review Cycle:** Indicate the registration review cycle for the entered case number. This field auto-populates and is not editable if a case number belongs to only one registration review cycle. This field is required.

- **Case Name:** The corresponding name for the entered case number. This field is not editable and auto-populates 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 field is required.

- **Cite Studies:** Select the check box to cite a study as part of the submission. Additional studies can be cited by selecting the 'Cite an additional MRID Number' link. Uncheck the 'Cite Studies' check box to remove all cited MRIDs. At least one MRID is required if the 'Cite Studies' check box is checked.

- **Company Name:** The name of the company under which the submission will be made. This field is not editable and is pre-populated from CDX.

Exhibit 10-6 shows a screen capture of the 'Voluntary Data Submission' screen with data entered:

Exhibit 10-6: VDS 'Voluntary Data Submission' Screen

Navigation: Enter data into the displayed fields as necessary.

Follow-up data submissions for a case number each start with a clean form (i.e., previously submitted information and documents do not display). However, the 'Case Number,' 'Registration Review Cycle,' and 'Case Name' fields are disabled and populated with data from a case's previous submission.

Exhibit 10-7 shows a screen capture of the 'Voluntary Data Submission' screen for a follow-up voluntary data submission:

Exhibit 10-7: VDS 'Voluntary Data Submission' Screen – Follow-Up Submission

After entering data into the fields on the 'Voluntary Data Submission' screen, users are required to upload at least one document.

Exhibit 10-8 shows a screen capture of the document upload section on the 'Voluntary Data Submission' screen:

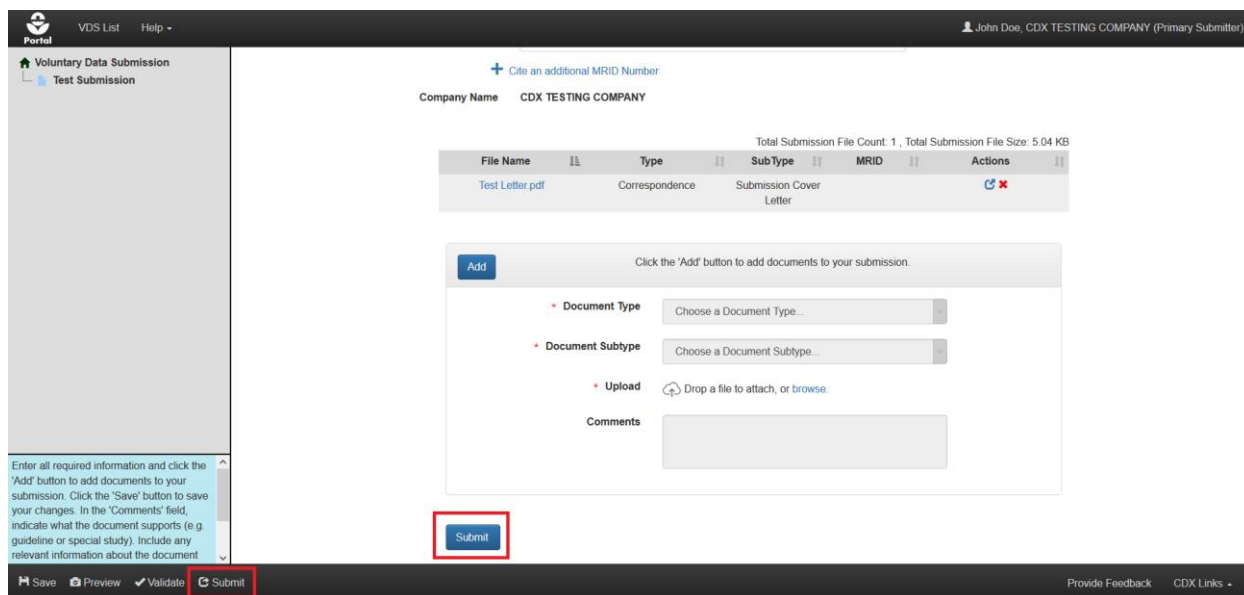**Exhibit 10-8: VDS 'Voluntary Data Submission' Screen – Upload Documents**

Navigation: Select the 'Add' button, select a document type and subtype, populate required fields, upload a document, and finally select the 'Save' button. The uploaded document will appear in the documents table in the center of the screen. To delete an uploaded document, select the corresponding red 'Delete' icon in the 'Action(s)' column.

Entered MRIDs are validated upon submission or when the 'Validate' button is selected in the application footer. Refer to **Section 5** for additional information about MRIDs.

Both Primary Submitters and Authorized Agents have the ability to make voluntary data submissions. Once all required information has been entered and the screen passes validation, the system will allow submission.

Exhibit 10-9 shows a screen capture of how to initiate the submission process on the 'Voluntary Data Submission' screen:

Exhibit 10-9: 'Voluntary Data Submission' Screen – Initiate Submission Process

Navigation: Select the 'Submit' button either in the application footer or on the screen to begin the submission process. Please refer to **Section 4.9** for assistance with the submission process.

Exhibit 10-10 shows a screen capture of a sample voluntary data submission email notification:
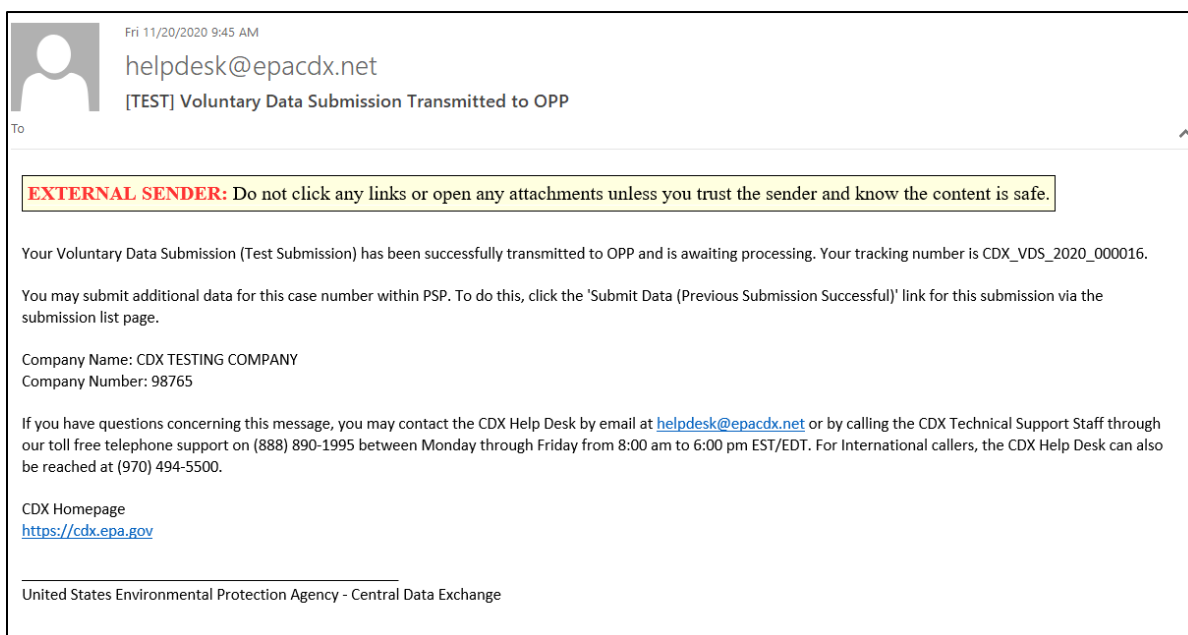
Exhibit 10-10: VDS Successful Transmission Email Notification

