Medicare Part B Average Sales Price (ASP) Module

Submitter User Guide

Version 0.1

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1. Purpose

The purpose of this user guide is to provide guidance and instructions to representatives of drug manufacturing companies as they submit federally required Medicare Part B drug Average Sales Price (ASP) data to the Centers for Medicare & Medicaid Services (CMS).

CMS uses the Fee-for-Service Data Collection System (FFSDCS) to house various Fee-for-Schedule modules.

The ASP Data Collection System, referred to within this user guide as the ASP Module, is one of the modules under the FFSDCS system, and offers the following:

- Provides users with an online-based software application for automating the collection, editing, and processing of drug product pricing data drug manufacturers submit on a quarterly basis.
- Establishes a relationship between the manufacturers' reported data and the billing codes Medicare providers use to calculate a weighted average sales price for each billing code.
- Establishes prices for billing codes to determine payment limits of Part B drugs on certain Medicare claims.
- Eliminates data entry errors, data formatting errors, and incomplete submitted data, and greatly reduces the process cycle and resource time needed to provide the pricing to contractors through automation of the manually intensive processes.
- Accepts, stores, validates, and calculates drug pricing on Medicare Part B drug data received for the Center for Medicare Management (CMM) stakeholders.

Section 303 (b) and (c) of the Medicare Modernization Act (MMA) of 2003 revised the payment methodology for the majority of Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs).

CMS applies the ASP methodology to the data drug manufacturers have submitted to the ASP Module. Per the MMA, ASP methodology determines the payment limit for these drugs. Local contractors calculate pricing for compounded drugs.

2. Logging in Using MFA

First time users must register and create an account in the CMS Enterprise Portal before logging in to the ASP Module. Refer to the ASP Module Registration User Guide for registration steps.

Once registration is complete, follow these steps to log in to the ASP Module as a Submitter using Multi-Factor Authentication (MFA):

1. Navigate to the CMS Enterprise Portal main page.

   The ASP Module Login Page opens. Refer to *Figure 1*.

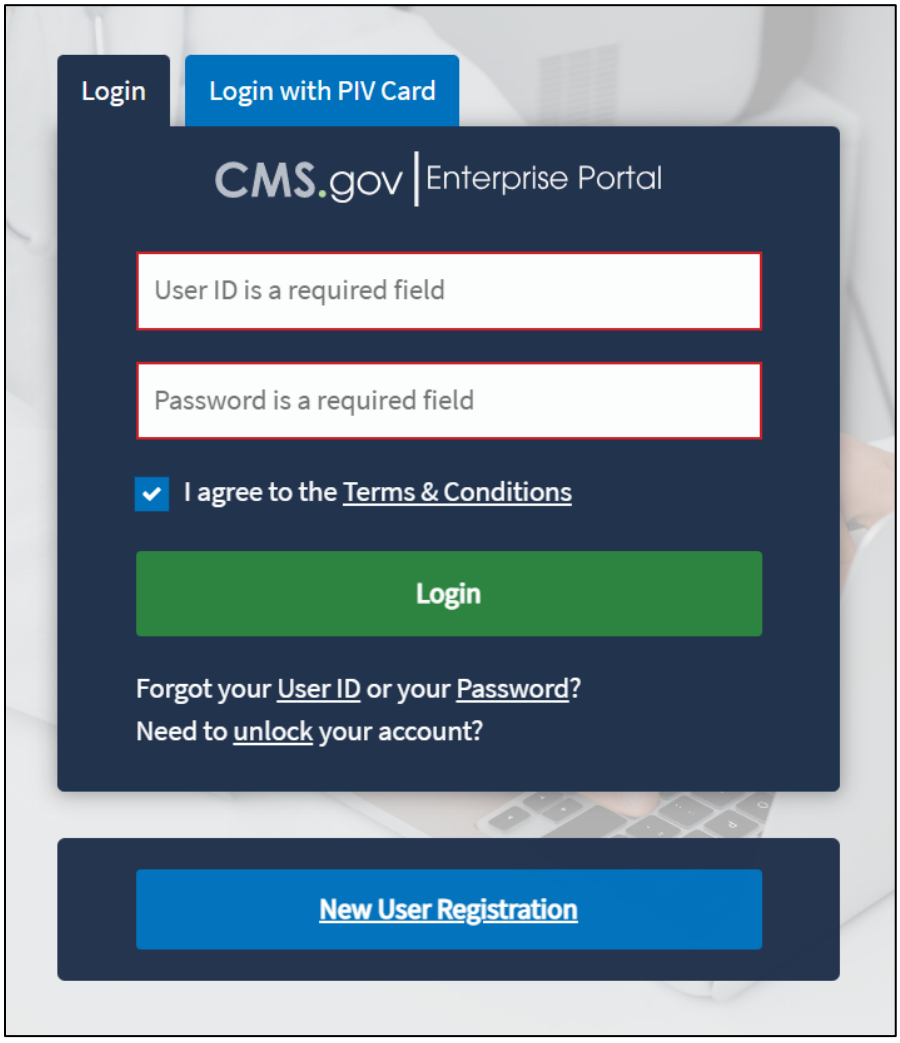

Figure 1: Logging in Using MFA - ASP Module Login

2. Enter your login information in the required **User ID** and **Password** fields.
3. Click the **Terms & Conditions** hyperlink and review the text in the pop-up window; close the window to move on to the next step.
4. Review the terms and conditions and select the **I agree to the Terms & Conditions** checkbox.

Note: By selecting this checkbox, you certify that you read and consent to monitoring while accessing and using the ASP Module. The terms and conditions link provides additional hyperlinks to the HHS Rules of Behavior and the CMS Privacy Act Statement.

5. Click **Login**.

Note: If you forget your user ID or password, click the **Forgot your User ID or your Password?** hyperlink under the **Login** button and follow the provided instructions. If you still cannot access your account and need to unlock it, click the **Need to unlock your account?** hyperlink under **Login** button.

The **Multi-Factor Authentication** page opens. Refer to *Figure 2*.

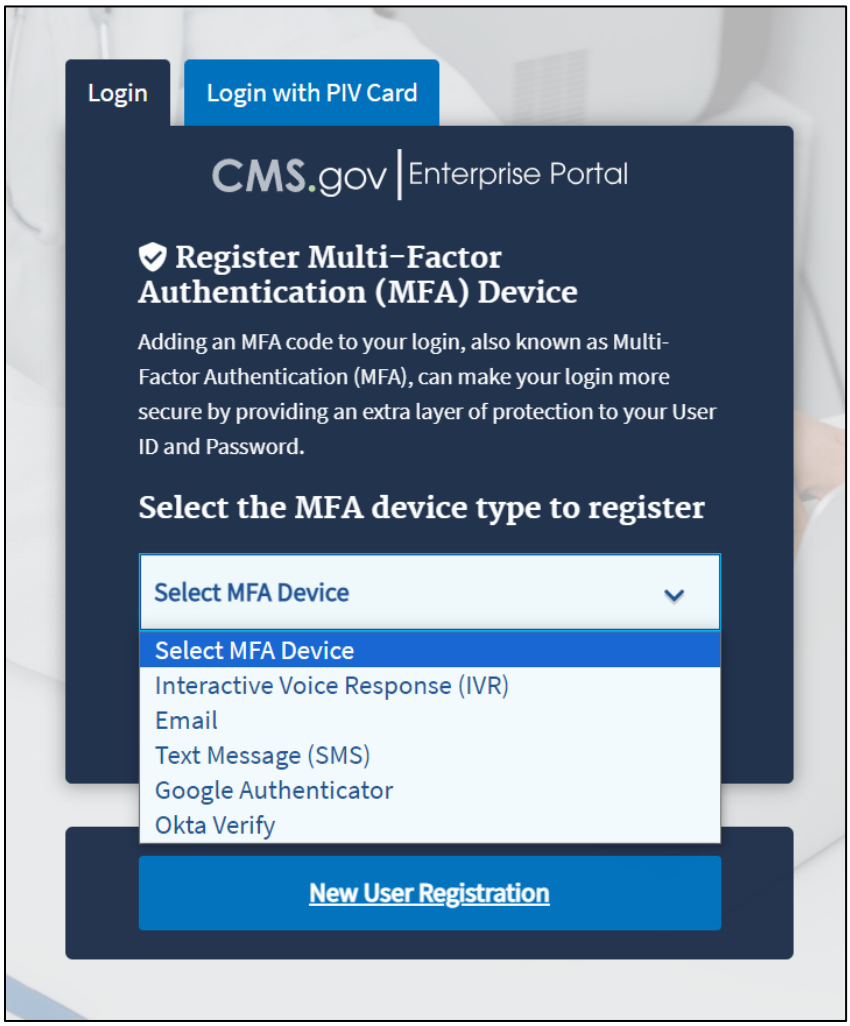

Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down Menu

To ensure the security of high value data submitted to the ASP Module, you must authenticate your identity using an MFA process. The first time you attempt to log in, you must choose an authentication method. Users have various authentication options, including Interactive Voice Response (IVR), Email, Text Message (Short Message Service (SMS)), Google Authenticator and Okta Verify.

6. Click the **Select MFA Device** drop-down menu; select your preferred MFA device type from the list. Whenever you log back into the ASP Module through this process, your preferred method of MFA reloads automatically.

Note: *Figure 3* demonstrates MFA registration using IVR as the selected option.

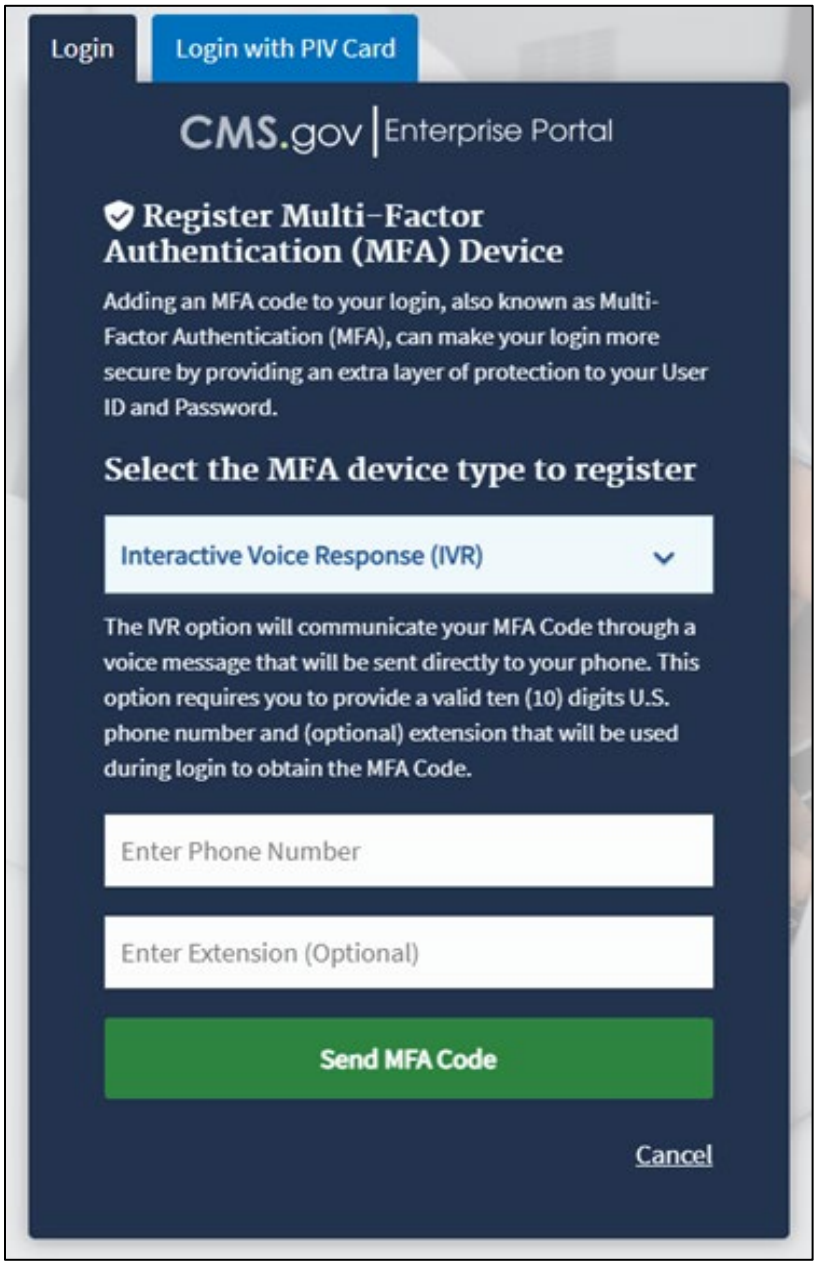

Figure 3: Logging in Using MFA - Multi-Factor Authentication - (IVR) Example

7. Enter your phone number in the **Phone Number** field; enter your extension in the **Extension** field, if necessary.
8. Click the **Send MFA Code** button to receive a six-digit code via your chosen contact method.

9. Record and enter the six-digit code you received into the **Enter MFA Code** field. Refer to *Figure 4*.

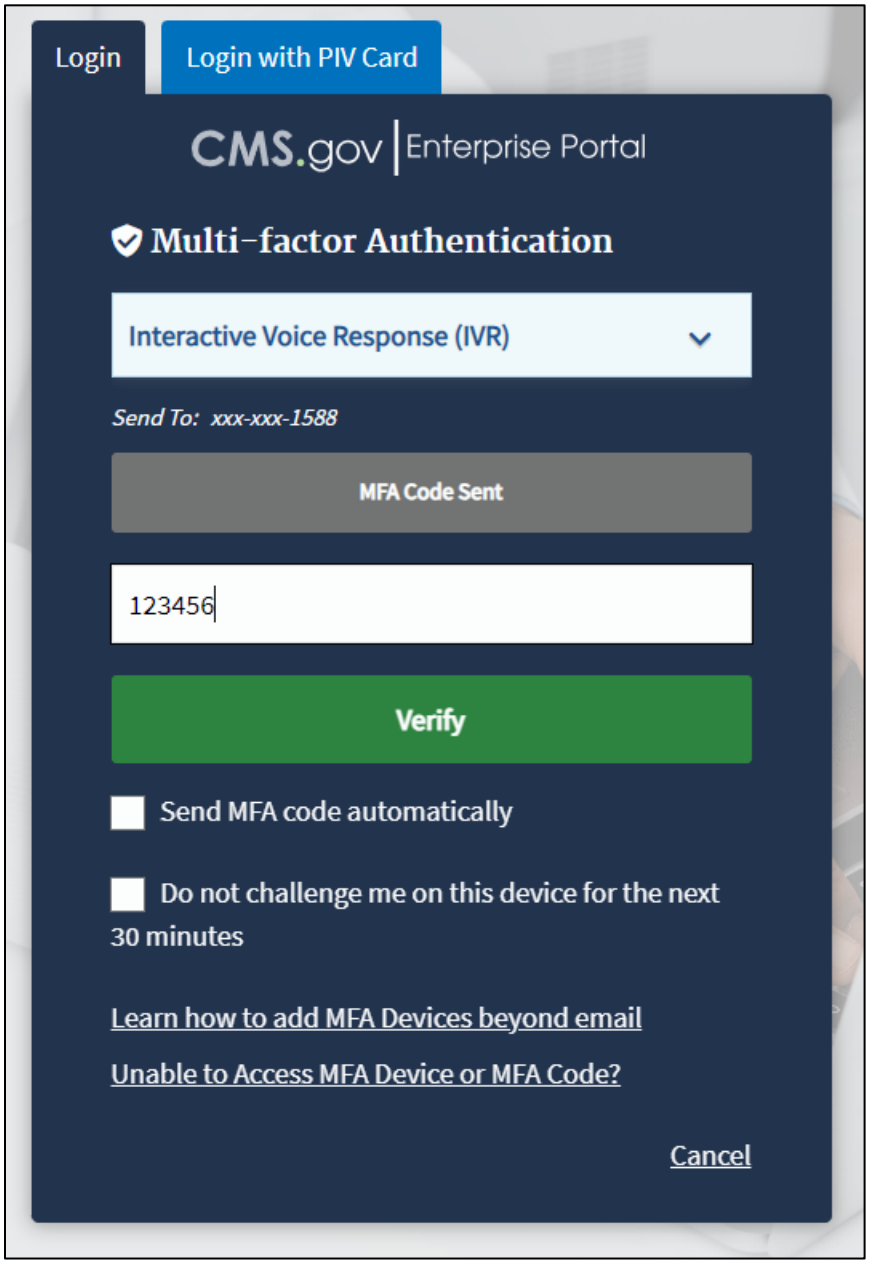

Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

10. Check the **Send MFA code automatically** and **Do not challenge me on this device for the next 30 minutes** checkboxes depending on your preference.

    Note: If you need help, click the L**earn how to add MFA Devices beyond email** and **Unable to Access MFA Devices or MFA Code?** hyperlinks.

11. Click the **Verify** button to confirm your identity and enter the ASP Module homepage.

    The **My Portal** landing page opens. Refer to *Figure 5.*

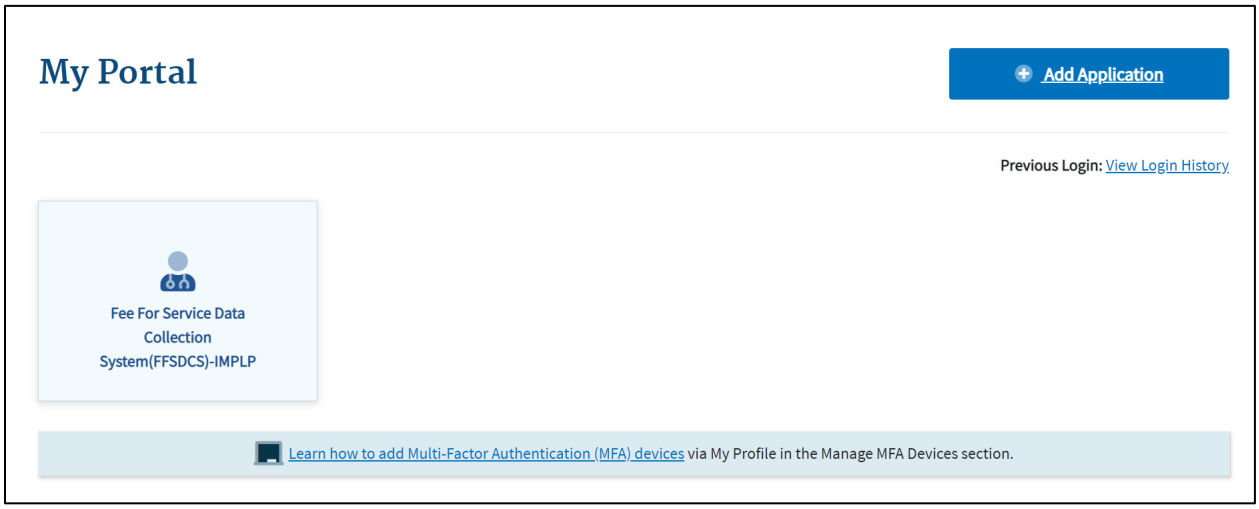

Figure 5: Logging in Using MFA - My Portal Landing Page

Note: Other CMS applications you have access to may display on the **My Portal** landing page.

12. Click the **Fee For Service Data Collection System (FFSDCS)** box.

    A Fee for Service Data Collection System (FFSDCS) drop-down menu displays. Refer to *Figure 6*.

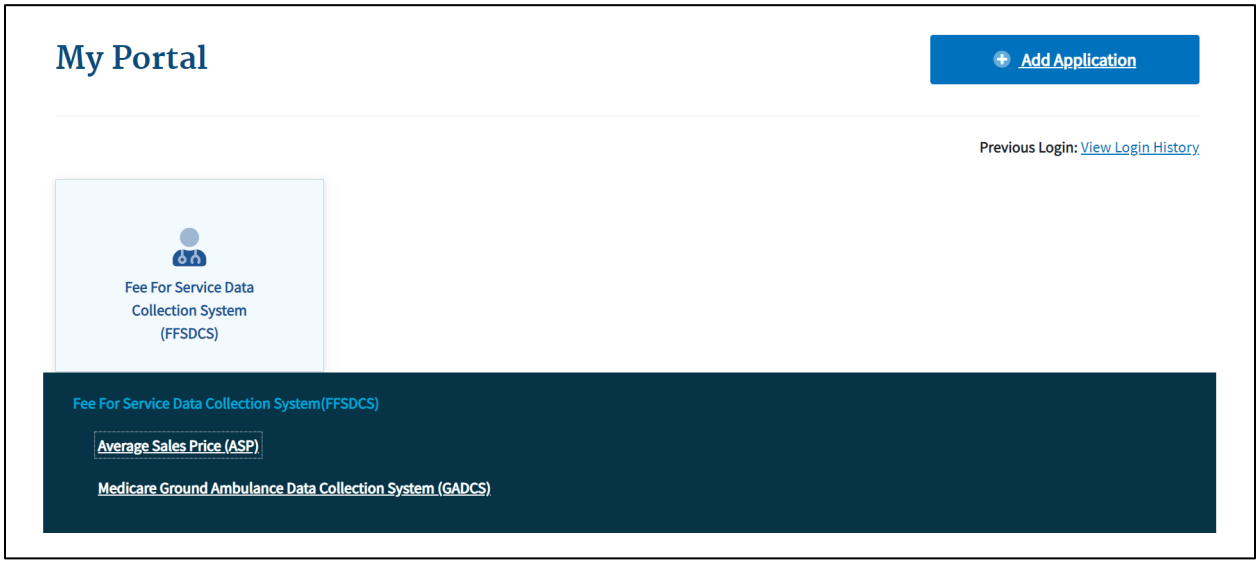

Figure 6: Logging in Using MFA - My Portal Landing Page - FFSDCS Drop-down Menu

13. Click the **Average Sales Price (ASP)** hyperlink.

    A full-page statement displays, titled **ASP Data for Drugs and Biologics Covered Under Medicare Part B**. The statement details recent statutory requirements stated in the Social Security Act (the Act), and the Consolidated Appropriations Act (CAA), 2021. These requirements hold that manufacturers must report their ASP data to CMS with precision on a quarterly basis without errors or miscalculations. Refer to *Figure 7*.

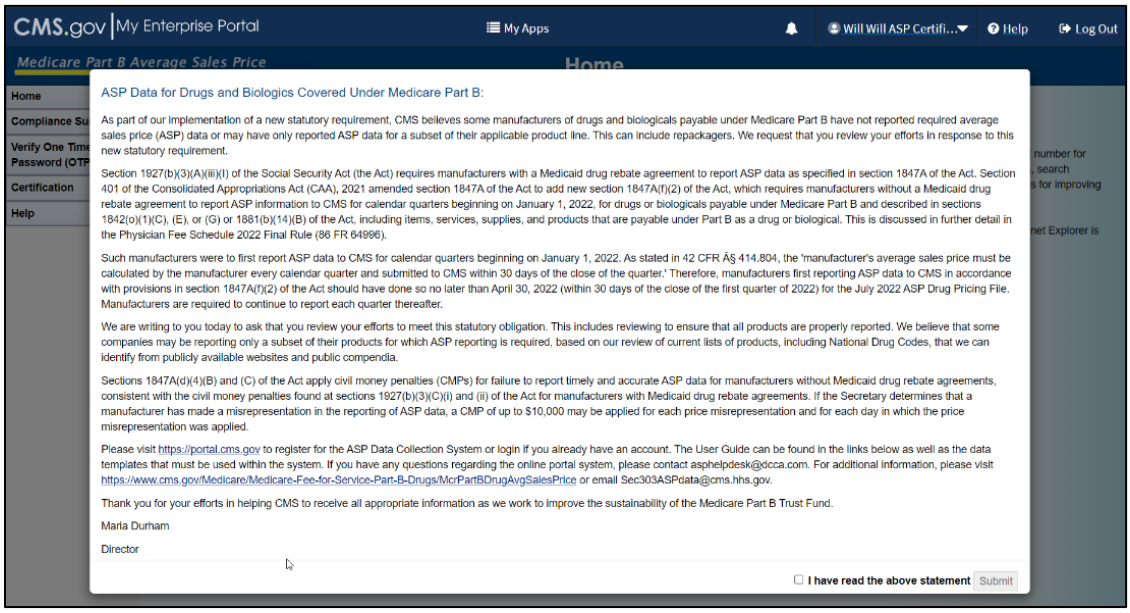

Figure 7: Logging in Using MFA - ASP Data for Drugs and Biologics Under Medicare Part B

14. Read the statement; select the **I have read the above statement** checkbox and click **Submit**.

    The Medicare Part B Average Sales Price homepage opens. Refer to *Figure 8*.

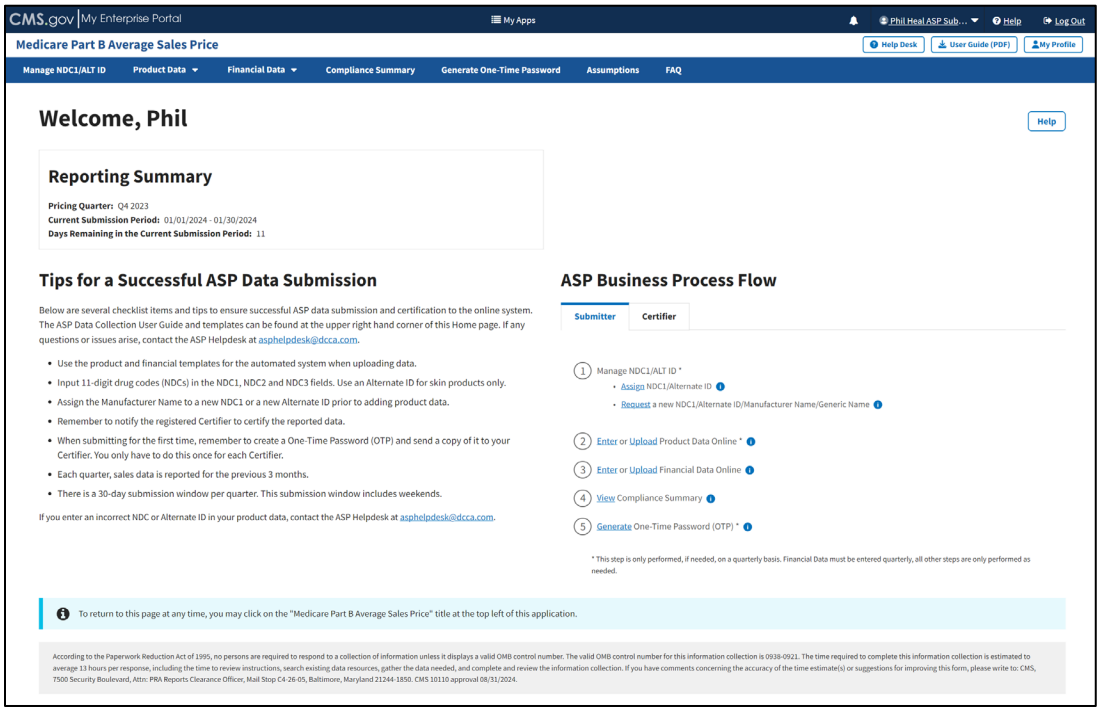

Figure 8: Medicare Part B Average Sales Price Homepage

3. ASP Homepage Menu Tabs

The following sections describe the functionality of each menu tab on the ASP homepage, including **Manage NDC1/ALT ID**, **Product Data**, **Financial Data**, **Compliance Summary**, **Generate One-Time Password**, **Assumptions** and **FAQ**.

3.1 Manage NDC1/ALT ID

Before you can enter product and financial data for your respective labeler codes (NDC1/ALT ID), you must assign those labeler codes to your unique user account.

The following sections describe how to assign NDC1s and Alternate IDs, as well as how to request a new NDC1, alternate ID, and manufacturer or generic name.

3.1.1 Assign by NDC1

Follow these steps to assign NDC1s:

1. From the Medicare Part B Average Sales Price homepage, click the **Manage NDC1/ALT ID** tab.

   The **Manage NDC1/ALT ID** page opens and displays the **Assign NDC1/ALT ID** tab by default. Refer to *Figure 9*.

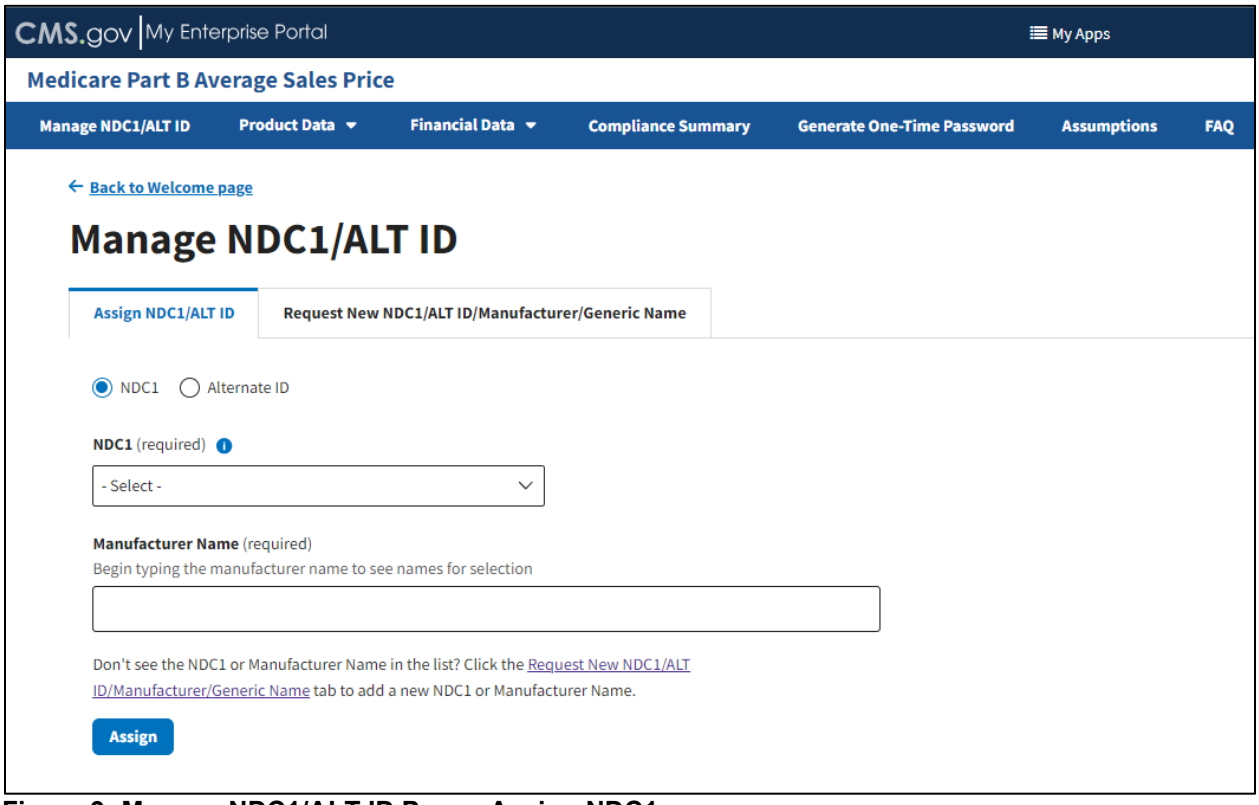

Figure 9: Manage NDC1/ALT ID Page - Assign NDC1

2. From the **Assign NDC1/ALT ID** tab, select the **NDC1** radio button to specify the product data you need to submit to the Module.

3. Under **NDC1 (required)**, click the -**Select-** drop-down menu to expand the list of submitted drugs and additional products in the Module to date; select the appropriate NDC1. Refer to *Figure 10*.

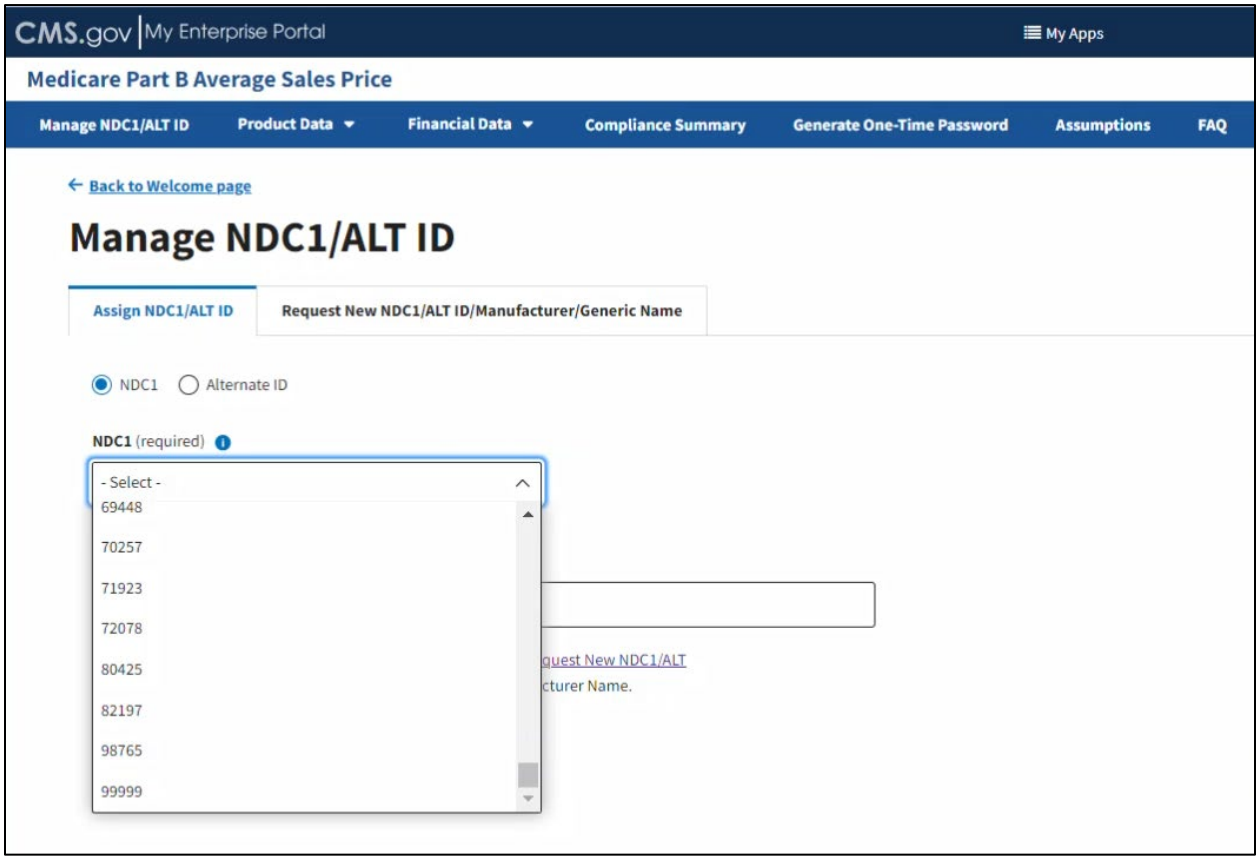

Figure 10: Manage NDC1/ALT ID Page - Assign NDC1 Drop-down Menu

3. Under **Manufacturer Name (required)**, type and select the appropriate manufacturer. Refer to *Figure 11*.

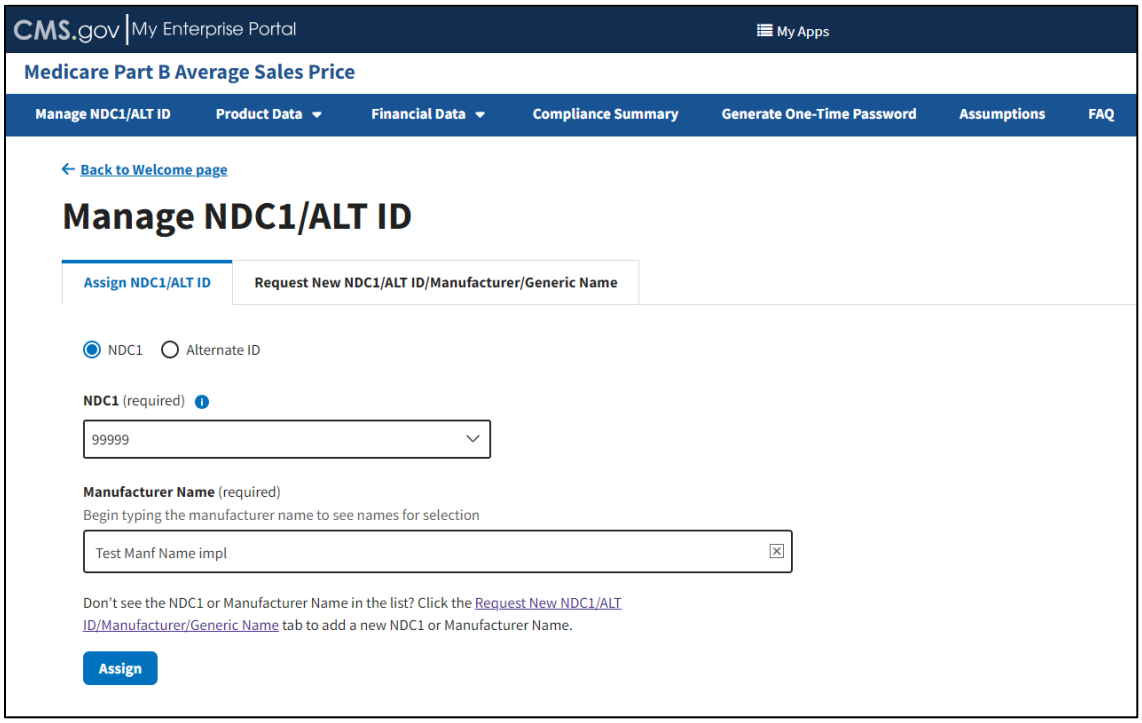

Figure 11: Manage NDC1/ALT ID Page - Enter NDC1 Manufacturer Name

4. Click **Assign** to submit your information.

   A message displays confirming you have successfully added your selections. Refer to *Figure 12*.

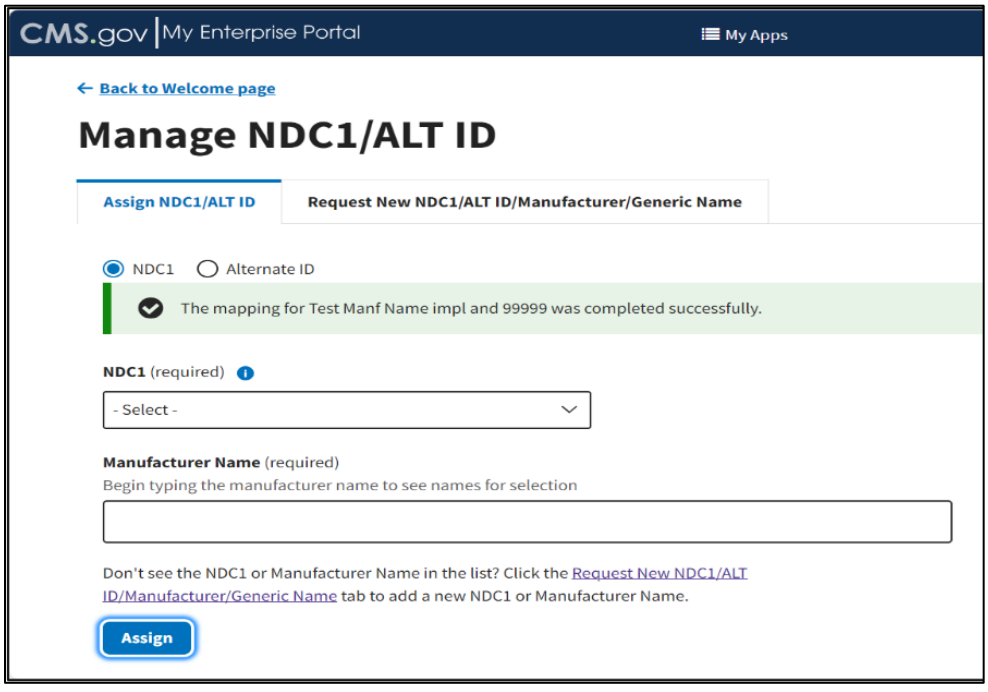

Figure 12: Manage NDC1/ALT ID - NDC1 Assigned Successfully

3.1.2 Assign by Alternate ID

Follow these steps to assign alternate IDs:

1. From the Medicare Part B Average Sales Price homepage, click the **Manage NDC1/ALT ID** tab.

   The **Manage NDC1/ALT ID** page opens and displays the **Assign NDC1/ALT ID** tab by default.

2. From the **Assign NDC1/ALT ID** tab, select the **Alternate ID** radio button.

   New fields specific to assigning an alternate ID display. Refer to *Figure 13*.

