

CVM eSubmitter New Product Description and Product Book Quick Guide

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I. Introduction

When eSubmitter was first deployed by CVM in 2011, the majority of Office of New Animal Drug Evaluation (ONADE) eSubmitter submission templates included the requirement for sponsors to provide product description information. At the time of the original deployment, these individual templates contained only a few variations across the different submission types. Over the course of the subsequent 9 years, there has been significant drift from that consistency as some templates were updated with new requirements or enhancements that were not uniformly implemented.

CVM has also received feedback from industry stakeholders that the repetitive entry of basic product information for each submission is burdensome and prone to data entry errors. CVM has observed inconsistencies with how product description information is presented across submissions for the same drug product. To address these concerns significant enhancements were made to the CVM eSubmitter application. An overview of those enhancements, as well as instructions to help industry users implement these features are included within this document.

Note: The improvements referenced within this document are currently only available within newly created ONADE submissions. Existing ONADE submissions, including ONADE submissions initiated before the release of the new features, as well as submission prepared for other CVM Offices will still use the older product description approach.

II. Limitations with the Original Approach

The primary limitations to how stakeholders have provided product description information to CVM are as follows:

- Industry stakeholders must populate the product description information starting from the beginning for each submission created. This creates greater opportunity for entry errors and inconsistencies.
- Each individual submission template contained its own product description questions. This implementation has created a maintenance issue when making updates to product description questions. Small changes required a large level of effort due to the need to update many templates.
- Product description questions are implemented inconsistently across over 100 ONADE submission type templates.

III. Overview of New Features

To correct these shortcomings, CVM has implemented several improvements regarding how the product description information is collected for ONADE submissions and how this information is managed by industry stakeholders.

An overview of the changes and the new or improved features are as follows:

1. Removed the product description questions from the ONADE submission templates
2. Created two standardized product description forms with variants for generic animal drug products
3. Developed a new Product Description tab that displays the appropriate form of the product description based on the submission type selected
4. Provided the ability to save product description information in a product book for future use
5. Included the ability to copy to or from the Product Book while building an ONADE submission
6. Created the ability for the review and management of the product description prior to copying from the product book into the submission template
7. Added options to update data stores in the Preferences dialog

IV. Accessing the New Product Description Tab

The product description questions have been removed from the individual ONADE templates and are now on the new Product Description tab that will be displayed following the Submission Type Selection screen. Users should select the appropriate submission type, classification code, review division then click next to display the new product description tab.

Note: The product description tab will only display when answering "No" to the amendment question on the submission type selection tab.

1. Product Description Layouts

There are two types of product description tab layouts within eSubmitter; short form and long form. Each form has a variant for generic animal drug products that contain reference listed new animal drug information. See below for an example of each type.

Short Form

Outline

- Submission Type Selection (NADA)
- CVM ONADE SUBMISSIONS
- NADA Chemistry Supplement (N/C/CI)
- Product Description
- 7.0 Product Description

Screen: 7.0 Product Description

It is required that the information within the Product Description section includes the latest Product information available at the time of the submission. Product Book support has been provided to aid in maintaining and managing Product Description information across submissions. For additional details, view the hint in the Product Book interface question below.

Please enter the product related information below (or use the buttons to the right to access previously saved product information)

Product Description Details

Does the drug product have a USP monograph?

Yes

No

Product Established Name: ⓘ

Proprietary Name (make sure that the entire proprietary name is entered including trademark symbols): ⓘ

Ω

Long Form

(Additional questions require scrolling)

Outline

- Submission Type Selection (NADA)
- CVM ONADE SUBMISSIONS
- Product Description
- Original NADA (N/A/OT)
- 7.0 Product Description

Screen: 7.0 Product Description

It is required that the information within the Product Description section includes the latest Product information available at the time of the submission. Product Book support has been provided to aid in maintaining and managing Product Description information across submissions. For additional details, view the hint in the Product Book interface question below.

Please enter the product related information below (or use the buttons to the right to access previously saved product information)

Product Description Details

Does the drug product have a USP monograph?

Yes

No

Product Established Name: ⓘ

Proprietary Name (make sure that the entire proprietary name is entered including trademark symbols): ⓘ

Ω

Pharmacological Category: ⓘ

Product Dosage Form, ROA, Target Animal Designations: ⓘ

0 items in the list

Dosage Form	Route of Administration	Target Animal

Active Pharmaceutical Ingredient(s): ⓘ

0 found in the list (1 required)

Ingredient Name	UNII Code

V. Product Description Template Questions

The questions contained within the product description section remain mainly unchanged from the previous version, except for the following areas:

A. Dosage Form, Route of Administration and Target Animal Information

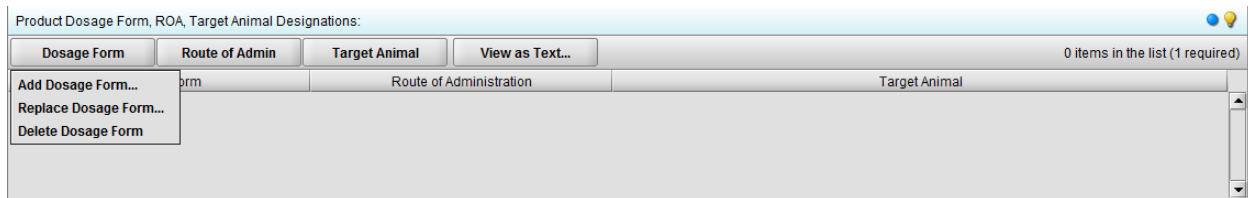
This question represents the hierarchical relationship of the product's dosage form(s), route of administration(s) (ROAs), and target animal(s). A product can include one or more dosage forms. Each dosage form can include one or more ROAs. Each ROA of a dosage form

can include one or more target animals. At a minimum, a product description must include at least one dosage form, with one ROA, and one target animal.

To build the hierarchical relationship, a dosage form must be selected before a ROA can be added, and a ROA before adding a target animal.

When representing the hierarchical relationship within the tabular view, items may appear repeated across rows for easier identification even though they have only been selected once. For example, a dosage form may contain two ROA's, each of which contain two target animals. In this scenario, the single dosage form will be repeated across all four rows, each ROA repeated across two rows, and each target animal within a single row.

1. Dosage Form Options



Clicking the Dosage Form button enables the following options:

- Add Dosage Form: Displays a dialog for selecting a dosage form. While one or more dosage forms can be added to a product, an individual dosage form can only be added once per product.
- Replace Dosage Form: Displays a dialog for selecting a new dosage form to replace the selected dosage form in the list. Note: the replacement includes all routes of administration/target animals associated with the selected dosage form.
- Delete Dosage Form: Deletes the selected dosage form from within the list.

Note: the deletion removes all route of administrations/target animals associated with the selected dosage form.