![CDX logo]

10.3 Continue Working on Saved Voluntary Data Submissions

In progress voluntary data submissions (i.e., submissions with the 'Awaiting User Completion' status) can be accessed via the 'Voluntary Data Submission List' screen.

Exhibit 10-11 shows a screen capture of the 'Voluntary Data Submission List' screen with an in-progress submission:

Exhibit 10-11: 'Voluntary Data Submission List' Screen – Manage In-Progress Submissions

Navigation: Select the blue link in the 'VDS ID' column to navigate to the 'Enter Passphrase' screen and access the selected submission. To delete a submission, select the corresponding 'Delete' icon in the 'Action(s)' column.

10.4 Voluntary Data Submission Tracking Number and Copy of Record

The ability to download a copy of record, view a CDX Tracking Number, and view submission documents becomes available on the 'Voluntary Data Submission List' screen once a submission is successfully submitted to OPP. Note that the copies of record available on the 'Voluntary Data Submission List' screen are only for the most recently submitted instance of a given submission.

Exhibit 10-12 shows a screen capture of CDX Tracking Numbers and submitted documents:

Exhibit 10-12: 'Voluntary Data Submission List' Screen - 'Show Detail' Icon

Navigation: Select the 'Show Detail' icon to view the CDX Tracking Number and submission documents.

Exhibit 10-13 shows a screen capture of the green 'Copy of Record' icons on the 'Voluntary Data Submission List' screen:

Exhibit 10-13: 'Voluntary Data Submission List' Screen - 'Copy of Record' Icon

Navigation: Select a green 'Copy of Record' icon in the 'Action(s)' column to navigate to the 'Download Copy of Record' screen.

Exhibit 10-14 shows a screen capture of the 'eSignature Widget' pop-up on the 'Download Copy of Record' screen:
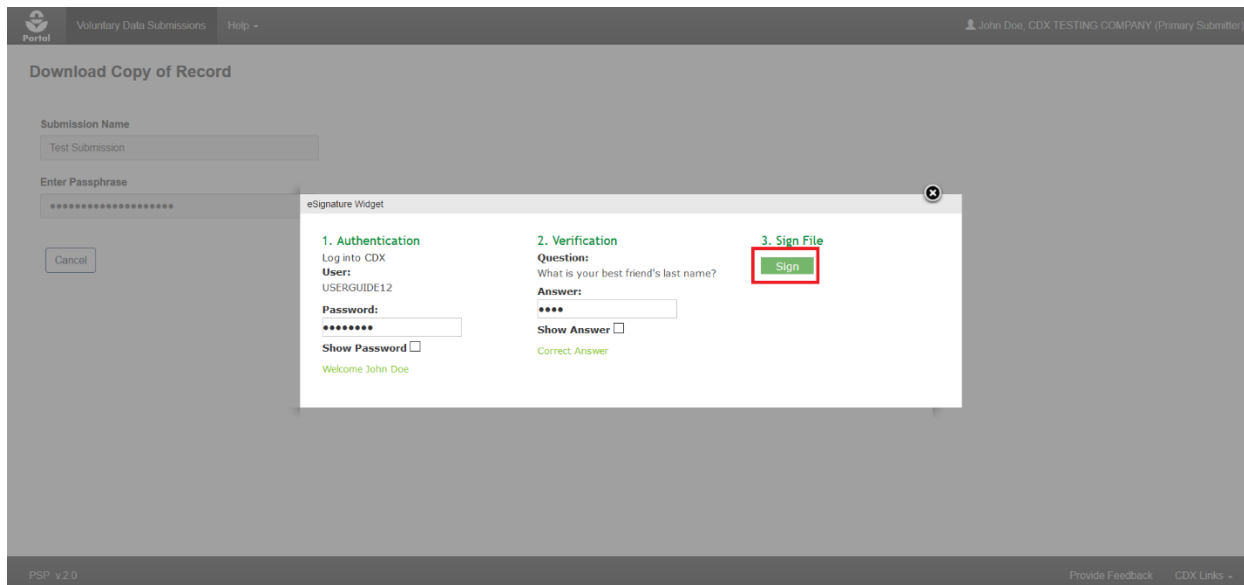
Exhibit 10-14: VDS 'Download Copy of Record' Screen – 'eSignature Widget' Pop-Up

Navigation: Enter the passphrase for the submission and then select the 'Continue' button. Select 'Accept' on the resulting pop-up message. Within the 'eSignature Widget' pop-up, enter the logged in user's CDX password and answer to one of the logged in user's CDX secret questions, and finally select the 'Sign' button.

Exhibit 10-15 shows a screen capture of the 'Download Copy of Record' screen:
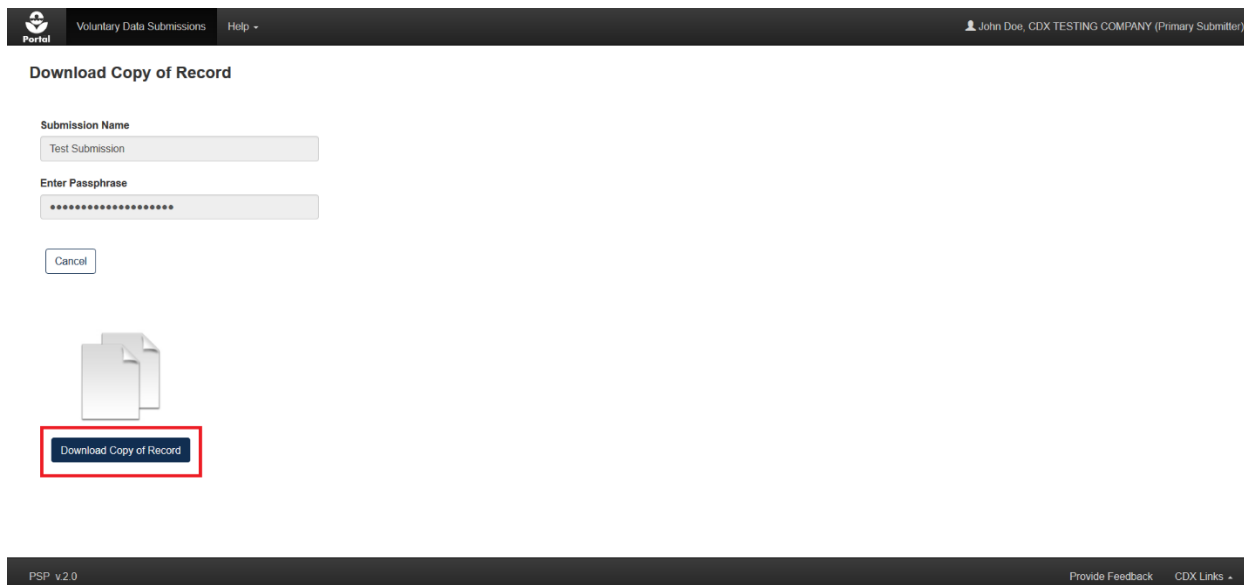
Exhibit 10-15: VDS 'Download Copy of Record' Screen – Download Button