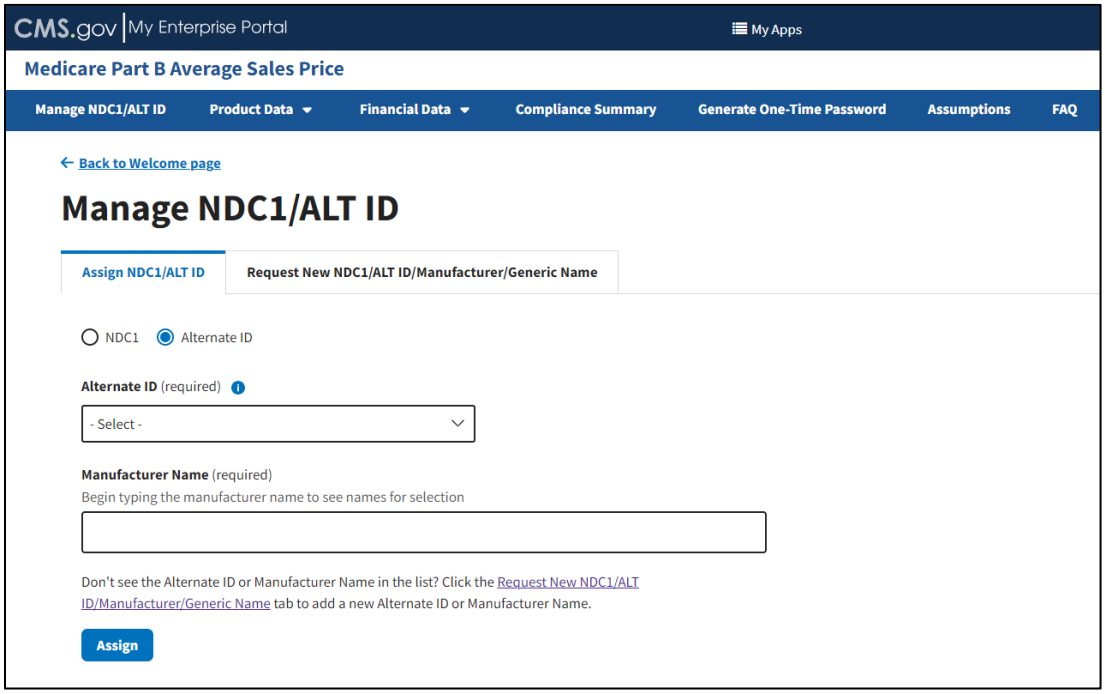

Figure 13: Manage NDC1/ALT ID Page - Assign ALT ID

3. Under **Alternate ID (required)**, click the -**Select-** drop-down menu to expand the list of submitted drugs and additional products in the Module to date; select the appropriate alternate ID. Refer to *Figure 14*.

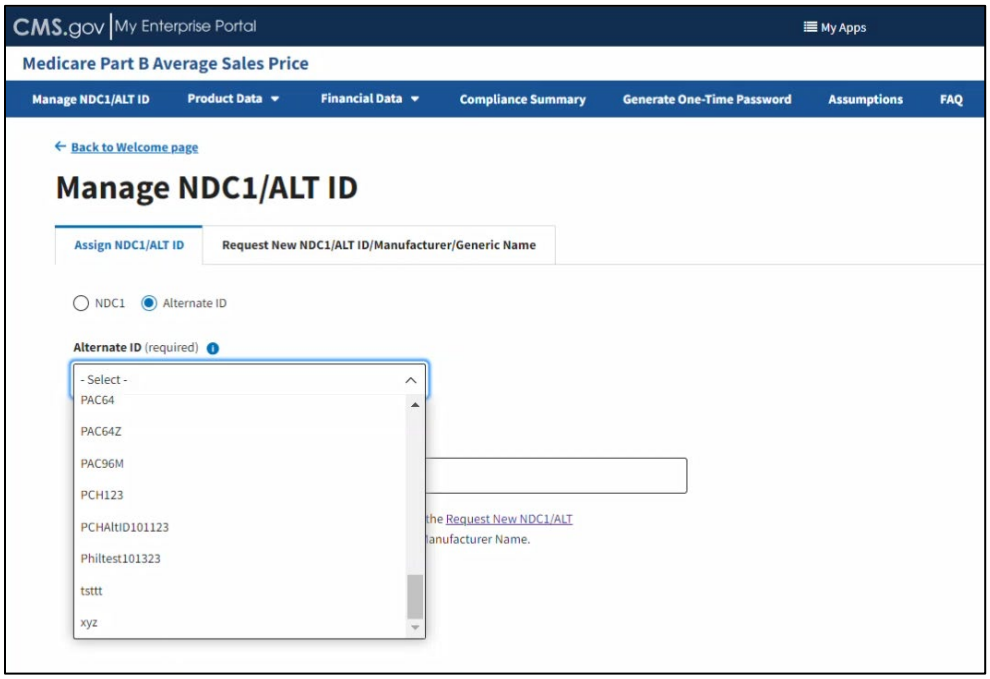

Figure 14: Manage NDC1/ALT ID Page - Assign ALT ID Drop-down Menu

4. In the **Manufacturer Name (required)** auto-fill field, begin to type the manufacturer name; select the appropriate manufacturer from the list that generates. Refer to *Figure 15*.

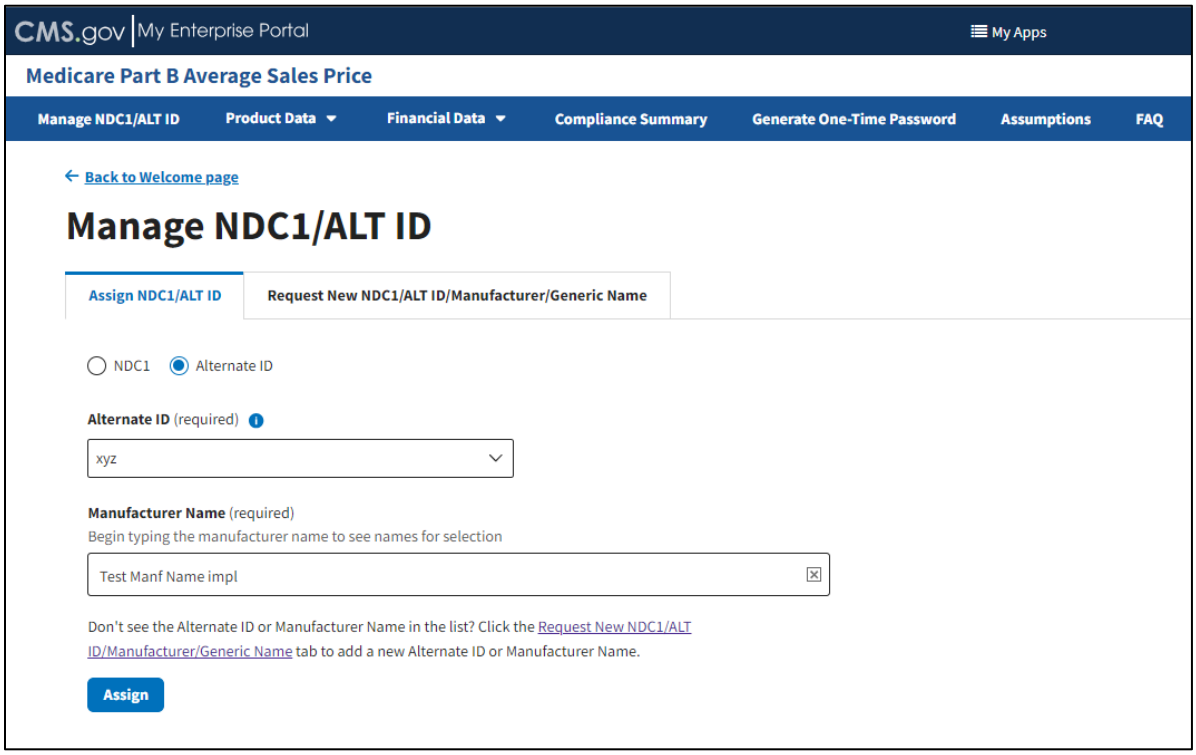

Figure 15: Manage NDC1/ALT ID Page - Enter ALT ID Manufacturer Name

5. Click **Assign** to submit your information.

   A message displays confirming you have successfully added your selections. Refer to *Figure 16*.

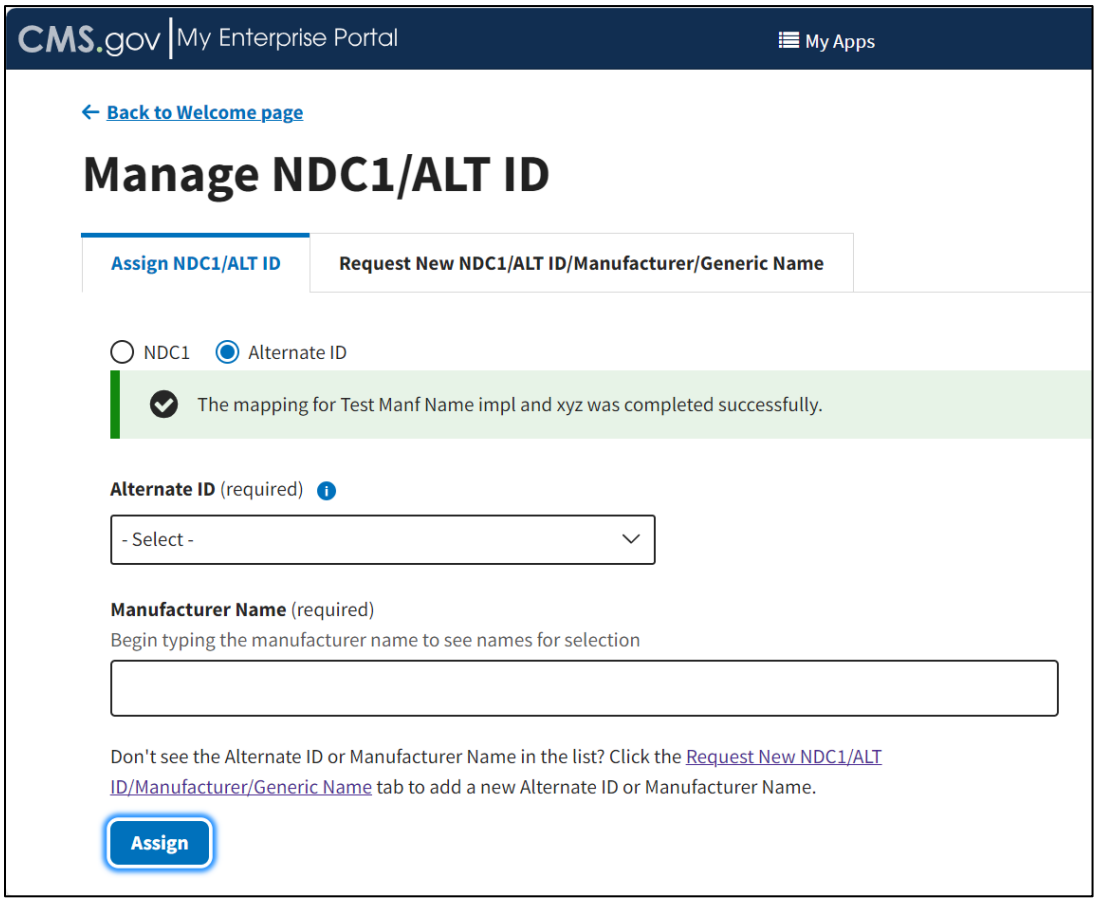

Figure 16: Manage NDC1/ALT ID - ALT ID Assigned Successfully

3.1.3 Request New NDC1/ALT ID/Manufacturer/Generic Name

The following sections describe how to request a new NDC1, ALT ID, manufacturer, and generic name.

3.1.3.1 Request New NDC1

Follow these steps to request a new NDC1:

1. Navigate to the **Manage NDC1/ALT ID** page, which automatically on the **Assign NDC1/ALT ID** tab.
2. Click the **Request New NDC1/ALT ID/Manufacturer/Generic Name** tab.

   The **Request New NDC1/ALT ID/Manufacturer/Generic Name** page opens, showing the status (**Pending**, **Approved**, or **Rejected**) for each submitted request. The Module organizes data by **Request Type**, **Requested Value** as well as **Request Date** and **Status** (**Pending**, **Approved**, or **Rejected**). Refer to *Figure 17*.

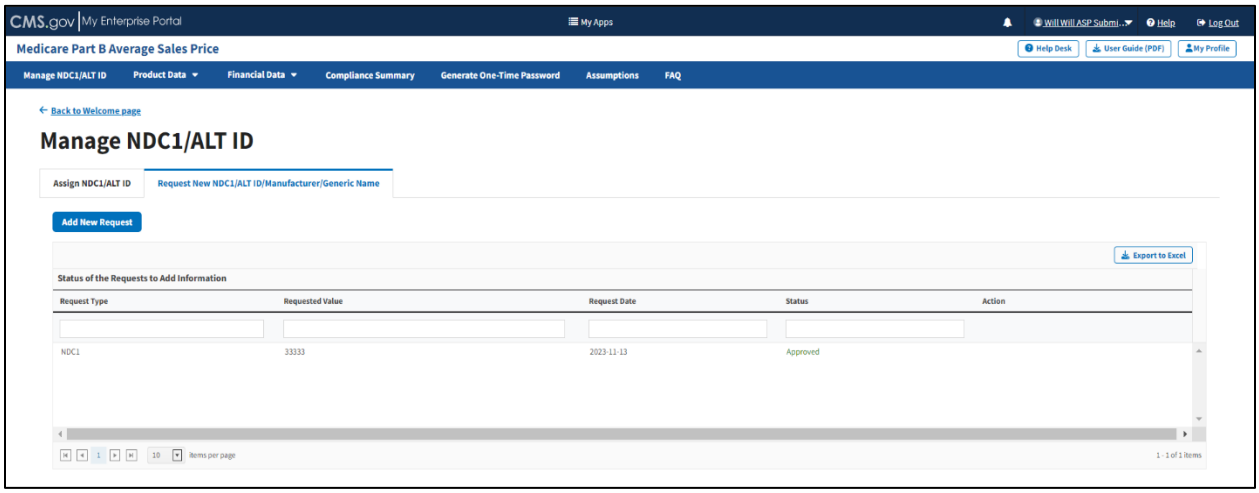

Figure 17: Request New NDC1/ALT ID/Manufacturer/Generic Name Page

3. Click the **Add New Request** button.

   An **Add New NDC1/ALT ID/Manufacturer/Generic Name** window opens. Refer to *Figure 18*.

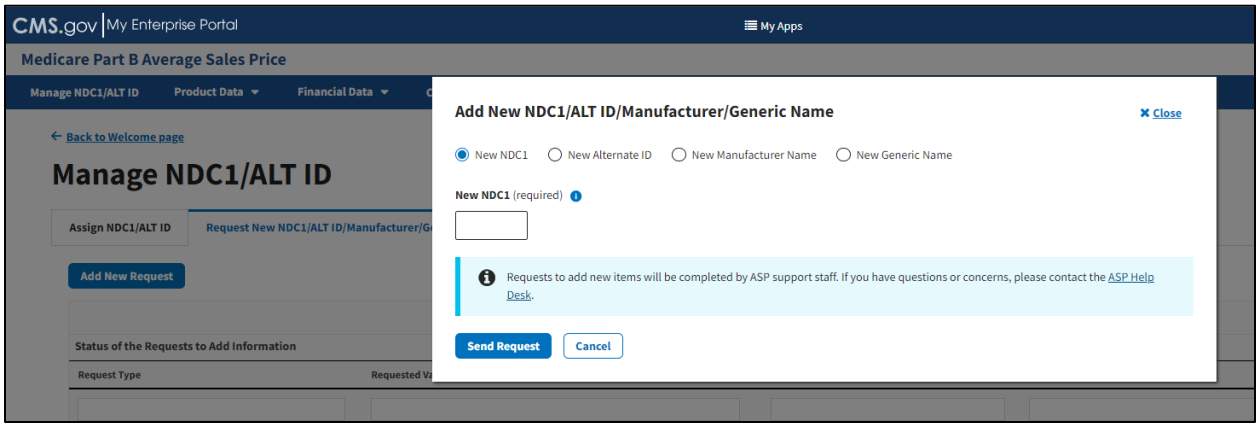

Figure 18: Request New NDC1/ALT ID/Manufacturer/Generic Name Page - Add New NDC1

4. Select the **New NDC1** radio button to specify the product data you need to submit to the Module. Note that the Module automatically defaults to select the **New NDC1**.
5. Under **New NDC1 (required)**, enter the appropriate NDC for the data product you are requesting to add to the Module. Refer to *Figure 19*.

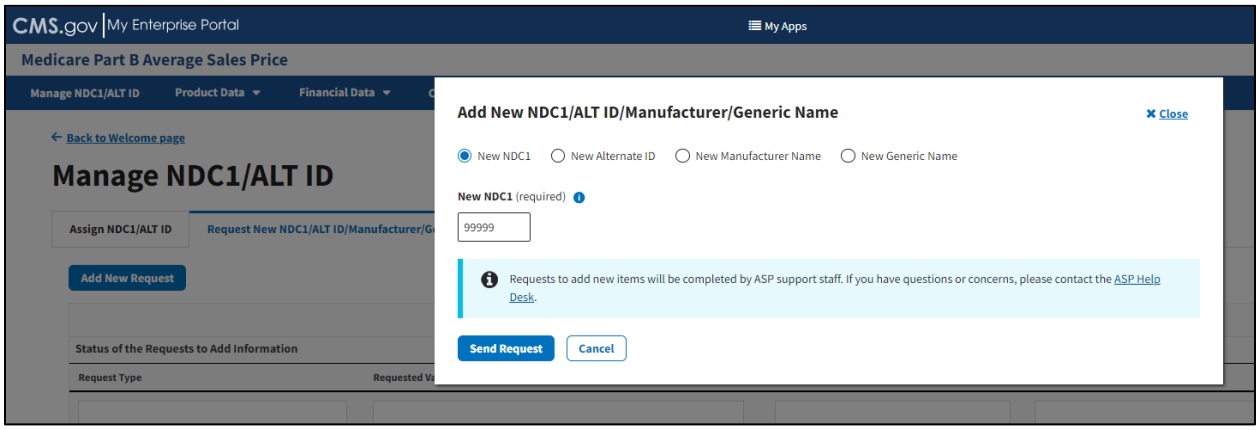

Figure 19: Request New NDC1 - Field Filled

6. Click **Send Request** to submit your information.

   A message displays confirming you have successfully added your selections. Refer to *Figure 20*.

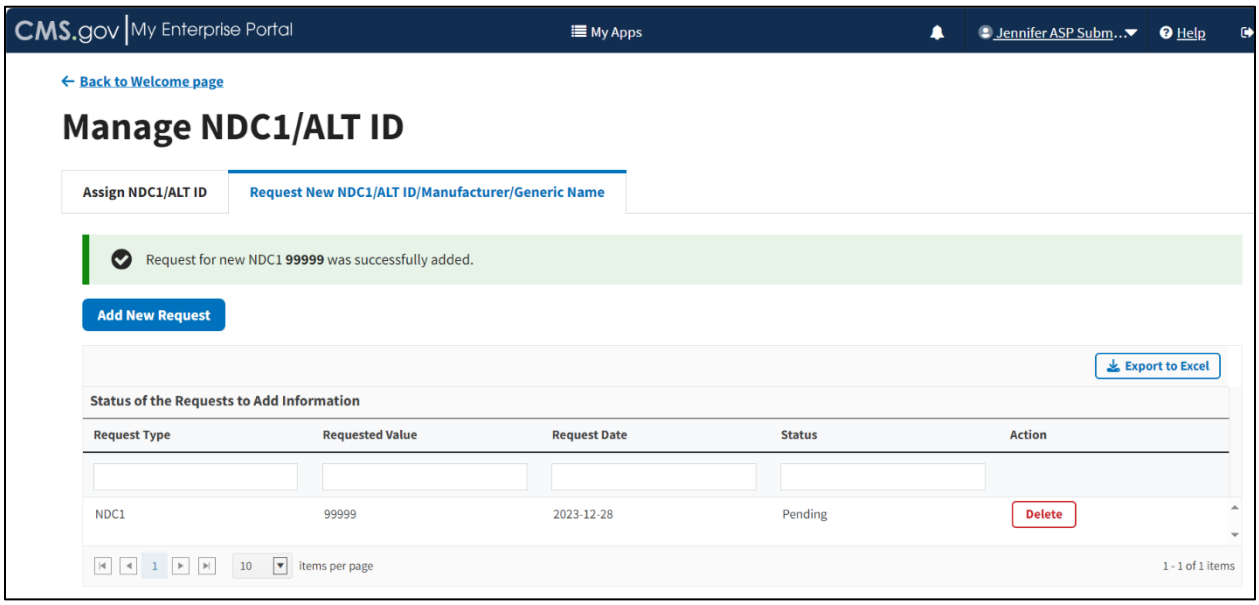

Figure 20: Request New NDC1 - NDC1 Successfully Added

3.1.3.2 Request New ALT ID

Follow these steps to request a new **Alternate ID**:

1. Click the **Add New Request** button. Refer to *Figure 20*.

   An **Add New NDC1/ALT ID/Manufacturer/Generic Name** window opens. Note that the Module automatically defaults to the **New NDC1** tab.

2. Select the **New Alternate ID** radio button to specify the product data you need to submit to the Module. Refer to *Figure 21*.

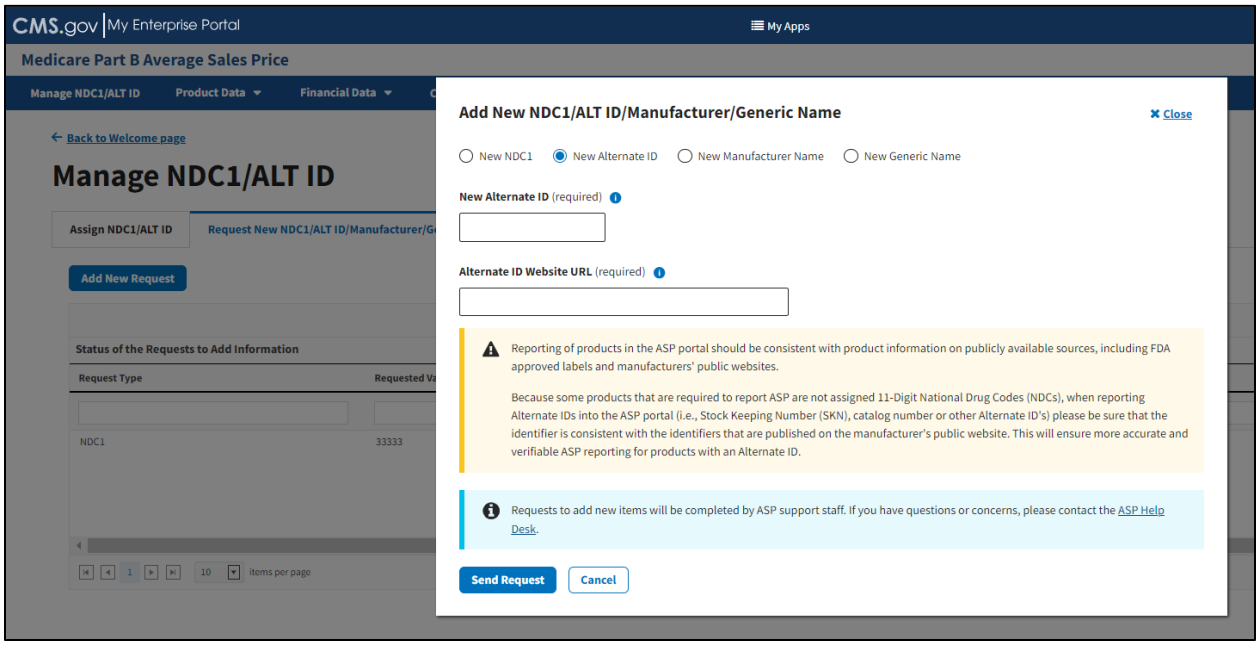

Figure 21: Request New NDC1/ALT ID/Manufacturer/Generic Name Page - Add New ALT ID

3. Under **New Alternate ID (required)**, enter the appropriate alternate ID for the product you want to add to the Module.
4. Under **Alternate ID Website URL (required)**, enter the hyperlink for the drug manufacturer's website. Refer to *Figure 22*.

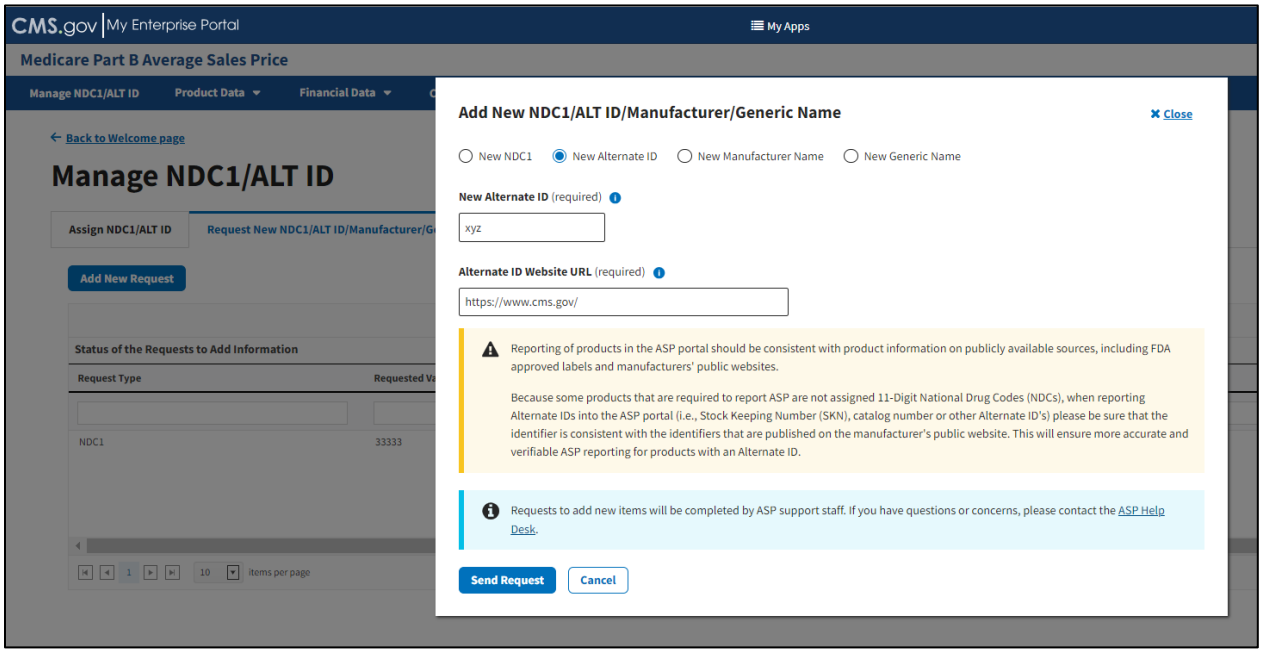

Figure 22: Request New Alternate ID - ALT ID Field Filled

5. Click the **Send Request** button to submit your information.

A message displays confirming you have successfully added your selections. Refer to *Figure 23*.

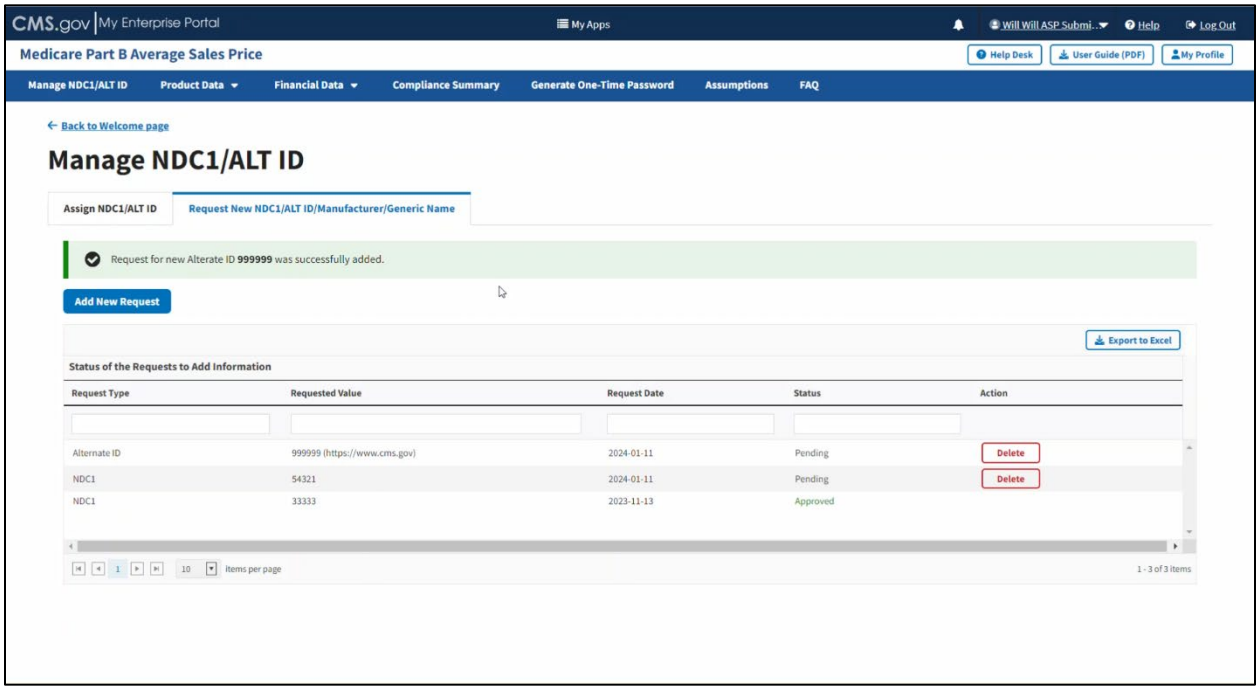

Figure 23: Request New Alternate ID - ALT ID Successfully Added

3.1.3.3 Request New Manufacturer Name or New Generic Name

Follow these steps to request a **New Manufacturer** or **New Generic Name**:

1. Click the **Add New Request** button. Refer to *Figure 23*.

   An **Add New NDC1/ALT ID/Manufacturer/Generic Name** window opens. Note that the Module automatically defaults to the **New NDC1** tab.

2. Select either the **New Manufacturer Name** or the **New Generic Name** radio button to specify the product data you need to submit to the Module.

   A new field displays as the next page opens for either selection. Refer to *Figure 24* and *Figure 25*.

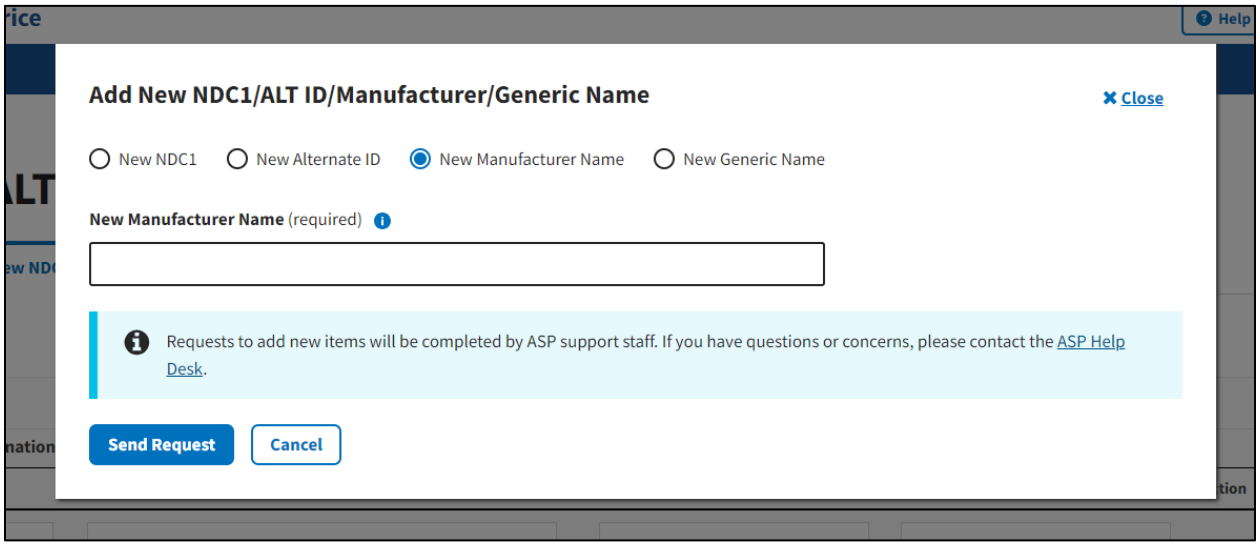

Figure 24: Request New Manufacturer Name

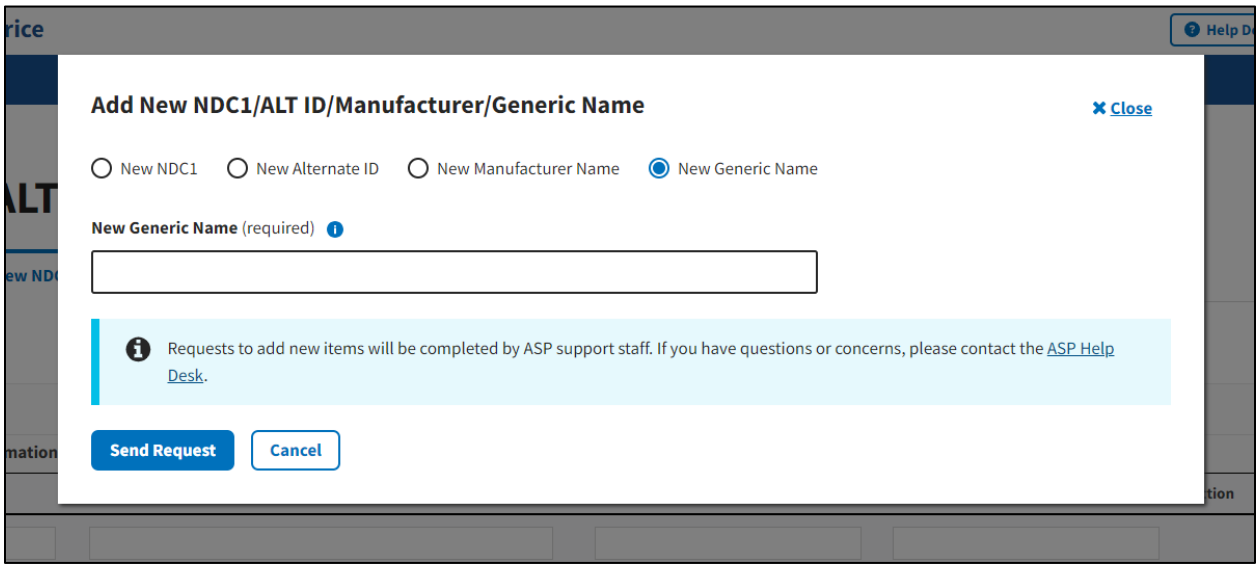

Figure 25: Request New Generic Name

3. Under **New Manufacturer Name (required)** or **New Generic Name (required)**, enter the appropriate information for the data product you want to add to the Module. Refer to *Figure 26* and *Figure 27*.

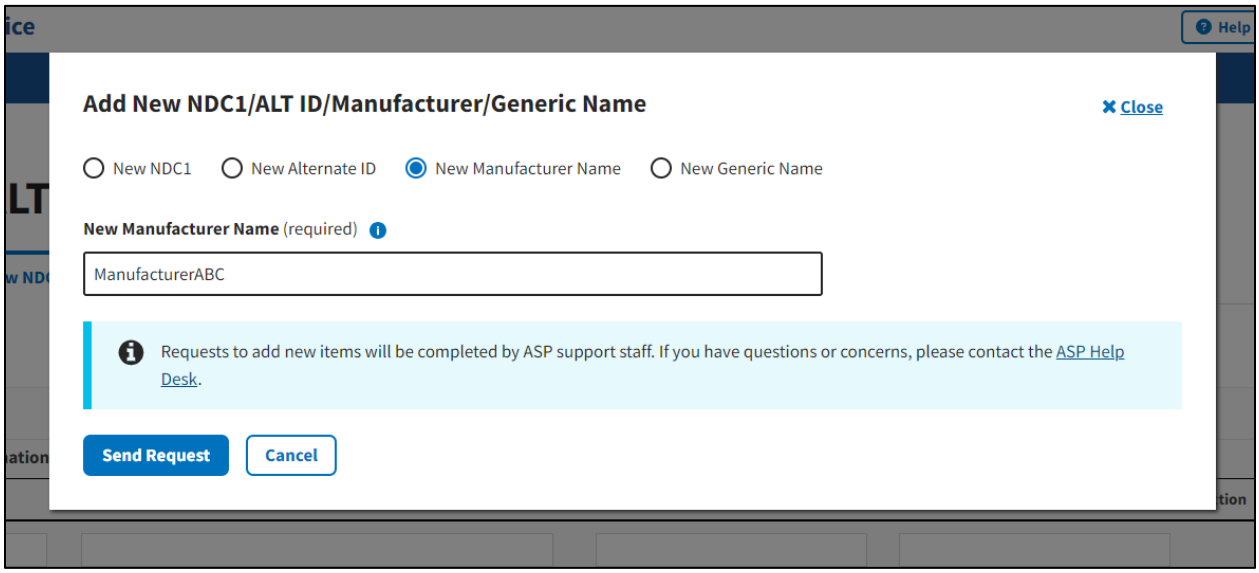

Figure 26: Request New Manufacturer Name - Field Populated

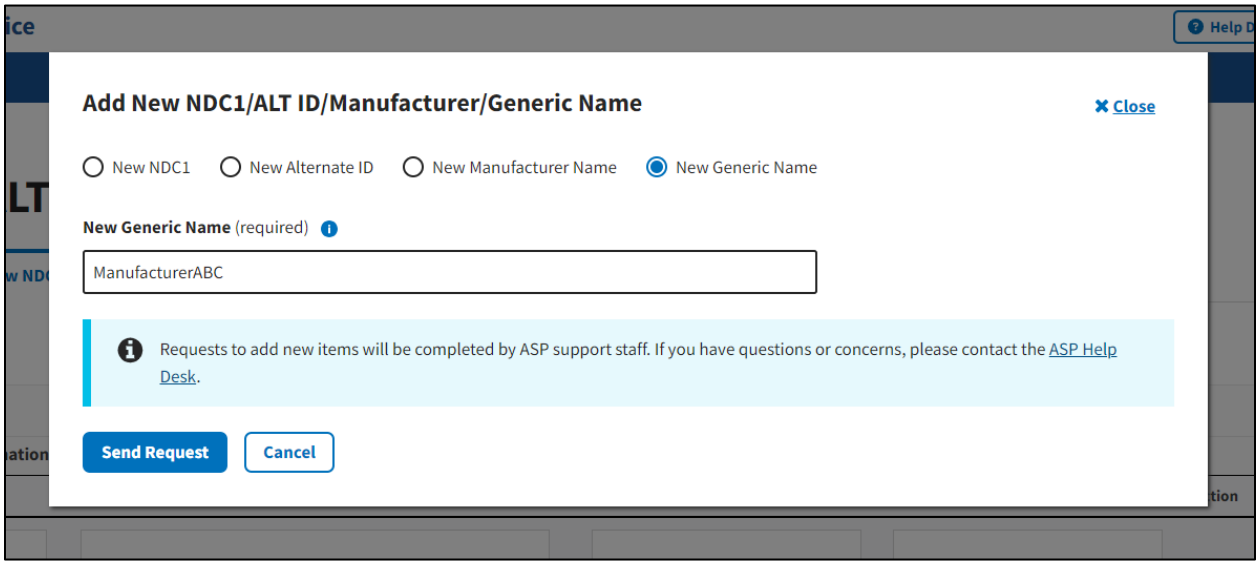

Figure 27: Request New Generic Name - Field Populated

4. Click **Send Request** to submit your information for either selection.

   A message displays confirming you have successfully added your selections. Refer to *Figure 28* and *Figure 29*.

