Centers for Medicare & Medicaid Services

CMS eXpedited Life Cycle (XLC)

Medicare Part B Drug Average Sales Price (ASP)

User Manual

Version 2.3

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1. Introduction

1.1 What is the Medicare Part B Drug Average Sales Price (ASP) Application?

Section 303 (b) and (c) of the Medicare Modernization Act (MMA) of 2003 revised the payment methodology for the vast majority of Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs). Per the MMA, beginning January 01, 2005, the ASP methodology is used to determine the payment limit for these drugs. Pricing for compounded drugs is performed by the local contractor. Additionally, the ASP methodology is used to determine the payment limit for certain eligible outlier service drugs and biologicals under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS), as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS). In accordance with Section 11101 of the Inflation Reduction Act of 2022, CMS also uses the ASP methodology to establish the inflation adjusted beneficiary coinsurance and inflationary rebates for certain single source drugs and biologicals with prices increasing at a rate faster than the rate of inflation. The ASP methodology is based on quarterly data submitted to the Centers for Medicare and Medicaid Services (CMS) by drug manufacturers. CMS supplies the Medicare Fee-for-Service (FFS) claims processing contractors with the drug pricing files for Medicare Part B drugs on a quarterly basis.

In general, under the ASP methodology, the payment limits are based on the volume-weighted average of the manufacturers' ASP. However, in certain instances, the payment limits are based on the Wholesale Acquisition Cost (WAC). Further, the payment limits for some drugs continue to be based on the Average Wholesale Price (AWP) methodology. These data (WAC and AWP) are published in drug pricing compendia, such as Redbook, Medi-span and First Databank. A Medicare Contractor retrieves the data from drug pricing compendia and provides the pricing data to CMS on a quarterly basis.

In addition, other considerations impact the ASP methodology. Under certain circumstances, the ASP-based payment limits for certain drugs may be replaced with a payment limit identified by the Office of the Inspector General (OIG). If errors in either the ASP data or the payment limit calculation occur, revised drug pricing files may be implemented. If drug manufacturers do not report ASP data or do not report timely, the accuracy of the payment limits may be impacted.

1.2 Purpose of the ASP Application

The purpose of the ASP Application is to:

- Provide users with an Internet-based software application for automating the collection, editing and processing of drug product pricing data received from drug manufacturers on a quarterly basis
- Eliminate data entry errors, data formatting errors, incomplete submitted data and to greatly reduce the process cycle time and resource time needed to provide the pricing to contractors through automation of the manually intensive processes
- Accepts and stores Medicare Part B drug data received from manufacturers

1.3 ASP Business Process

Drug Manufacturers report ASPs by National Drug Codes (NDC), which are 11-digit identifiers that indicate the manufacturer of the drug, the product dosage form, and package size. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis in one of two methods. Drug product data may be submitted either by uploading a file or keying data into a predefined data entry screen. In both instances, data are edited and saved awaiting the manufacturer to certify the accuracy of the data. During the 30-day submission period after the end of the quarter.

Thirty days after the beginning of each quarter (calendar year), manufacturers are required to submit pricing of their Medicare Part B (not paid on a cost or perspective payment basis) qualifying drugs. Once drug manufacturers are registered with the Medicare Part B ASP drug submission application, they need to choose either to submit their data online or upload the data via file transfer. A majority of the drugs are injectable drugs furnished by physicians and other qualified practitioners.

If the drug manufacturer decides to enter their Medicare Part B ASP drug information online, then they log on to the secure website and enter the required drug information into the online application. Validations and error messages ensure that the drug manufacturer is entering data in adherence to the application requirements.

If the drug manufacturer has a large amount of drug data to report to Medicare, they may decide to submit their Medicare Part B ASP drug information by uploading their data via file transfer. In this case, the ASP drug data are entered into a formatted file that is in compliance with Medicare's specifications and it is uploaded. Along with the submission, the user can submit any pertinent information to share with CM regarding their drug product data submissions. The user can view and check their submitted file and resubmit, if necessary. If the file records do not meet the file transfer validations and edits, then they are rejected, and the drug manufacturer can resubmit the drug data through file transfer or enter it online. With both submission options, the drug manufacturer must certify the accuracy of the data at the time of submission in order for it to be accepted. Regardless, every instance a drug manufacturer submits data they must submit a drug certification along with their submission and they may submit multiple times within a submission time period. Once data have been submitted, the drug manufacturer can view all drug data certified in the current reporting period and view whether current and previous drug submissions are in compliance with the reporting requirements. With drug data corrections within the current reporting period, the user can correct the drug data via data entry or upload. If data needs to be reported after the quarter has ended, the drug manufacturer has the capability to report restated ASP data via upload or online for any reporting period (greater than or equal to Quarter 3 2018) to the ASP application at any time.

CM assigns each drug to one or more billing codes and determine the billing units per billing code. The ASP for each billing code is calculated based on the weighted average of all ASPs within a billing code. Where a billing code does not exist, users may submit a request for one to be established.