Navigation: Select the 'Download Copy of Record' button to download a zip file containing a PDF representation of the submission and any submitted files.

11 Registration Review Label Submissions

This section describes the process to prepare a registration review label submission in PSP. Users may upload submission cover letters, 8570-1 forms, and draft labels to support their submission. As elsewhere in PSP, registration review label (RRL) submissions support real-time validations, status updates, and email notifications to ensure a streamlined experience.

Note: Both Primary Submitter and Authorized Agent users associated with a company number will be able to share and see the same submissions.

Exhibit 11-1 shows a screen capture of how to access the 'Registration Review Label' application from the PSP 'Home' screen:
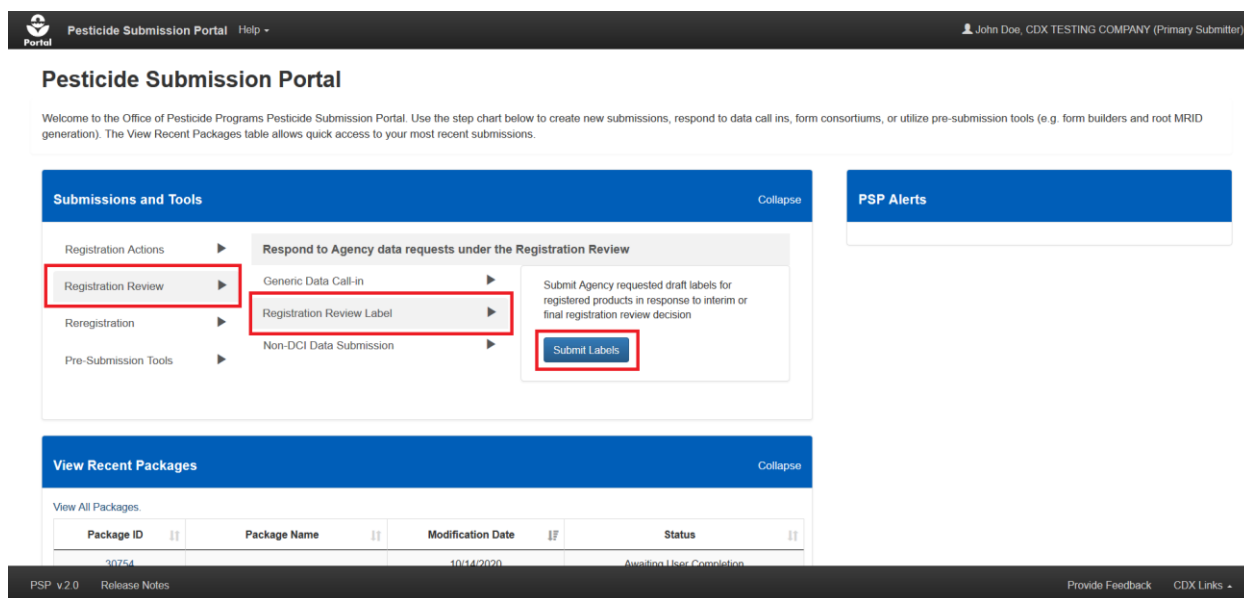
Exhibit 11-1: Pesticide Submission Portal – Registration Review Label Option

Navigation: In the 'Submissions and Tools' panel, select the 'Registration Review' option in the first column, next select the 'Registration Review Label' option in the second column, and finally select the 'Submit Labels' button.

11.1 Registration Review Label Submission List Screen

The 'Registration Review Label Submission List' screen displays a company's registration review label submissions and their associated details and statuses. Both in-progress and submitted registration review label submissions are visible via this screen. The 'Registration Review Label Submission List' screen has the following features to assist a registrant locate and obtain up-to-date submission information:

- The 'Viewing' and 'Status' filters narrow displayed results to the selected option(s)

- Each column is sortable to cluster similar submissions

- Completed submissions display a 'Show Detail' icon next to the RRL ID number that reveals the tracking numbers associated with the submission

- Completed Data Submissions can be viewed by selecting the blue "i" icon in the 'Status' column

- The 'Status' column indicates at which stage a submission is. A complete listing of all statuses is displayed on the screen.

Exhibit 11-2 shows a screen capture of the 'Registration Review Label Submission List' screen:

Exhibit 11-2: 'Registration Review Label Submission List' Screen

11.2   Create and Prepare a Registration Review Label Submission

To create a registration review label submission, select the 'Create Registration Review Label Submission' button on the 'Registration Review Label Submission List' screen or identify a previously made registration review label submission with the 'Submit Data (Previous Submission Successful' status.

Important: A separate passphrase must be created for each registration review label submission. However, unlike other submission types, if the passphrase for an in-progress, previously submitted registration review label submission is forgotten, a new submission may be created to overwrite the previous in-progress submission.

Exhibit 11-3 shows a screen capture of how to create a registration review label submission on the 'Registration Review Label Submission List' screen:

Exhibit 11-3: 'Registration Review Label Submission List' Screen – Create Submission

Navigation: Select either the 'Create Registration Review Label Submission' button or the 'Submit Data (Previous Submission Successful)' link to navigate to the 'Create Passphrase' screen and create a new submission. Refer to **Section 4.7.1** for assistance with navigating the 'Create Passphrase' screen.

Exhibit 11-4 shows a screen capture of how to access the 'Previous Data Submissions' screen from the 'Registration Review Label Submission List' screen to create a new submission because a passphrase was forgotten:

Exhibit 11-4: 'Registration Review Label Submission List' Screen - 'Show Previous Submission' Icon

Navigation: Select a 'Show Previous Data Submission(s)' blue 'i' icon in the 'Data Submission' column to navigate to the 'Previous Data Submissions' pop-up.