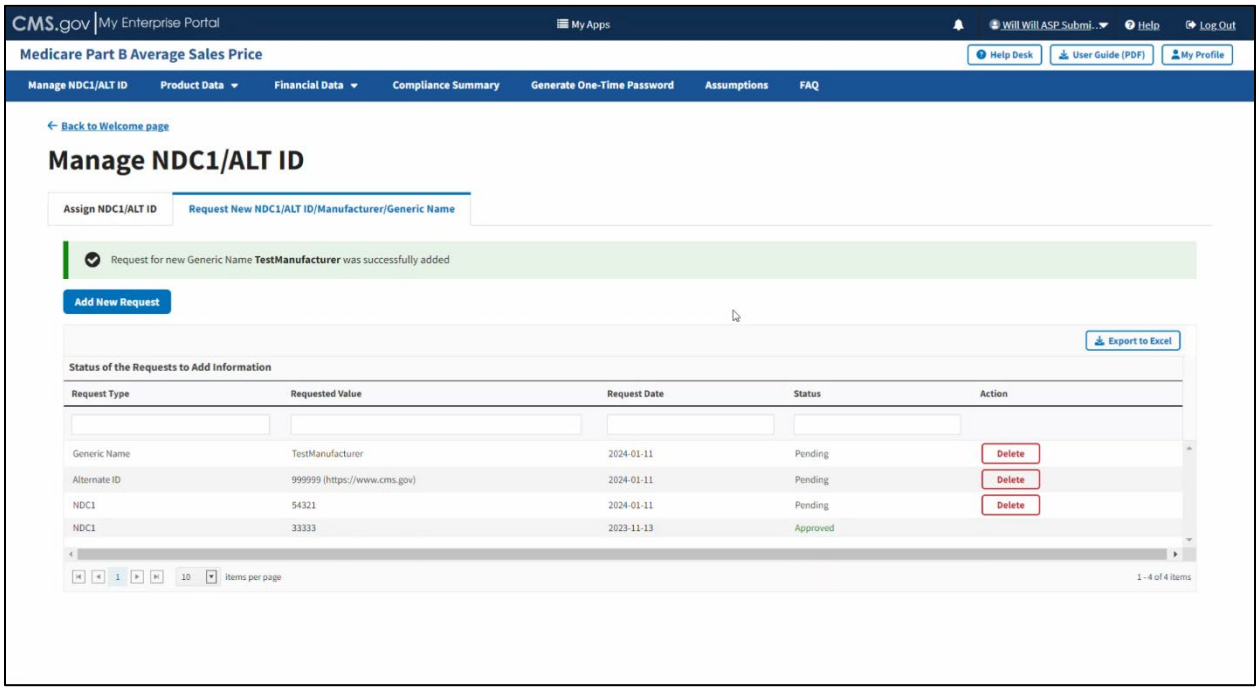

Figure 28: Request New Manufacturer Name - Successfully Added

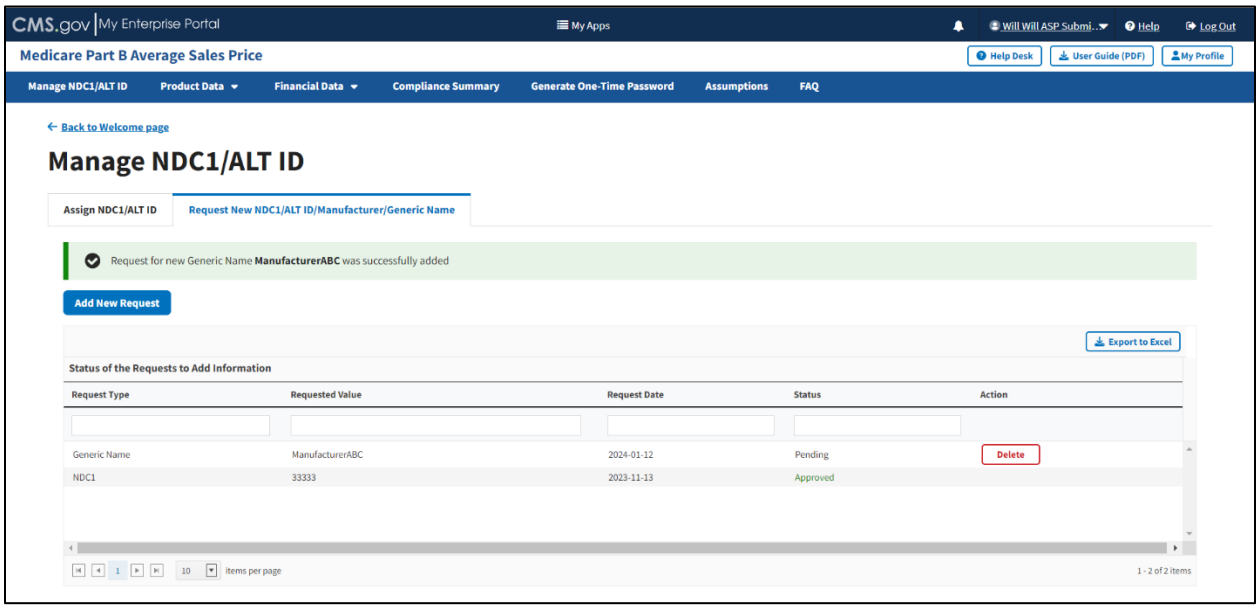

Figure 29: Request New Generic Name - Successfully Added

Note: ASP support staff complete requests to add new items. Contact asphelpdesk@dcca.com for further questions or concerns about the process.

3.2 Product Data

Drug manufacturers must submit quarterly drug pricing data using a file transfer process, or through online data entry in the ASP module. Drug data consists of product and financial data.

Click the **Product Data** tab on the Medicare Part B Average Sales Price homepage to view the drop-down menu for the **Add/Update Product Data, Upload Product Data**, and **View Drugs** tabs. Refer to *Figure 30*.

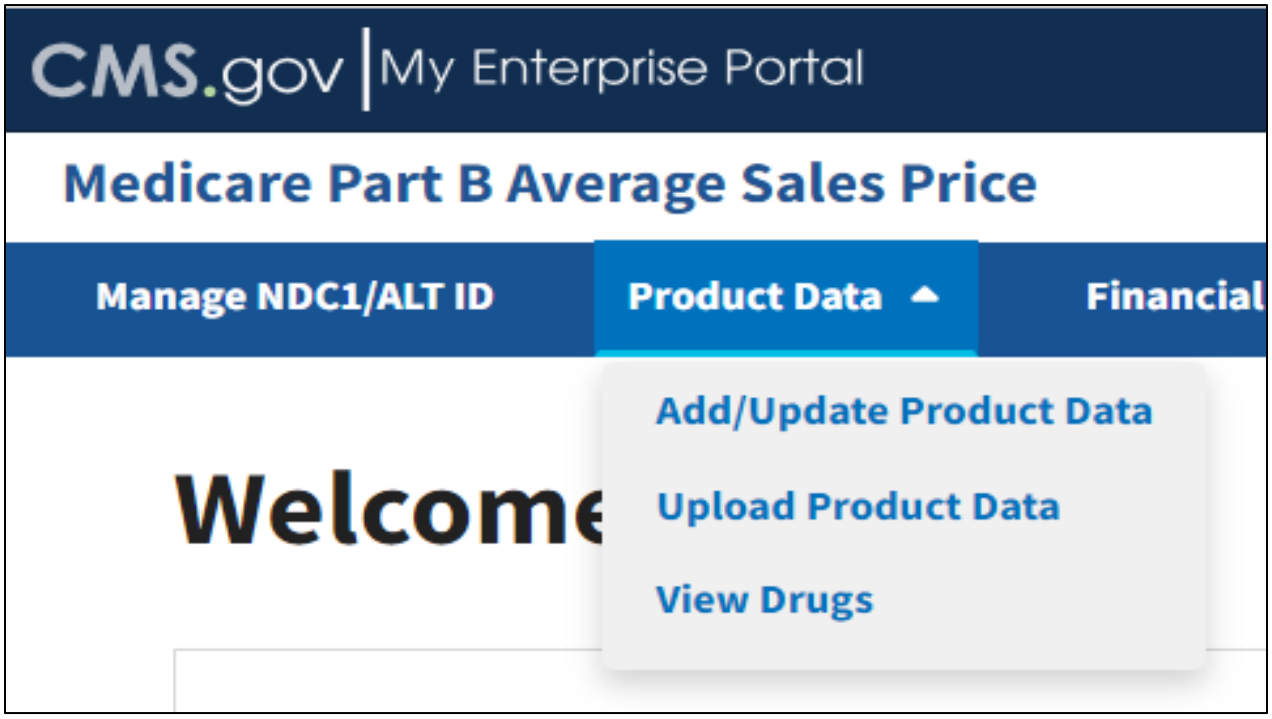

Figure 30: Product Data - Main Drop-down Menu

The following sections describe how to add/update, upload product data, and view drugs.

3.2.1 Add/Update Product Data

Follow these steps to add and/or update product data:

1. From the Medicare Part B Average Sales Price homepage, click the **Product Data** tab; then select the **Add/Update Product Data** tab.

   The **Add/Update Product Data** page opens with default selections. Refer to *Figure 31*.

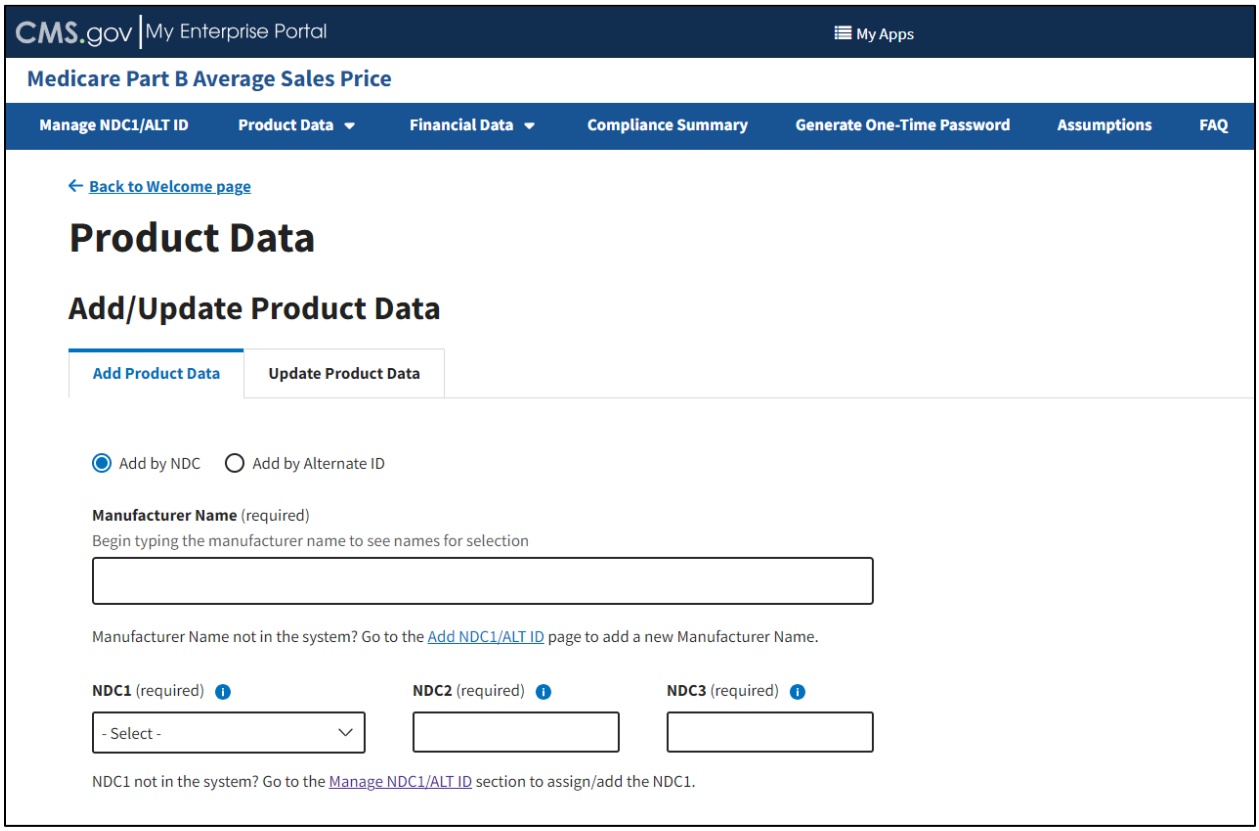

Figure 31: Add/Update Product Data

Note: It is imperative that the spelling matches each time you enter product data for the same drug manufacturer. The spelling must also match when entering data under the **Upload Product Data** tab.

3.2.1.1 Add Product Data by NDC

Follow these steps to add product data by NDC:

1. From the **Add Product Data** page, select the **Add by NDC** radio button if it is not already selected when the page opens.
2. In the **Manufacturer Name (required)** field, begin to type and then select the appropriate manufacturer.
3. Under **NDC1 (required)**, click the **-Select-** drop-down menu to expand the list of submitted drugs and additional products in the Module to date; select your required NDC1* code.
4. Enter your 4-digit number in the **NDC2* (required)** field.
5. Enter your 2-digit number in the **NDC3* (required)** field.

   As you complete the **NDC3* (required)** field, the **Add Product Data** page expands to display multiple drop-down menus and empty fields.
6. Enter or select the required information as follows:

a. Select the **Drug has brand name** checkbox if the product you are submitting has a brand name. (If so, a new empty field displays to submit the brand name; type information here as needed.)
b. Click the **Generic Name (required)** drop-down menu; select the generic name you need to enter for your product.

Note: Return to the **Manage NDC1/ALT ID** page if you cannot find the appropriate generic name in the system. Refer to *Section 3.1 - Manage NDC1/ALT ID* for guidance.

c. Enter the volume per item in the **Volume Per Item (required)** field.
d. Click the **Unit for Volume Per Item (required)** drop-down; select the appropriate option for your product.
e. Enter the appropriate number in the **Number of Items per NDC (required)** field.
f. Click the Package **Type (required)** drop-down; select the appropriate package type.
g. Enter the strength in the **Strength (required)** field.
h. Click the **Unit for Strength (required)** drop-down; select the appropriate unit.
i. Enter the FDA application number in the **FDA Application Number (required)** field.
j. Enter the FDA application supplement number in the **FDA Application Supplement Number** field, if applicable.

Note: Click the **Add Additional FDA Application Numbers** button if applicable for the drug, and repeat steps i and j.

k. Enter the FDA approval date in the **FDA Approval Date (required)** field.
l. Click the **FDA Approval Type (required)** drop-down; select the appropriate approval type.
m. Enter the first marketing date in the **First Marketing Date (required)** field.
n. Enter the date of first sale in the **Date of First Sale (required)** field.
o. Enter the WAC in the **Wholesale Acquisition Cost (required)** field.

Note: The **Wholesale Acquisition Cost (required)** field is required and displays when the **First Marketing Date** occurs after the current reporting period.

Note: The date of first sale cannot occur before the FDA approval date and must occur prior to the current reporting period start date.

7. Confirm your selections. Refer to *Figure 32*.

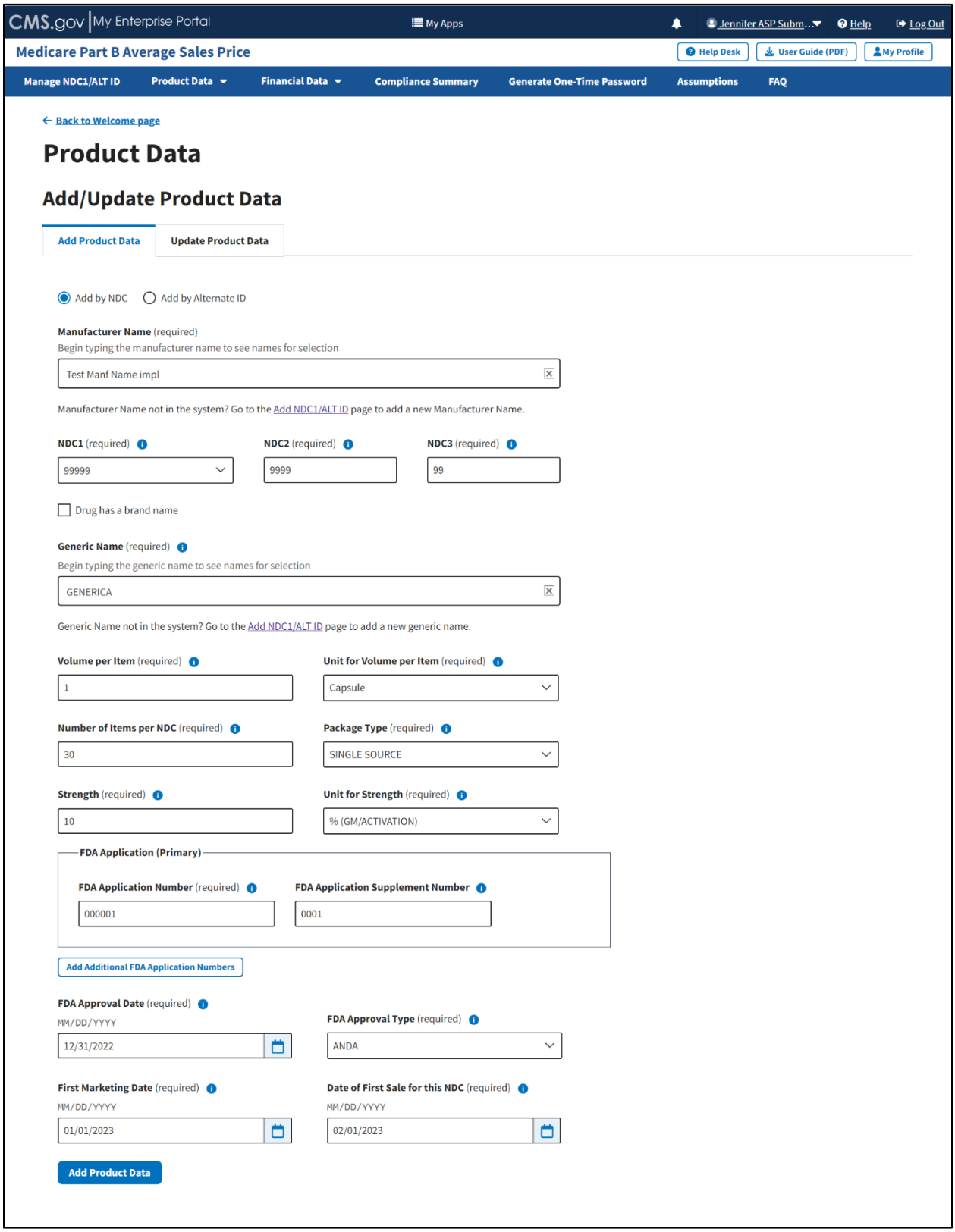

Figure 32: Add/Update Product Data Fields Populated

8. Click **Add Product Data** to submit your information.

   A message displays confirming you have successfully added your **select**ions. Refer to *Figure 33*.

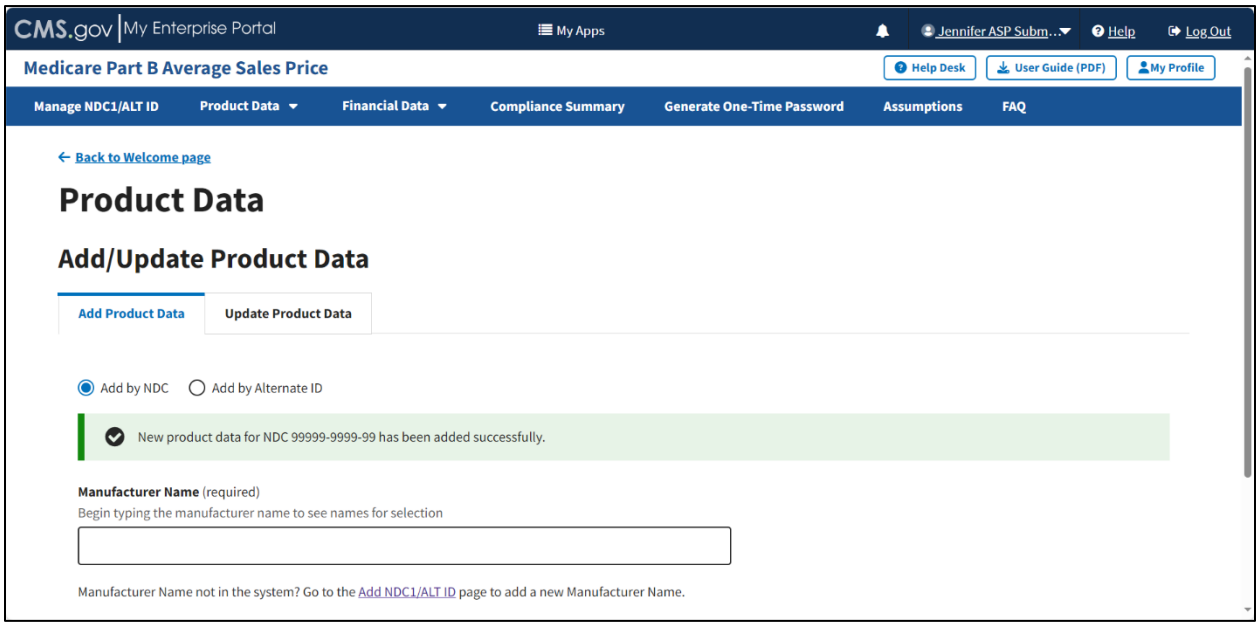

Figure 33: Add/Update Product Data Successfully Added

Note: It is imperative that the spelling matches each time you enter product data for the same drug manufacturer. The spelling must also match when entering data under the **Upload Product Data** tab.

3.2.1.2 Add Product Data by Alternate ID

Follow these steps to add product data by alternate ID:

1. From the **Add/Update Product Data** page, select the **Add by Alternate ID** radio button.

   The **Add Product Data** page expands to display new empty fields. Refer to *Figure 34*.

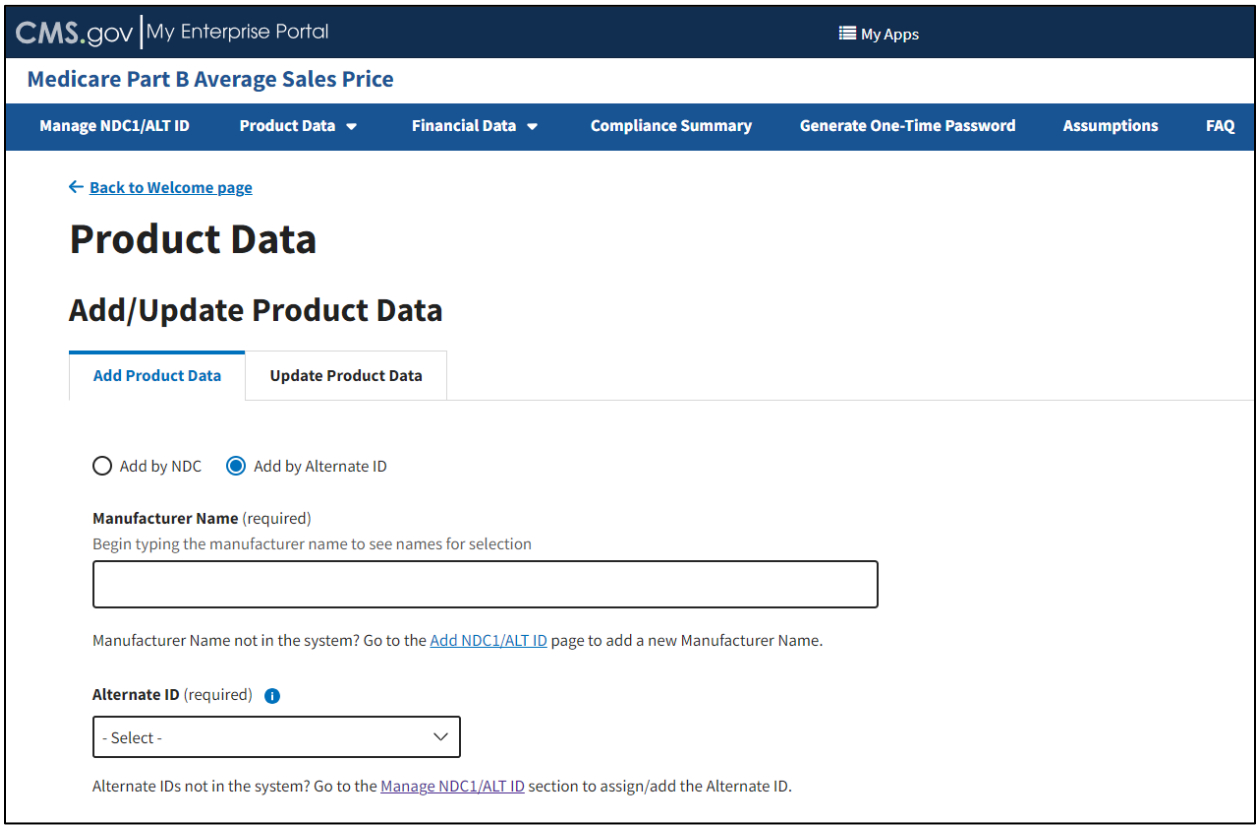

Figure 34: Add Product Data by Alternate ID

2. Under **Manufacturer Name (required)**, begin to type and then select the appropriate manufacturer.
3. Under **Alternate ID (required)**, click the **-Select-** drop-down to expand the list. Select the required alternate ID code. Refer to *Figure 35*.

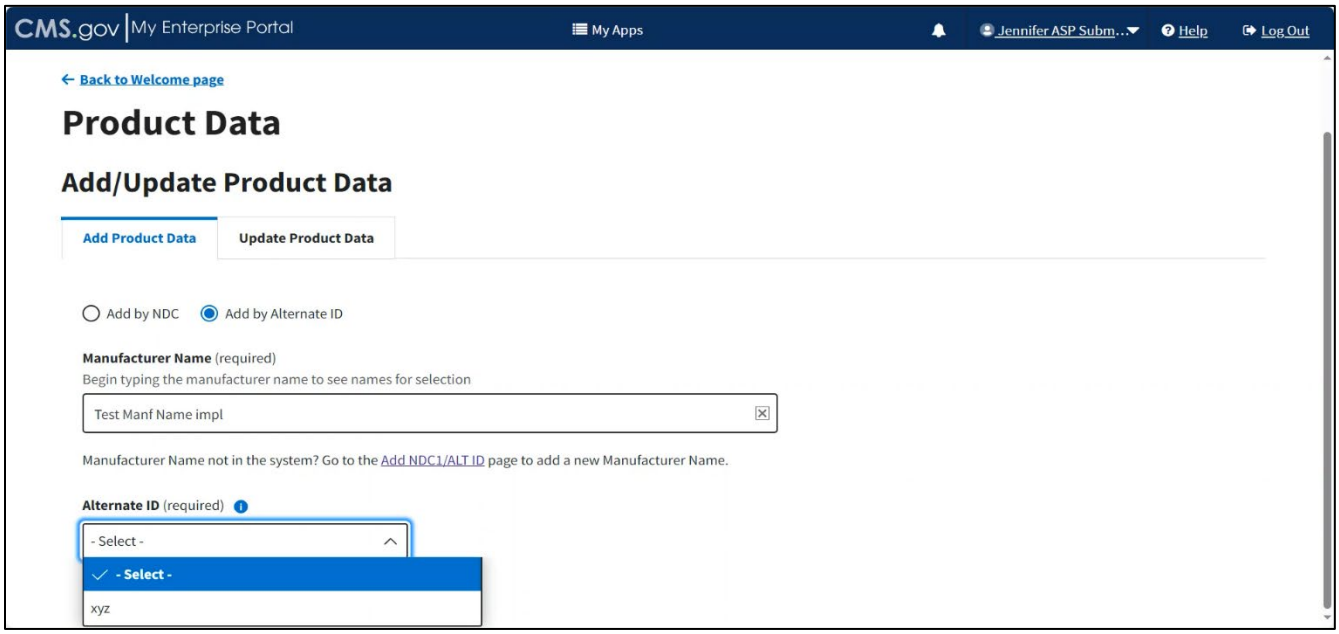

Figure 35: Add Product Data by Alternate ID - Fields Populated

As you complete the **Alternate ID (required)** field, the **Add Product Data** page expands to show multiple drop-down menus and empty fields.

4. Enter or select the required information as follows:
   a. Enter the uniform resource locator (URL) to the manufacturer website in the **Manufacturer's Website URL** (**required)** field for verification purposes.
   b. Select the **Drug has a brand name** checkbox if the product you are submitting has a brand name. (If so, a new empty field displays in which to enter the brand name; type information here as needed.)
   c. Click the **Generic Name (required)** drop-down; select the generic name you need to enter for your product.

   Note: Return to the **Manage NDC1/ALT ID** page if you cannot find the appropriate generic name in the system. Refer to *Section 3.1 - Manage NDC1/ALT ID* for guidance.

   d. Enter the volume per item in the **Volume Per Item (required)** field.
   e. Click the **Unit for Volume Per Item (required)** drop-down; select the appropriate option for your product.
   f. Enter the appropriate number in the **Number of Items per Alternate ID (required)** field.
   g. Click the **Package Type (required)** drop-down; select the appropriate package type.
   h. Enter the strength in the **Strength (required)** field.
   i. Click the **Unit for Strength (required)** drop-down; select the appropriate unit.
   j. Enter the FDA registration number in the **FDA Registration Number (required)** field.
   k. Enter the FDA approval date in the **FDA Approval Date (required)** field.
   l. Enter the FDA approval type in the **FDA Approval Type (required)** field.

m. Enter the first marketing date in the **First Marketing Date (required)** field.

n. Enter the date of first sale in the **Date of First Sale for this ALT ID (required)** field.

Note: The date of first sale cannot occur before the FDA approval date and must occur prior to the current reporting period start date.

5. Confirm your selections; click **Add Product Data** to submit your information**.** Refer to *Figure 36*.

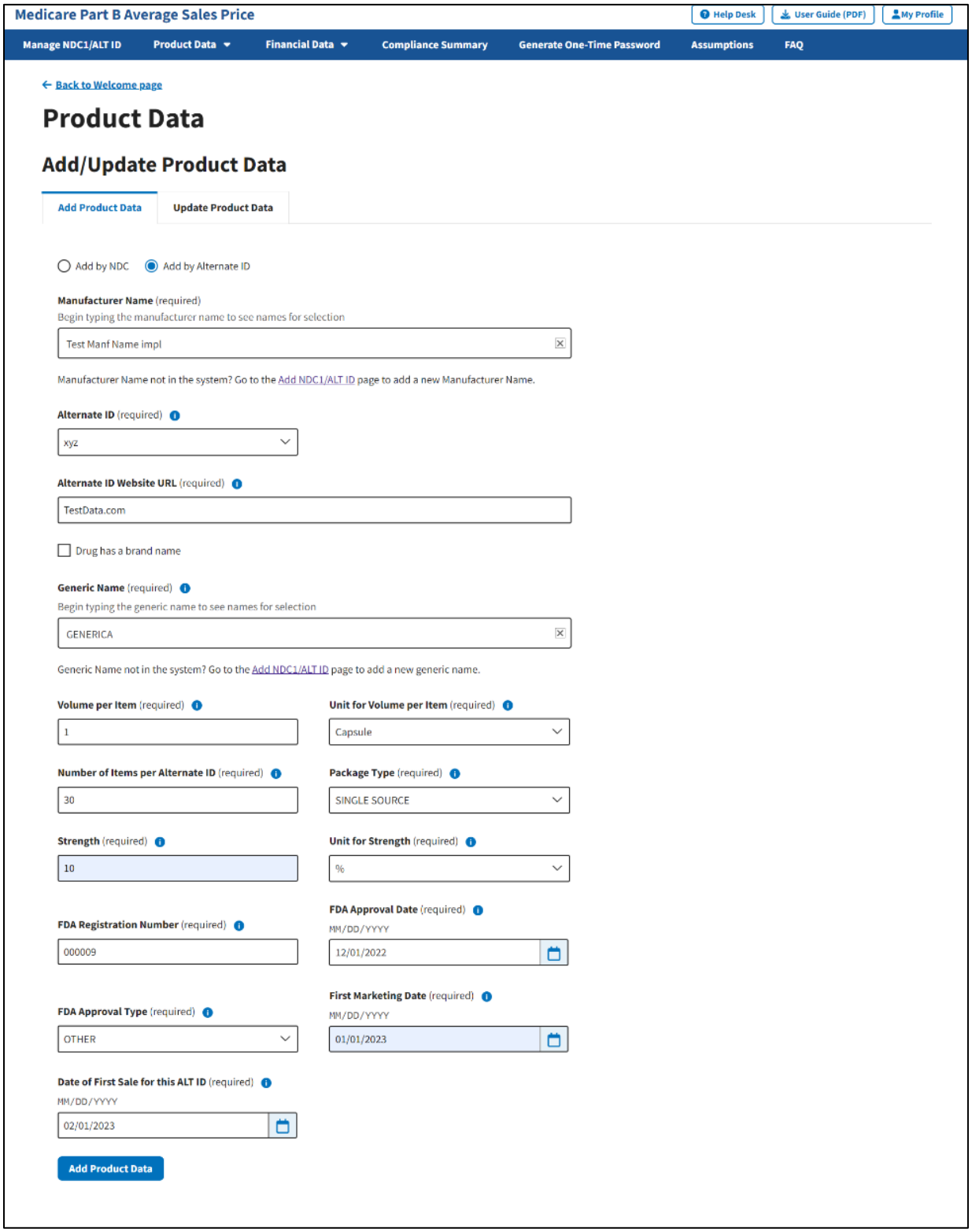

Figure 36: Add Product Data by Alternate ID - Additional Fields

A message displays confirming you have successfully added your product data. Refer to *Figure 37*.

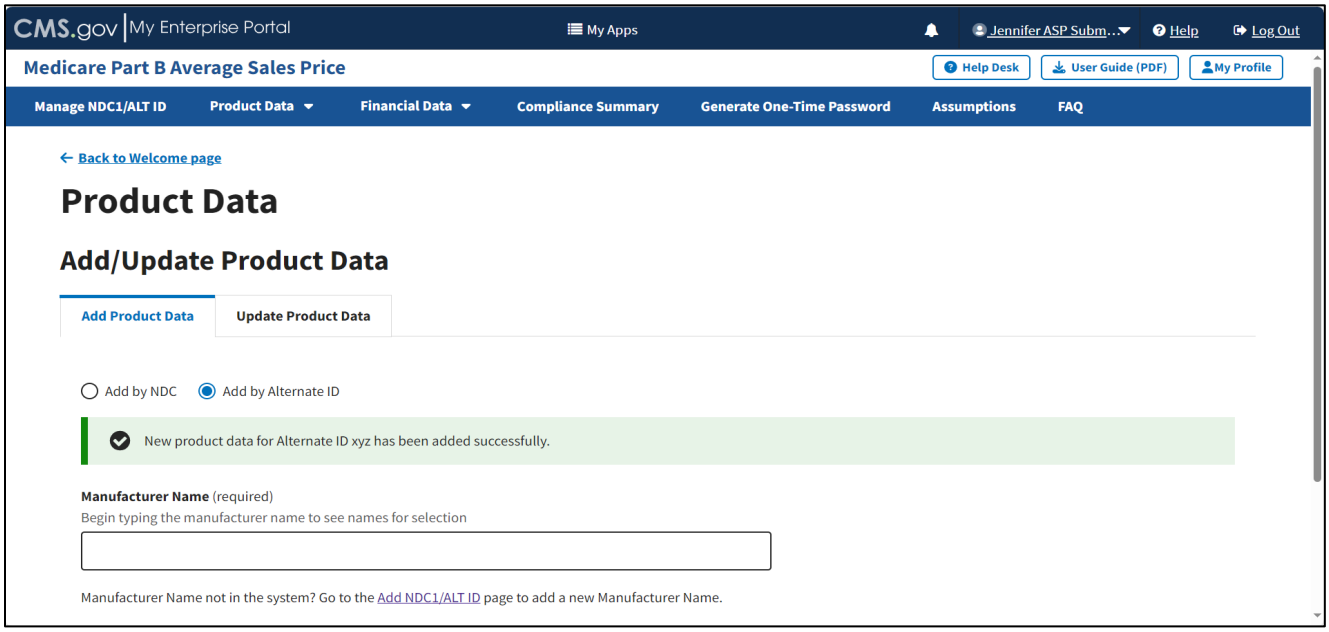

Figure 37: Product Data by Alternate ID Added Successfully

Note: It is imperative that the spelling matches each time you enter product data for the same drug manufacturer. The spelling must also match when entering data under the **Upload Product Data** tab.

3.2.1.3 Update Product Data by NDC

Follow these steps to update product data by NDC:

1. From the **Add/Update Product Data** page, select the **Update Product Data** tab; then, select the **Update by NDC** radio button if it is not already selected when the page opens. Refer to *Figure 38*.

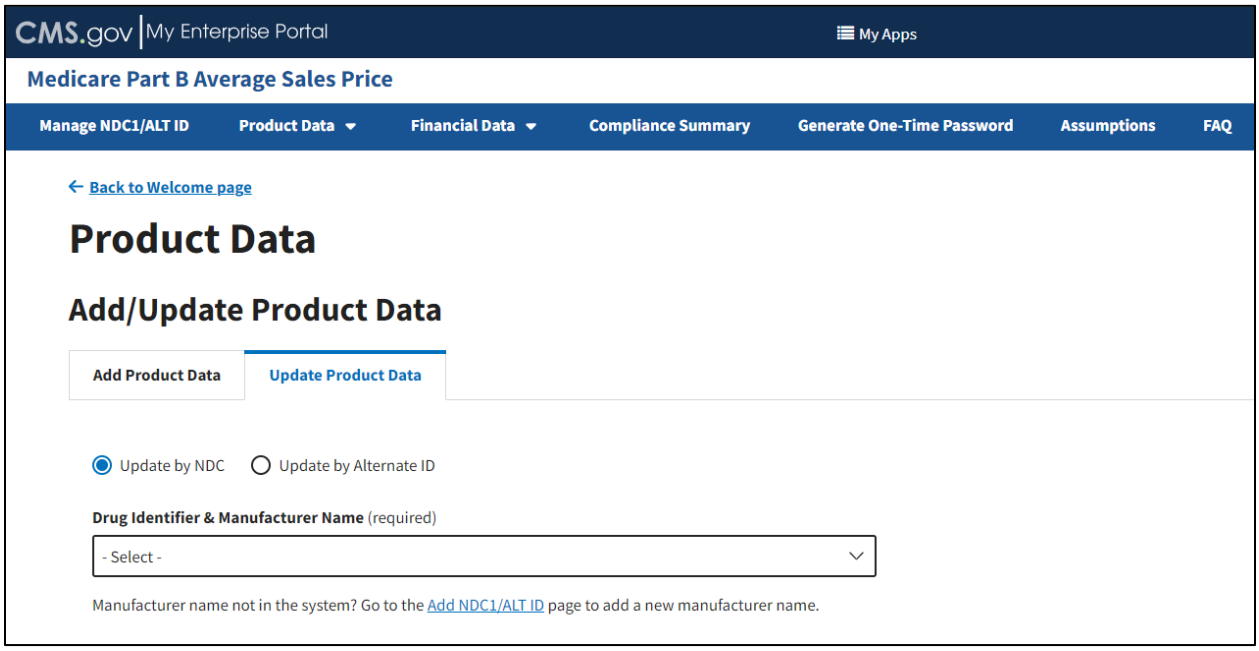

Figure 38: Update Product Data - Drug Identifier & Manufacturer Name

2. In the **Drug Identifier & Manufacturer Name (required)** drop-down menu, click **- Select-** to expand the list of submitted drugs and additional products in the Module to date; select the appropriate drug identifier.

   The page automatically loads the product data for that specific drug. Refer to *Figure 39*.

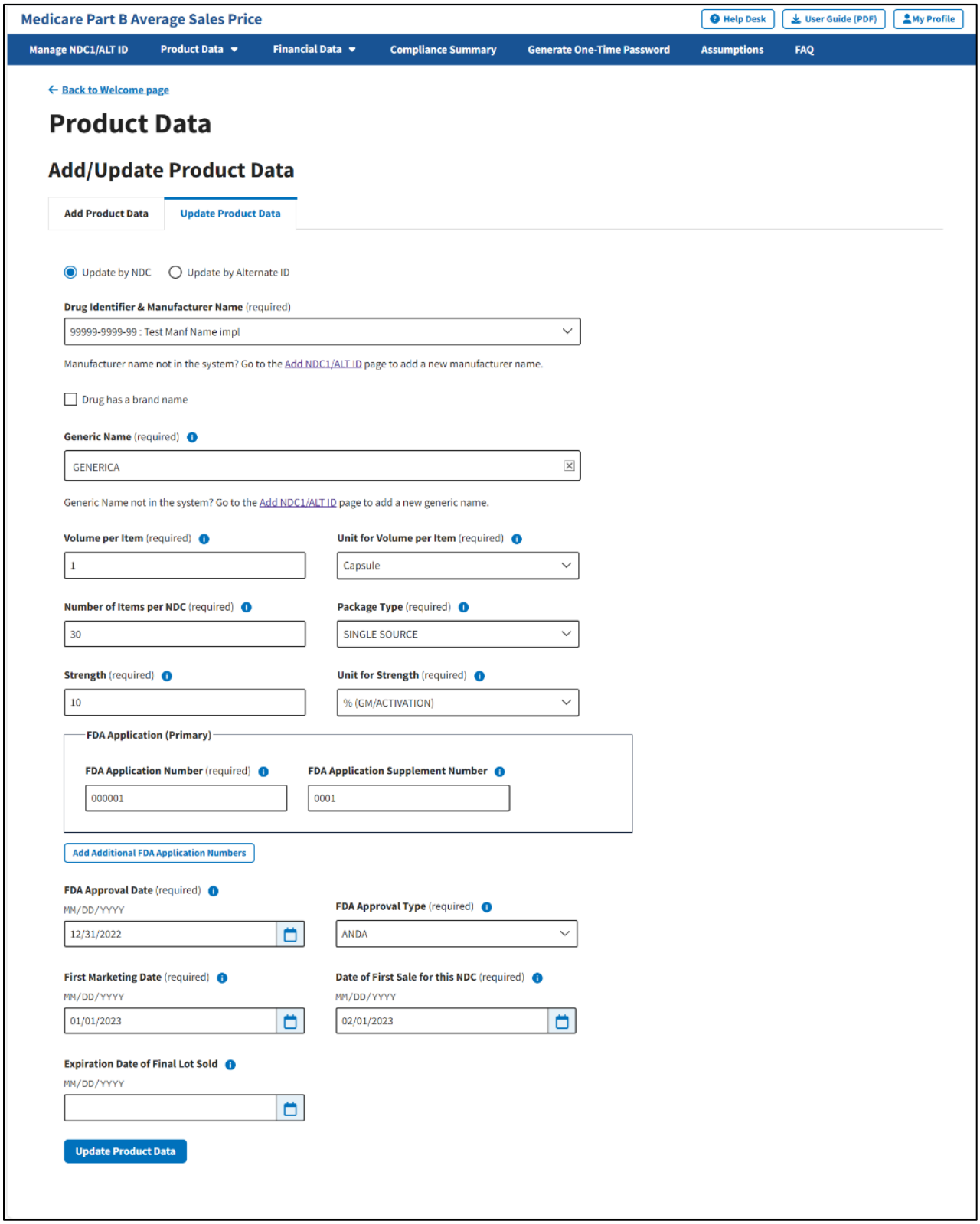

Figure 39: Update Product Data by NDC

3. Review all your information in the appropriate boxes previously submitted in *Section 3.2 - Product Data*.
4. Confirm your selections; click **Update Product Data** to submit any changes in your drug product data.