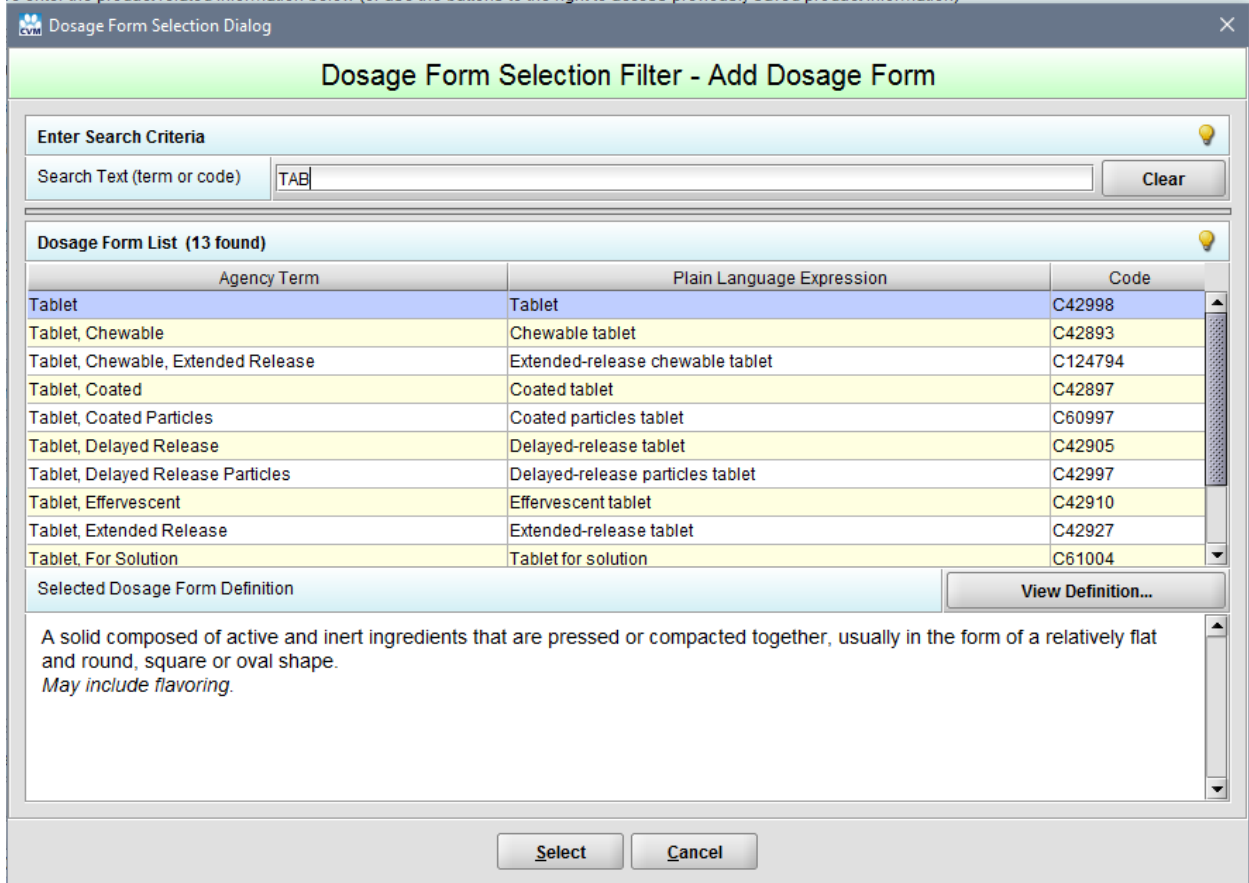
a. Add Dosage Form Dialog

The Search Text option performs a search of all available Dosage Forms containing the search text provided. Specifically, the Agency Term or Code (depending on whether numerics are entered) are filtered and updated in the Dosage Form List accordingly.

When searching within the Agency Term, the search attempts to locate words beginning with the search text provided.

When no search is provided, the entire Dosage Form list is presented.

A Clear button is provided to quickly clear the search text.



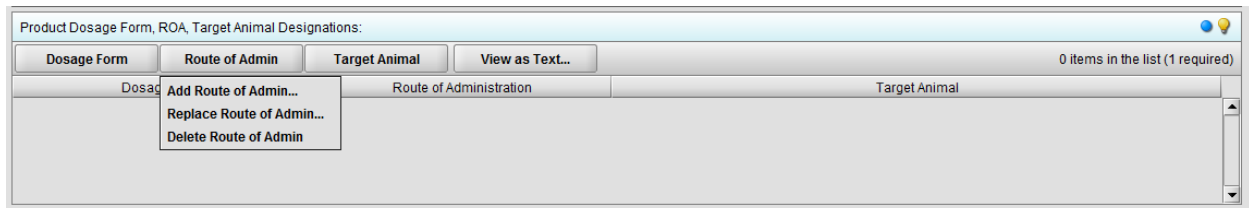
The Dosage Form List presents all the Dosage Form items matching the search text, or all Dosage Form items available when no search text is provided. The list header also contains a count of Dosage Form items currently contained within the list.

A Dosage Form can be selected using one of the following methods:

- Using the mouse and double-clicking the row to be selected
- Using the Enter key on the keyboard to select the currently highlighted row
- Activating the Select button to select the currently highlighted row

The Selected Dosage Form Definition area is automatically populated to reflect the CVM definition associated with Dosage Form selected from the list. A button is also included to display the definition in a separate popup dialog (useful for longer definitions that require scrolling to view).

2. Route of Administration Options



Clicking the Route of Admin button enables the following options:

- **Add Route of Admin:** Displays a dialog for selecting a route of administration for the selected dosage form. While one or more routes of administration can be added to a dosage form, an individual route of administration can only be added once per dosage form.
- **Replace Route of Admin:** Displays a dialog for selecting a new route of administration to replace the selected route of administration in the list. Note: the replacement includes all target animals associated with the selected route of administration.
- **Delete Route of Admin:** Deletes the selected route of administration from within the list.

Note: the deletion also removes all target animals associated with the selected route of administration.

a. **Add Route of Admin Dialog**

The Search Text option performs a search of all available Route of Administrations containing the search text provided. Specifically, the Term or Code (depending on whether numerics are entered) are filtered and updated in the Route of Administration List accordingly.

When searching within the Term, the search attempts to locate words beginning with the search text provided.

When no search is provided the entire Route of Administration list is presented.

A Clear option is provided to quickly clear the search text.

Route of Administration Selection Dialog

Route of Administration Selection Filter - Add Route of Administration

Enter Search Criteria

Search Text (term or code)

Route of Administration List (53 found)

Term	Code
Intramammary	C79137
Intramedullary	C38253
Intrameningeal	C38254
Intramuscular	C28161
Intraocular	C38255
Intraovarian	C38256
Intrapericardial	C38257
Intraperitoneal	C38258
Intrapleural	C38259
Intraprostatic	C38260

Selected Route of Administration Definition

Administration of a drug within the amnion.