Exhibit 11-5 shows a screen capture of how to create a submission on the 'Previous Data Submissions' pop-up because a passphrase was forgotten for an in-progress submission:

Exhibit 11-5: RRL 'Previous Data Submissions' Pop-Up

Navigation: Select the 'Create New Data Submission' button to create a passphrase for a new Data Submission. Please note that creating a new data submission will completely delete any un-submitted, in-progress information.

11.2.1   Registration Review Label Screen

After creating or entering a passphrase, the application navigates to the first and only screen within a voluntary data submission, the 'Registration Review Label' screen. This screen allows all necessary information for a submission to be entered to be entered.

The following fields are displayed on the 'Registration Review Label' screen:

- **Submission Name:** Enter a name for the registration review label submission. This field is required.

- **Case Number:** Indicate the registration review case number for a submission. This field is required.

- **Registration Review Cycle:** Indicate the registration review cycle for the entered case number. This field auto-populates and is not editable if a case number belongs to only one registration review cycle. This field is required.

- **Case Name:** The corresponding name for the entered case number. This field is not editable and auto-populates when a valid case number is entered into the 'Case Number' field.

- **Reason for Submitting:** Please explain the reason for the registration review label submission. This field is required.

- **Company Name:** The name of the company under which the submission will be made. This field is not editable and is pulled from CDX.

Exhibit 11-6 shows a screen capture of the 'Registration Review Label' screen with data entered:

Exhibit 11-6: RRL 'Registration Review Label' Screen

Navigation: Enter data into the displayed fields as necessary.

Follow-up submissions for a case number each start with a clean form (i.e., previously submitted information and documents do not display). However, the 'Case Number,' 'Registration Review

Cycle,' and 'Case Name' fields are disabled and populated with data from a case's previous submission.

Exhibit 11-7 shows a screen capture of the 'Registration Review Label' screen for a follow-up submission:

Exhibit 11-7: RRL 'Registration Review Label' Screen - Follow-Up Submission

After entering data into the fields on the 'Registration Review Label' screen, users are required to upload at least one of each of the available document types (i.e., submission cover letter, 8570-1 form, and draft label) for an initial submission and at least one 8570-1 form and one draft label for each product registration number specified.

Exhibit 11-8 below displays a screen capture of the document upload section of the 'Registration Review Label' screen:
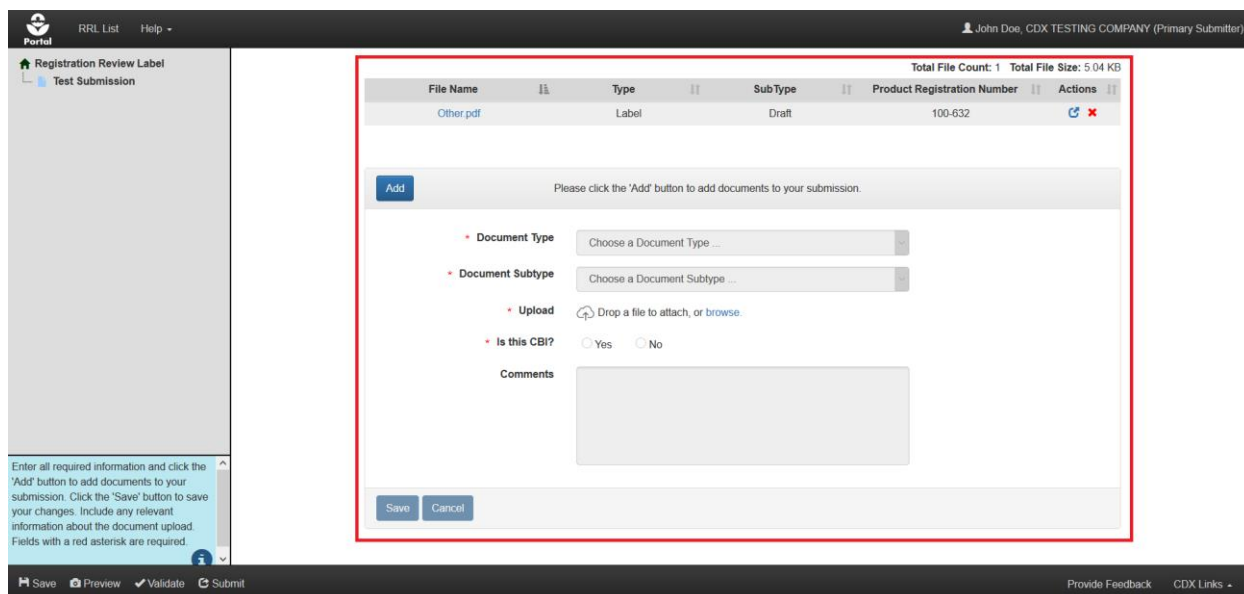
Exhibit 11-8: RRL 'Registration Review Label' Screen – Upload Documents

Navigation: Select the 'Add' button, select a document type and subtype, populate required fields, upload a document, and finally select the 'Save' button. The uploaded document will appear in the documents table in the center of the screen. To delete an uploaded document, select the corresponding red 'Delete' icon in the 'Action(s)' column.

Note: Registration numbers are validated at the time the document is uploaded and during the submission process.

Both Primary Submitters and Authorized Agents have the ability to submit registration review labels. Once all required information has been entered and the screen passes validation, the system will allow submission.

Exhibit 11-9 shows a screen capture of how to initiate the submission process on the 'Registration Review Label' screen:
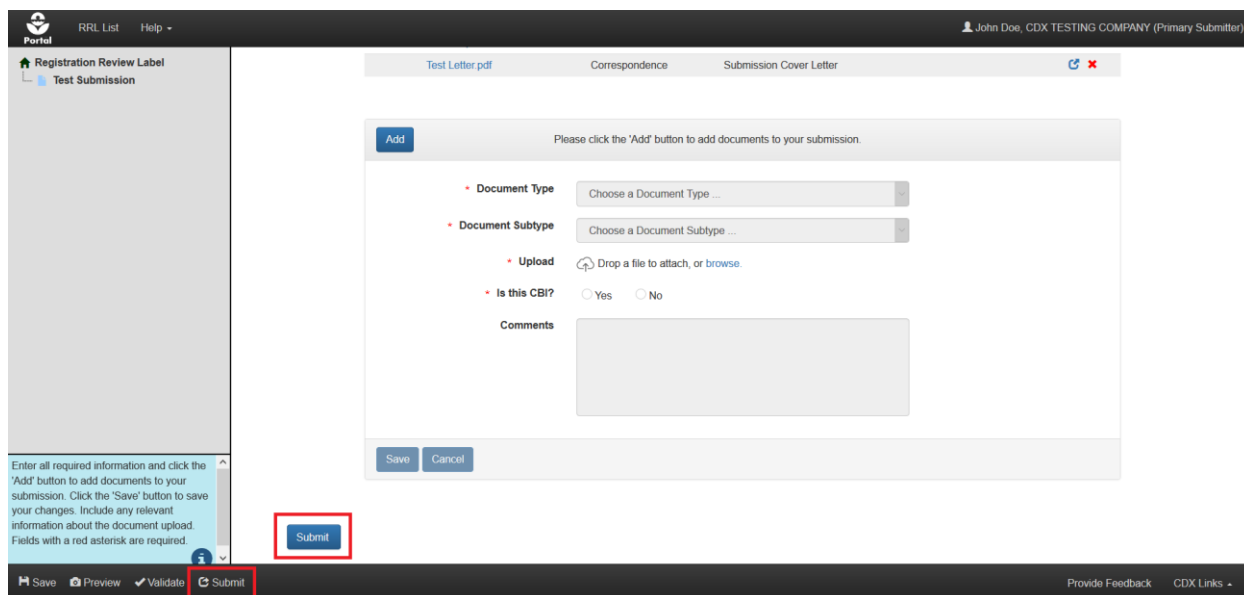
Exhibit 11-9: RRL 'Registration Review Label' Screen – Initiate Submission Process