   A message displays confirming you have successfully updated your product data. Refer to *Figure 40*.

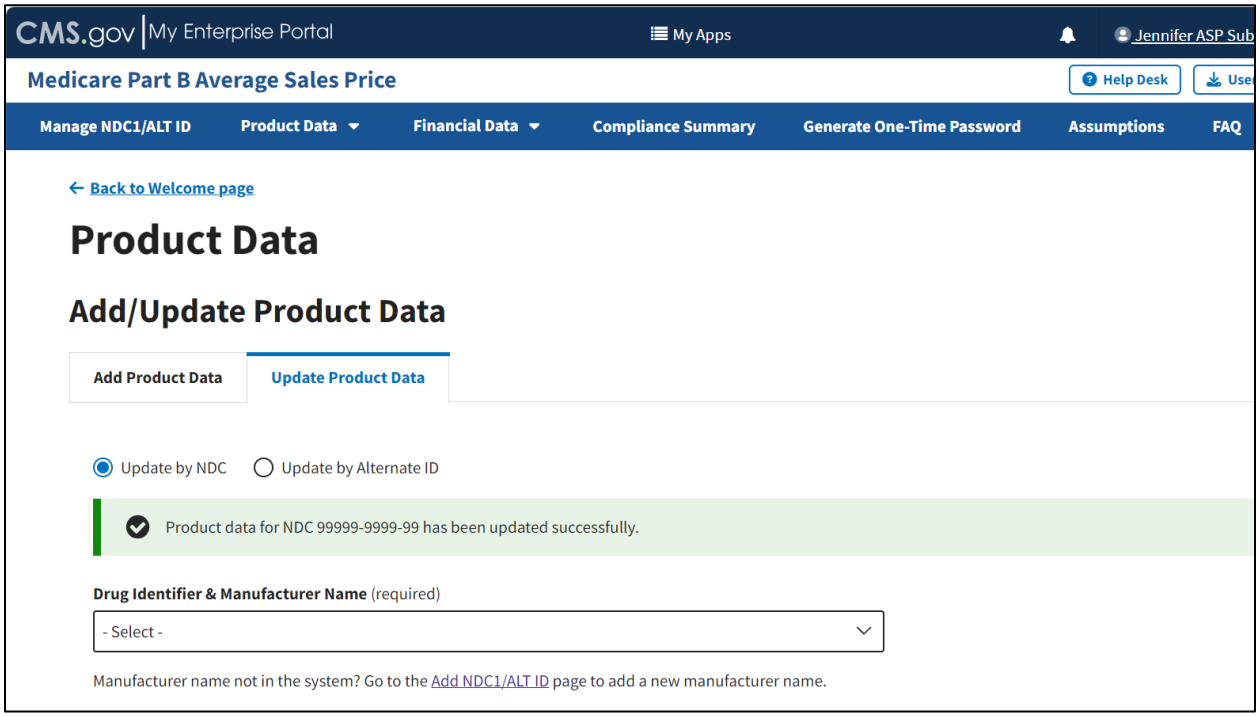

Figure 40: Update Product Data by NDC - Data Updated Successfully

3.2.1.4 Update Product Data by Alternate ID

Follow these steps to update product data by Alternate ID:

1. From the **Add/Update Product Data** page, select the **Update Product Data** tab; then, select the **Update by Alternate ID** radio button. Refer to *Figure 41*.

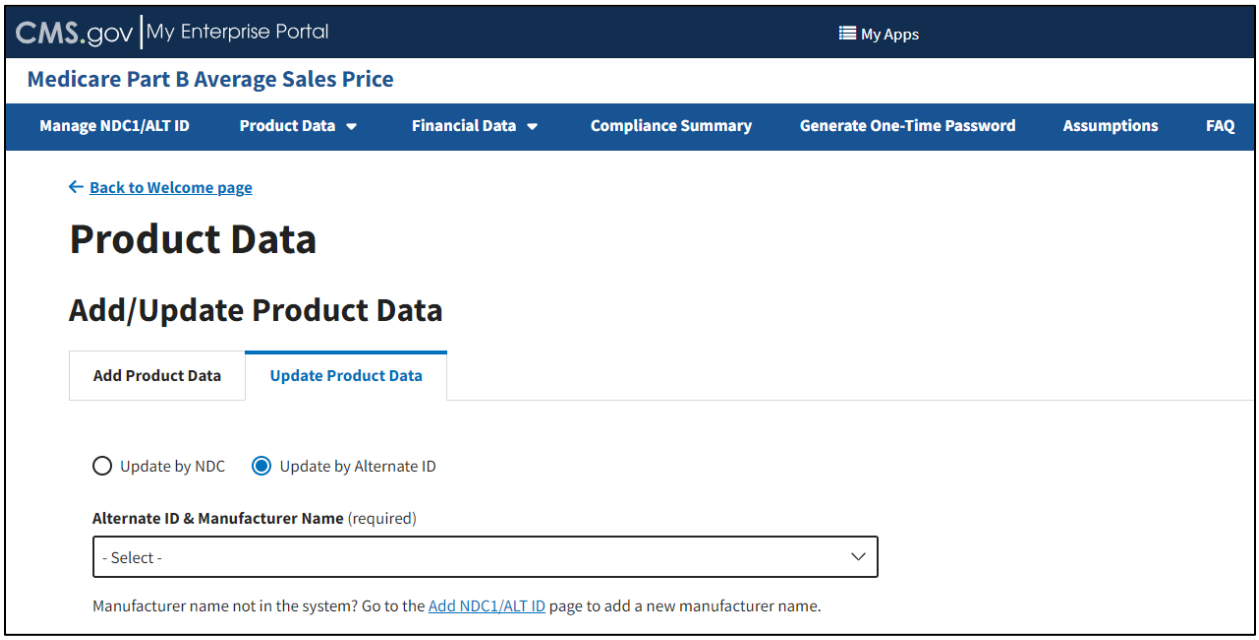

Figure 41: Update Product Data by Alternate ID

2. Under the **Alternate ID & Manufacturer Name (required)** drop-down; click the **-Select-** drop-down to expand the list; select the appropriate information.

   The page automatically loads the product data for that specific drug. Refer to *Figure 42*.

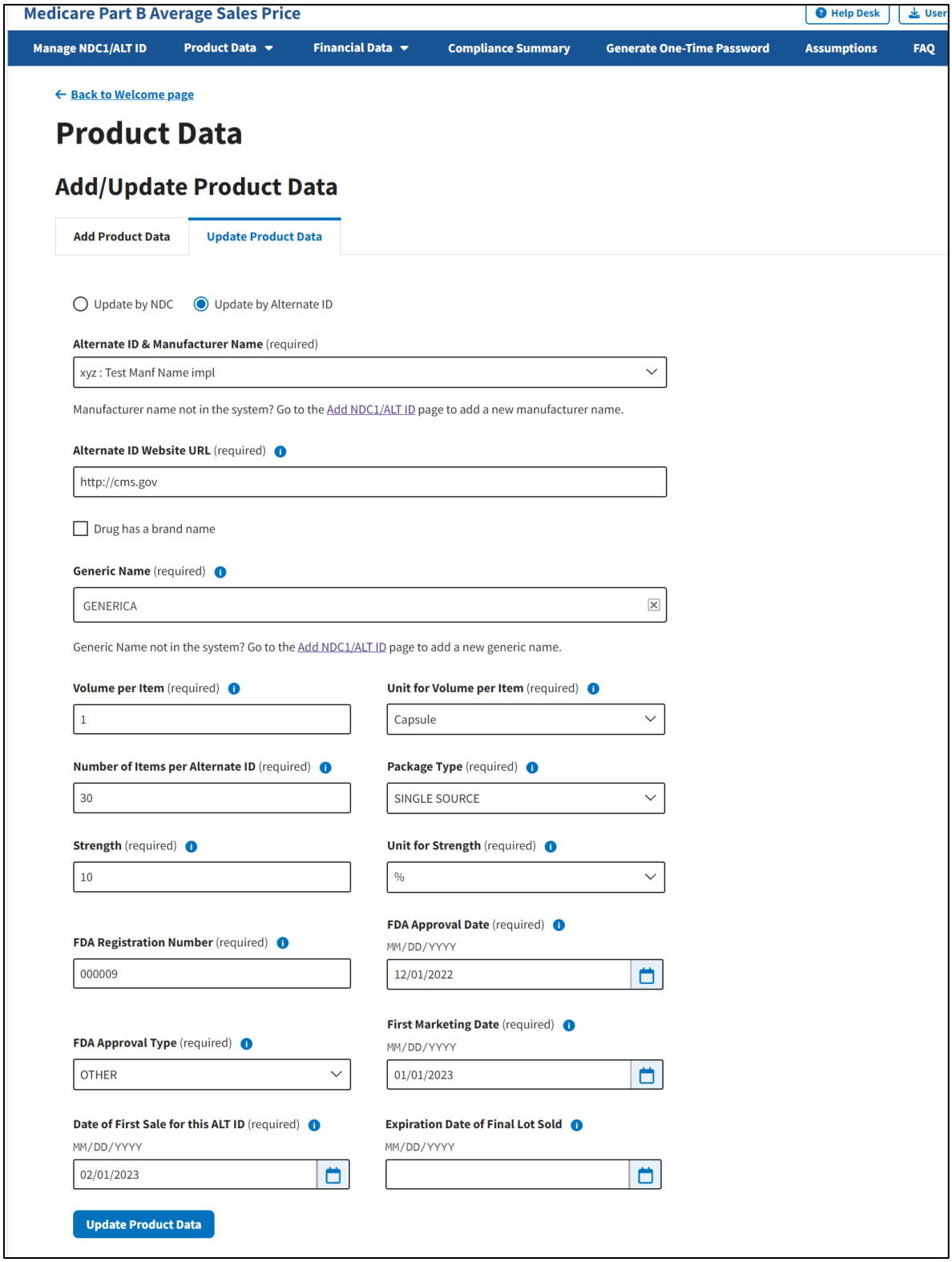

Figure 42: Update Product Data by Alternate ID - Drug Identifier Drop-down Menu

3. Review all your information in the appropriate boxes previously submitted in *Section 3.2 - Product Data*.
4. Confirm your selections; click **Update Product Data** to submit any changes in your drug product data.

   A message displays confirming you have successfully updated your product data. Refer to *Figure 43*.

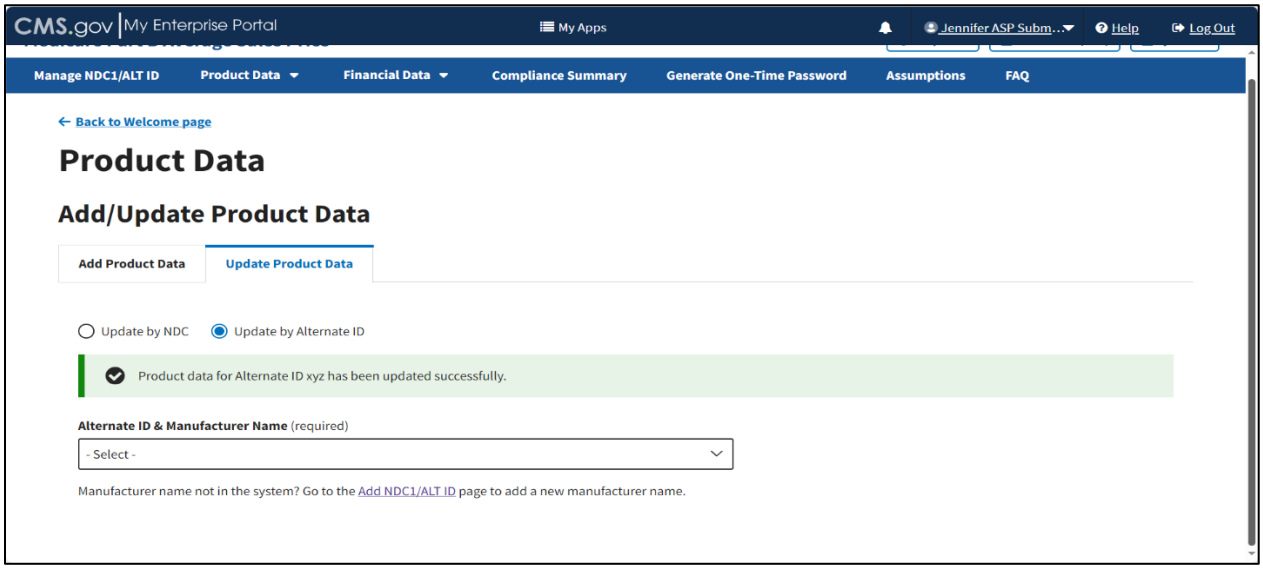

Figure 43: Update Product Data by Alternate ID - Updated Successfully

3.2.2 Upload Product Data

Follow these steps to upload product data:

1. From the Medicare Part B Average Sales Price homepage, click the **Product Data** tab; then select the **Upload Product Data** tab.

   The **Upload Product Data** page opens, listing the financial quarter and year for the upcoming reporting period. Refer to *Figure 44*.

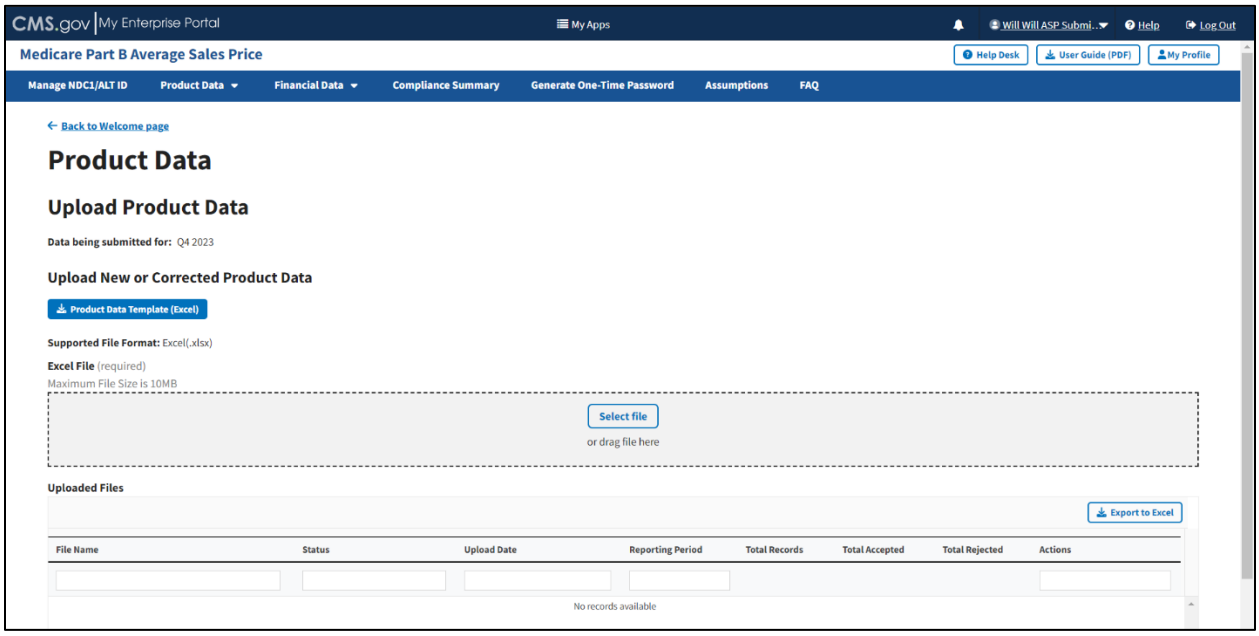

Figure 44: Upload Product Data - New or Corrected

Note: Click the **Product Data Template (Excel)** box to download a copy of the product data template.

2. Upon preparing your **.xlsx file (required)** and verifying your information for accuracy, click **Select File**; then select the Excel file in the dialog box. You may also drag the file into the **Select File** box. Refer to *Figure 45*.

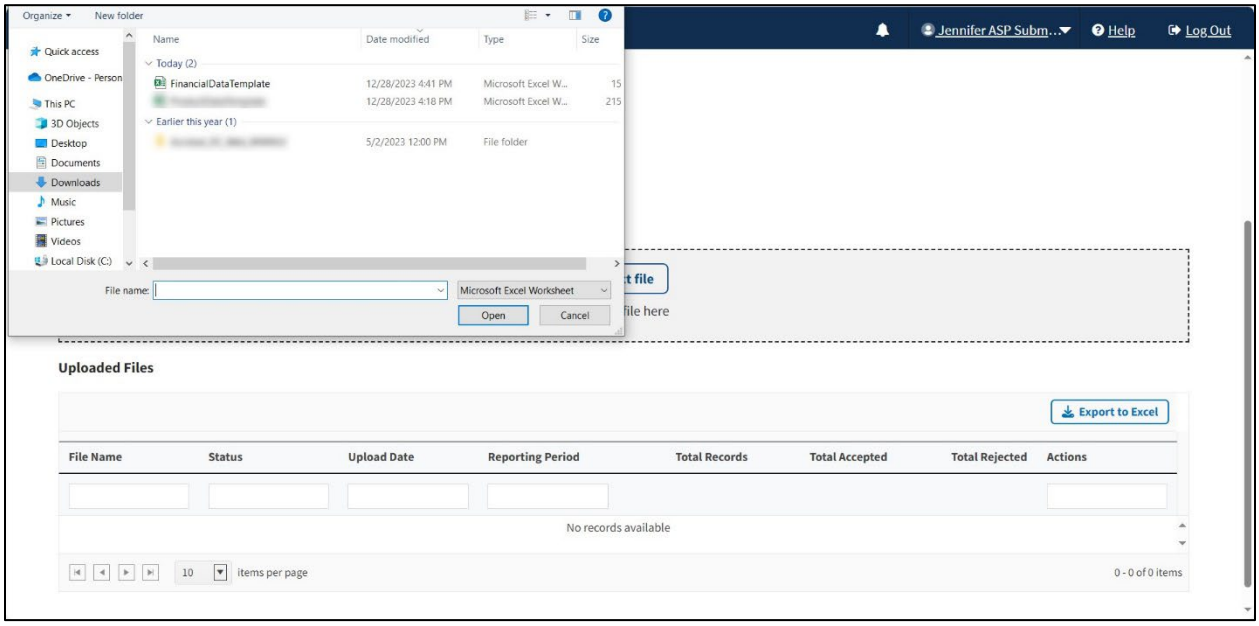

Figure 45: Upload Product Data - Uploading Files from Desktop

A download bar displays as your file uploads. A message displays confirming you have successfully uploaded your **.xlsx file**. Refer to *Figure 46*.

Note: If the Module cannot process your file, an error message displays, and a **New Report** generates under **Uploaded Files**.

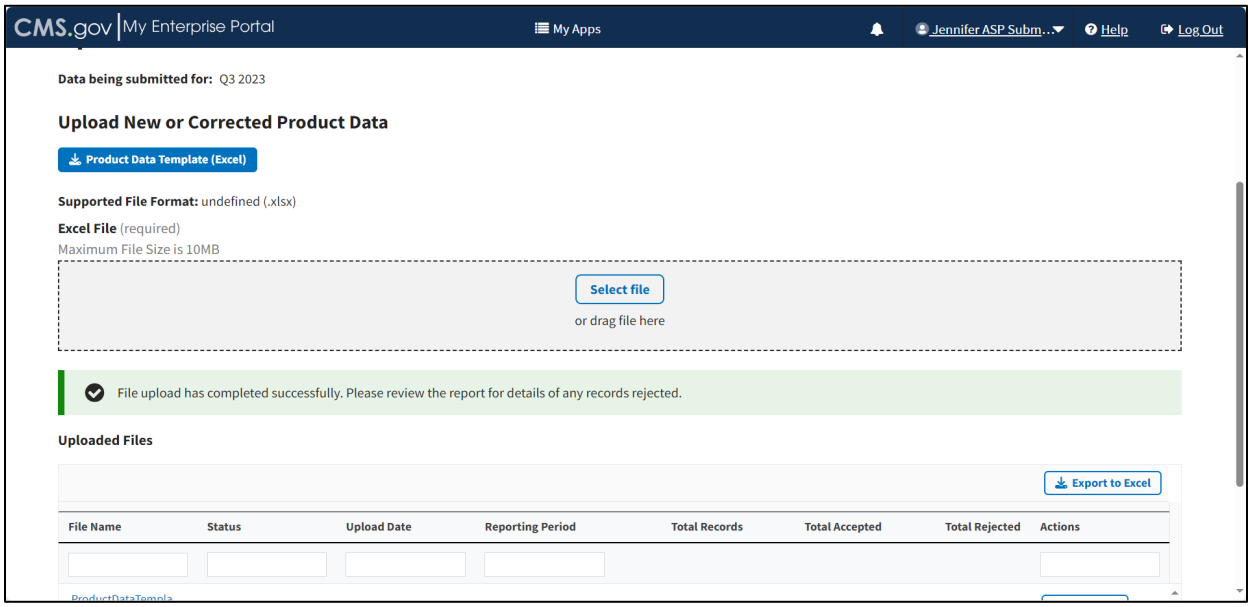

Figure 46: Upload Product Data - New File Successfully Uploaded

3. Refresh your browser to allow the system to update and display your new file.

The **Uploaded Files** section displays files you uploaded recently as well as previous files still in the Module. Refer to *Figure 47*.

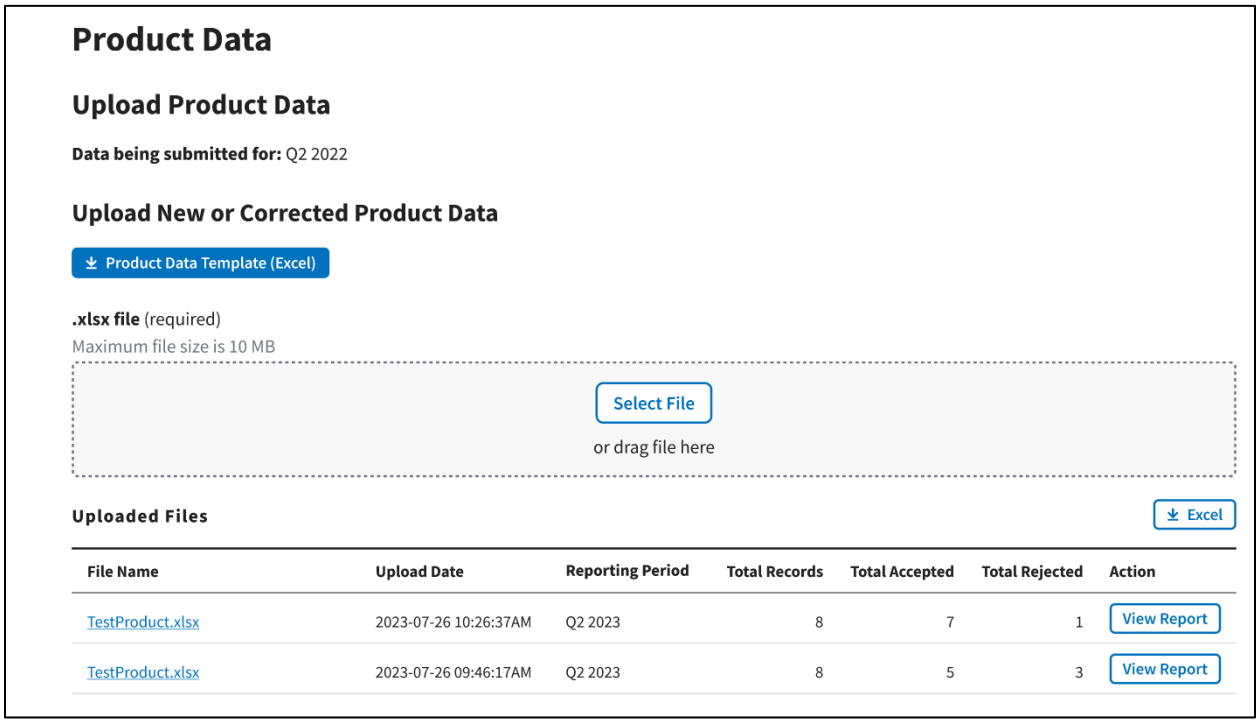

Figure 47: Upload Product Data - Uploaded Files

Each uploaded file displays the **File Name**, **Upload Date**, **Reporting Period**, **Total Records**, **Total Accepted**, **Total Rejected**, and **Action** categories submitted to the Module.

4. Click **View Report** under **Action** in the **Uploaded Files** section to view the full report for a submitted file.

   The report opens on the next page. Refer to *Figure 48*.

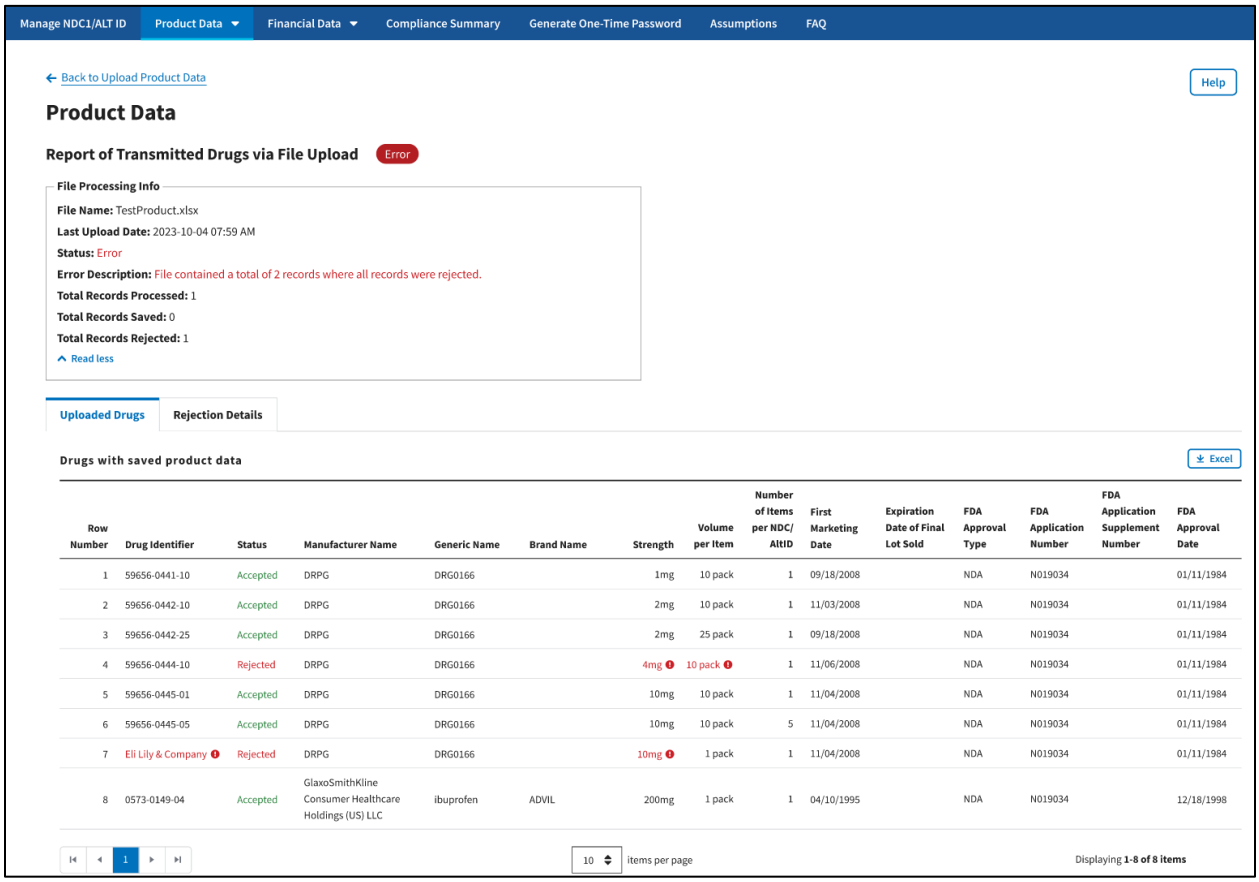

Figure 48: Upload Product Data - Full Report of Transmitted Drugs via File Upload

5. Click the **Read More** tab under the **Report of Transmitted Drugs via File Upload** to view all **File Processing Information** related to this report.

   The report lists all uploaded drugs with saved product data in the ASP system. The Module organizes the full list by row number and includes each drug identifier, status, and all previously submitted information from the **Add Product Data** sections.

   Note: The Module highlights errors in red. Hover over the red text to display information about the specific error.

6. Click the **Rejection Details** tab.

   A listing of drugs with rejected product data displays. Refer to *Figure 49*.

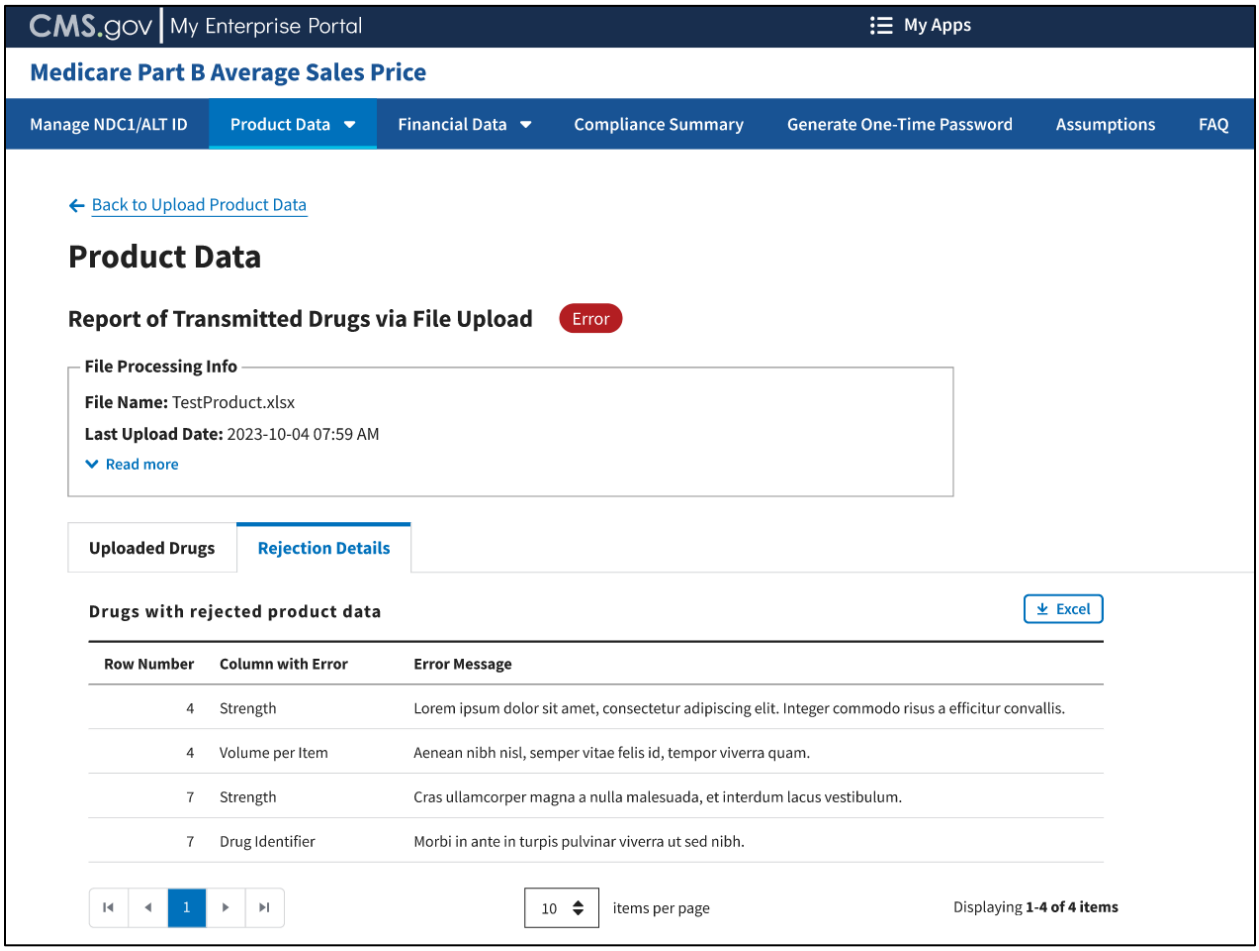

Figure 49: Upload Product Data - Reported Rejection Details

The Module lists all errors found in submitted data by **Row Number**, **Column with Error**, and **Error Message** under **Drugs with Rejected Product Data**.

7. Return to the **Add/Update Product Data** section of the Module to request any changes to your product data.

3.2.3 View Drugs

Drug manufacturers can use the ASP module to view drug data submitted during the current reporting period. However, manufacturers cannot update or edit drug data using this feature. From the Medicare Part B Average Sales Price homepage, click the **Product Data** tab; then select the **View Drugs** tab to view the **View Drugs** page.

The following sections describe how to view active and expired drugs.

3.2.3.1 View Active Drugs

From the **View Drugs** page, the **Active Drugs** tab displays by default. Refer to *Figure 50*.

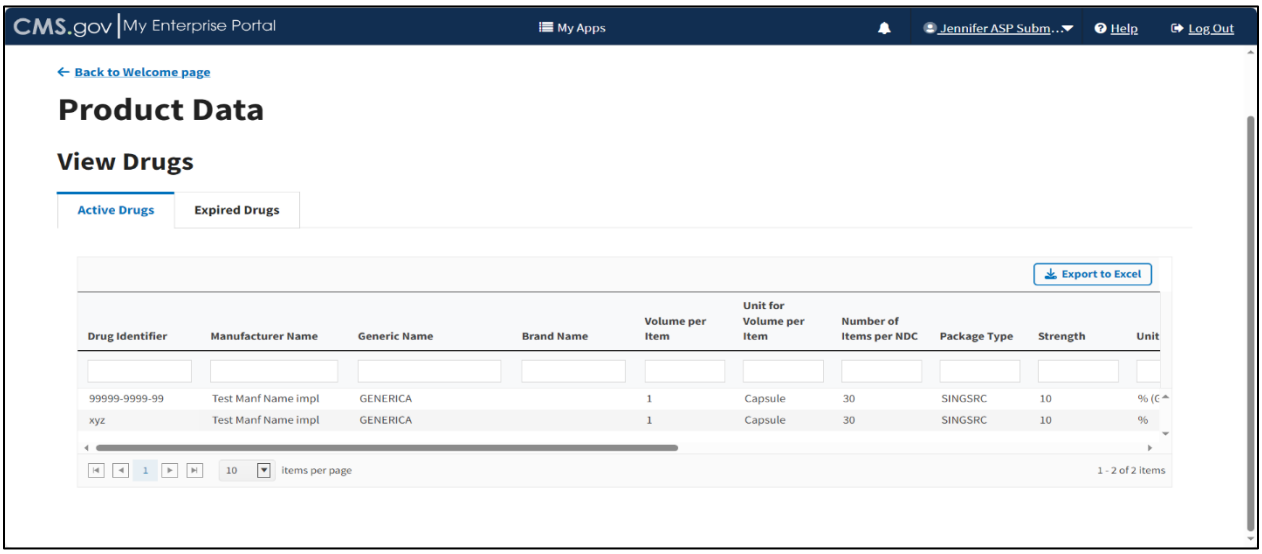

Figure 50: Product Data - View Active Drugs

Follow these steps to view submitted drug data for **Active Drugs** from the **View Drugs** page:

1. Scroll through the list of active drugs to view submitted data and status.

   The Module organizes all active drugs by **Drug Identifier**, **Manufacturer Name**, **Generic Name**, **Brand Name**, **Volume per Item**, **Unit for Volume per Item**, **Number of Items per NDC**, **Package Type**, and **Strength** categories, and previously submitted information from the **Add Product Data** sections.

2. Click the arrows on the bottom left to scroll through all submitted drugs by page. View, filter, and sort active drugs by clicking on the category name.

   Note: Click the **Export to Excel** button to download all products under the **Compliance Summary**.

3.2.3.2 View Expired Drugs

Follow these steps to view submitted drug data for **Expired Drugs**:

1. From the **View Drugs** page, select the **Expired Drugs** tab.

   The **Expired Drugs** page opens. Refer to *Figure 51*.

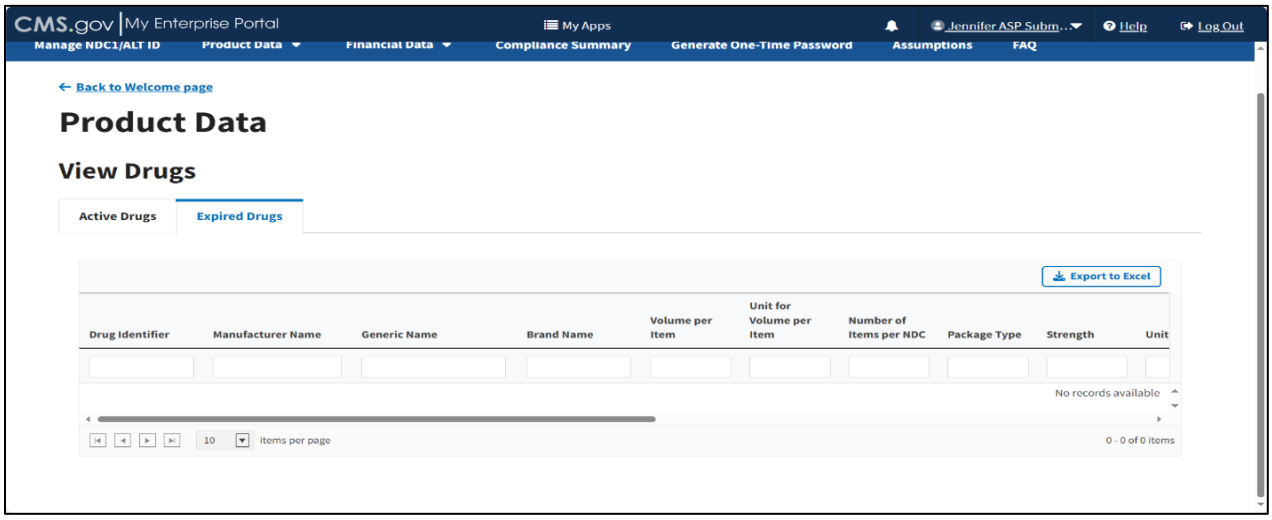

Figure 51: Product Data - View Expired Drugs

2. Scroll through the list of expired drugs to view submitted data and status.

   The Module organizes expired drugs by **Drug Identifier**, **Manufacturer Name**, **Generic Name**, **Brand Name**, **Volume per Item**, **Unit for Volume per Item**, **Number of Items per NDC**, **Package Type**, and **Strength** categories, and previously submitted information from the **Add Product Data** sections.

3. Click the arrows on the bottom left to scroll through all submitted drugs by page. View, filter, and sort active drugs by clicking on the category name.
4. Click the **Export to Excel** button to download all expired drug products.

3.3 Financial Data

Click the **Financial Data** tab on the Medicare Part B Average Sales Price homepage to view the drop-down menu tabs, **Add/Update Financial Data for Current Quarter**, **Upload Financial Data for Current Quarter**, **Restate Financial Data or Add for Prior Quarters**, and **Upload Financial Data for Prior Quarters**. Refer to *Figure 52*.

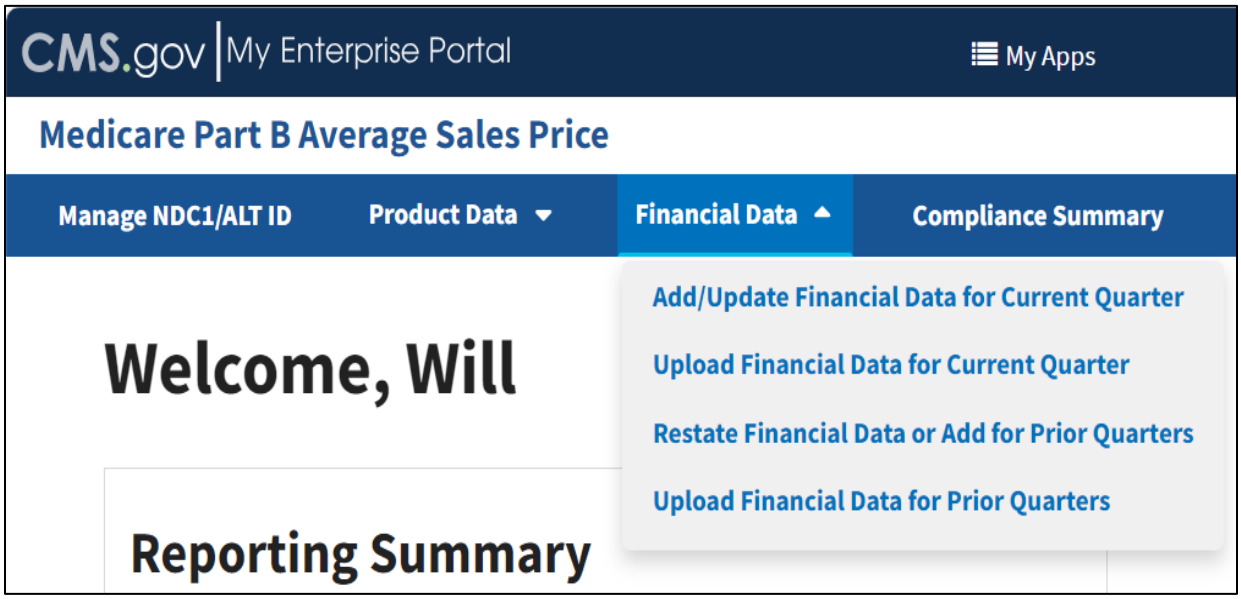

Figure 52: Financial Data - Main Drop-down

The following sections describe how to add/update and upload financial data.