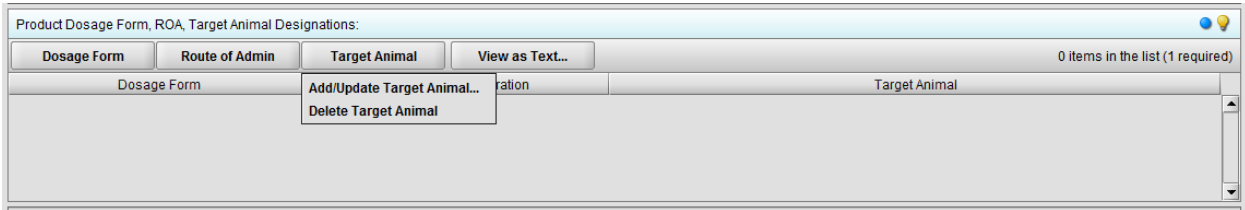
The Route of Administration List presents all the Route of Administration items matching the search text, or all Route of Administration items available when no search text is provided. The list header also contains a count of Route of Administration items currently contained within the list.

A Route of Administration can be selected using one of the following methods:

- Using the mouse and double-clicking the row to be selected
- Using the Enter key on the keyboard to select the currently highlighted row
- Activating the Select button to select the currently highlighted row

The Selected Route of Administration Definition area is automatically populated to reflect the definition associated with the selected Route of Administration within the list. A button is also included to display the definition in a separate popup dialog (useful for longer definitions that require scrolling to view).

3. Target Animal Options



Clicking the Target Animal button enables the following options:

- Add/Update Target Animal: Displays a dialog for managing the target animals included for the selected route of administration. Within the dialog, target animals can be added, deleted, and reordered.
- Delete Target Animal: Deletes the selected target animal from within the list and its association to the selected route of administration and dosage form.

a. Add/Update Target Animal Dialog

Follow the 3-step process to identify all the target animals for your product.

Step 1: Select Filter Criteria

The Target Animal dictionary is separated into four main Categories [Major Animal (Non-Food), Major Food Animal, Minor Species, and Aquatic], as well as several Classes specific to each category.

Start by selecting an appropriate category, and if needed, a class within the category to create a subset of target animals from which to select.

Target Animal Selection Dialog

Target Animal Selection (Add/Update Selected List)

Step 1 Select Filter Criteria

Select a Category Filter: **Major Food Animal** | Select a Class Filter: **Cattle**

Step 2 Select Target Animal(s)

Filtered Target Animal List (33 found) Add Selected | Add as Exception

Target Animal	Category	Class
Beef Cattle	Major Food Animal	Cattle
Beef Calves	Major Food Animal	Cattle
Beef Calves less than 2 months of age	Major Food Animal	Cattle
Beef Calves 2 months of age and older	Major Food Animal	Cattle
Beef Steers	Major Food Animal	Cattle
Growing Beef Steers on Pasture (stocker, feeder, and slaughter)	Major Food Animal	Cattle
Growing Beef Steers in Dry Lot	Major Food Animal	Cattle

Selected Target Animal Definition (if available) View Definition...

Target Animal: **Beef Calves less than 2 months of age**
 Beef calves considered pre-ruminating and nursing their dams from birth until 2 months of age.

Step 3 Review/Accept Selected Target Animal(s)

Selected Target Animal List (2 added) Remove from Selected List | Change Exception Status | View Definition... | Add Manually... | ↑ | ↓

Target Animal
Beef Cattle
Except: Beef Calves less than 2 months of age

Accept | Cancel

Step 2: Select a Target Animal

Select a target animal from the filtered target animal list. Some target animals may contain an additional definition for clarity. If a highlighted target animal contains a definition, it will be viewable below the filtered list.

The target animal list is arranged in a hierarchy of higher-level and lower-level terms. When selecting a higher-level term, you are accepting all lower-level terms contained within. For example, selecting 'Beef Cattle' automatically assumes Beef Calves, Beef Steers, Beef Heifers, Beef Bulls, and Beef Cows. It is preferred that a higher-level term be selected when inclusive of all sub-terms, rather than selecting all the sub-terms individually.

There are two approaches to handling exceptions within a higher-level term. You can either select the higher-level term and identify any exceptions or select just the lower-level terms. It depends on which more logically defines the target animal. For example, selecting 'Beef Cattle except Beef Cows' is preferred over selecting all sub-terms of Beef Cattle but Beef Cows. However, selecting 'Beef Bulls and Beef Cows' is preferred over selecting Beef Cattle and three exceptions.

Once an appropriate target animal has been identified within the filtered List, you can add it to the selected list (i.e., within Step 3) using one of the following options:

- Using the mouse to select the target animal within the list with a double-click
- Using the Enter key on the keyboard to select the target animal
- Selecting the target animal (using mouse or keyboard) and activating the 'Add Selected' button

- Selecting the target animal (using mouse or keyboard) and activating the 'Add as Exception' button

Step 3: Review/Accept Selected Target Animal(s)

Review the target animals added to the selected target animal list, and make any adjustments as needed, prior to accepting the selections and closing the dialog. Note: the selected list will initially be populated with all previously selected target animal(s) from the product description.

With regards to any target animal exceptions added to the selected list, exceptions should always be listed directly below the associated higher-level term. Options are available to move target animals up and down within the selected list to ensure proper ordering.

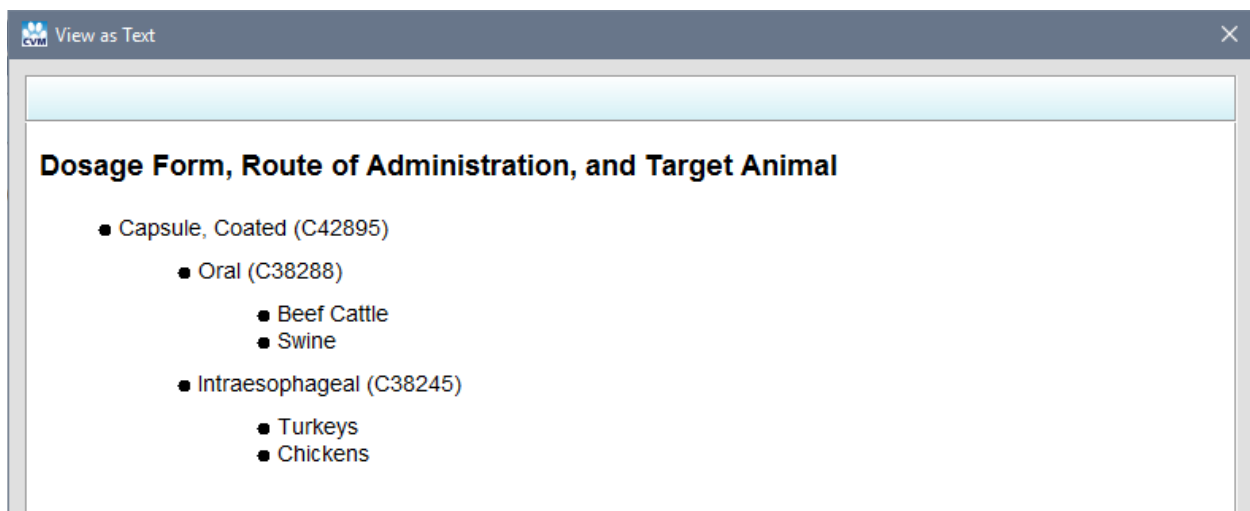
There are several options available for managing the selected list:

- Remove from Selected List: Permanently removes the selected target animal from the selected list
- Change Exception Status: Switches the exception status of the selected target animal
- View Definition: Displays the definition, if available, of the selected target animal within the selected list
- Add Manually: Provides an option for manually entering a target animal that does not exist within the target animal dictionary (see Note below for additional information regarding manually entered target animals)
- Move Item Up: Moves the selected target animal up within the selected list
- Move Item Down: Moves the selected target animal down within the selected list

Note: Target animals should only be added manually when they cannot be found based on a search of the CVM Target Animal Dictionary. Before an animal drug can be approved, any new target animal terms must either be added by CVM to the dictionary or the target animal referenced for the drug be replaced with an existing term.

4. View as Text Option

Clicking the View as Text button displays the relationship within a hierarchical (outline) view.



When representing the hierarchical relationship within the tabular view, items may appear repeated across rows for easier identification even though they have only been selected once. For example, a dosage form may contain two ROA's, each of which contain two target animals. In this scenario, the single dosage form will be repeated across all four rows, each ROA repeated across two rows, and each target animal within a single row.

Product Dosage Form, ROA, Target Animal Designations:

4 items in the list (1 required)

Dosage Form	Route of Administration	Target Animal
Capsule, Coated	Oral	Beef Cattle
Capsule, Coated	Oral	Swine
Capsule, Coated	Intraesophageal	Turkeys
Capsule, Coated	Intraesophageal	Chickens

B. Active Pharmaceutical Ingredient Information

This item collects the active pharmaceutical ingredients for the product. The selection process is based on the ingredients included within the FDA Global Substance Registration System (SRS) that contains over 90,000 ingredients. At a minimum, a product must include at least one active pharmaceutical ingredient.

Active Pharmaceutical Ingredient(s):

3 found in the list (1 required)

Ingredient Name	UNII Code
PENICILLIN G PROCAINE	17R794ESYN
RACTOPAMINE HYDROCHLORIDE	309G9J93TP
NEOMYCIN SULFATE	057Y626693

The following options are available:

- Add Ingredient (+ button): Displays a dialog for selecting an active ingredient from the SRS dictionary.
- Delete Selected Ingredient (- button): Deletes the selected active ingredient from the list.
- Move Ingredient Up (up arrow button): Moves the selected active ingredient up one row within the list.
- Move Ingredient Down (down arrow button): Moves the selected active ingredient down one row within the list.

When selecting the Add Ingredient Option, the Ingredient Selection Dialog box will open. Follow the 3-step process to identify all the active ingredients in your product.

Step 1: Enter Search Criteria

The ingredient dictionary contains over 90,000 ingredients. Thus, to aid in searching for a specific ingredient, we have provided a three-keyword search capability of the ingredient name and a single keyword search for the ingredient UNII code. Each keyword provided within the search criteria must match a word within an ingredient name or the UNII code for that ingredient to be included in the search results list. In addition, a clear option is provided to re-initialize the search criteria and search results list.

The matching process is based on words within an ingredient name beginning with the text provided within each of the search keywords provided. The more keywords and text provided in the search criteria, the more refined the results. However, due to the large number of ingredients available, a search keyword must contain at least three characters in

order to be included within the search. The search results are presented almost instantaneously as search text is entered.

For example: PENICILLIN G PROCAINE can be easily located by searching for two keywords PEN and PRO, or NEOMYCIN SULFATE by searching for NEO and SUL.

While less commonly used, some ingredient names within the system are based on names concatenated with special characters into one large text string. In this case, the search ignores all special characters and assumes the text within as separate searchable words.

Ingredient Selection Filter

Step 1: Enter Search Criteria to Locate Ingredient(s) for Selection

Search by Ingredient Name or UNII Code. Up to three keywords may be used. Each keyword must contain at least three characters to be included within the search. Select the 'hint' option available within the Step 1 header for additional guidance on how searches are performed.

Keyword Search: By Name By UNII Code:

Step 2: Add Ingredient from Search Results to the Selected List

Ingredient Search Results List (3 found)

Ingredient Name	UNII Code
NEODYMIUM SULFATE	4Q1946CN7K
NEOMYCIN C SULFATE	88L7V8H11U
NEOMYCIN SULFATE	057Y626693

Step 3: Review/Accept Selected Ingredient(s)

Selected Ingredient(s) List (3 found)

Ingredient Name	UNII Code
PENICILLIN G PROCAINE	17R794ESYN
RACTOPAMINE HYDROCHLORIDE	309G9J93TP
GENTAMICIN SULFATE	8X7386QRLV

Step 2: Add Ingredient to the Selected List

The results of the search performed in Step 1 are presented within the ingredient search results list, as well as a count of the number of ingredients found.

The goal of this step is to select the required ingredient(s) and add them to the selected ingredient list (presented in Step 3).

Ingredients can be selected from the search results list using one of three options:

- Using the mouse to select the ingredient within the list with a double-click to add
- Using the Enter key on the keyboard to select the ingredient to add
- Selecting the ingredient (using the mouse or keyboard) and activating the 'Add to Selected List' button to add

Step 3: Review/Accept Selected Ingredient(s)

The selected ingredient(s) list contains all ingredients located and selected as part of steps 1 and 2. It also contains a count of all ingredients currently selected. In addition, it maintains (by default) all selected ingredients from previous instances of opening the Ingredient Selection Dialog for this product description.

The goal of this step is to review and either accept the selected ingredient(s) (by selecting the OK button) or reject any changes (by selecting the Cancel button) and closing the dialog box.

Selected ingredients can be removed from the list using one of three options:

- Using the mouse to select the ingredient within the list with a double-click to remove
- Using the keyboard to select the ingredient and pressing the ENTER key to remove
- Selecting the ingredient (using the mouse or keyboard) and activating the 'Remove from Selected List' button to remove

In addition, ingredients can be manually added to the selected list when not found through a search by selecting the 'Add Manually...' button

Note: Ingredients should only be added manually when they cannot be found based on a search (i.e., above) of the FDA Global Substance Registration System (SRS). New ingredients must be added to FDA SRS before an animal drug can be approved by CVM.