Navigation: Select the 'Submit' button either in the application footer or on the screen to begin the submission process. Please refer to **Section 4.9** for assistance with the submission process.

Exhibit 11-10 shows a screen capture of a sample registration review label submission notification email:
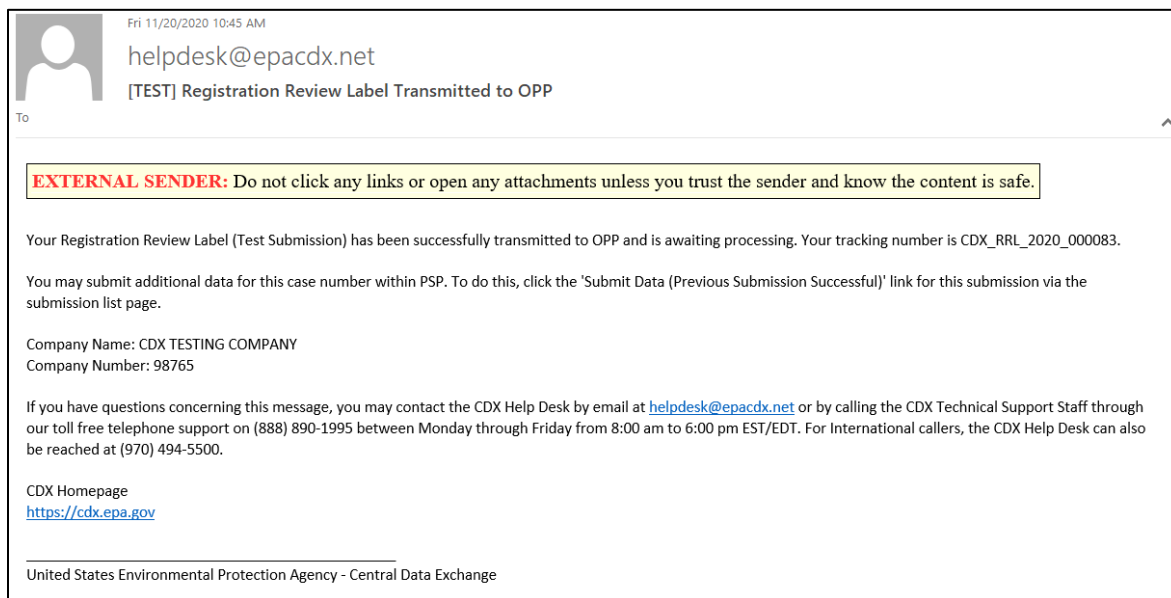
Exhibit 11-10: RRL Successful Transmission Notification Email

![CDX logo]

11.3   Continue Working on Saved Registration Review Label Submissions

In progress registration review label submissions (i.e., submissions with the 'Awaiting User Completion status) can be accessed via the 'Voluntary Data Submission List' screen.

Exhibit 11-11 shows a screen capture of the 'Registration Review Label Submission List' screen with an in-progress submission:

Exhibit 11-11: 'Registration Review Label Submission List' Screen – Manage In-Progress Submissions

Navigation: Select a blue link in the 'VDS ID' column to navigate to the 'Enter Passphrase' screen and access the selected submission. To delete a submission, select the corresponding 'Delete' icon in the 'Action(s)' column.

11.4   Registration Review Label Submission Tracking Number and Copy of Record

The ability to download a copy of record, view a CDX Tracking Number, and view submission documents becomes available on the 'Registration Review Label Submission List' screen once a submission is successfully submitted to OPP. Note that the copies of record available on the 'Voluntary Data Submission List' screen are only for the most recently submitted instance of a given submission.

Exhibit 11-12 shows a screen capture of CDX Tracking Numbers and submitted documents:

Exhibit 11-12: 'Registration Review Label Submission List' Screen - 'Show Detail' Icon

Navigation: Select the 'Show Detail' icon to view the CDX Tracking Number and submitted documents.

Exhibit 11-13 shows a screen capture of the green 'Copy of Record' icons on the 'Registration Review Label Submission List' screen:
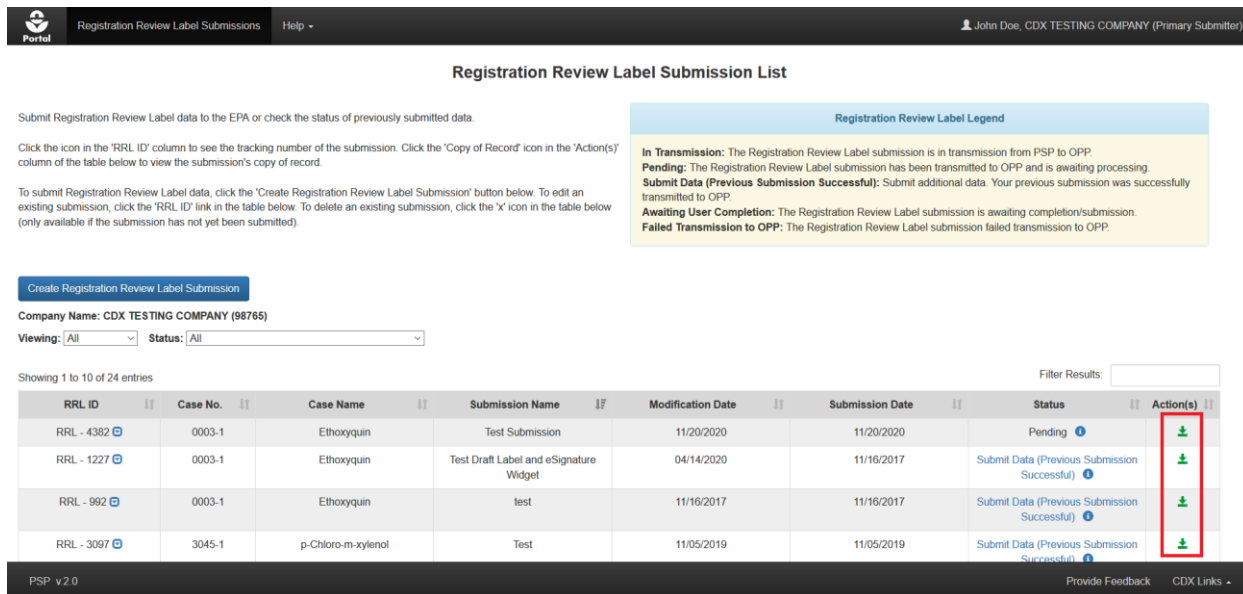
Exhibit 11-13: 'Registration Review Label Submission List' Screen - 'Copy of Record' Icon