3.3.1 Add/Update Financial Data

Follow these steps to add or update financial data:

1. Click the **Add/Update Financial Data for Current Quarter** tab.

   The **Add/Update Financial Data** page opens with default selections. Refer to *Figure 53*.

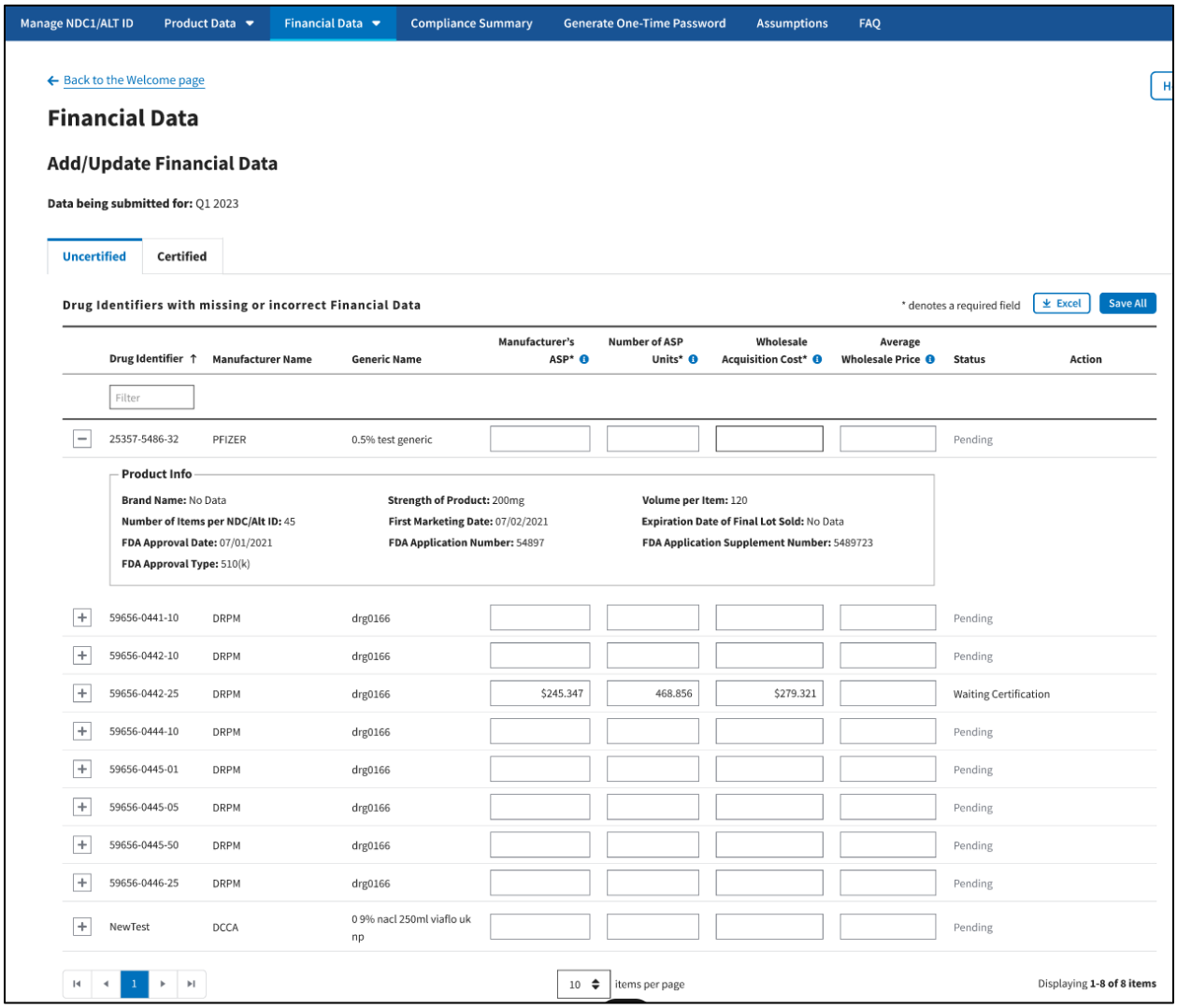

Figure 53: Add/Update Financial Data

Note: The Module collects data submissions for the upcoming financial quarter. As an example, figures in this section feature data submitted for Q1 2023.

3.3.1.1 Add/Update Financial Data for Uncertified Drugs

Follow these steps to add/update financial data for uncertified drugs:

1. From the **Add/Update Financial Data** page, select the **Uncertified Drugs** tab if it is not already selected.

   Note: The Module denotes the **Manufacturer's ASP**, **Number of ASP Units**, and **Wholesale Acquisition Cost** fields with an (*) to indicate that each field is required.

2. Enter or edit any missing or inaccurate financial data for your submitted drug products.
3. As you add or update information onto the page, click the **Save All** button to save your changes in the Module.

Note: As an alternative to entering data directly into the Module, under **Drug Identifiers with Missing or Incorrect Financial Data**, you can click the Excel box on the right side to convert all information on this page into an Excel file.

4. Scroll through the list of submitted drugs and products on the page. Filter through all the information by clicking on the category name.
5. Click the arrows on the bottom left to scroll through all submitted drugs by page.
6. Click the plus symbol on each row of the table to expand each product's information and view additional categories, including **Brand Name**, **FDA Approval** and all other information previously submitted or acknowledged in the **Product Data** section. Refer to *Figure 54.*

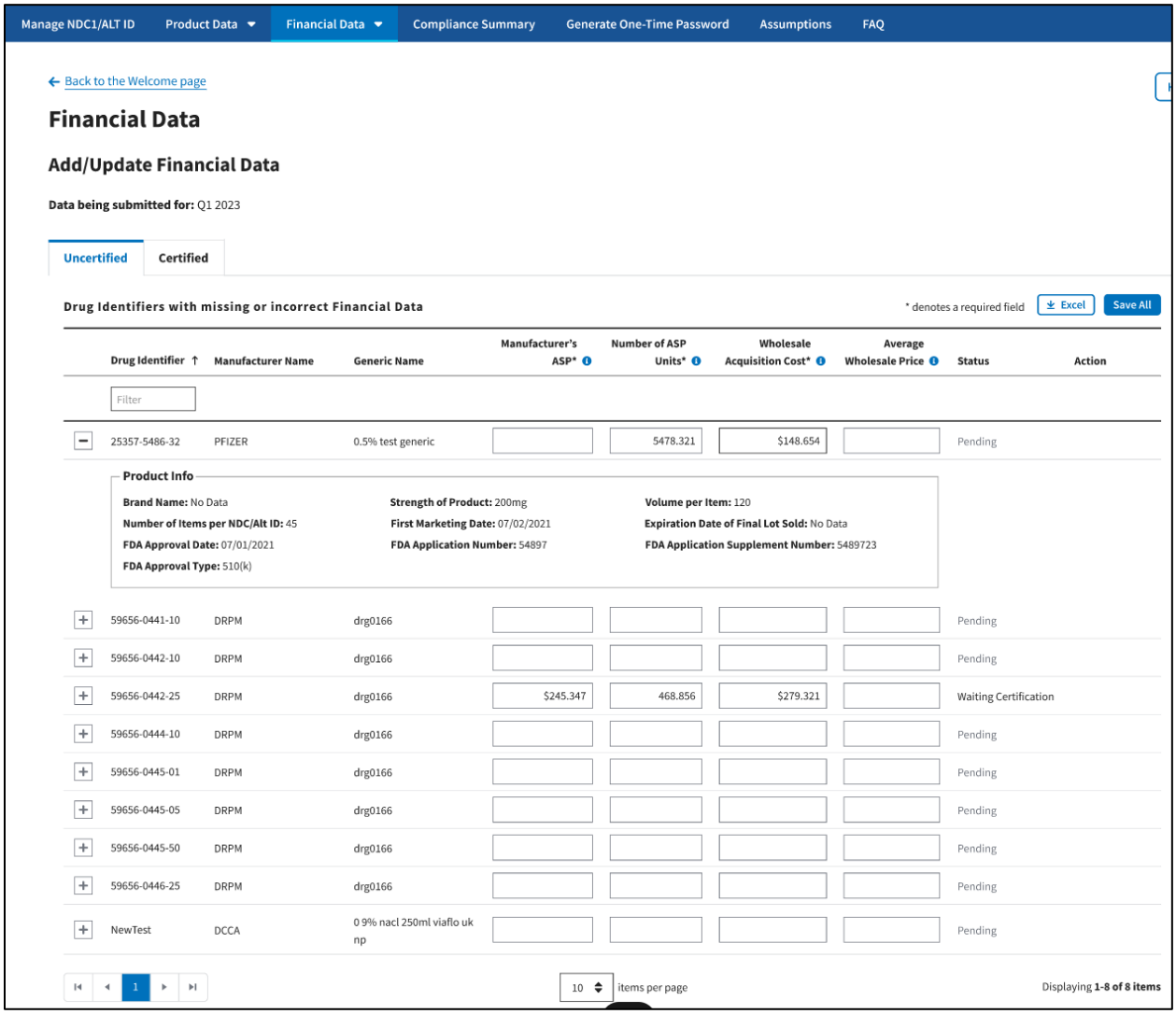

Figure 54: Add/Update Financial Data - Drug Identifiers with Missing or Incorrect Data

7. Enter and review your information to ensure the highest level of accuracy in data reporting.
8. Click the **Save All** button to submit your information to the Module.

The page reopens and returns to default selections. A message displays confirming you have successfully updated your financial data. Refer to *Figure 55*.

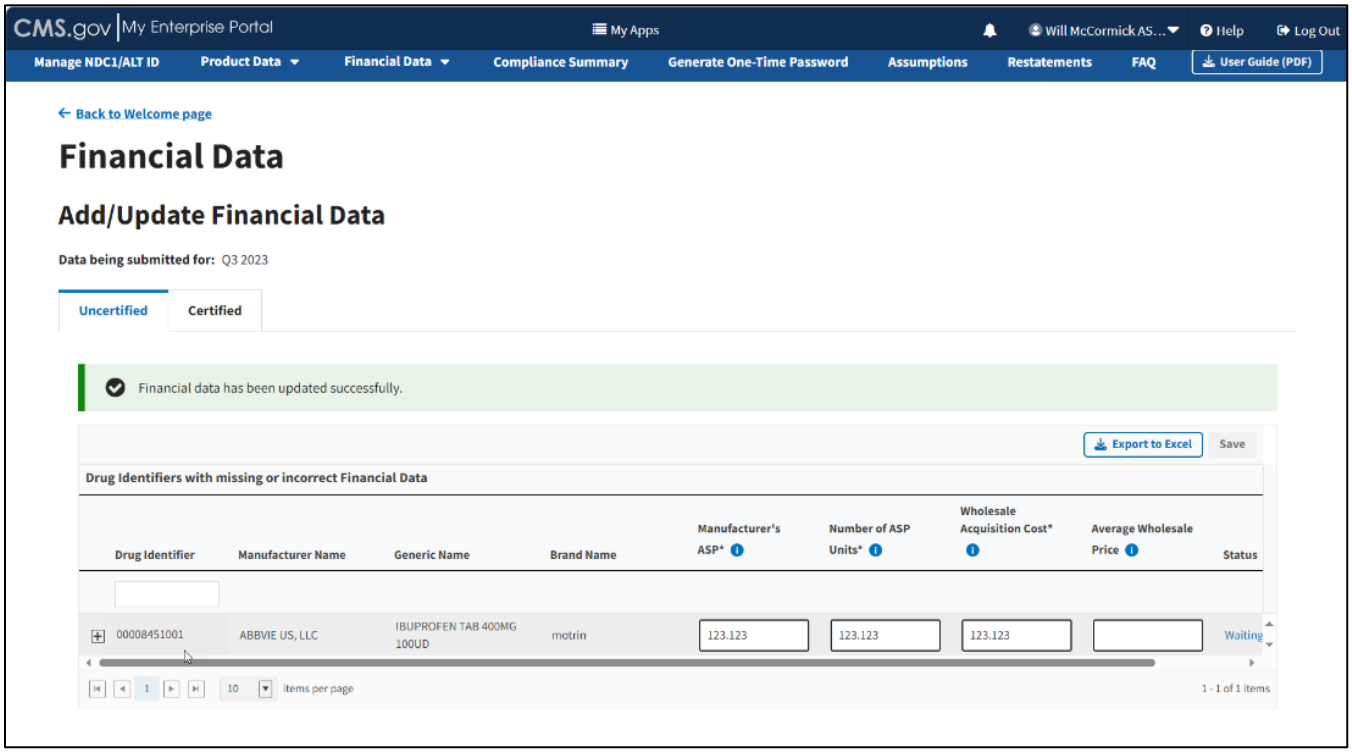

Figure 55: Add/Update Financial Data Successfully Added

Note: When there is an error in the submitted data or a missing field, the page opens each box in red or yellow to flag an error.

The expanded menu also shows **Action** items, such as **View Errors/Warnings** and **Save Changes**. Refer to *Figure 56*.

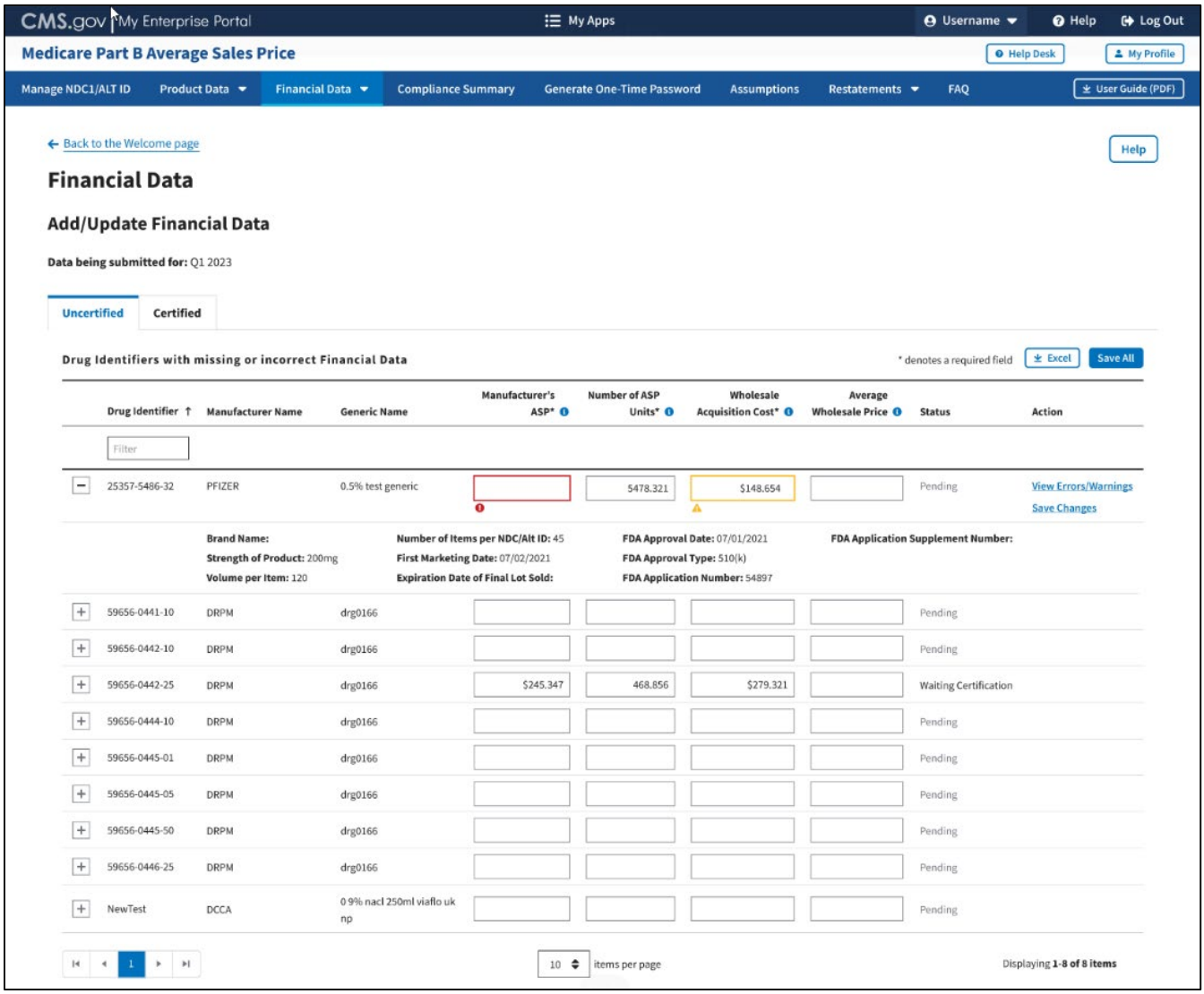

Figure 56: Add/Update Financial Data - Error Menu

9. Click on **View Errors/Warnings** for more information regarding the data reporting errors in your submitted financial data.

   A new window opens and displays a listing with descriptions of various errors and warnings. Refer to *Figure 57*.

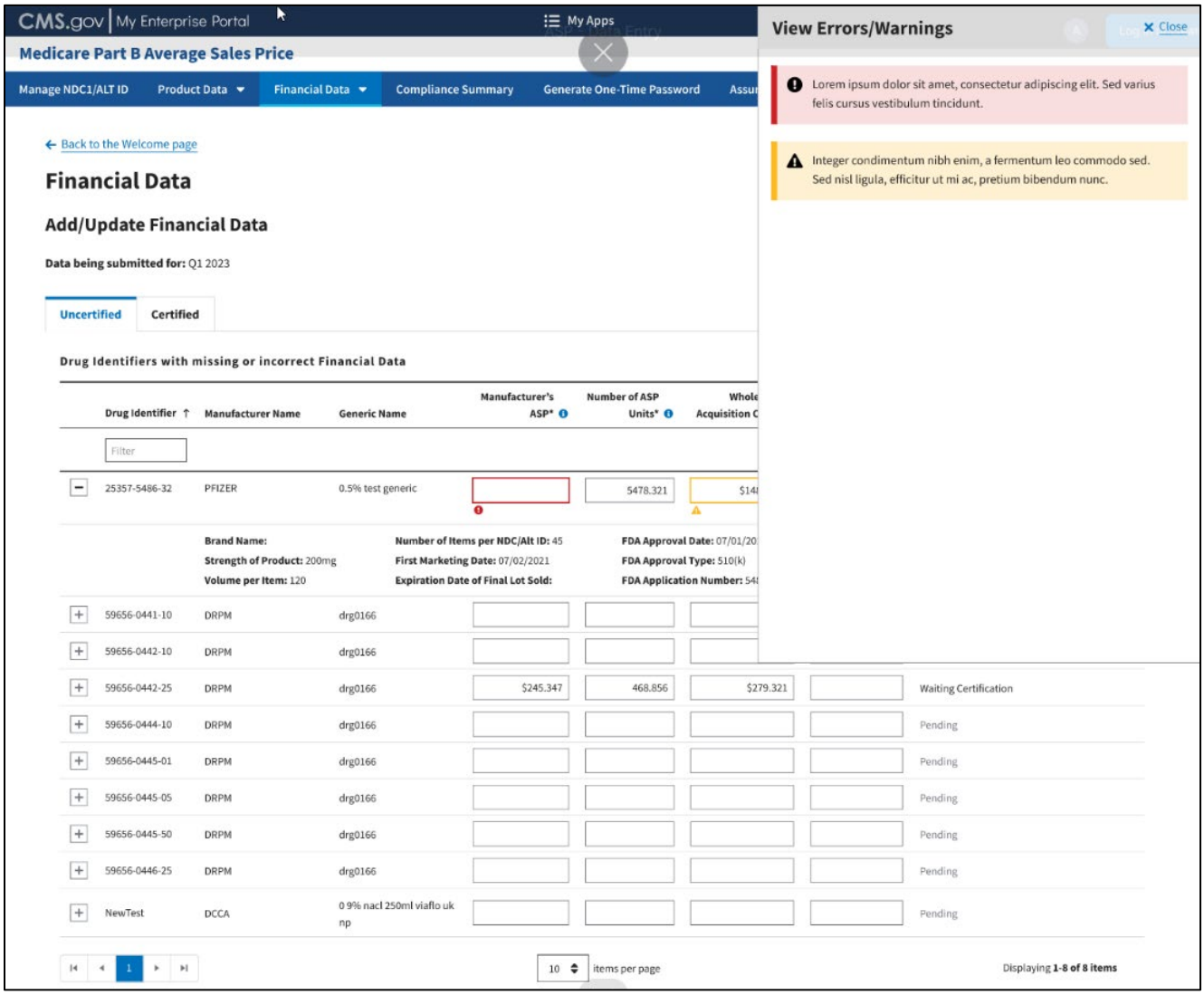

Figure 57: Add/Update Financial Data - View Errors/Warnings Page

10. Click **Save Changes** once you address any errors and confirm your product data is accurate.

    A message displays confirming that you have successfully added your data. Refer to *Figure 58*.

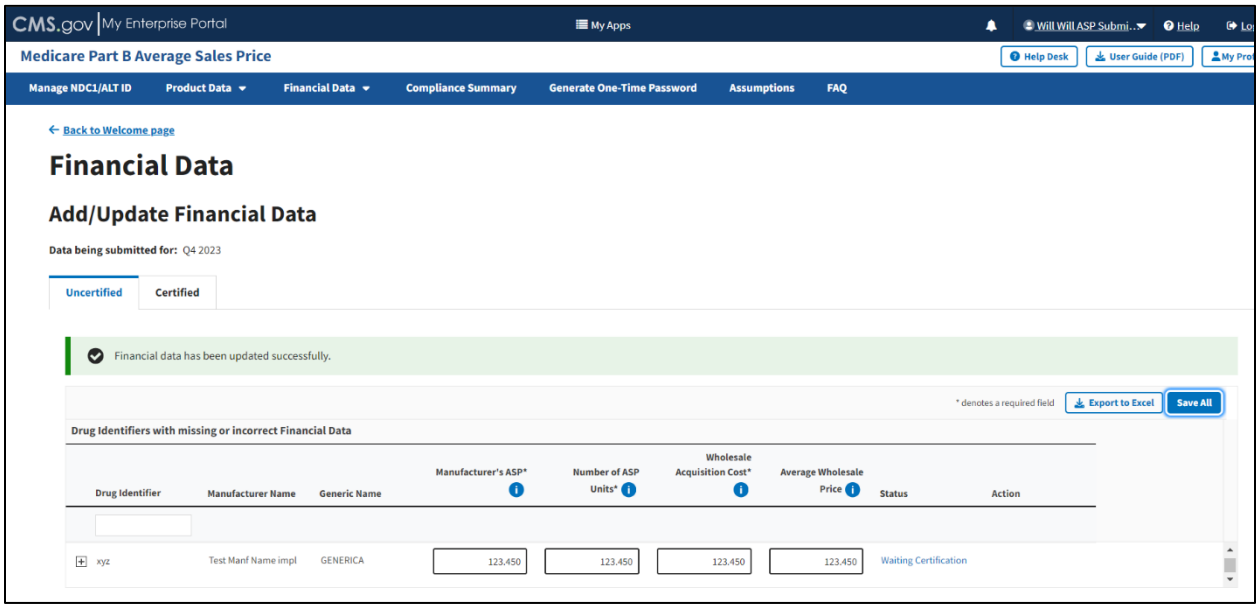

Figure 58: Add/Update Financial Data - Successfully Updated

3.3.2 Add/Update Financial Data - Certified Drugs

The Module collects data submissions for the upcoming financial quarter. Follow these steps to view submitted data for certified drugs:

1. From the **Add/Update Financial Data** page, select the **Certified Drugs** tab.

   The **Certified Drugs** page opens. Refer to *Figure 59.*

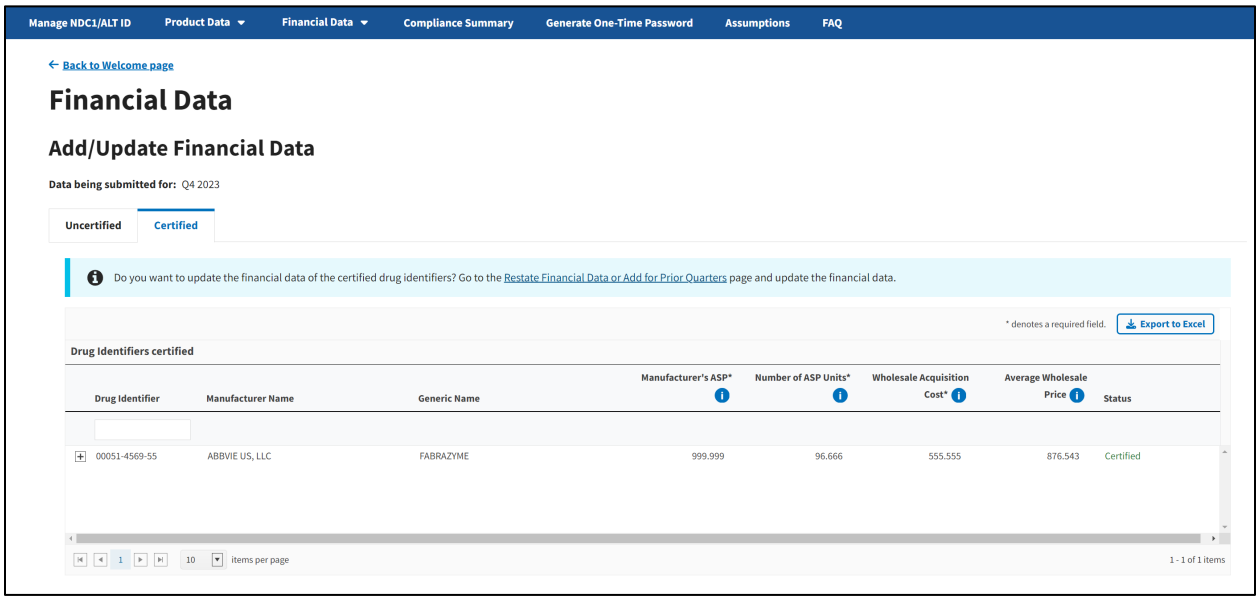

Figure 59: Add/Update Financial Data - Certified Drugs

Note: To update financial data for Certified drug identifiers, refer to the steps in *Section 3.4.1- Add/Update Restate Financial Data*.

2. Under **Drug Identifiers certified**, click the **Export to Excel** button to convert all information on this page into an Excel file.

   Note: The Module denotes the **Manufacturer's ASP**, **Number of ASP Units**, and **Wholesale Acquisition Cost** fields with an (*) to indicate that each field is required.

3. Scroll through the list of certified drugs and products on the page. Filter through all the information by clicking on your preferred category name.
4. Click the arrows on the bottom left to scroll through all submitted drugs by page.
5. Click on the plus symbol on each row of the table to expand each product's information and view additional categories, including **Brand Name**, **FDA Approval** and all other information previously submitted or acknowledged in the **Product Data** section. Refer to *Figure 60*.

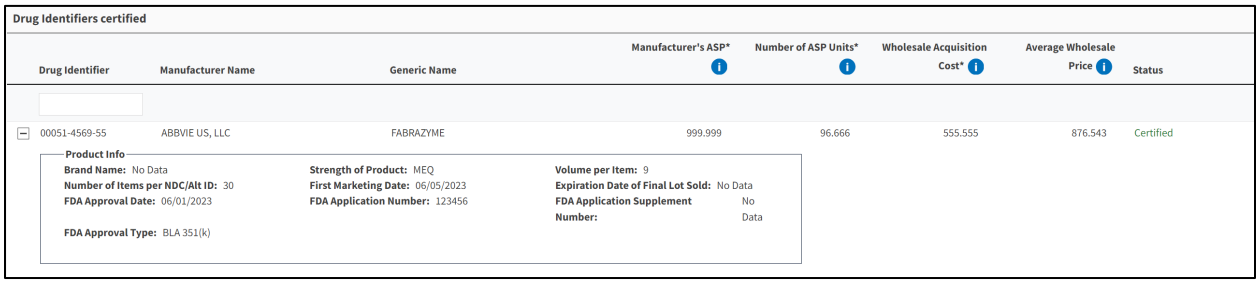

Figure 60: Add/Update Financial Data - Certified Drugs More Information

3.3.3 Upload Financial Data

Follow these steps to upload financial data:

1. From the Medicare Part B Average Sales Price homepage, click the **Financial Data** tab; then select the **Upload Financial Data for Current Quarter** tab.
2. The **Upload New or Corrected Financial Data** page opens, listing the financial quarter and year for the upcoming reporting period. Refer to *Figure 61*.

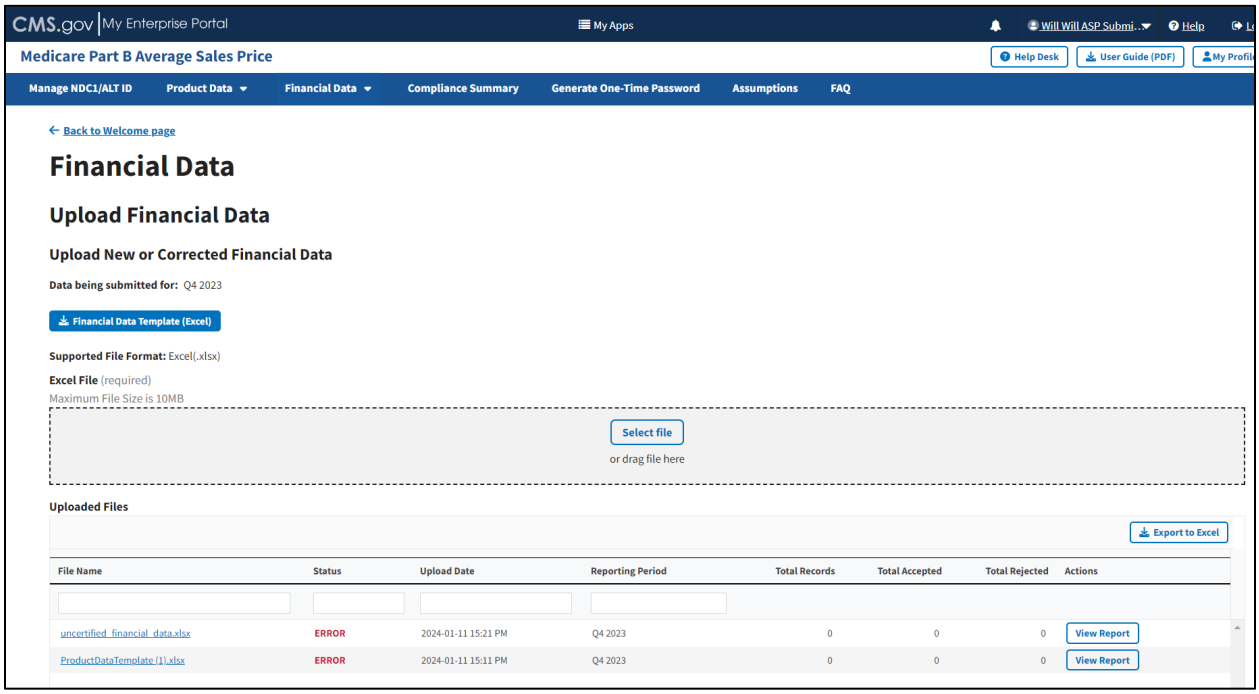

Figure 61: Upload Product Data - New or Corrected

Note: Under **Data being submitted for: (current quarter)**, click **Financial Data Template (Excel)** to download a financial data template.

3. Upon preparing your **.xlsx file (required)** and verifying your information for accuracy, click **Select File** to browse your desktop and upload the file to the Module. You may also drag the file into the **Select File** box. Refer to *Figure 62*.

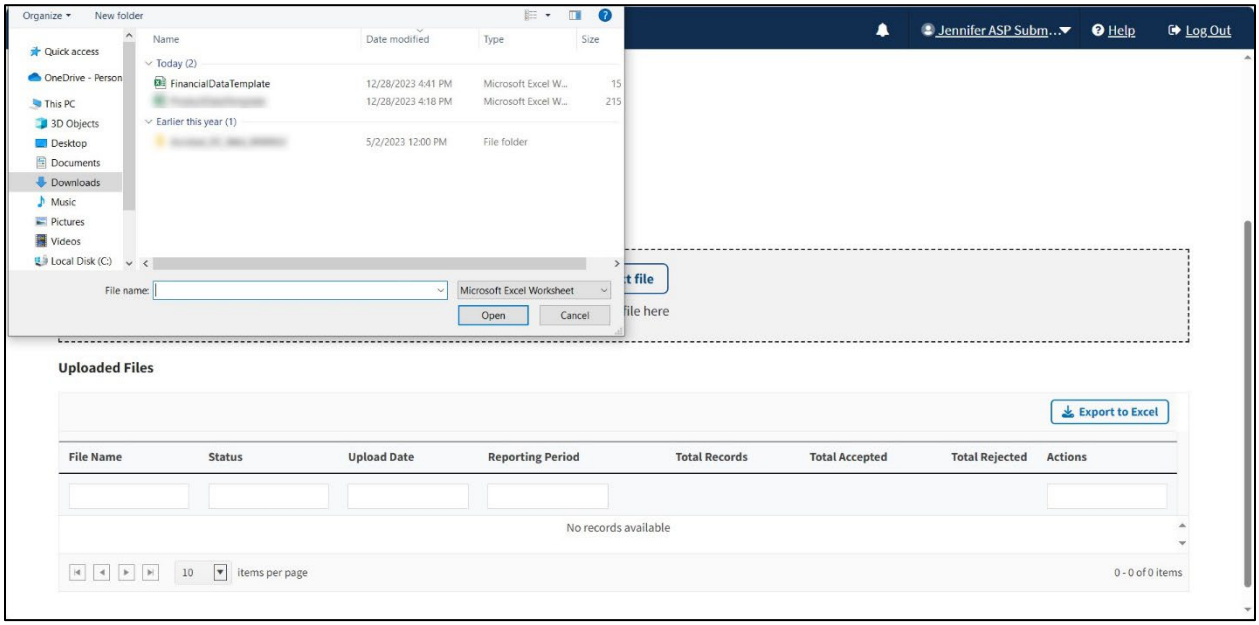

Figure 62: Upload Financial Data - Uploading Files from Desktop

A download bar displays as your file uploads. A message displays confirming you have successfully uploaded your **.xlsx file**. Refer to *Figure 63*.

Note: If the Module cannot process your file, an error message displays, and a **New Report** generates under **Uploaded Files**.

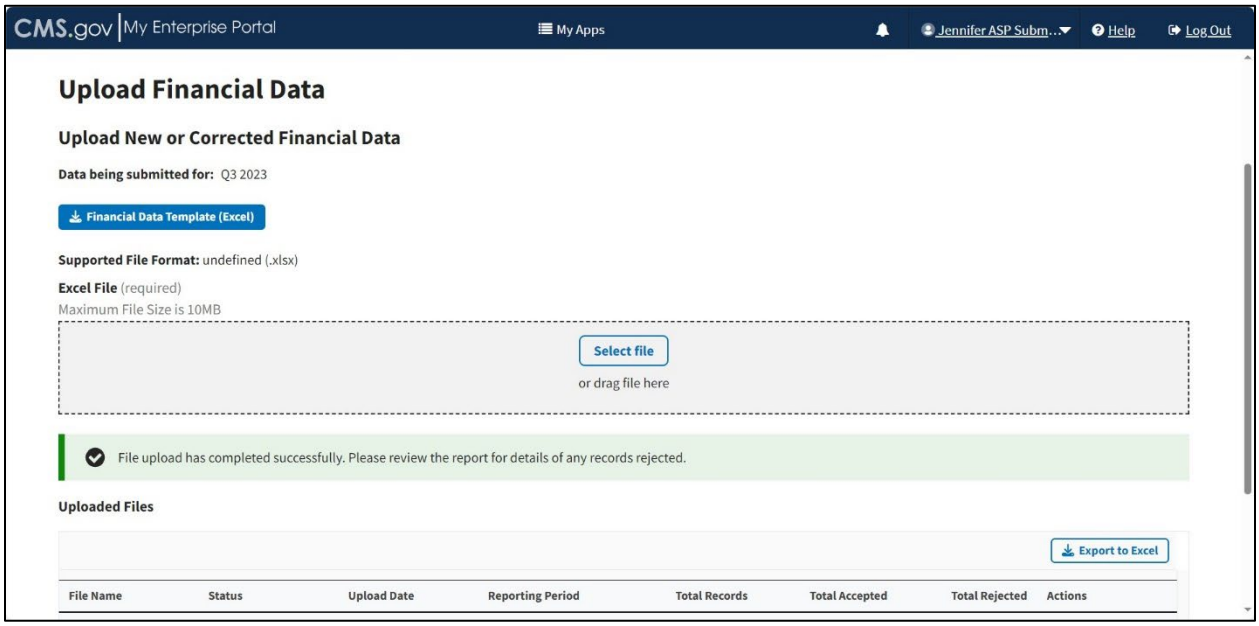

Figure 63: Upload Financial Data Page - New File Successfully Uploaded

4. Refresh your browser to allow the system to update and display your new file.
5. The **Uploaded Files** section displays files you uploaded recently as well as previous files still in the Module. Refer to *Figure 64*.

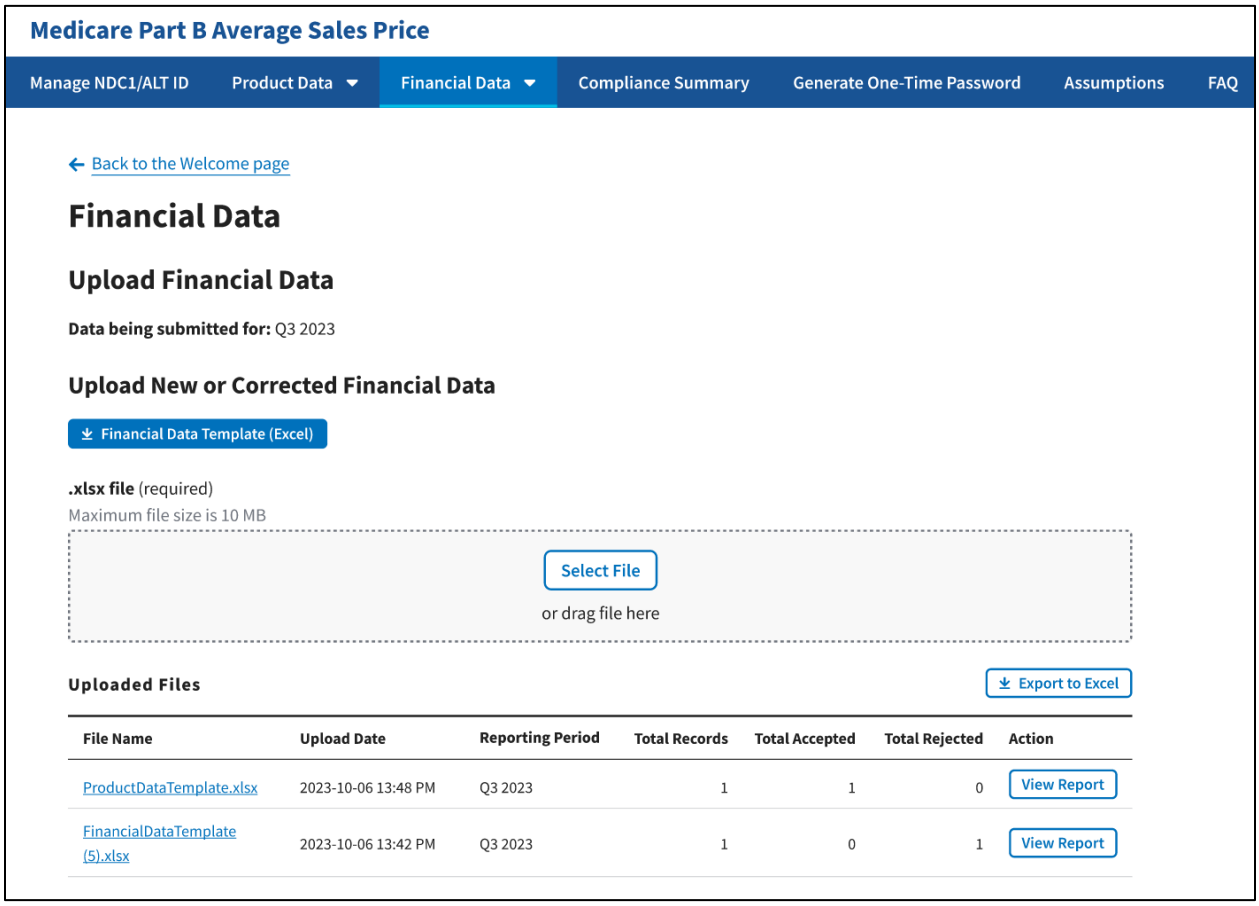

Figure 64: Upload Financial Data - Uploaded Files

Each uploaded file displays the **File Name**, **Upload Date**, **Reporting Period**, **Total Records**, **Total Accepted**, **Total Rejected,** and **Action** categories submitted to the Module.