VI. Saving and Retrieving Product Description Information

There are two approaches to building the Product Book. The first is to open the Product Book within a submission to copy a product description into the submission or make any changes and save them to the Product Book. The second method is to manage the overall contents (outside of a submission) using the Product Book option within the Tools menu.

A. Copying to Product Book

The most common approach to building the product book is to manually enter the product description information into the submission data entry when first created and select Copy to Product Book to preserve it for future submissions. The full product description can be built and modified over time as the product moves through the development lifecycle.

For example, when establishing a new INAD you can populate the information known at that time corresponding to the required questions within the product description based on the submission type selected. In this example only the USP monograph, product established name, dosage form, route of administration and target animal questions are required.

Screen: 7.0 Product Description

It is required that the information within the Product Description section includes the latest Product information available at the time of the submission. Product Book support has been provided to aid in maintaining and managing Product Description information across submissions. For additional details, view the hint in the Product Book interface question below.

Please enter the product related information below (or use the buttons to the right to access previously saved product information)

Product Description Details

Does the drug product have a USP monograph? ●

Yes
 No

Product Established Name: ●

New Great Product Established Name

Proprietary Name (make sure that the entire proprietary name is entered including trademark symbols): ●

Ω

Pharmacological Category:

Product Dosage Form, ROA, Target Animal Designations: ●

2 items in the list (1 required)

Dosage Form	Route of Administration	Target Animal
Aerosol	Sublingual	Dog
Aerosol	Sublingual	Except: Puppies

After populating the known information, select the Copy to Product Book button (with the green upward arrow) to ensure the data are captured within the Product Book for the next submission related to this product.

Screen: 7.0 Product Description

It is required that the information within the Product Description section includes the latest Product information available at the time of the submission. Product Book support has been provided to aid in maintaining and managing Product Description information across submissions. For additional details, view the hint in the Product Book interface question below.

Please enter the product related information below (or use the buttons to the right to access previously saved product information)

Product Description Details

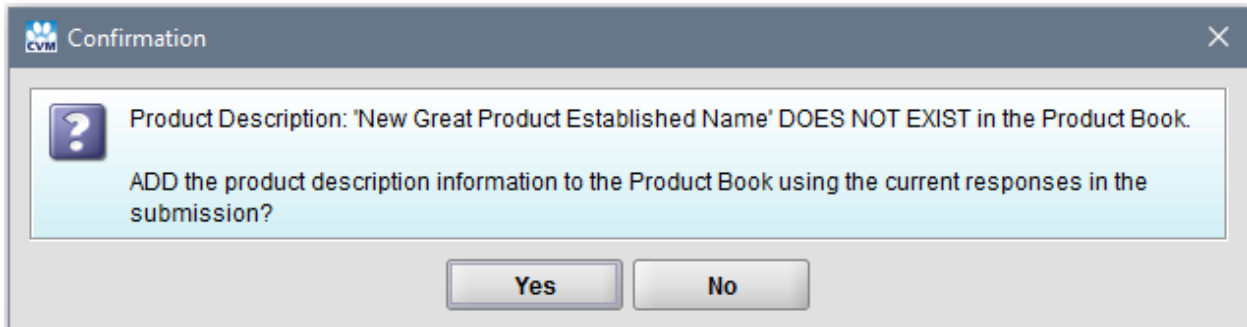
Note: The 'Copy to Product Book' button (green upward arrow) is highlighted with a red box in the original image.

After selecting the Copy to Product Book button, a confirmation screen will be presented.

Confirmation ✕

Copy the Product Description information from the submission responses to the Product Book?

If the *established name* entered does not already exist in the product book, you will receive another confirmation message.



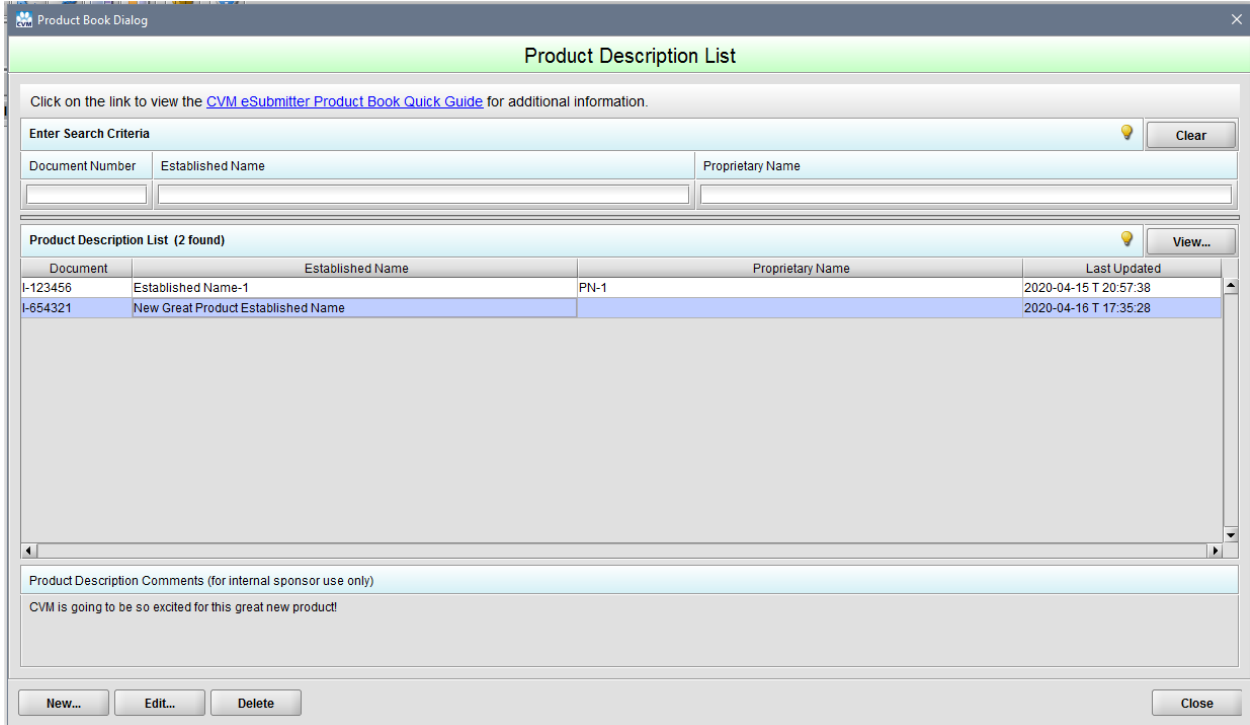
Selecting Yes on the confirmation screen will create the record and provide a message that the creation was successful.



Note: When the new record is created using this method, the document type and document number information will automatically be populated (if available) in the product book entry.

B. Product Book Tool

The Product Book is used to manage the overall contents (outside of a submission) of the product descriptions. The Product Book can be accessed directly by navigating to the Tools menu and selecting Product book.