Navigation: Select a green 'Copy of Record' icon in the 'Action(s)' column to navigate to the 'Download Copy of Record' screen.

Exhibit 11-14 shows a screen capture of the 'eSignature Widget' pop-up on the 'Download Copy of Record' screen:
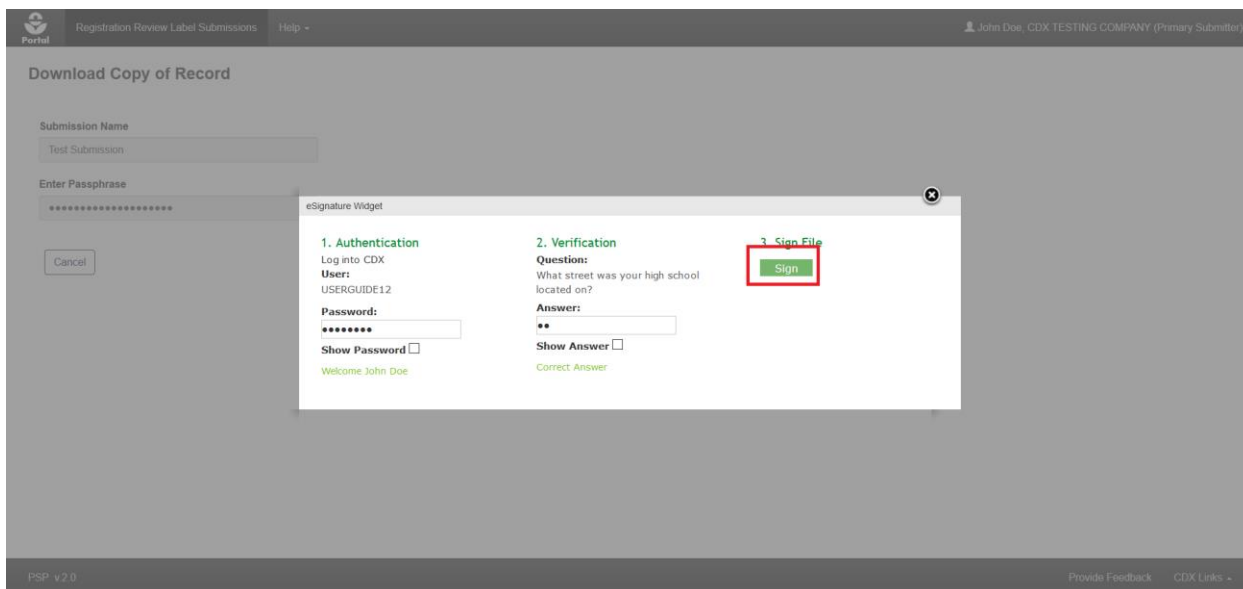
Exhibit 11-14: RRL 'Download Copy of Record' Screen – 'eSignature Widget' Pop-Up

Navigation: Enter the passphrase for the submission and then select the 'Continue' button. Select 'Accept' on the resulting pop-up message. Within the 'eSignature Widget' pop-up, enter the logged in user's CDX password and answer to one of the logged in user's CDX secret questions, and finally select the 'Sign' button.

Exhibit 11-15 shows a screen capture of the 'Download Copy of Record' screen:
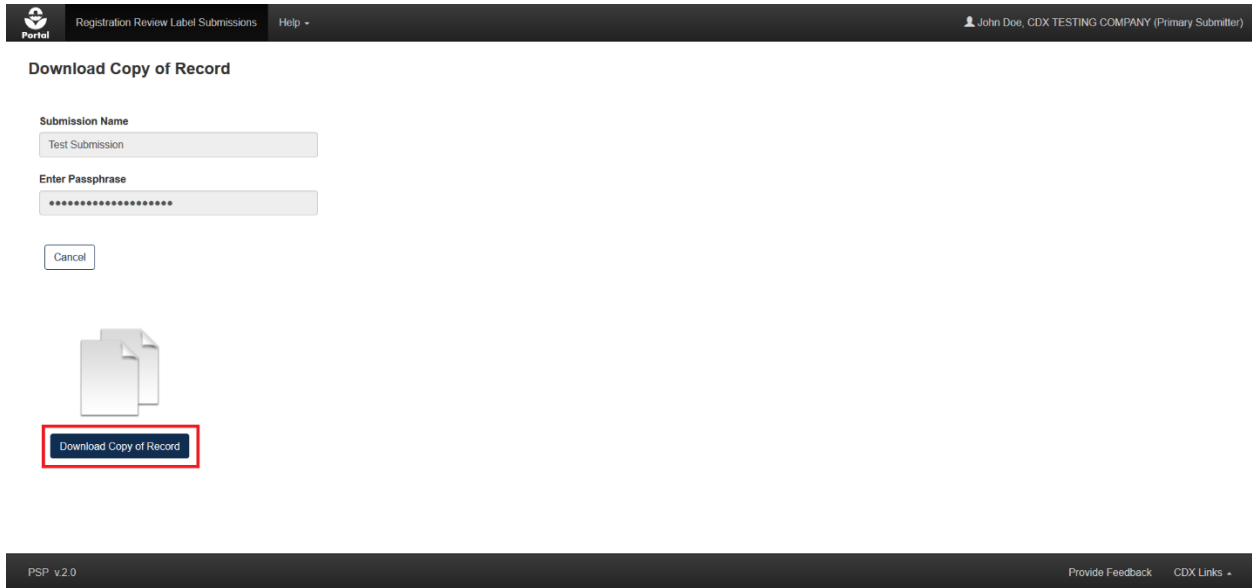
Exhibit 11-15: RRL 'Download Copy of Record' Screen - Download Button

Navigation: Select the 'Download Copy of Record' button to download a zip file containing a PDF representation of the submission and any submitted files.