6. Click **View Report** under **Action** in the **Uploaded Files** section to view the full report for a submitted file.

   The report opens on the next page. Refer to *Figure 65*.

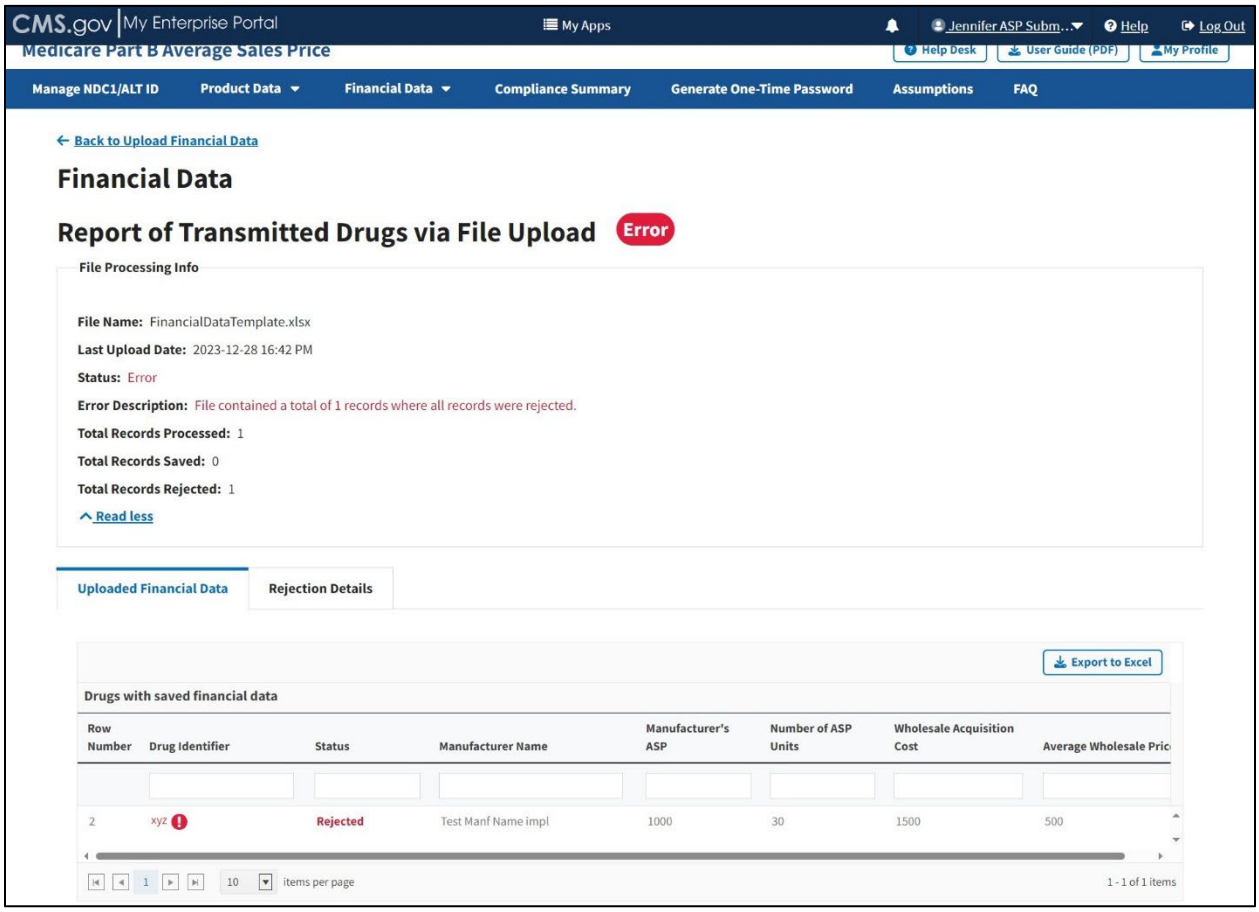

Figure 65: Upload Financial Data - Report of Transmitted Drugs via File Upload

7. Click the **Read More** link under the **Report of Transmitted Drugs via File Upload** near the top of the page to view all **File Processing Information** related to this report.

   The report lists all drugs with saved product data in the ASP system. The Module organizes the full list by row number and includes each drug identifier, status, and all previously submitted information from the **Add Product Data** sections.

   Note: The Module highlights errors in red. Hover over the red text to display information about the specific error.

8. Click the **Rejection Details** tab.

   A listing of drug identifiers with rejected financial data displays. Refer to *Figure 66.*

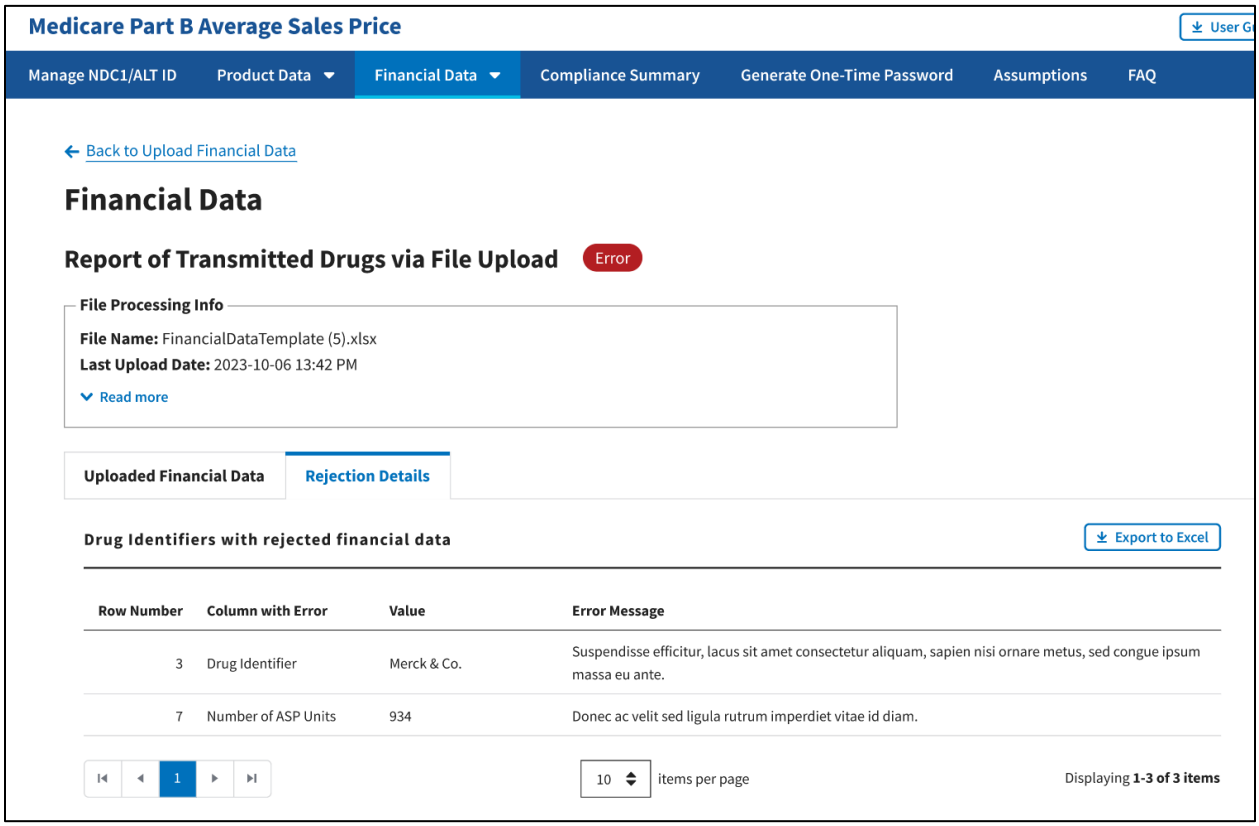

Figure 66: Upload Financial Data - Reported Rejection Details

The Module lists all errors found in submitted data by **Row Number**, **Column with Error**, and **Error Message** under **Drugs with Rejected Product Data**.

9. Return to the **Add/Update Financial Data** section of the Module to request any changes to your product data.

3.4 Re-Statements

Manufacturers of drugs and biologicals payable under Medicare Part B have an obligation to report accurate ASP data to CMS, including addressing data miscalculations and other errors in previously submitted data. Upon identifying an error, manufacturers must submit corrected data through the ASP Module. Additionally, CMS may identify an error and contact the manufacturer to request corrected data.

CMS evaluates resubmitted data and decides whether to issue a restatement of the payment limit. Criteria evaluated includes, but is not limited to, timing of the corrected data, changes to the payment limit, and/or administrative burden.

The following sections describe how to add/update or upload restate financial data using the online data entry process.

3.4.1 Add/Update Restate Financial Data

Follow these steps to add/update restate financial data:

1. Click the **Financial Data** tab; select **Restate Financial Data or Add for Prior Quarters**. Refer to *Figure 67*.

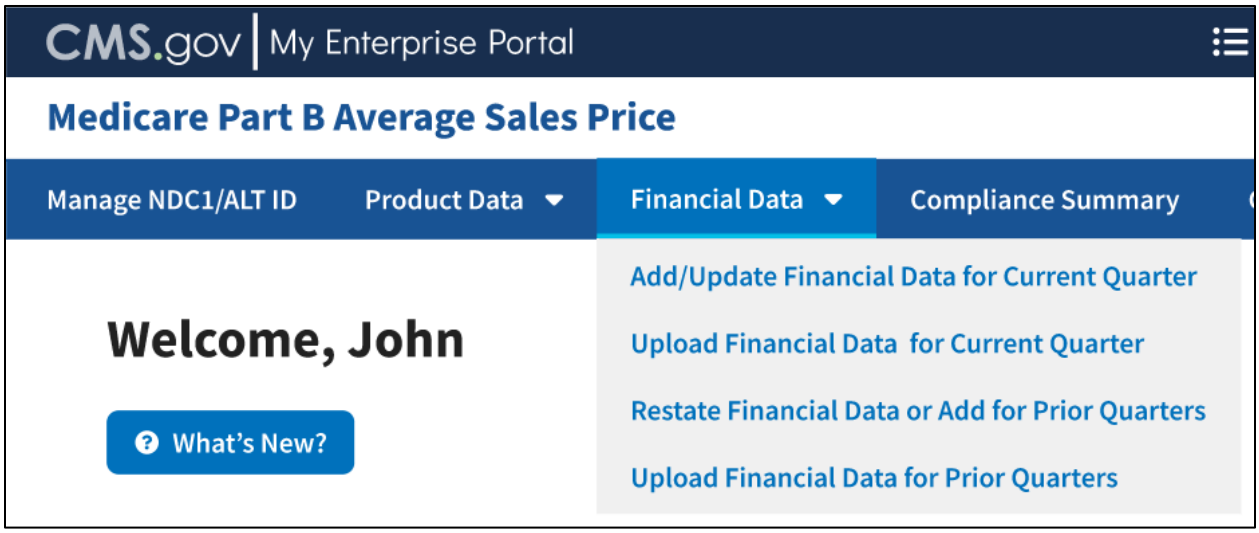

Figure 67: Financial Data - Main Dropdown

The **Restate Financial Data or Add for Prior Quarters** page opens, listing the financial quarter and year for the upcoming reporting period. Refer to *Figure 68*.

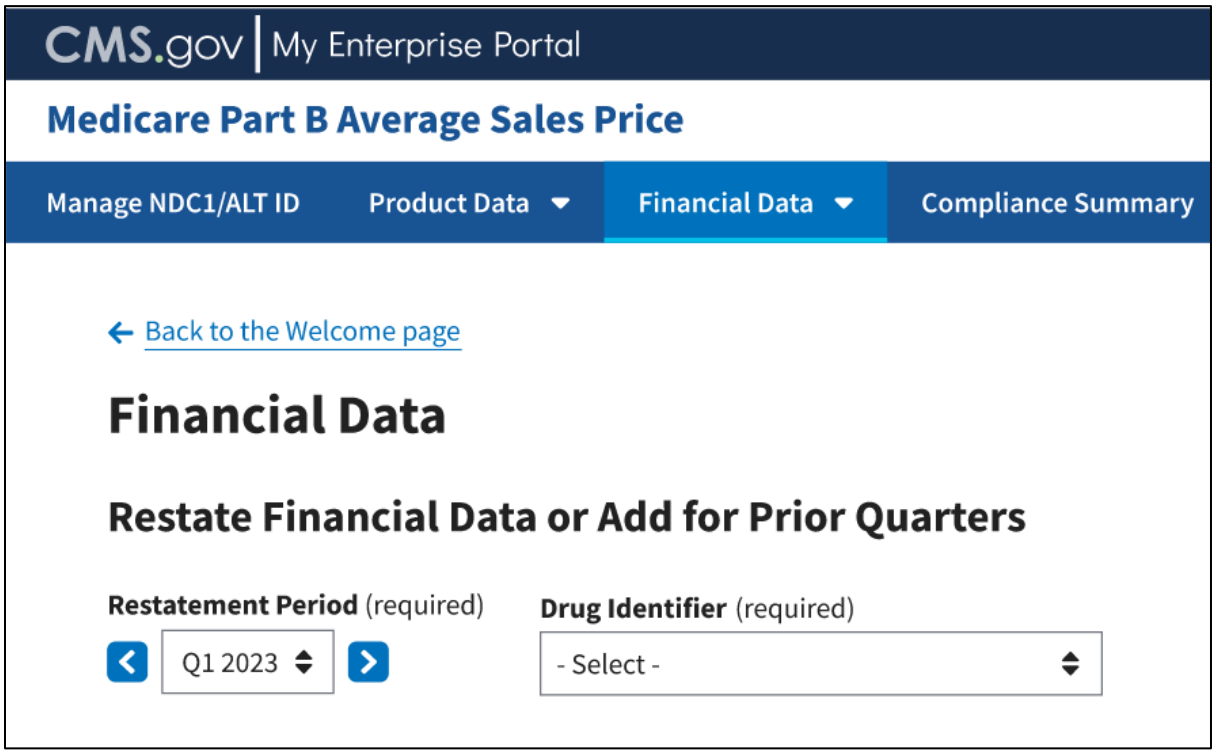

Figure 68: Financial Data - Add/Update Restate Financial Data

Note: Click the **Restatement Period (required)** tab in the top left to scroll through previous quarters. Click the blue arrows to navigate to a previous quarter starting with the most recent or next quarter.

2. Click the **-Select-** box under **Drug Identifier (required)** to expand the list of submitted drugs in the Module. Refer to *Figure 69*.

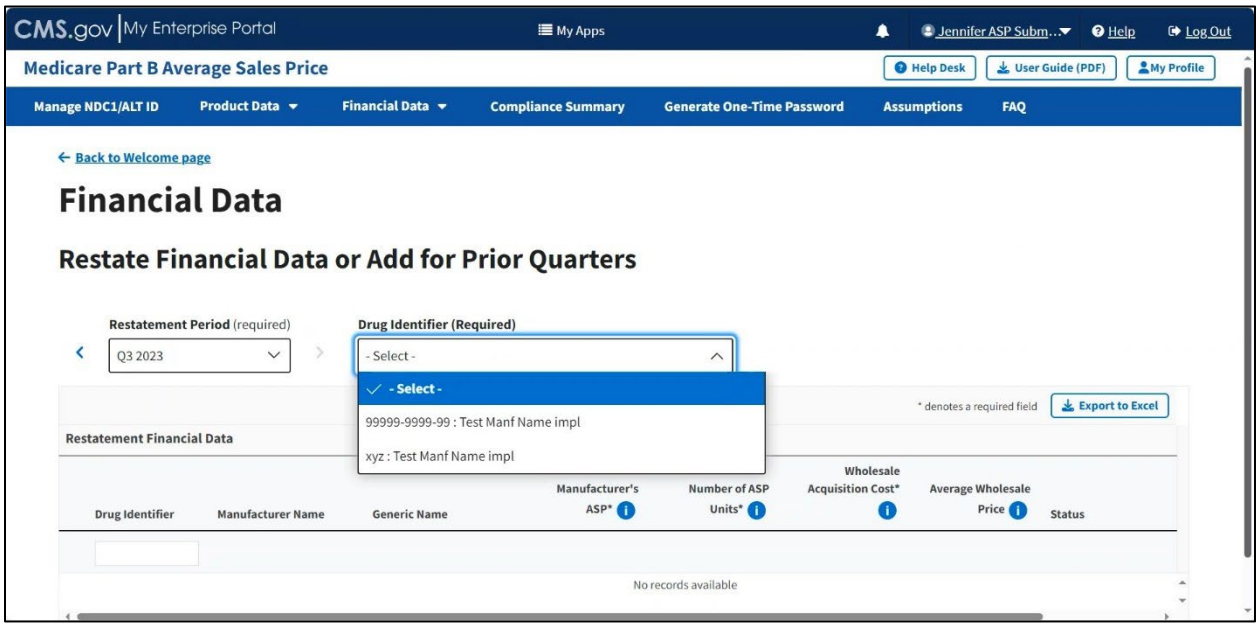

Figure 69: Add/Update Restate Financial Data - Drug Identifier Drop-down

3. Select the **Drug Identifier** you need to close the list. Once you click a product, the **Review Restatement List** expands to show current restatements. Refer to *Figure 70*.

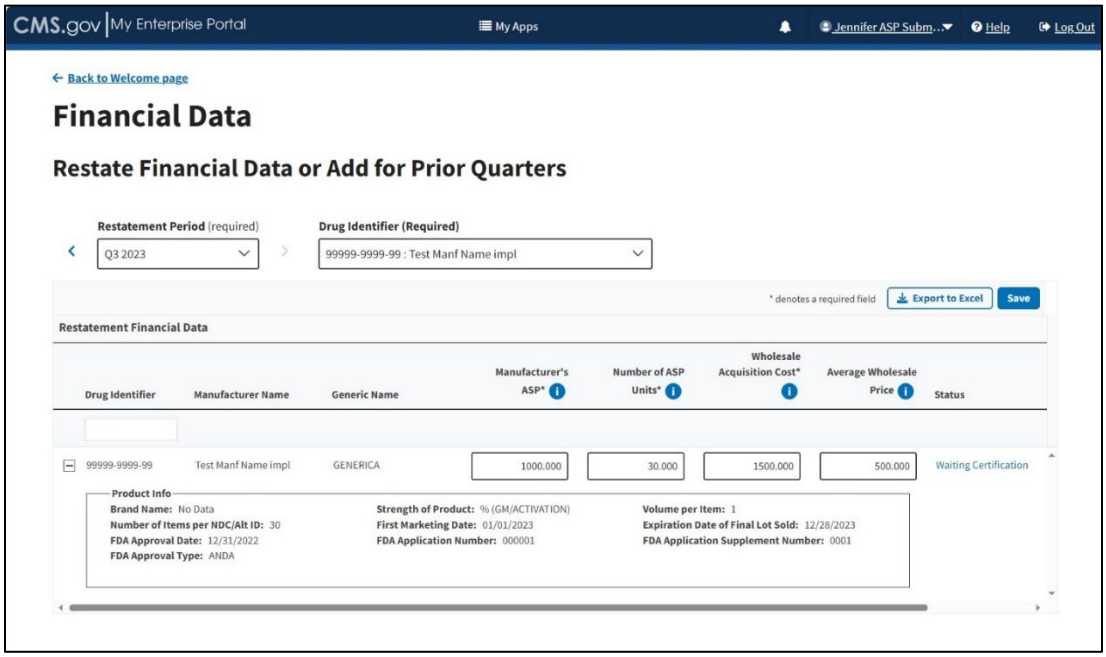

Figure 70: Add/Update Restate Page - Review Restatement List

4. Review and make any corrections necessary for the drug to the **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost (all required)** and **Average Wholesale Price** fields.
5. Click the **plus** symbol on each row of the table to expand each product's information and view additional categories previously submitted or acknowledged in the **Product Data** section.
6. Click the **Save** button to submit your data.

   A message displays confirming you have successfully updated your **Restate Financial Data**. Refer to *Figure 71*.

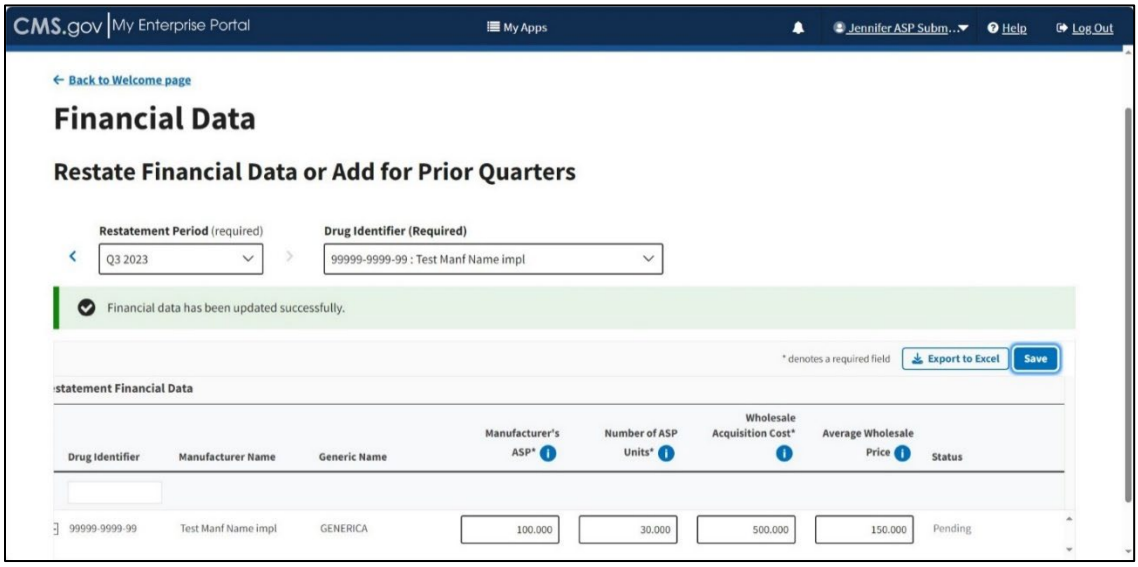

Figure 71: Add/Update Restate Page - Restate Data Successfully Saved

7. Contact your Certifier to recertify the corrected data you submitted to the Module.

3.4.2 Upload Restate Financial Data

Follow these steps to upload restate financial data:

1. From the Medicare Part B Average Sales Price homepage, click the **Financial Data** tab; then select the **Upload Financial Data for Prior Quarters** tab. Refer to *Figure 80*.

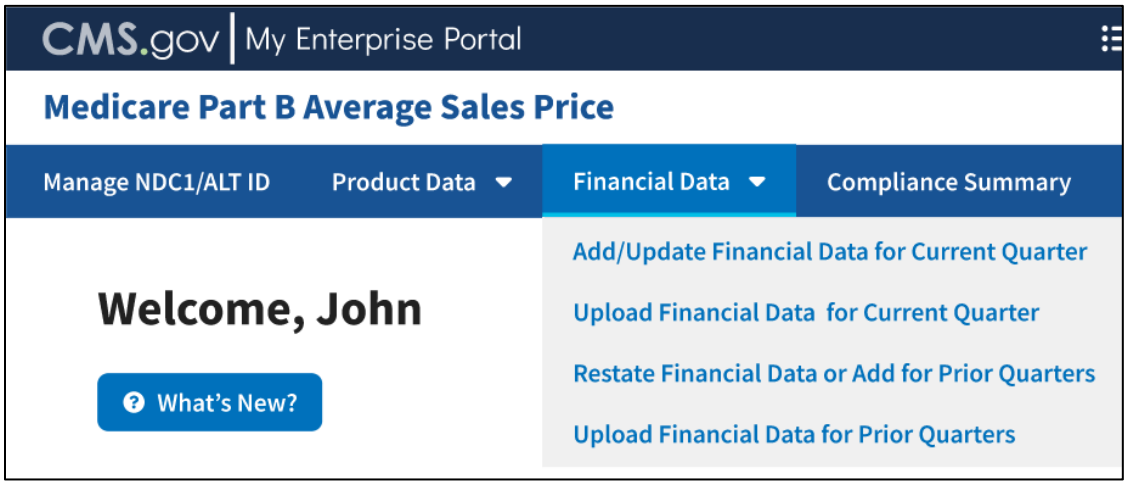

Figure 72: Financial Data - Main Drop-down

The **Upload Financial Data for Prior Quarters** page opens, listing the financial quarter and year for the upcoming reporting period. Refer to *Figure 73*.

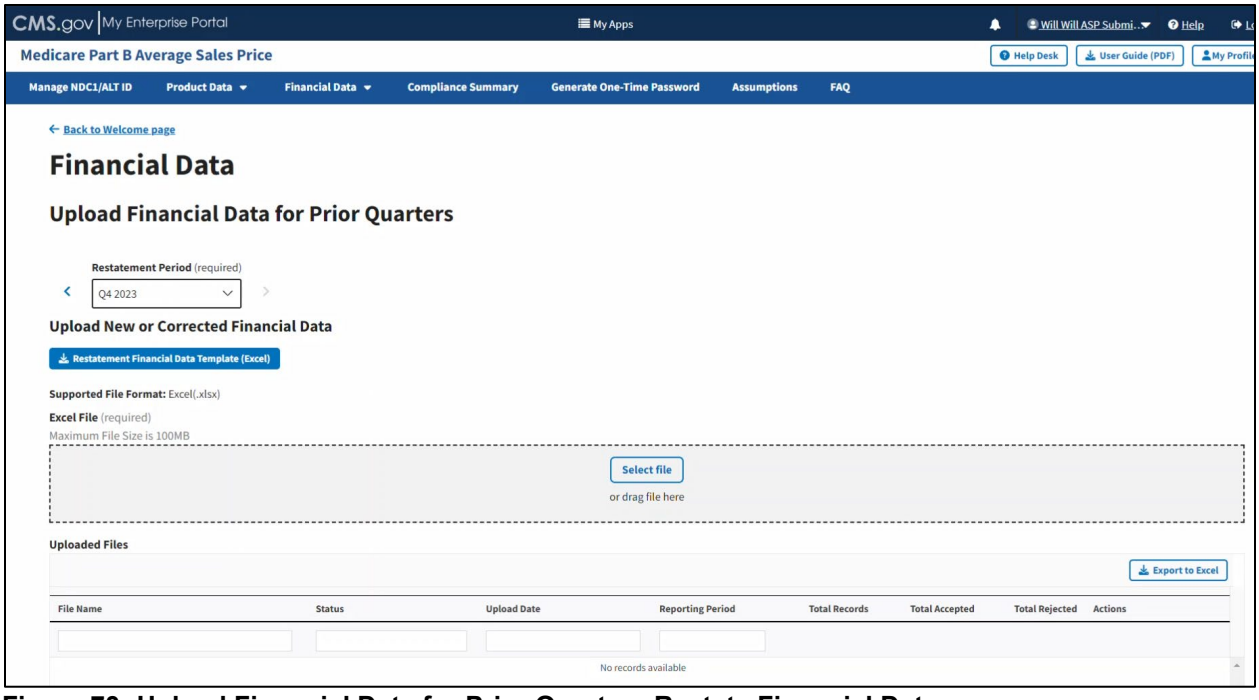

Figure 73: Upload Financial Data for Prior Quarters Restate Financial Data

Note: Under **Data being submitted for (current quarter)**, there is a **Restatement Financial Data Template** (Excel) available for download. Click the box to download a desktop copy.

2. Upon preparing your **.xlsx file (required)** and verifying your information for accuracy, click **Select File** to browse your desktop and upload the file to the Module. You may also drag the file into the **Select File** box. Refer to *Figure 74*.

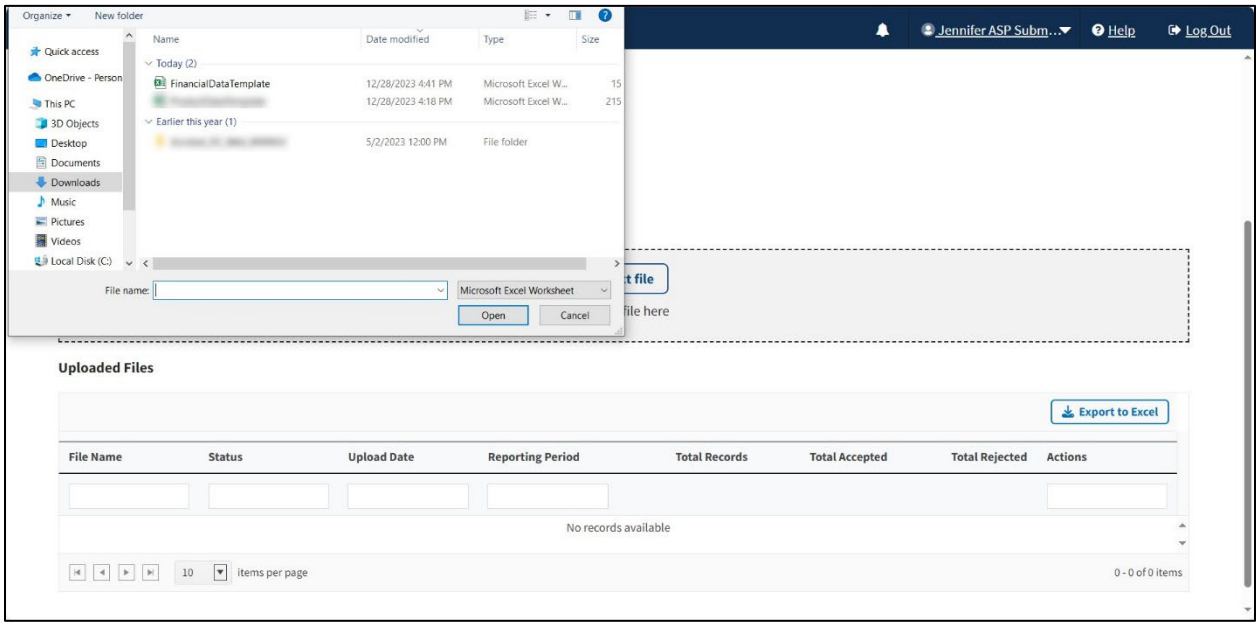

Figure 74: Upload Financial Data for Prior Quarters - Uploading Files from Desktop

A download bar displays as your file uploads. A message displays confirming you have successfully uploaded your **.xlsx file**. Refer to *Figure 75*.

Note: If the Module cannot process your file, an error message displays, and a **New Report** generates under **Uploaded Files**.

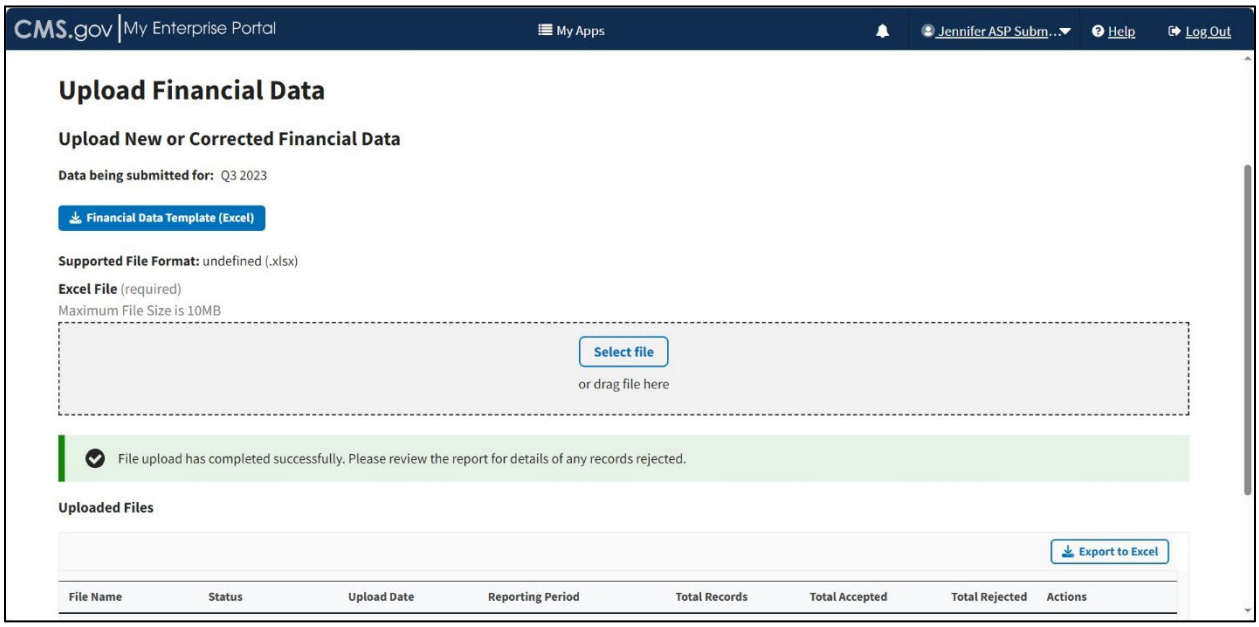

Figure 75: Upload Financial Data for Prior Quarters - New File Successfully Uploaded

The **Uploaded Files** section displays files you uploaded recently as well as previous files still in the Module. Refer to *Figure 76*.

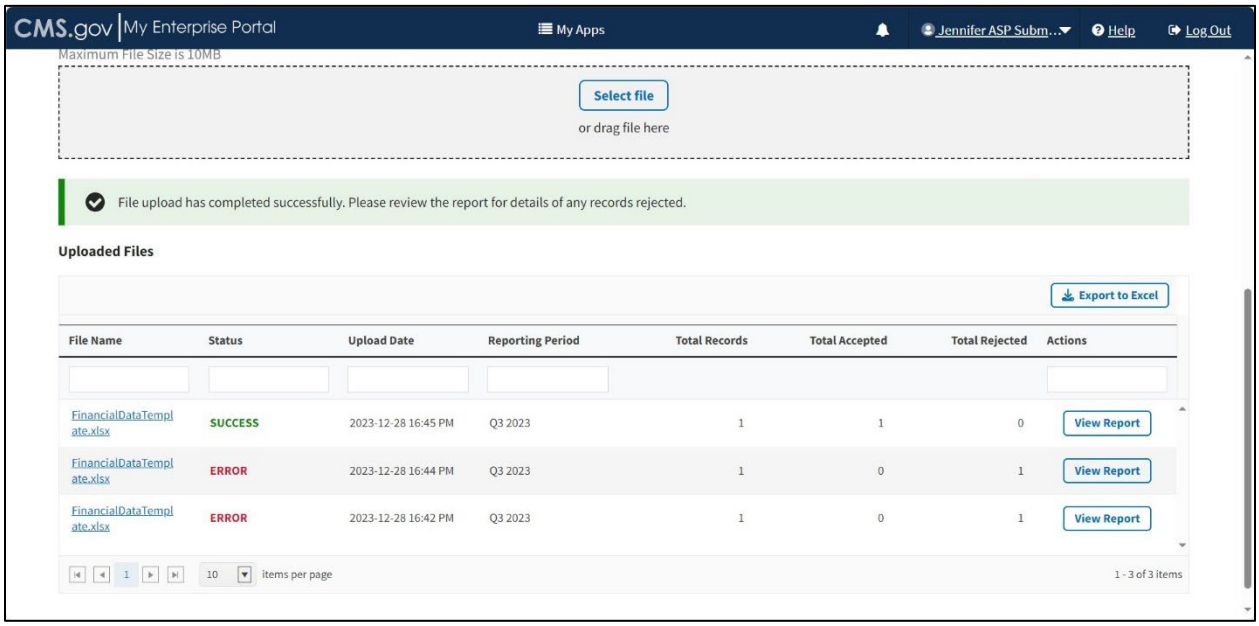

Figure 76: Upload Financial Data for Prior Quarters - Uploaded Files

Each uploaded file displays the **File Name**, **Status**, **Upload Date**, **Reporting Period**, **Total Records**, **Total Accepted**, **Total Rejected**, and **Actions** categories submitted to the Module.

3. Click **View Report** under **Actions** in the **Uploaded Files** section to view the full report for a submitted file.

   The report opens on the next page. Refer to *Figure 77*.

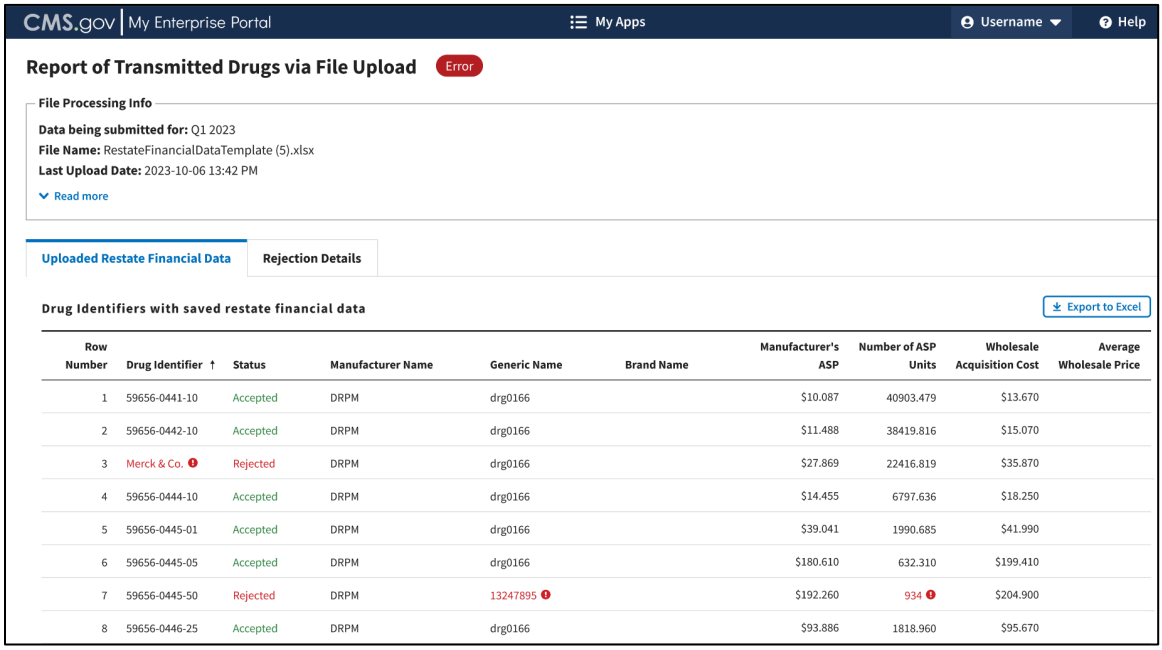

Figure 77: Upload Financial Data for Prior Quarters - Report of Transmitted Drugs

4. Click the **Read More** tab under the **Report of Transmitted Drugs via File Upload** to view all **File Processing Information** related to this report.

   The report lists all drug identifiers with saved restate financial data in the ASP system. The Module organizes the full list by row number and includes each drug identifier, status, and other previously submitted information from the **Add Product Data** sections.

   Note: The Module highlights errors in red. Hover over the red text to display information about the specific error.

5. Click the **Rejection Details** tab.

   A listing of drug identifiers with rejected restate financial data displays. Refer to *Figure 78*.

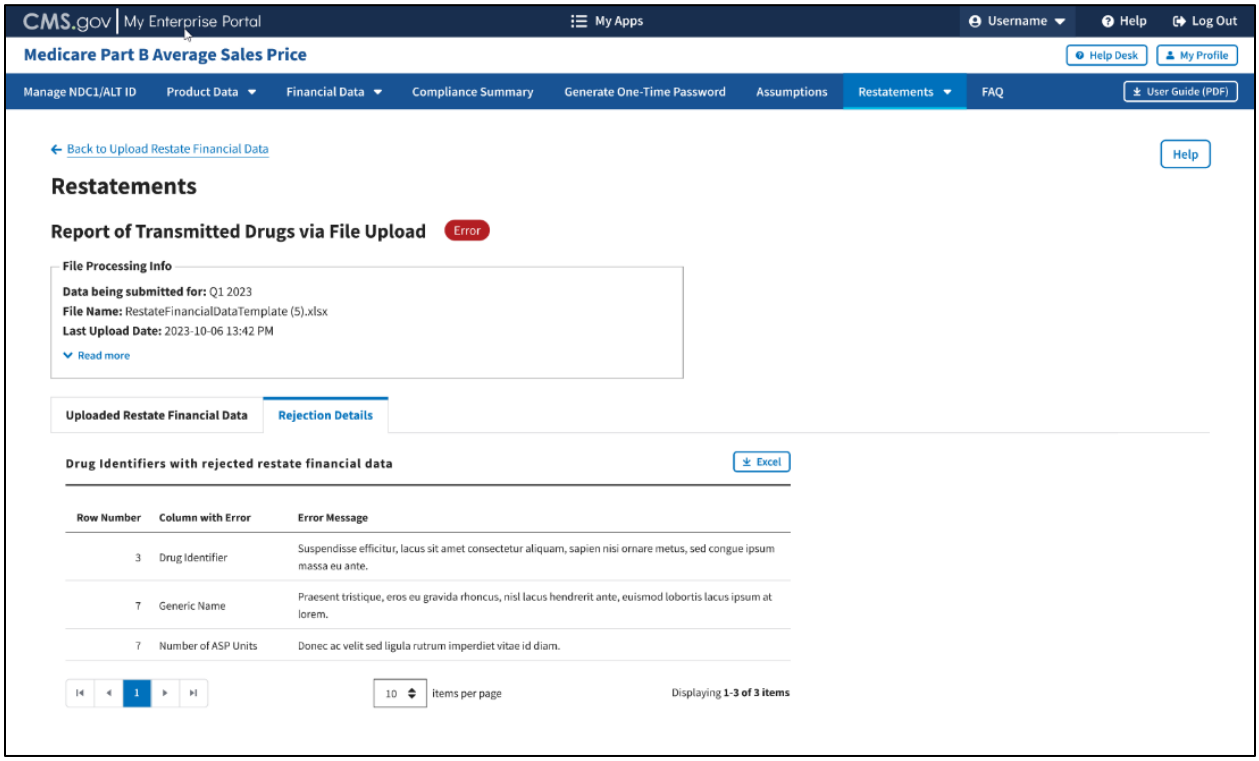

Figure 78: Upload Financial Data for Prior Quarters - Reported Rejection Details

   The Module lists all errors found in submitted data by **Row Number**, **Column with Error**, and **Error Message** under **Drug identifiers with rejected restate financial data**.