The Product Book Dialog supports the following primary uses:

1. Searching Saved Product Descriptions

The Search capability allows for searching across all Product Descriptions contained within the Product Book. The fields available for searching include document number, established name, and proprietary name. Specifically, the search locates all product descriptions where words within the search text either match exactly or begin with the search text provided. Multiple search fields are supported.

When no search text is provided, all product descriptions within the Product Book are included. A Clear option is also provided to quickly clear the search text and display all Product Descriptions.

2. Product Description List

The Product Description List presents all the product descriptions matching the search text, or all product descriptions available when no search text is provided. The list contains the document reference, established name, proprietary name, and last updated date/time stamp.

The following options are available:

- View: Displays all details related to the selected product description.
- New: Allows for a new product description to be added to the list.
- Edit: Allows for details on the selected product description to be updated.
- Delete: Allows for the selected product description to be permanently deleted from the list.

Note: The default behavior of some operations is dependent on the method used to open the Product Book. For example, using the mouse and double-clicking the row selected, or using the Enter key on the keyboard to select the currently highlighted row initiates an Edit operation when opened from the menu and a Select operation when opened within a submission.

3. Create a New Product Description

Select New on the Product Book Dialog to open the Add Product Description dialog which is used to create a product description item without the need to start a new submission. Creating a new Product Description only requires the entry of a product established name prior to being saved to the list.

This dialog contains three questions that are not included in the product description template:

- Check box indicating the product description is for a generic animal drug
- Document Type
- Document Number

Add Product Description Item

Is the product description for a Generic Animal Drug?

Document Identifier (for reference only)

Document Type:

Document Number:

Product Description Details

Does the drug product have a USP monograph?

Yes

No

Product Established Name:

Proprietary Name (make sure that the entire proprietary name is entered including trademark symbols):

Pharmacological Category:

Product Dosage Form, ROA, and Target Animal Designations:

0 items in the list

Dosage Form	Route of Administration	Target Animal

Selecting the check box indicates the product description is for a generic animal drug determines whether the RLNAD questions are available for entry towards the bottom of the data entry form.

Checking the Generic Animal Drug status displays the RLNAD questions, while unchecking the status hides the RLNAD questions from view.

Note: These questions will be automatically included in the Product Description Template when ANADA or JINAD document types are selected only.

Reference Listed Product Details	
(A)NADA Document Number:	<input type="text"/>
RLNAD Product Established Name:	<input type="text"/>
Proprietary Name:	<input type="text"/>
Firm Name of (A)NADA Owner:	<input type="text"/>

The comments section is an optional entry for sponsor use only and is not included as part of any submission content. It is provided to aid sponsors in the overall management and identification of product descriptions by allowing the capture of additional information related to each product description. This will be displayed in the Product Description List dialog only and will **NOT** be included with your submission to CVM.

Product Description Comments (for internal sponsor use only)
<input type="text"/>

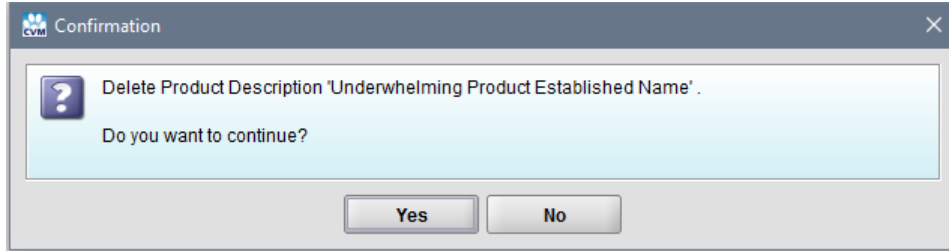
All remaining Product Description questions are identical to what was resented in the submission templates. For instructions on the new Dosage Form, Route of Administration, Target Animal and/or Active Pharmaceutical Ingredients questions, see sections **V. A.** and **V. B.** above.

4. Edit an Existing Product Description

Select Edit on the Product Book Dialog to open the Edit Product Description dialog which is used to modify the existing product description highlighted in the list. Saving the modified Product Description only requires the presence of a product established name.

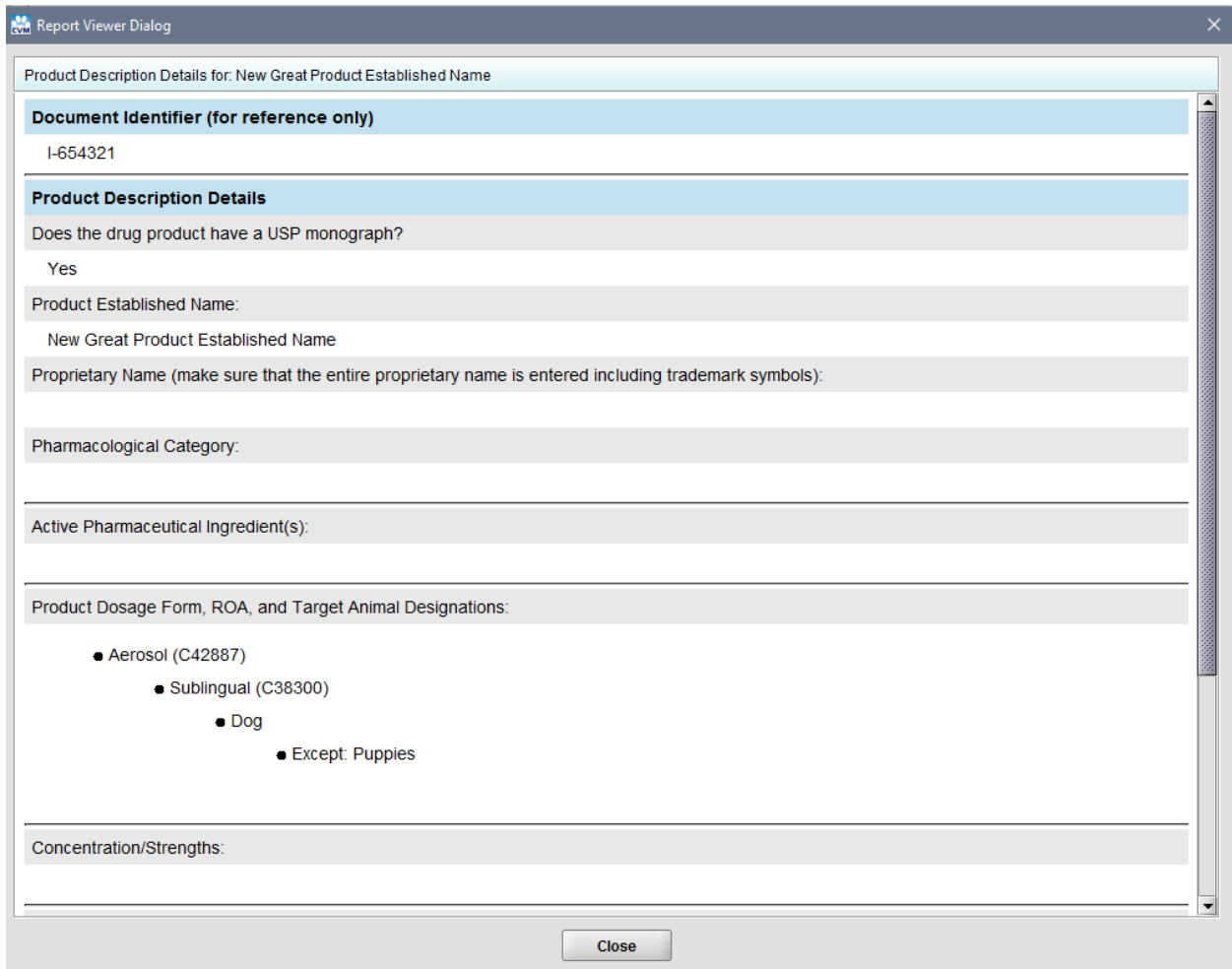
5. Delete an Existing Product Description