12 Foreign Purchaser Acknowledgement Statements (FPAS)

This section describes the process to prepare a submission containing FPAS information using the PSP application.

12.1 Create Submission

The 'Create Submission' button is located in the 'Foreign Purchase Acknowledgement Statements' column on the 'Pesticide Submission Portal' home screen. Selecting this button kicks off the FPAS submission creation process.

Exhibit 12-1 shows a screen capture of the 'Create Submission' button on the PSP 'Home' screen:
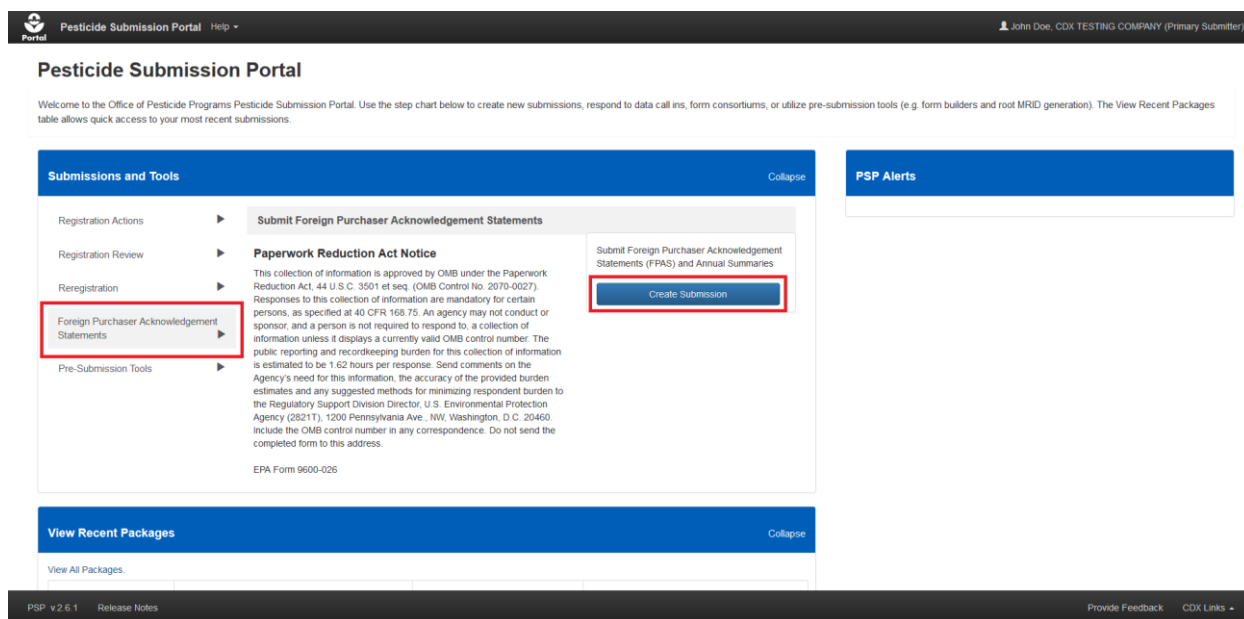
Exhibit 12-1: PSP 'Home' Screen - 'Create FPAS Submission'

Navigation: In the 'Submissions and Tools' panel, select the 'Foreign Purchaser Acknowledgement Statements' option in the first column, then select the 'Create Submission' button to navigate to the 'Create Passphrase' screen and create a submission. Please refer to **Section 4.7.1** for additional information about creating a passphrase.

Important: The same passphrase must be used throughout the life of a submission. The user who creates a submission is responsible for remembering its passphrase and only distributing it to authorized persons. **<u>OPP is unable to retrieve a passphrase or unlock a submission if the passphrase is lost or forgotten</u>**. OPP suggests that each company use the same passphrase for all submissions. A shared passphrase ensures that someone from the same company can retrieve and/or complete the submission should the package creator be unavailable. A 'Passphrase Hint' may be created to assist with passphrase recall.

12.2 Foreign Purchaser Acknowledgement Statements Information Screen

The 'Foreign Purchaser Acknowledgement Statements Information' screen collects data about a FPAS submission and is where FPAS files are added to a submission. The following fields are displayed on the 'Package Information' screen with required fields denoted with a red asterisk:

- **Package Name:** Enter a name for the submission. This field is required.

- **Description:** Enter a description for the submission. This field is optional.

- **Upload Cover Letter:** Either drag and drop a cover letter file or select the 'browse' link to select a file to upload. Empty, protected, and non-PDF files are not allowed. Document file names should neither exceed 200 characters, nor be duplicated. This field is required.

- **Does the Cover Letter File Contain CBI?:** Indicate whether an uploaded cover letter contains CBI. This field only displays when a cover letter file is saved to the submission and is required when displayed.

The 'Add Foreign Purchaser Acknowledgement Statements' section allows users to create FPAS entries for each applicable product and save them to a submission. The following fields are displayed in the 'Add Foreign Purchaser Acknowledgement Statements' window after selecting the 'Add New' button:

- **FPAS Type:** Indicate whether the FPAS entry is an 'Annual Summary' or standalone 'Foreign Purchaser Acknowledgement Statement.' This field is required.

- **Product Name:** Enter the product name for the FPAS entry. This field is required.

- **Select a File to Upload:** Either drag and drop a file or select the 'browse' link to select a file to upload. Empty, protected, and non-PDF files are not allowed. Document file names should neither exceed 200 characters, nor be duplicated. This field is required.

- **Does the selected file contain CBI?:** Indicate whether an uploaded file contains CBI. This field is required.