6. Return to the **Add/Update Financial Data** section of the Module to request any changes to your product data.
7. Contact your Certifier to recertify the corrected data you submitted to the Module.

3.5 Compliance Summary

The features in the **Compliance Summary** section allow drug manufacturers to determine if their products meet the current submission reporting requirements.

The **Compliance Summary** consists of the following sections:

- **Missing**: Displays drug products that are missing financial data for the selected reporting period.
- **Pending**: Displays drug products that are both pending certification and pending restatement certification, combined under one tab.
- **Certified**: Displays previously certified drug products for the selected reporting period.

  Note: Financial data will be suppressed for prior quarters.
- **New**: Displays drug products with a first marketing date in the same reporting period.
- **Off Cycle**: Displays drug products added on or after the first day of the submission window of the current quarter.
- **Expired**: Displays drug products that have an expired date of final lot sold. A drug product that expired in an earlier quarter will continue to show in subsequent quarters.

Follow these steps to navigate the **Compliance Summary** section:

1. **From the** Medicare Part B Average Sales Price homepage, click the **Compliance Summary** tab.

   The **Compliance Summary** page opens. The page displays the status for each submitted drug product regarding the drug manufacturer's compliance for the selected reporting period. The page automatically defaults to the **Missing** tab. Refer to *Figure 79*.

   Note: *Figure 79* shows an alert message under **Reporting Period** stating that there are drug products in need of attention.

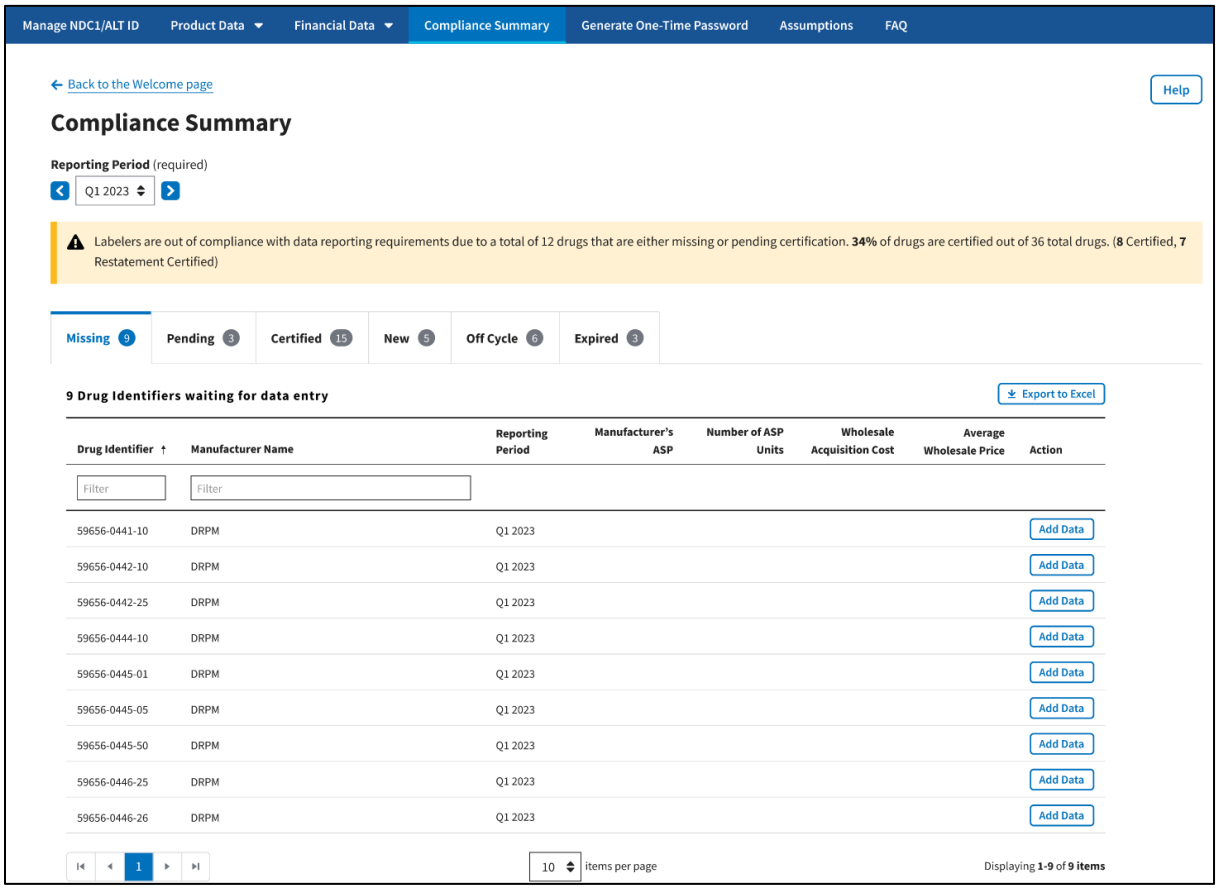

Figure 79: Compliance Summary

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Click the blue arrows to navigate to a previous quarter starting with the most recent or next quarter.

3.5.1 Missing

Follow these steps to add data in the **Missing** tab of the **Compliance Summary**:

1. Under **Drug Identifiers waiting for data entry**, review and identify the missing fields or incorrect financial information to address; confirm the accuracy of all the necessary financial information listed on the page.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price** fields.

   Note: Click the **Export to Excel** button to download all products under the **Missing** tab.

2. Click the **Add Data** tab next to the appropriate drug product.

   An **Add Financial Data** window opens. Refer to *Figure 80*.

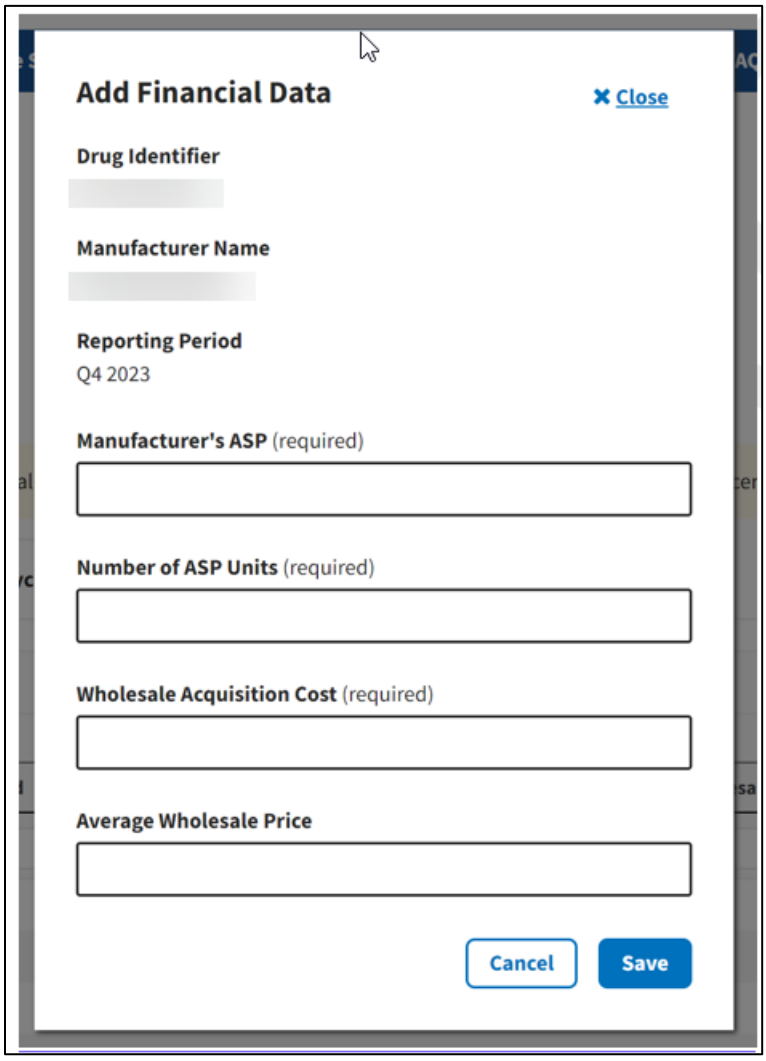

Figure 80: Compliance Summary - Add Data Screen

3. Type the requested information in the empty **Manufacturer's ASP (required)**, **Number of ASP Units (required)**, **Wholesale Acquisition Cost (required)**, and **Average Wholesale Price (required)** fields.
4. Click **Save** to submit your information to the Module.

   A message displays confirming you have successfully added your data, and that your product is now pending certification. Refer to *Figure 81*.

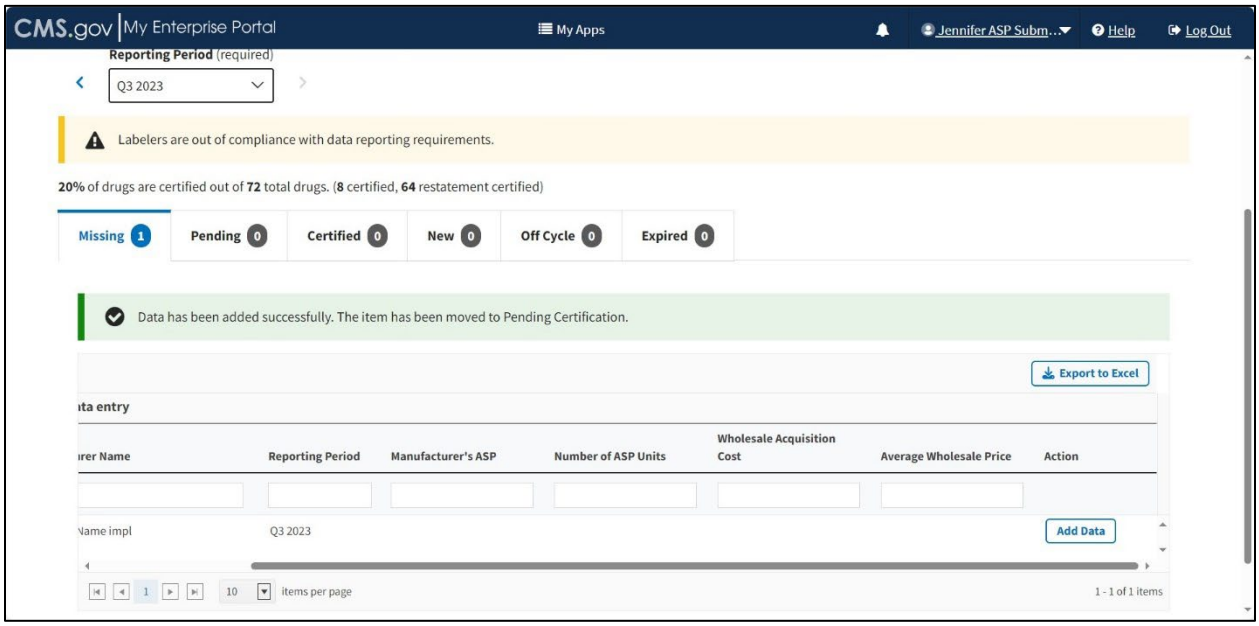

Figure 81: Compliance Summary - Successfully Saved

3.5.2 Pending

Follow these steps to review your data in the **Pending** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Pending** tab.

   The **Pending** tab displays. Refer to *Figure 82*.

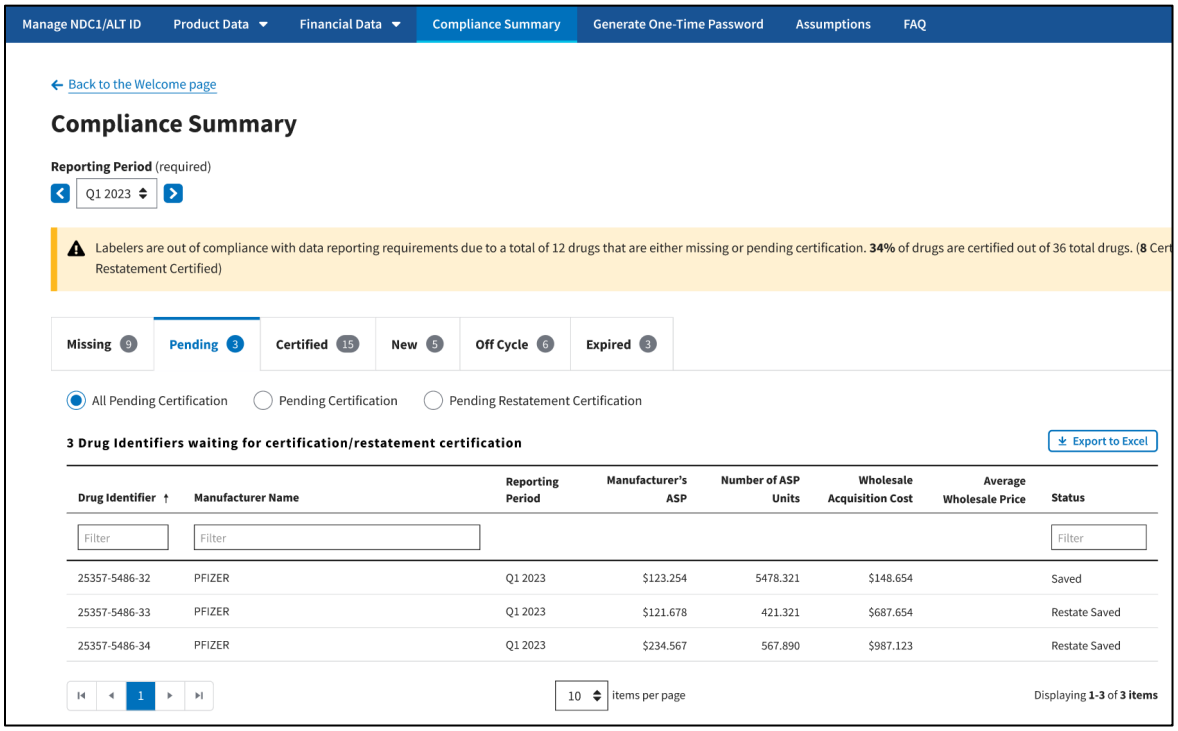

Figure 82: Compliance Summary - All Pending Certification

The Module automatically selects the **All Pending Certification** radio button, and the page displays the drug identifiers waiting for certification/restatement certification.

Note: Click the **Export to Excel** button to download all products under the **Pending** tab.

2. Under **Drug Identifiers Waiting for Certification/Restatement Certification**, review your information in the appropriate boxes previously submitted in *Section 3.2 - Product Data* and *Section 3.3 - Financial Data*.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Status** fields.

3. Click the **Pending Certification** radio button to filter only for drugs pending certification. Refer to *Figure 83*.

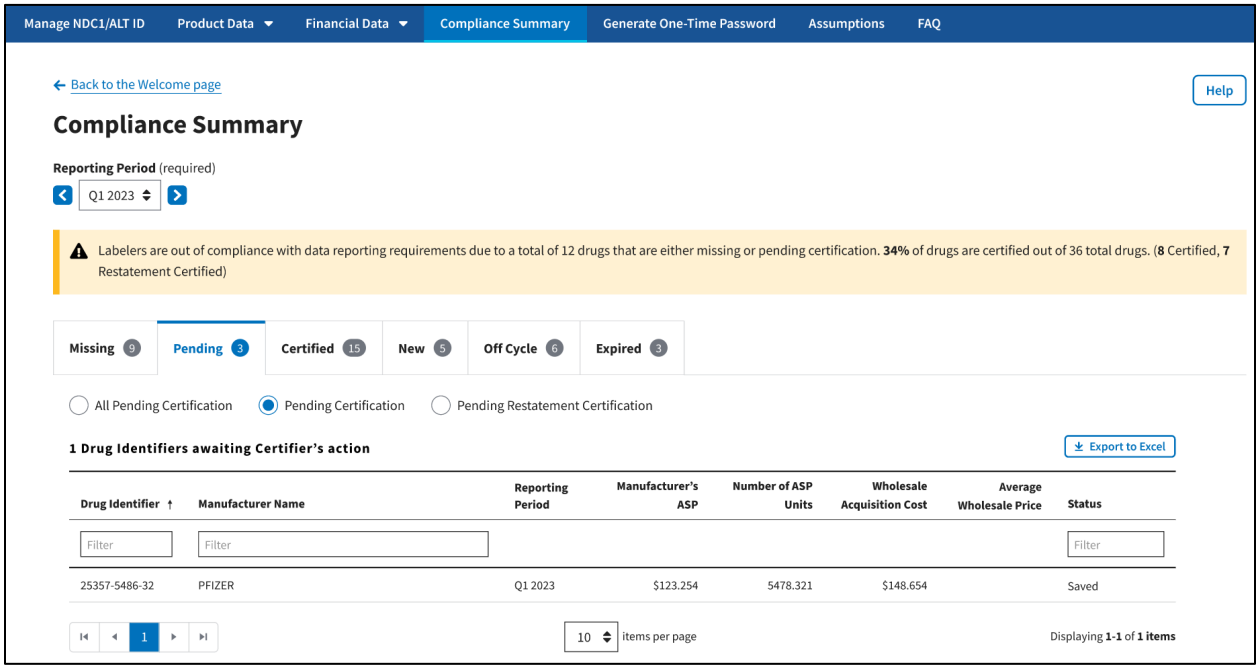

Figure 83: Compliance Summary - Pending Certification

Note: Click the **Export to Excel** box to download all products under the **Pending** tab.

4. **Review** the information previously submitted in *Section 3.2 - Product Data*.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Status** fields.

5. Click the **Pending Restatement Certification** radio button to filter only for drugs that are pending restatement certification. Refer to *Figure 84*.

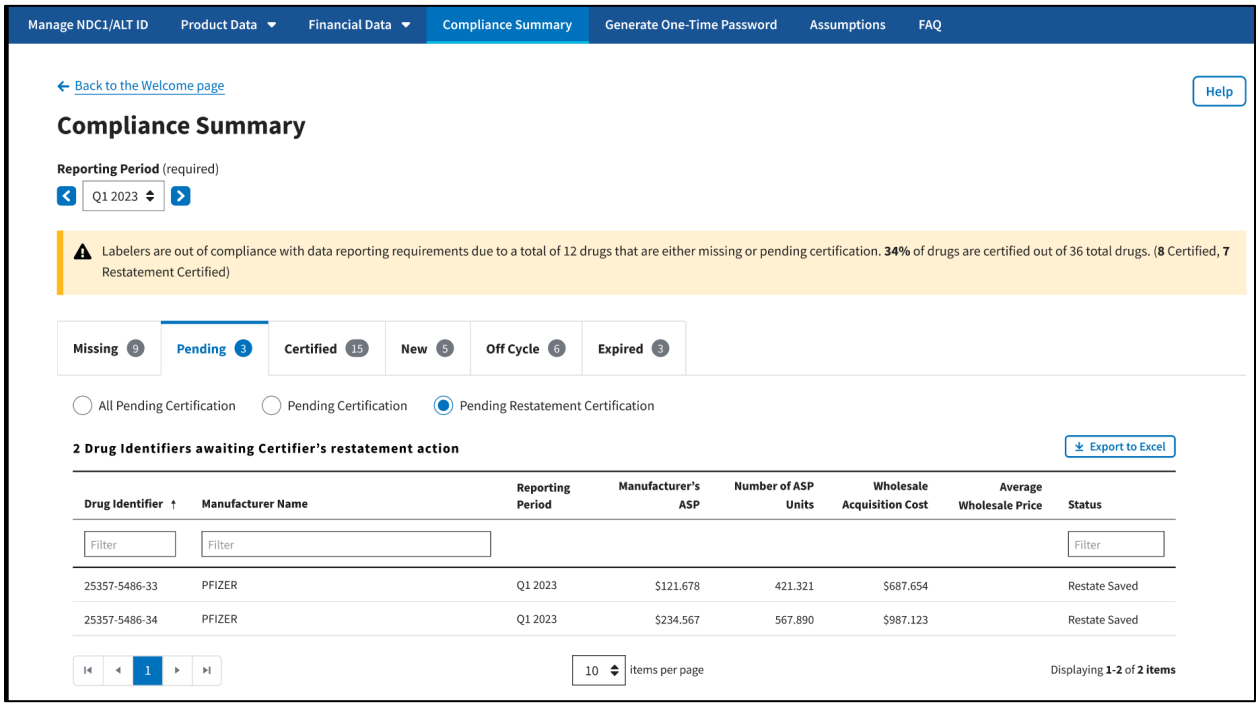

Figure 84: Compliance Summary - Pending Restatement Certification

Note: Click the **Export to Excel** button to download all products under the **Pending** tab.

6. **Review** all your information in the appropriate boxes previously submitted in *Section 3.2 - Product Data* and *Section 3.3 - Financial Data*.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**, and **Status** fields.

3.5.3 Certified

Follow these steps to review your data in the **Certified** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Certified** tab.

   The **Certified** page displays. The Module automatically selects the **All Certified** radio button. Refer to *Figure 85*.

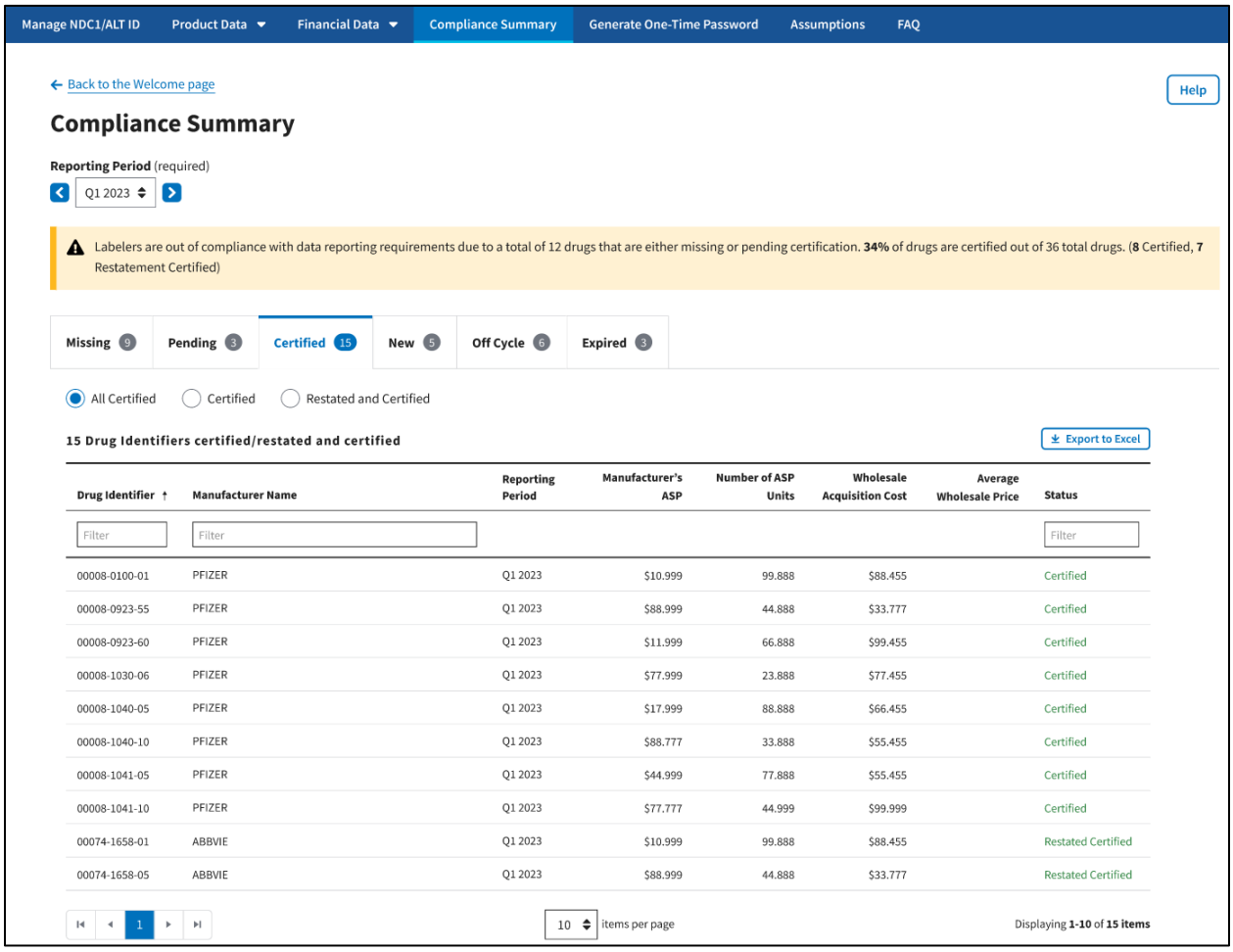

Figure 85: Compliance Summary - All Certified

Note: Click the **Export to Excel** button to download all products under the **Certified** tab.

2. Review all your information in the appropriate boxes previously submitted in *Section 3.2 - Product Data* and *Section 3.3 - Financial Data*.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**, and **Status** fields.

3. Click the **Certified** radio button to filter only for certified drugs. Refer to *Figure 86*.

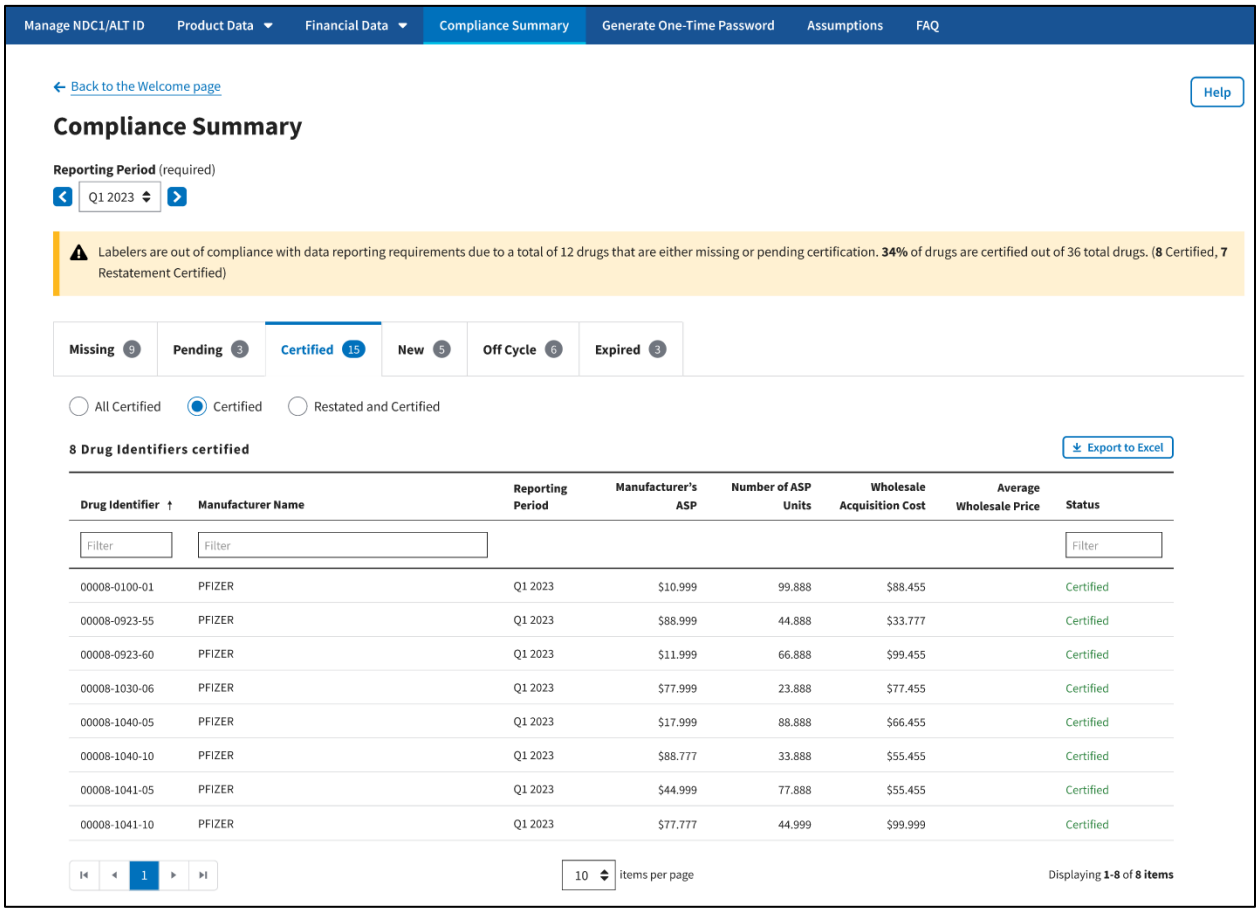

Figure 86: Compliance Summary - Certified

Note: Click the **Export to Excel** button to download all products under the **Certified** tab.

4. Review your information for accuracy.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**, and **Status** fields.

5. Click the **Restated and Certified** radio button to filter only for restated and certified drugs. Refer to *Figure 87*.

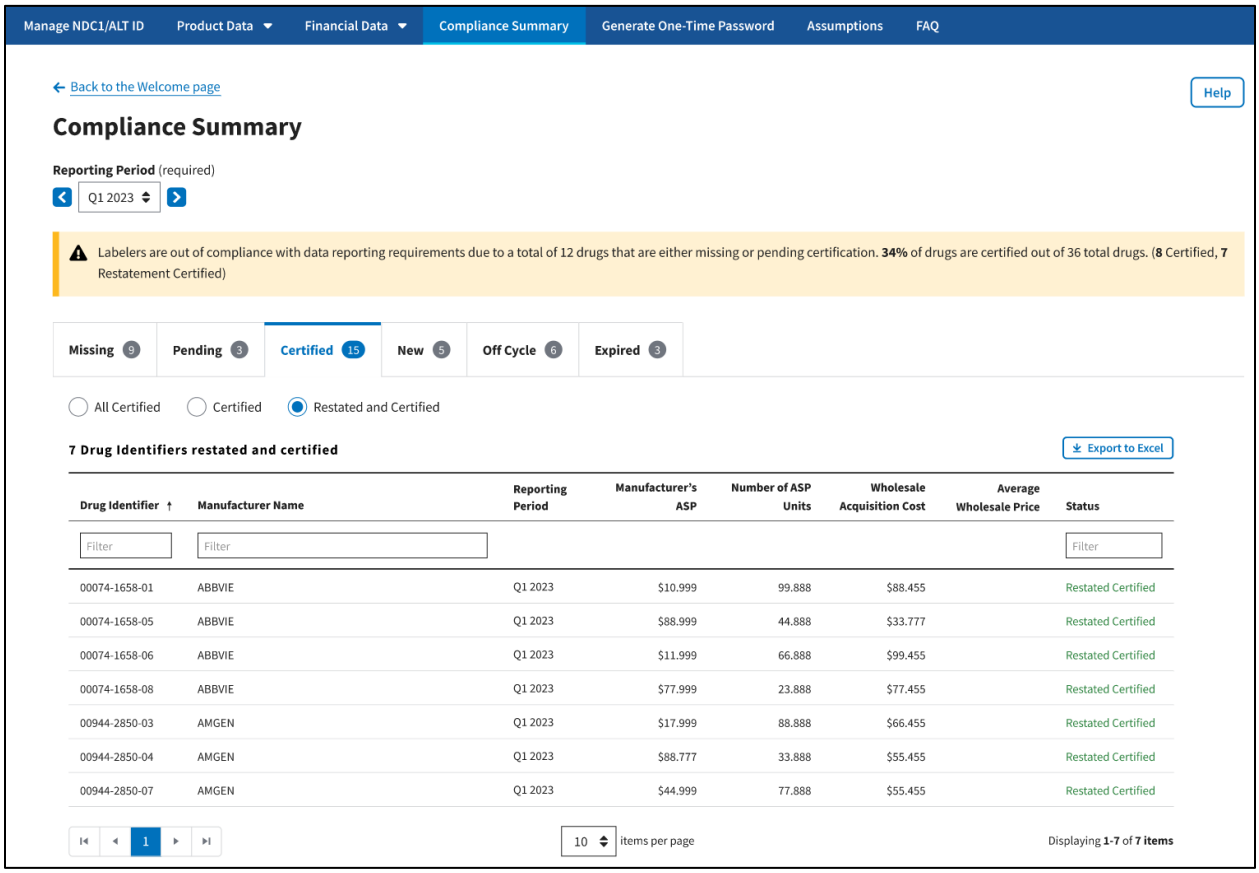

Figure 87: Compliance Summary - Restated and Certified

Note: Click the **Export to Excel** box if you need to download all products under the **Certified** tab.

6. Review your information for accuracy.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**, and **Status** fields.

3.5.4 New

Follow these steps to review your data in the **New** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **New** tab.

   The **New** page displays. Refer to *Figure 88*.

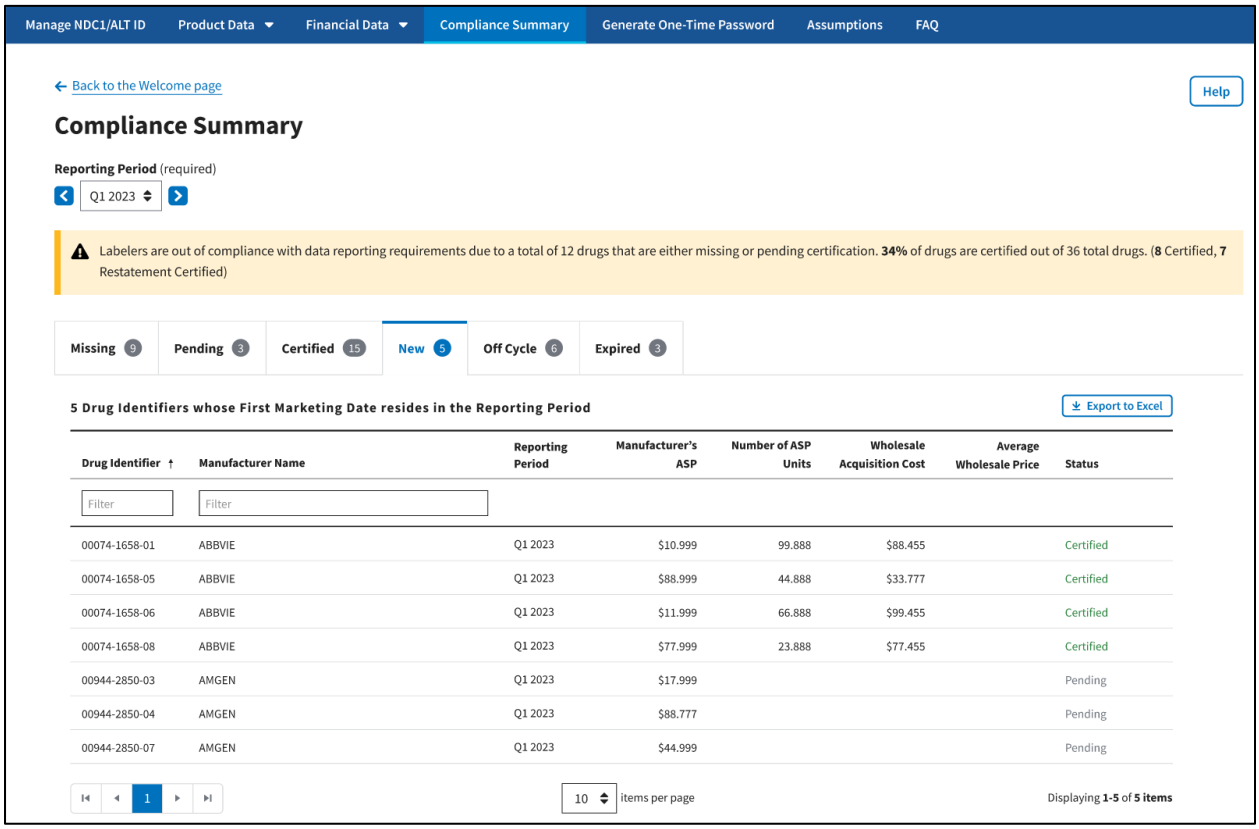

Figure 88: Compliance Summary - New

Note: Click the **Export to Excel** button to download all products under the **New** tab.

2. Review your information for accuracy.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**, and **Status** fields.

3.5.5 Off Cycle

Follow these steps to review your data in the **Off Cycle** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Off Cycle** tab.

   The **Off Cycle** page displays. Refer to *Figure 89*.

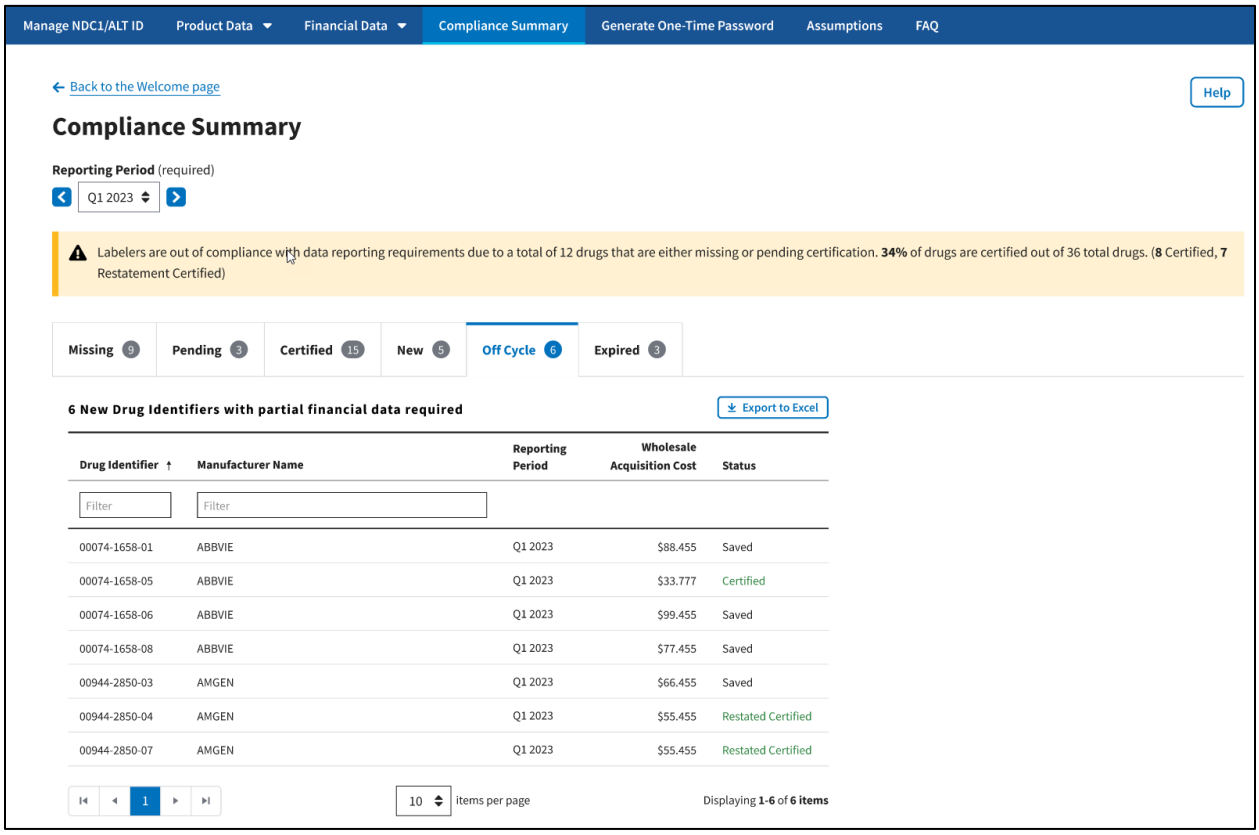

Figure 89: Compliance Summary - Off Cycle

Note: Click the **Export to Excel** button to download all products under the **Off Cycle** tab.

2. Review your information for accuracy.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Wholesale Acquisition Cost**, and **Status** fields.

3.5.6 Expired

Follow these steps to review your data in the **Expired** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Expired** tab.
2. The **Expired** page displays. Refer to *Figure 90*.