Select Delete on the Product Book Dialog to permanently delete the product description highlighted in the list. A confirmation dialog will open prior to the record being deleted.



6. View Product Description Details

Select View on the Product Book Dialog to open the Report Viewer Dialog for the product description highlighted in the list.

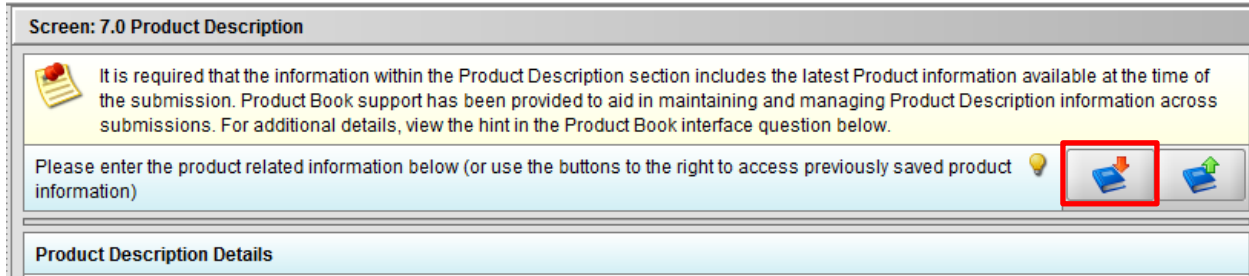


C. Copying from Product Book

When building a submission which already has a product description entry saved in the product book, the information can be copied from the product book. This functions similarly to the address book functionality in the contact information sections of the template.

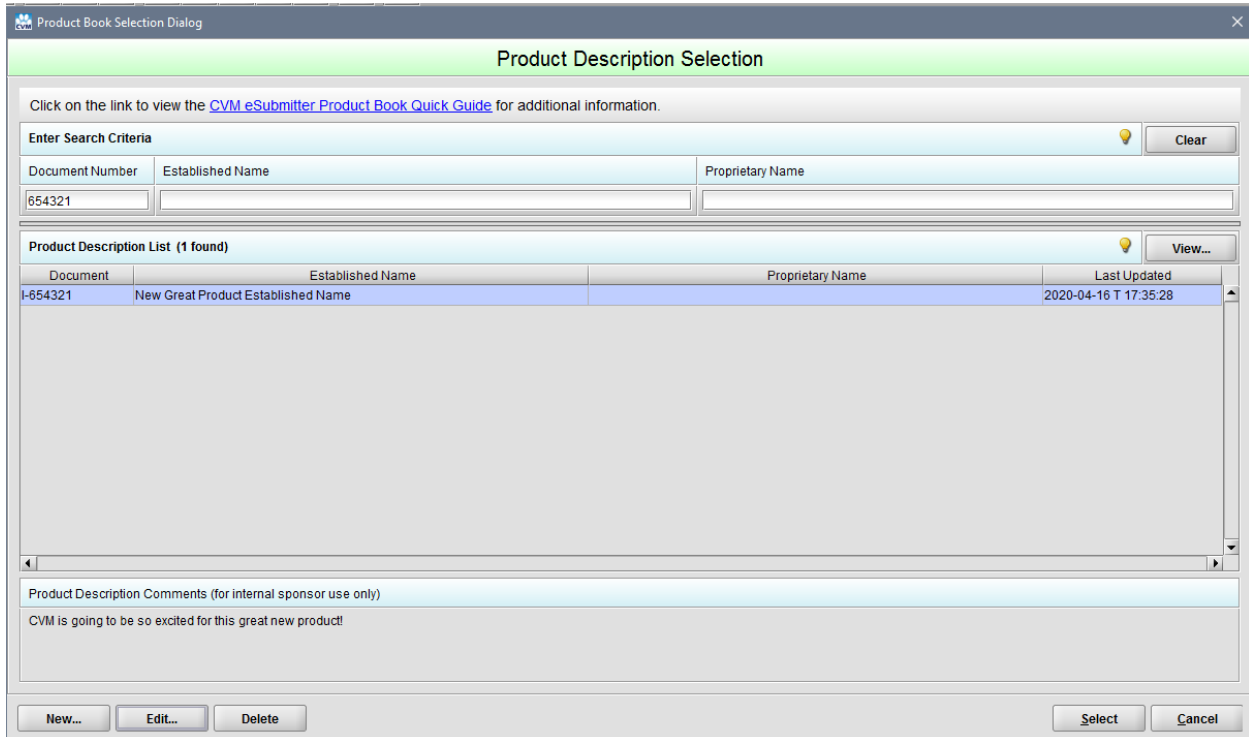
To access the new Product Description tab, users should select the appropriate submission type, classification code, and review division and then click next to display the new product description tab. The following steps describe the process for copying a product description from the Product Book:

1. On the Product Description tab, select the Copy from Product Book button (with the red downward arrow) to open the Product Book dialog



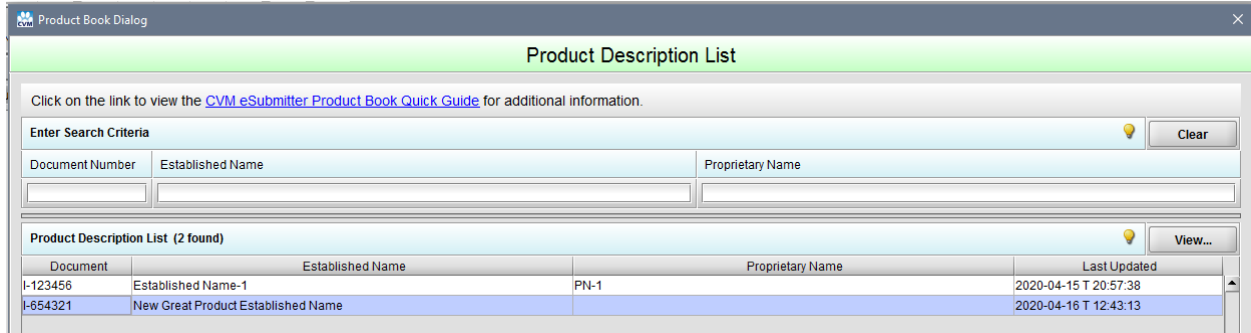
Search for the product description. The Search capability allows for searching across all Product Descriptions contained within the Product Book. The fields available for searching include document number, established name, and proprietary name. Specifically, the search locates all product descriptions where words within the search text either match exactly or begin with the search text provided. Multiple search fields are supported.