Exhibit 12-2 shows a screen capture of the 'Foreign Purchaser Acknowledgement Statements Information' screen:
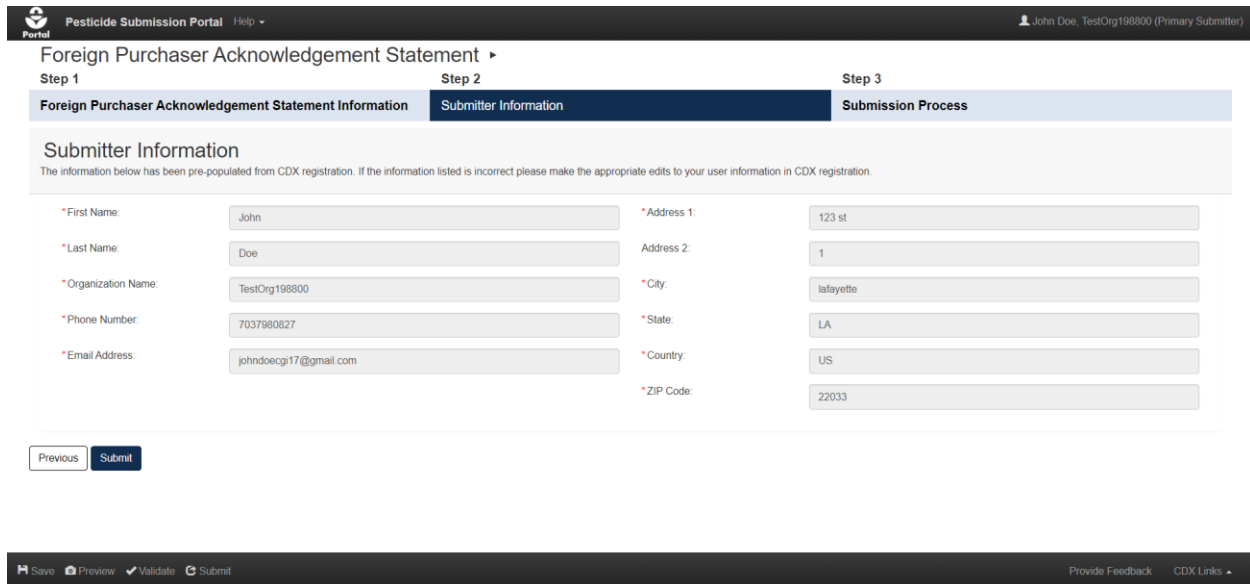
Exhibit 12-2: 'Foreign Purchaser Acknowledgement Statements Information' Screen

Navigation: Fill out all necessary submission information fields and select the 'Add New' button to display the FPAS data entry window. Complete all FPAS or Annual Summary fields, upload a file, and finally select the 'Save' button. Repeat this process until all required FPAS/Annual Summary entries for the submission are saved in the table on the left side of the screen and then select the 'Next' button to navigate to the 'Submitter Information' screen.

12.3 Submitter Information Screen

The 'Submitter Information' screen requires the submitter (the currently logged in user) to review their contact information as provided from CDX. This serves as both a check to ensure that the contact information is current in CDX and a reminder for which company the submission will be made.

Exhibit 12-3 shows a screen capture of the 'Submitter Information' screen:

Exhibit 12-3: 'Submitter Information' Screen

Navigation: Review the displayed submitter information for accuracy and then select the 'Submit' button to begin the submission process.

12.4　Submission Process Screen

The 'Submission Process' screen verifies whether a submission meets minimum validation standards. If issues are identified during the global validation review, the screen will indicate that validation failed and a comprehensive list of validation errors will appear. All validation errors must be resolved before a package can be submitted. If the application does not identify any validation errors, the screen will indicate that no issues were found and the user will be able to continue the submission process.

Users may also review a PDF representation of all data and files included within a submission by selecting the 'View PDF' button. An official copy of record, including this PDF representation, becomes available after a submission completes processing to EPA. Please refer to **Section 6.6** for additional information about accessing copies of record and reviewing submission statuses.

Lastly, the 'Submission Process' screen allows a user to sign, encrypt, and send their submission to EPA using the CDX eSignature Widget. Please refer to **Section 4.9.3** for additional information about CROMERR and the electronic signature process.

Exhibit 12-4 shows a screen capture of the 'Submission Process' screen:
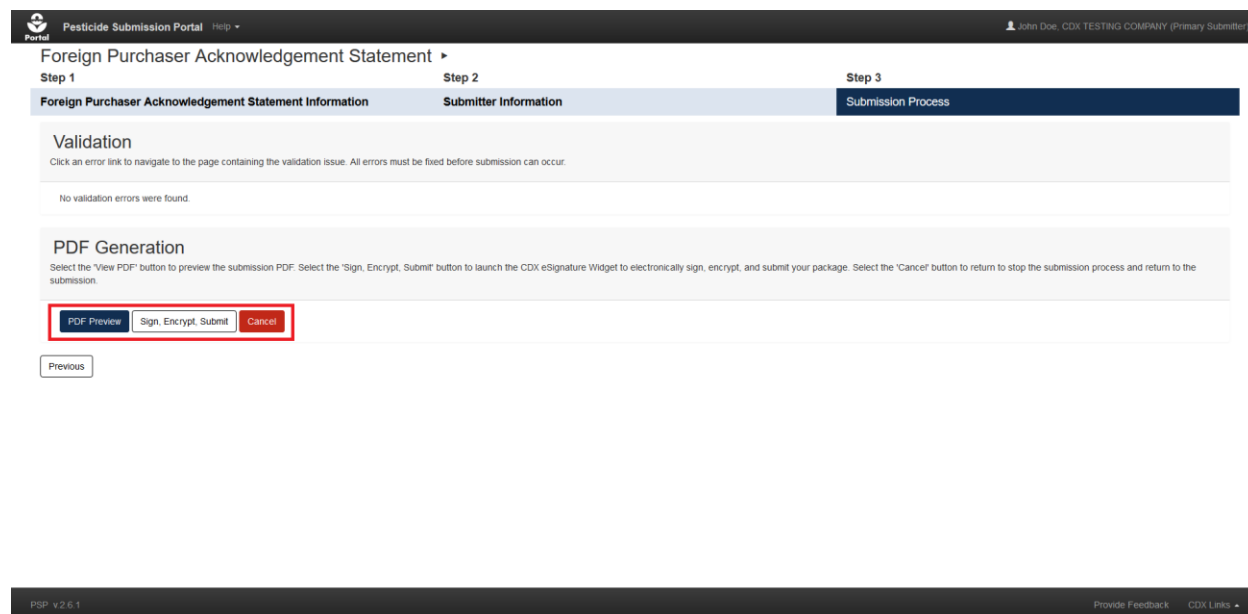
Exhibit 12-4: 'Submission Process' Screen

Navigation: Select the 'View PDF' button to review the submission PDF. Select the 'Sign, Encrypt, Submit' button to launch the CDX eSignature Widget to electronically sign, encrypt, and submit the package to EPA.

13 Appendix A - Definitions, Acronyms, and Abbreviations

Acronym	Full Name
CBI	Confidential Business Information
CDX	Central Data Exchange
CDXHD	Central Data Exchange Help Desk
CoR	Copy of Record
CRM	Chemical Review Manager
DCI	Data Call-In
CROMERR	Cross-Media Electronic Reporting Regulation Security System
eCSF	Electronic Confidential Statement of Formula
EPA	Environmental Protection Agency
IT	Information Technology
MRID	Master Record Identification Number
OPP	Office of Pesticide Programs
OPPEL	OPP Electronic Label
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
RRL	Registration Review Label
PC Code	Pesticide Chemical Code

14   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 14-1** 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 14-2**)
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

Regulatory Action	Format	Examples
Pre-Application	CompanyNumPASeq	• 2382PA1 • 54022PA16

Exhibit 14-1 Admin Number Examples

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

Exhibit 14-2 File Symbol