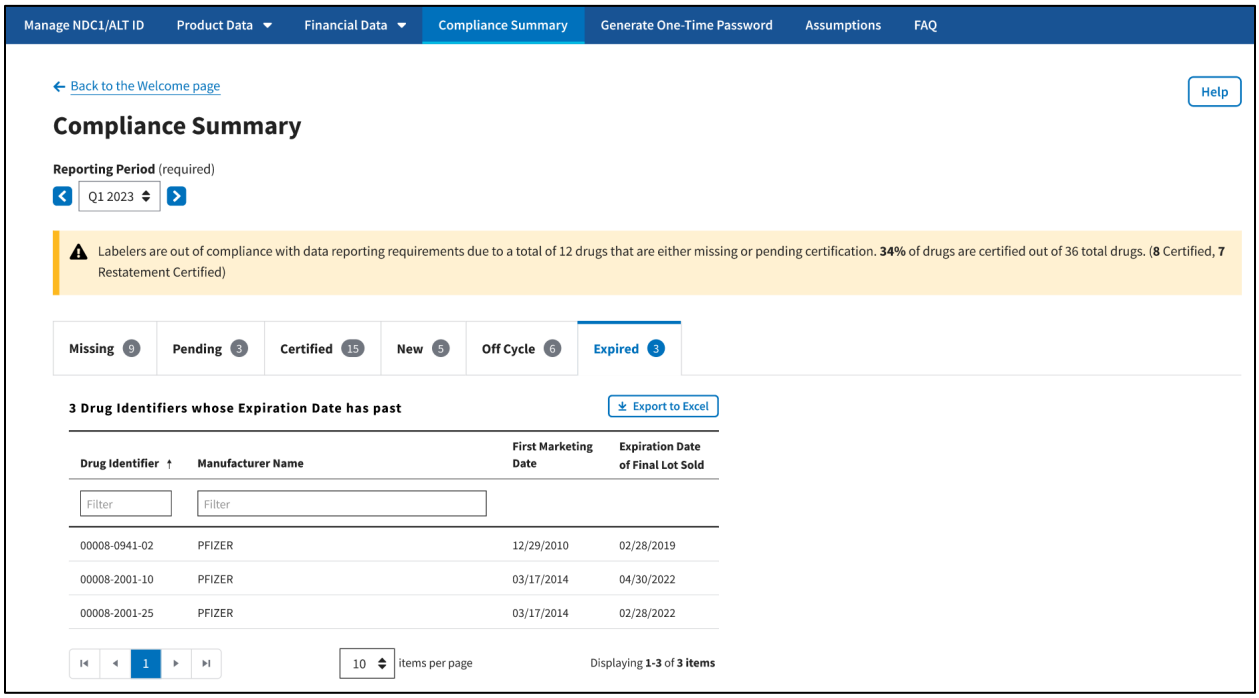

Figure 90: Compliance Summary - Expired

Note: Click the **Export to Excel** box if you need to download all products under the **Expired** tab.

3. Review your information for accuracy.

   The Module organizes the full list by **Drug Identifier** and **Manufacturer Name** and includes **First Marketing Date** and **Expiration Date of Final Lot Sold** fields.

3.6 Generate One-Time Password

Once you successfully enter product and financial data in the ASP Module, you can generate a one-time password (OTP) for each manufacturer name. Note the following about OTPs:

- OTPs protect sensitive information and product specific drug-data from tampering or alterations by others outside of the Submitter or Certifier.
- The OTP is a one-time authentication step to link a Submitter to a Certifier within the system. This step does not need to take place during every submission. There can only be one active Certifier per manufacturer. If the Certifier changes, the Submitter must create and share a new OTP with the new Certifier.
- The Submitter and Certifier cannot be the same person within your organization.
- You can share the OTP with the Certifier. This passcode will remain the same for as long as the Certifier is the same person in your organization who uses the ASP Module.
- If the OTP expires, you can generate another OTP and provide it to the Certifier again.

Note: Refer to the Certifier User Guide for more information about the Certifier role.

Follow these steps to generate an OTP:

1. From the Medicare Part B ASP Homepage, click the **Generate One-Time Password** tab.

   The **Generate One-Time Password** page opens. Refer to *Figure 91*.

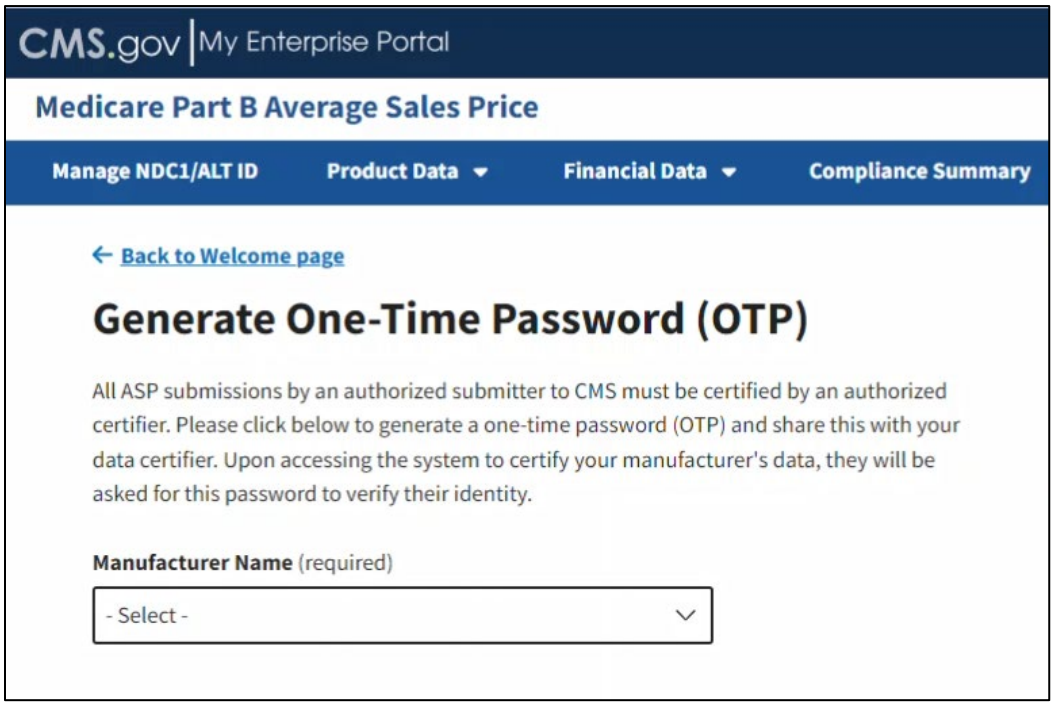

Figure 91: Generate One-Time Password

2. Click the **-Select-** box under **Manufacturer Name (required)** to expand the list. Refer to *Figure 92*.

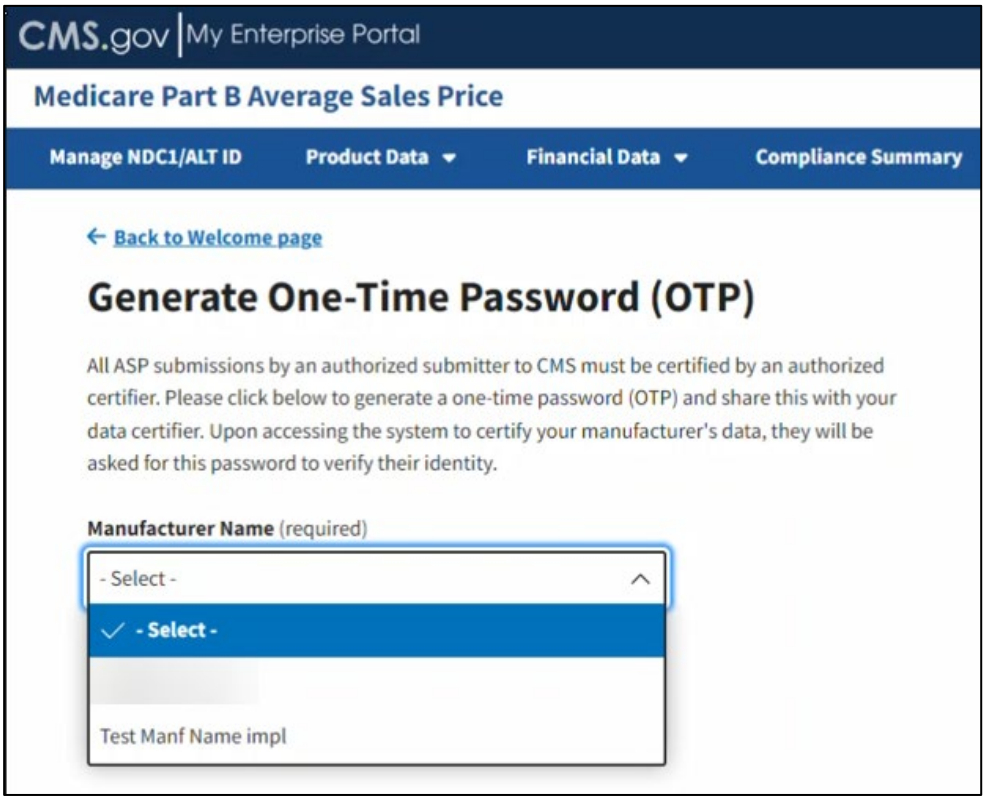

Figure 92: Generate One-Time Password - Manufacturer Name

3. Select the appropriate manufacturer name.

   A new OTP displays. Refer to *Figure 93*.

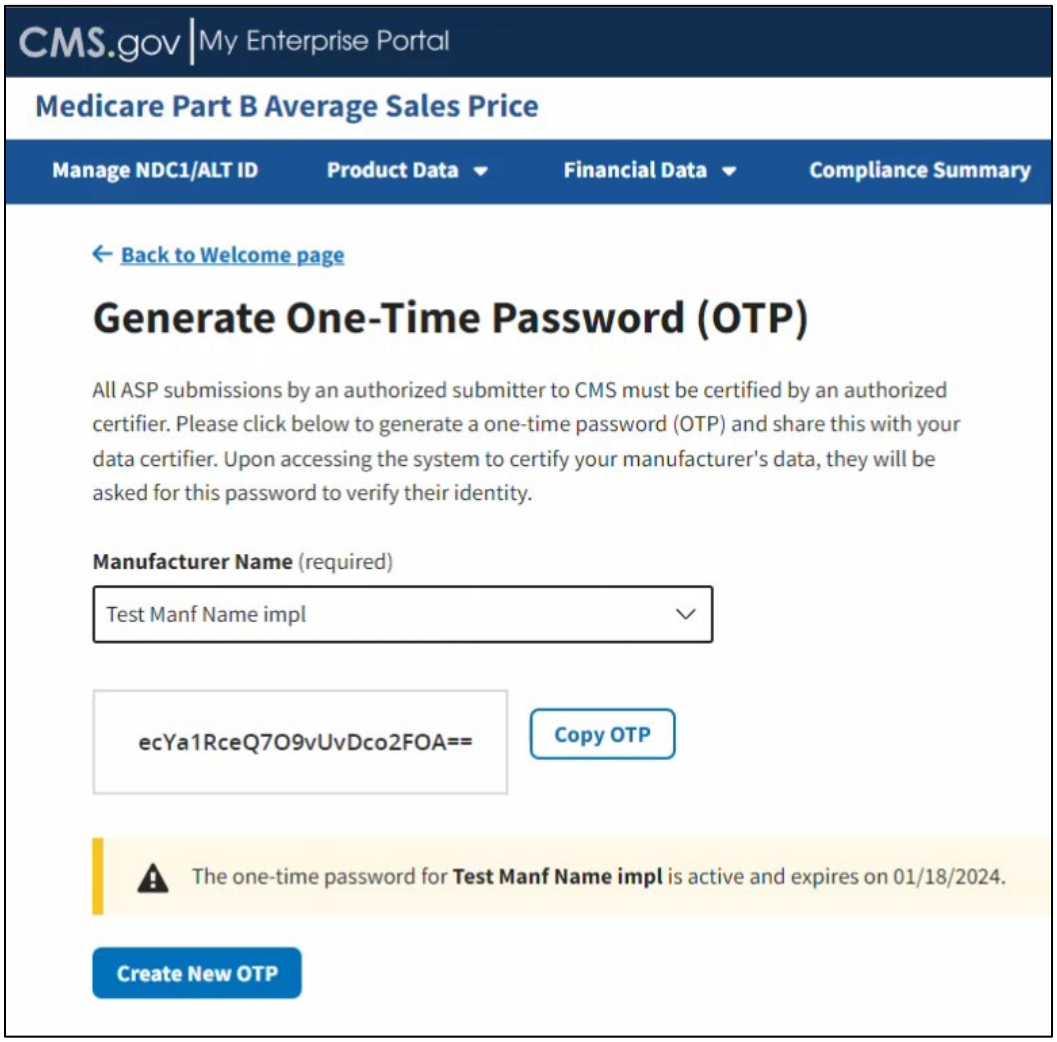

Figure 93: Generate One-Time Password - Password Created

4. Click **Copy OTP** to copy your OTP.

   Hover text indicates that you have successfully copied the new password. Refer to *Figure 94*.

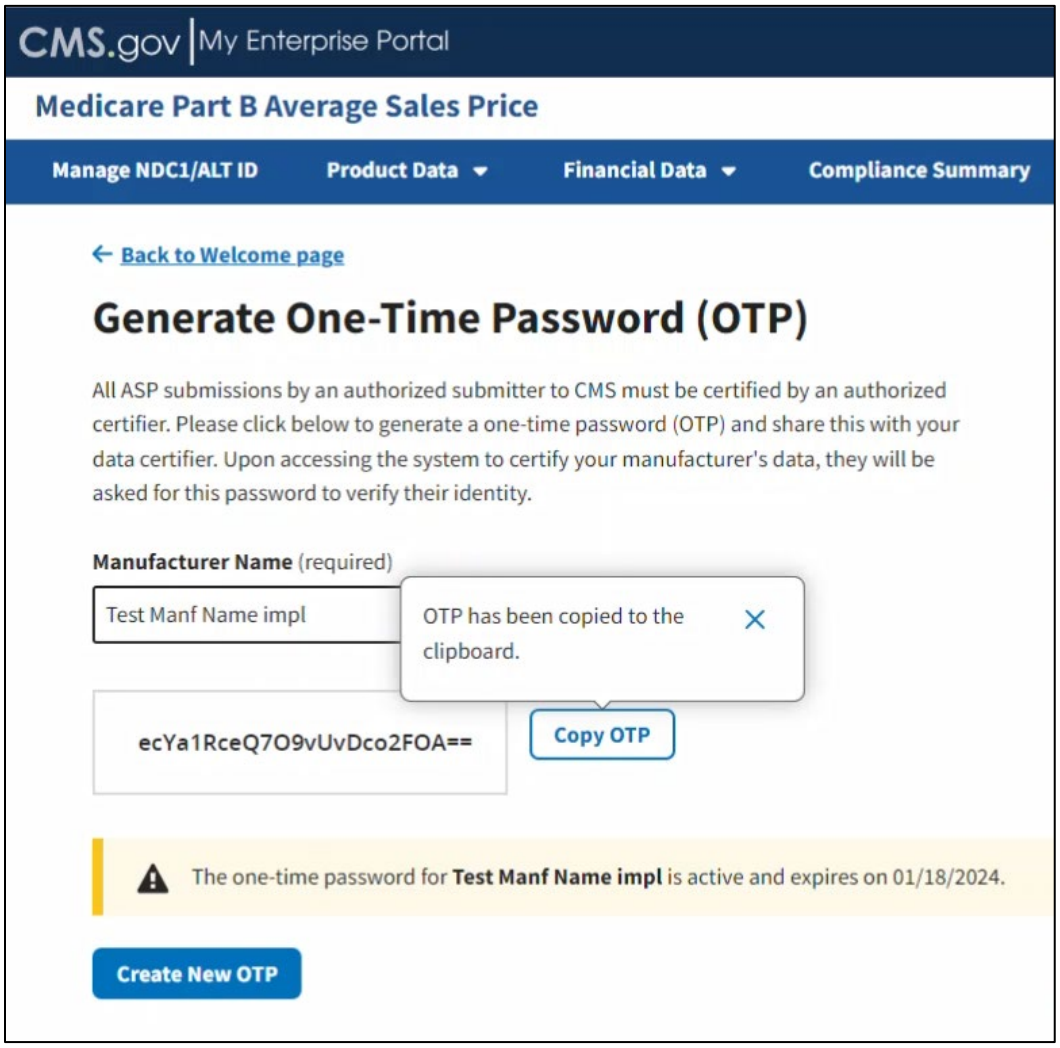

Figure 94: Generate One-Time Password - Password Copied

5. Copy the OTP and send it to your Certifier. You must recreate the OTP if the Certifier cannot confirm the OTP on the Module, or if it expires.

   Note: A message displays at the bottom of the window noting the expiration date for your new password. The Certifier must log in to the ASP Module to use that OTP before the noted expiration date.

   Note: An OTP is only valid for seven days. After seven days, you must generate a new OTP.

3.7 Assumptions

Drug manufacturers can submit comments regarding their certifications to CMS. Manufacturers may submit these comments for either the current or prior reporting periods.

Follow these steps to submit certification assumptions to CMS:

1. From the Medicare Part B Average Sales Price homepage, click the **Assumptions** tab.

The **Assumptions** page opens, and defaults to the current quarter and year. Refer to *Figure 95*.

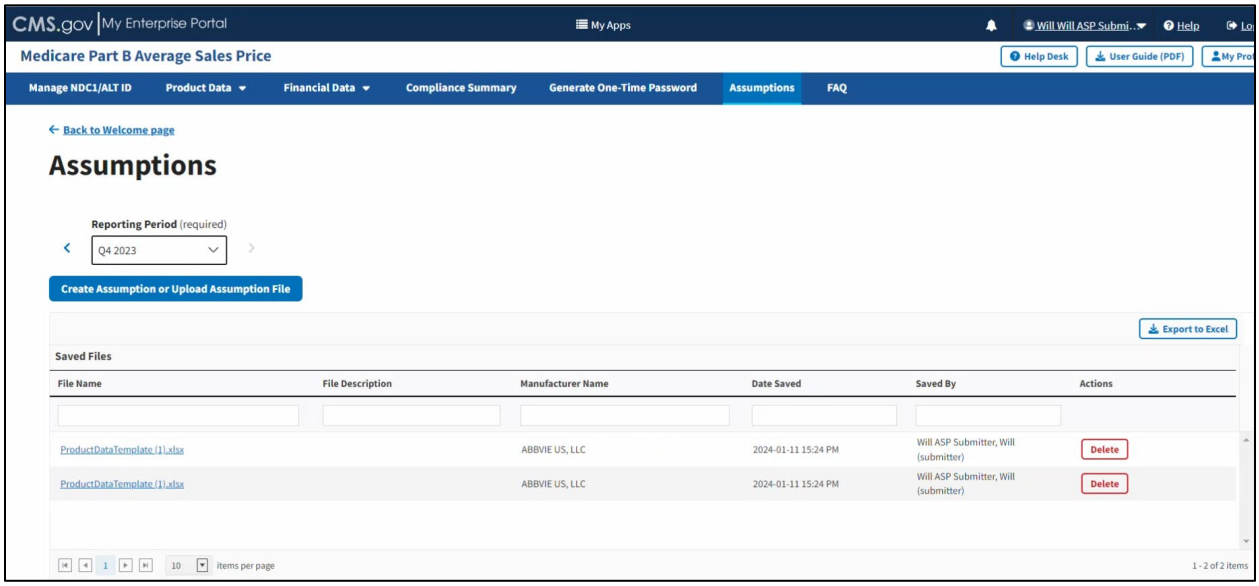

Figure 95: Assumptions

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Use the drop-down menu to navigate a previous quarter starting with the most recent, or the next quarter.

Note: Click the **Export to Excel** box to download all products under the **Assumptions** tab.

3.7.1 Create Assumption

Follow these steps to create an assumption:

1. Click the **Create Assumption or Upload Assumption File** button.

   The **Create Assumption or Upload Assumption File** window displays. The Module automatically defaults to the **Create Assumption** radio button with a **Manufacturer Name (required)** drop-down menu and empty **Short Description** and **Text for Assumption file** fields. Refer to *Figure 96*.

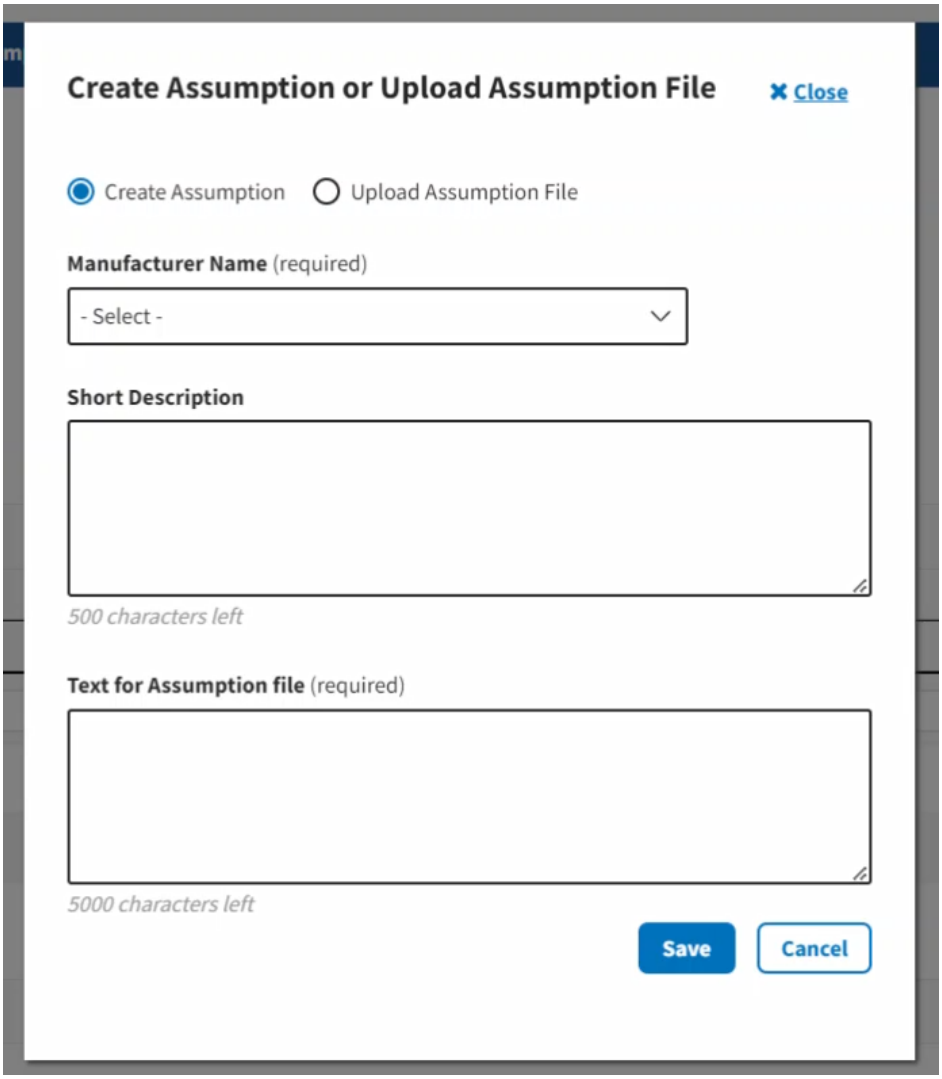

Figure 96: Assumptions - Create Assumption or Upload Assumption File

2. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.
3. Complete the **Short Description** and **Text for Assumption file** fields.

   Note: The **Short Description** field is optional and allows for 500 characters of text to provide a summary of the complete assumption you are submitting to CMS. The **Text for Assumption file** field is required and allows for 5000 characters to provide as much detail as possible related to the selected period's financial submission.
4. Click the **Save** button.

   A message displays confirming you have successfully created your **Assumption**. Refer to *Figure 97*.

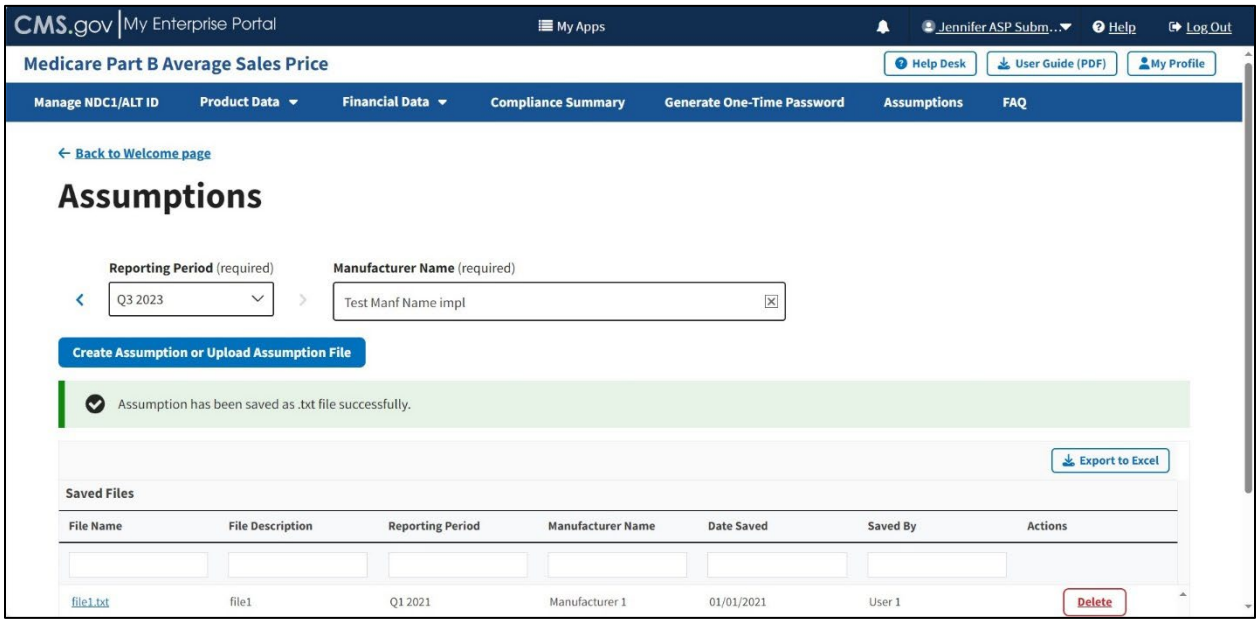

Figure 97: New Assumption Successfully Created

3.7.2 Upload Assumption File

Follow these steps to upload an assumption file to the Module:

1. Click the **Create Assumption or Upload Assumption File** tab.

   The **Create Assumption or Upload Assumption File** window displays. The Module automatically defaults to the **Create Assumption** radio button.

2. Click the **Upload Assumption File** radio button.

   A **Manufacturer Name (required)** drop-down menu and empty **File Description** field display. Refer to *Figure 98*.

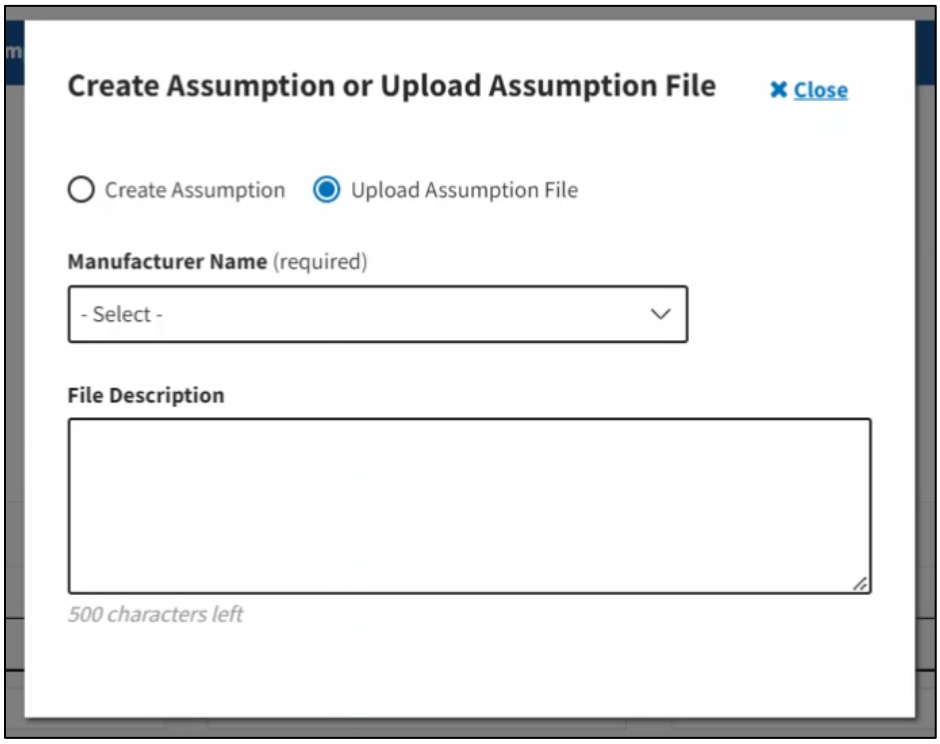

Figure 98: Upload Assumption File

3. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.

   As you select your manufacturer name, new fields display on the screen. Refer to *Figure 99*.

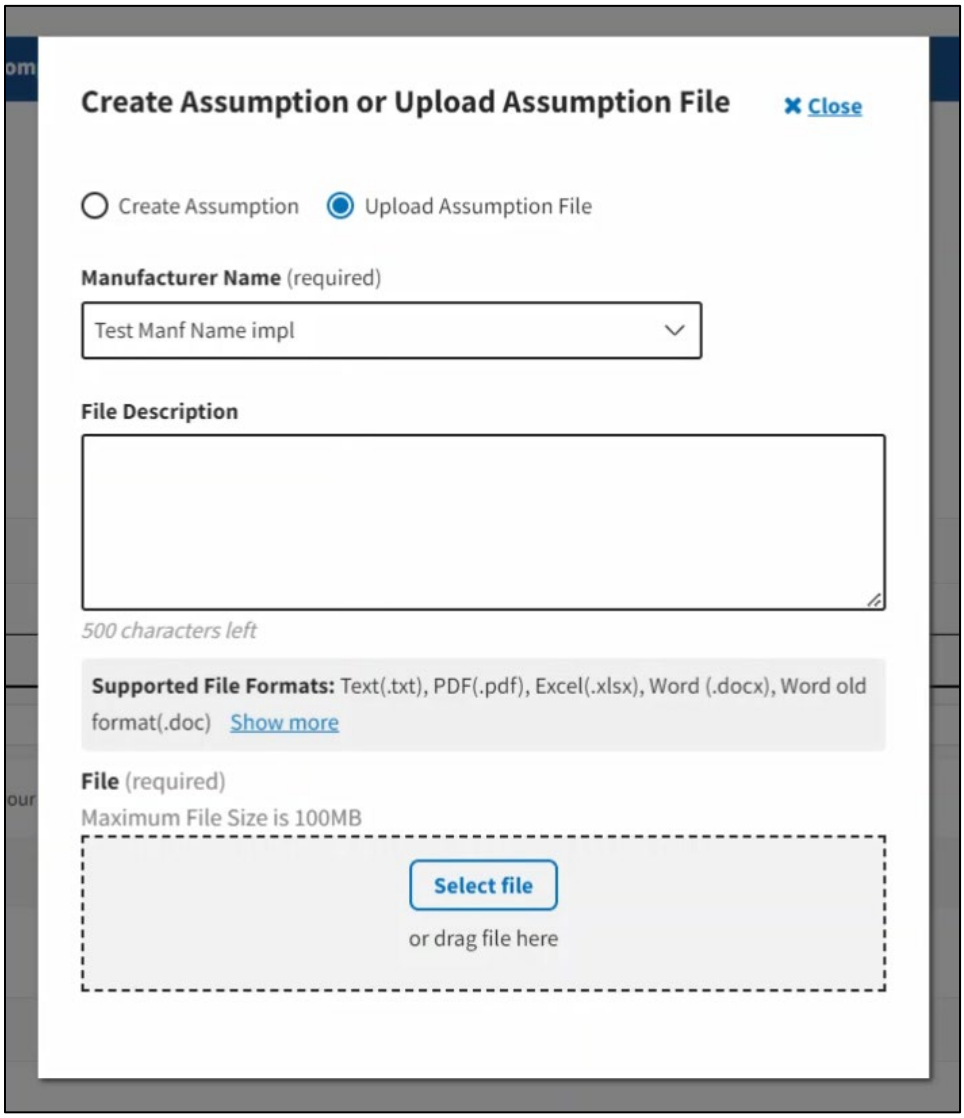

Figure 99: Upload Assumption File - Expanded Fields

4. In the **File Description** field, enter your assumption about a data submission. You have 500 characters of total text to comment about your submission in this section.

   Note: Click the **Show More** tab to display all **Supported File Formats** available in the Module for you to use in your **Assumption File** upload.

5. Click **Select File** to browse your desktop and upload your **Assumption File** to the Module. You may also drag your **Assumption File** into the **Select File** box. Refer to *Figure 100*.

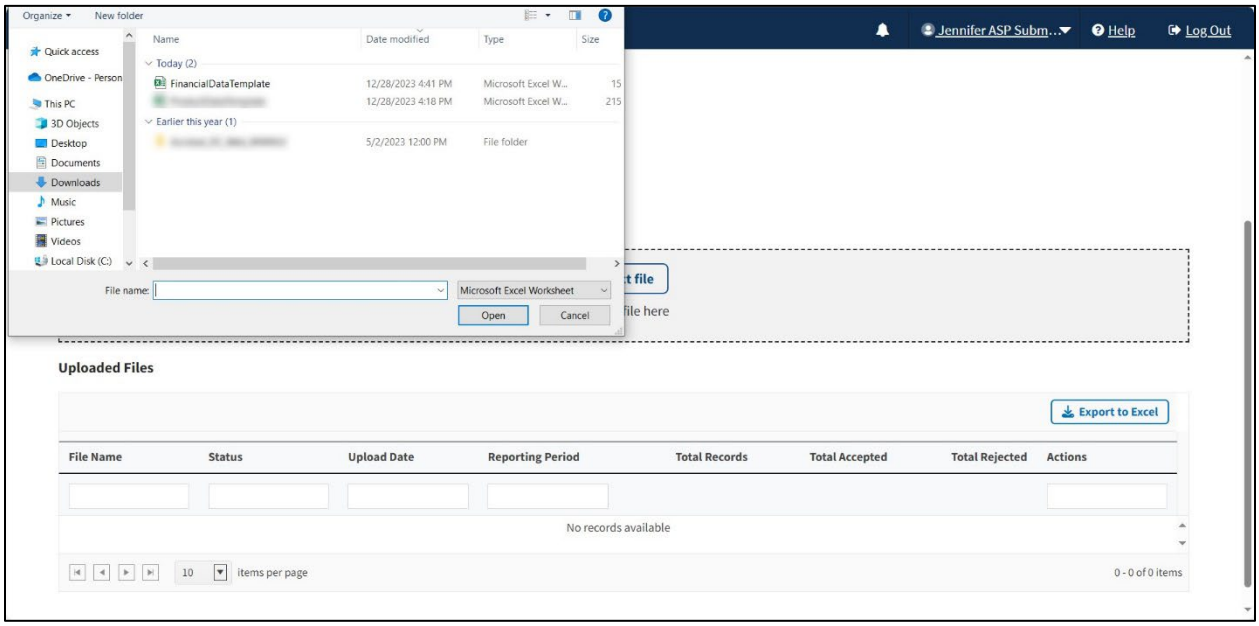

Figure 100: Upload Assumption File - Uploading Files from Desktop

A download bar displays as your file uploads. A message opens to confirm you have successfully uploaded your **Assumption File**. Refer to *Figure 101*.

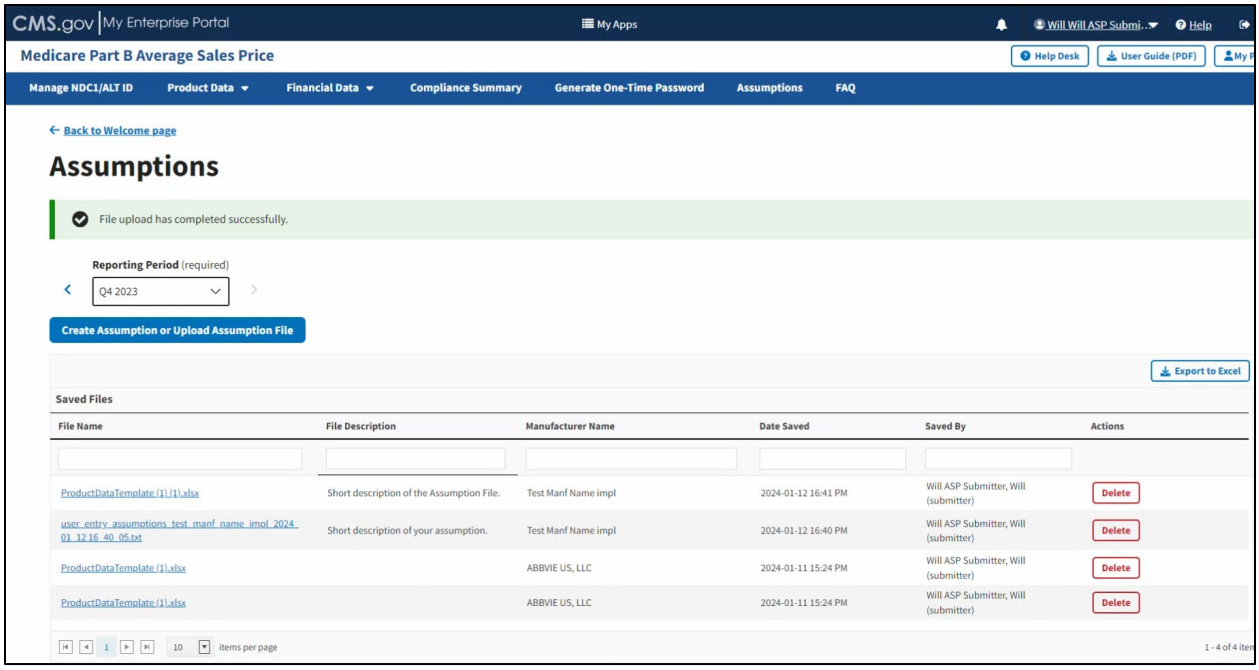

Figure 101: Upload Assumption File - Successfully Added

4. Technical Support Contact Information

Contact the FFSDCS (ASP) Application Helpdesk for issues such as:

- Account unlock
- Password reset
- Registration process questions
- System availability escalations

Table 1 provides contact information for technical support.

Table 1: Technical Support Contacts

Email Address	Phone Number	Hours
ASPHelpDesk@dcca.com	1-844-876-0765	9:00 a.m. to 6:00 p.m. Eastern Standard Time (EST), Monday through Friday

Appendix A: Revision History

Table 2 provides a revision history for this document.

Table 2: Revision History

Version Number	Date	Author/Editor	Description of Change
0.1	01/22/2024	Index Analytics	DTS-ASP-Submitter-UserGuide • Initial draft following collaboration between DCCA and Index Analytics and incorporation of feedback from CMS • Various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections

Appendix B: Glossary

Table 3 provides a list of terms, acronyms, and definitions in this document.

Table 3: Glossary

Expanded Form	Acronym/Term	Definition
Alternate ID Code	Alt ID	An alternate ID code is an alternative labeler code for end users to use as a different form of ID for specific NDCs within the ASP Module, especially for biosimilars and other non-traditional drug products.
Average Sales Price	ASP	ASP refers to the price at which an organization typically sells a certain class of good or service. CMS uses manufacturer-reported ASPs, based on manufacturers' actual quarterly drug sales, to calculate provider payment amounts for these drugs. Federal law defines the price.
Center for Medicare Management	CMM	The CMM oversees the fee-for-service Medicare program.
Centers for Medicare & Medicaid Services	CMS	CMS is a federal agency within the U.S. Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards.
Consolidated Appropriations Act, 2021	CAA	The CAA establishes protections for consumers related to surprise billing and transparency in health care. The No Surprises Act (NSA) is part of the CAA.
Eastern Standard Time	EST	EST is the standard time in the 5th time zone west of Greenwich, reckoned at the 75th meridian. This time zone is in the eastern part of the United States.
Fee-for-Service	FFS	FFS is the traditional method of reimbursing physicians, hospitals, and other healthcare providers for their services.
Fee-for-Service Data Collection System	FFSDCS	FFSDCS is an instrument to collect cost, revenue, utilization, and other information for fee-for-service claims.
Identifier	ID	An ID is a unique identifying set of characters assigned to a person or persons to ensure privacy and security on a computer system or network.
Identity Management	IDM	IDM is the process of managing user access to data.
Interactive Voice Response	IVR	IVR is a technology that allows a computer to detect voice and DTMF keypad inputs.
Medicare	NA	Medicare is the federal system of health insurance for people over 65 years of age and for certain younger people with disabilities.

Expanded Form	Acronym/Term	Definition
Medicare Modernization Act	MMA	The MMA, or Medicare Prescription Drug, Improvement, and Modernization Act, is a federal law.
Medicare Part B	NA	Medicare Part B is the part of Medicare that covers doctor services, outpatient hospital care, and other medical services that Part A does not cover such as physical and occupational therapy, X-rays, medical equipment, or limited ambulance service.
Multifactor Authentication	MFA	MFA is a security system that implements more than one form of authentication to verify the legitimacy of a transaction.
National Drug Code	NDC	The NDC is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologics the FDA recognizes.
Okta	NA	Okta is an enterprise-grade, identity management service, built for the cloud, but compatible with many on-premises applications.
One-Time Password	OTP	An OTP is a password that is valid for only one login session or transaction.
Short Message Service	SMS	SMS is a text messaging service component of phone, web, or mobile communication systems. It uses standardized communication protocols to allow fixed-line or mobile phone devices to exchange short text messages.
Social Security Act	SSA	The SSA is a law that provides income to retired workers aged 65 or older.
Uniform Resource Locator	URL	The URL is a global address of documents and other resources on the World Wide Web.
Wholesale Acquisition Cost	WAC	WAC is an estimate of the manufacturer list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. Federal law defines this price.

Appendix C: Figures and Tables

List of Figures

List of Tables