Note: When entering the Product Description Selection dialog, the document number entered for the submission is pre-populated.

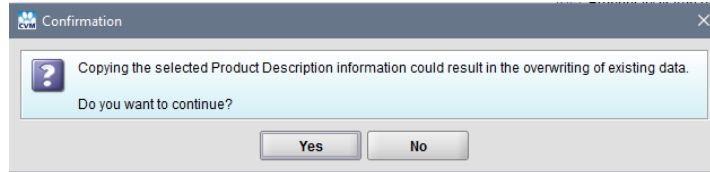


When no search text is provided, all product descriptions within the Product Book are included. A Clear option is also provided to quickly clear the search

text and display all product descriptions. If not found, add the product to the Product Book filling in all the information known at the time



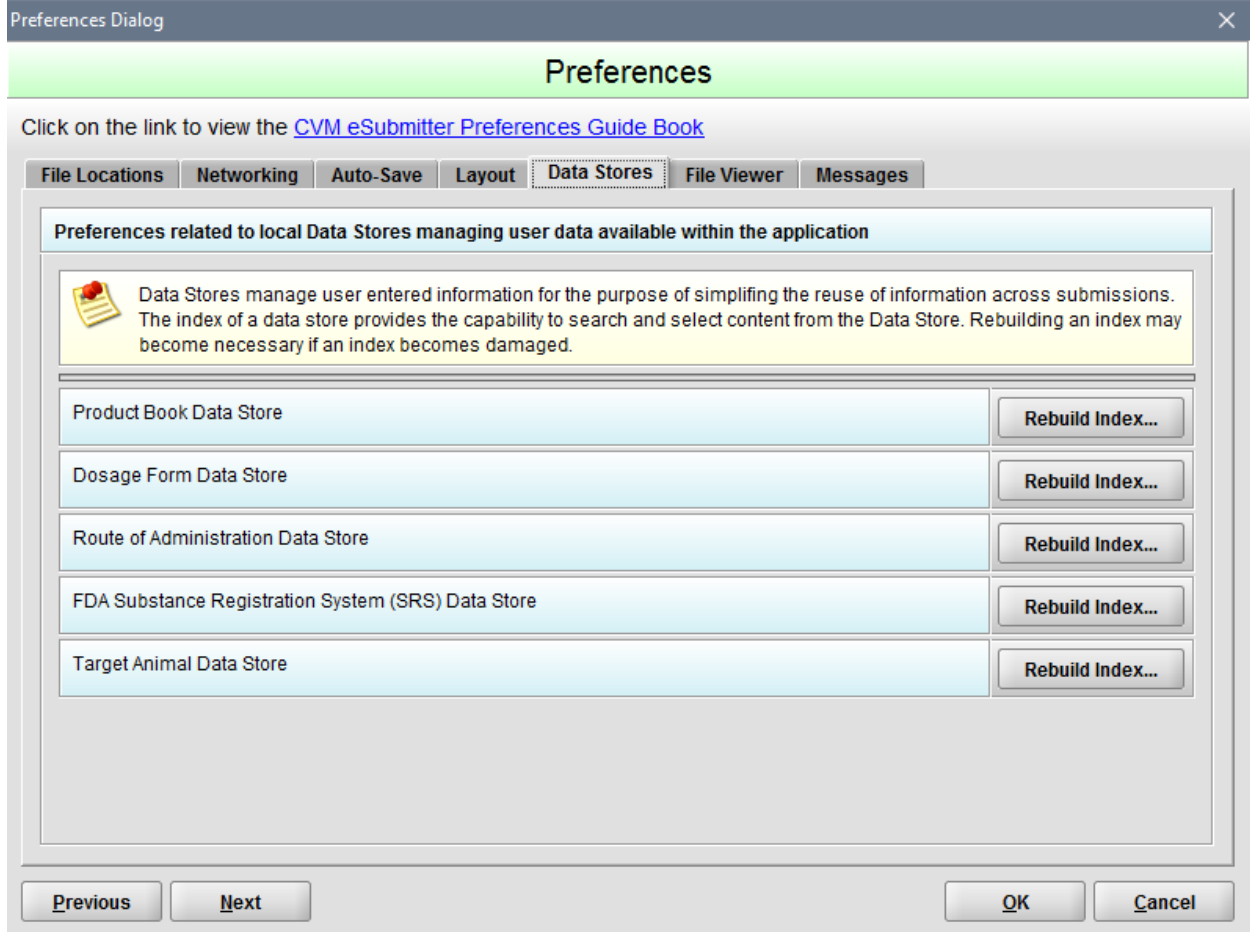
2. Select the product description to copy the information into the submission (closing the Product Book dialog). After selecting the entry, a confirmation screen will be presented informing you that any information currently populated in the template will be overwritten by the information copied from the product book.



3. Review the product description information to ensure it is accurate and contains the latest known information. If not, update the necessary information within the submission screen
4. If any product description information was updated within the submission, select the Copy to Product Book button (with the green upward arrow) to ensure all the latest updates are captured within the Product Book for the next submission related to this product

VII. Data Stores and Index Rebuilding

Access to the data store rebuilding options can be found in the eSubmitter Preferences Dialog. This is accessed from the File menu by selecting Preferences and then selecting the Data Stores tab.



The only instances an index should ever become damaged, and need to be rebuilt, is when a failure occurs during the update of the index files or when the files are accidentally deleted by a user or system. The most likely cause would be a system issue detected during an update (e.g., inadequate write privileges to the location, out of disk space, unknown system crash, multiple users updating the files at the same time).

CVM eSubmitter uses indices for two scenarios, static dictionary lookups (e.g., dosage form, route of administration, ingredients (SRS), target animal) and dynamic data stores of user content (e.g., product book). Static dictionaries would only be recreated by the application when updates to a dictionary are deployed in a release, which would be infrequent. Dynamic data stores would be updated whenever users add or update content within the data store. However, these types of updates (e.g., to product book content) are used minimally during submission preparation and likely would only cause a problem when performed simultaneously in a shared environment (multiple users accessing files at the same location). Precautions have been implemented to minimize any impacts.

In both scenarios, indices are only used to support searching of content, they are not the source of the content. All the data is maintained in separate XML files stored locally within the system; thus, allowing the indices to be recreated at any time with no loss of data. The purpose for supporting the rebuilding of indices within the application preferences is precautionary and only for the unexpected event.