Either users, through quality review or drug manufacturers, may identify errors in the data. The drug manufacturer submits any corrected data so that users can re-calculate the ASP for any affected billing code.

Once the drug manufacturer submits the Reporting Manufacturer data and it is successfully received by CM/Division of Data Analysis and Market-based Pricing (DDAMBP) they process and prepare the data accordingly for the ASP calculation. If the ASP Reporting Manufacturer Data submission falls within the 30-day deadline, then, thereafter, the CM/DDAMBP runs drug

submission reports. These reports include Impact Analysis Report, Management Reports and Manufacturer Reports.

1.4 The user creates an output file to share with OIG, so they can complete ASP comparison studies. Updates with the Average Manufacturer Price (AMP) provided by OIG are added to the drug pricing file to replace the ASP for some billing codes. ASP User Roles

The ASP Application is a role-based application. This means that certain application functions have been linked to specific "user role profiles." The ASP Application user roles are as follows:

- Drug Manufacturers: Drug manufacturers can be either Submitters and Certifiers of data
- CM Personnel: Responsible for the calculation and quality of the Part B drug prices

1.5 ASP Reference Materials

The following additional reference materials are utilized in order to successfully submit and certify applicable data into the ASP data collection application:

- EIDM User Guide
- ASP Data Reporting Templates
- Contextual Help

Click on EIDM Links for any assistance with using the application and to view applicable videos

2. ASP Application Access

Users are required to access the CMS Portal at https://portal.cms.gov to begin the registration and role assignment process.

CMS has established the Enterprise Identity Management (EIDM) system to provide our Business Partners with a means to apply for, obtain approval, and receive a single User ID they can use to access one or more CMS applications. The EIDM Authentication System prompts the user to create a username and password that conforms to the system's policies; this user ID and password is not affiliated with the user's CMS User ID (Enterprise User Administration [EUA]) and password. After the user successfully creates a username and password, the user must create security questions and answers. The user must then re-log in with the new credentials and request the specific Fee-for-Service Data Collection System (FFSDCS) ASP Submitter or ASP Certifier role as applicable. FFSDCS is a system umbrella that houses various Fee-for-Schedule modules. ASP is one of the modules under the FFSDCS system.

As part of the role request process the EIDM Authentication System begins the Remote Identity Proofing (RIPD) process. RIDP is the process of validating sufficient information about the user (e.g., credit history, personal demographic information, and other indicators) to uniquely identify an individual. After the user's identity is verified, the CMS Portal pushes the user's data to CM to review the role request and approve it.

The registration process also involves Multi-Factor Authentication (MFA). This allows the user to authenticate their phone/tablet/PC/laptop, text message Short Message Service (SMS), Interactive Voice Response (IVR), E-mail, and One-Time Security Code.

For additional details on EIDM, review the EIDM User Guide.

2.1 ASP Data Collection Application Access Process

ASP users with an existing CMS Portal username and password can skip Section 2.1.1 and continue on to Section 2.1.2 Requesting ASP Application Access. Users should allot up to 72 hours to receive access to the ASP Portal following the submission of a CMS Portal username and password and request for access to the ASP application.

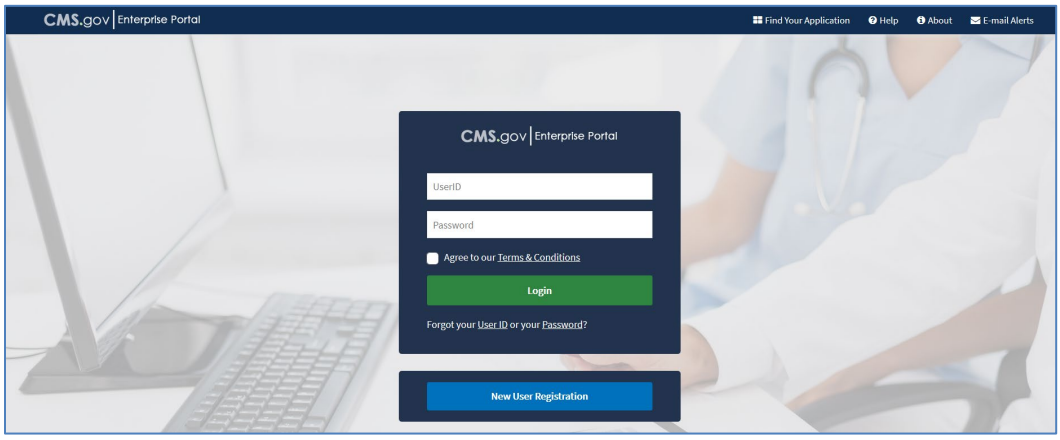
2.1.1 Obtaining a CMS EIDM Username and Password

A CMS EIDM username and password are required in order to access the ASP Application. Perform the following steps in order to receive the required credentials:

1. Access the CMS Portal by entering the following Uniform Resource Locator (URL) in your browser: https://portal.cms.gov.

   The CMS Enterprise Portal Home Page is shown in Figure 2-1.

Figure 2-1: CMS Enterprise Portal Home Page



2. Click on the **New User Registration** button.

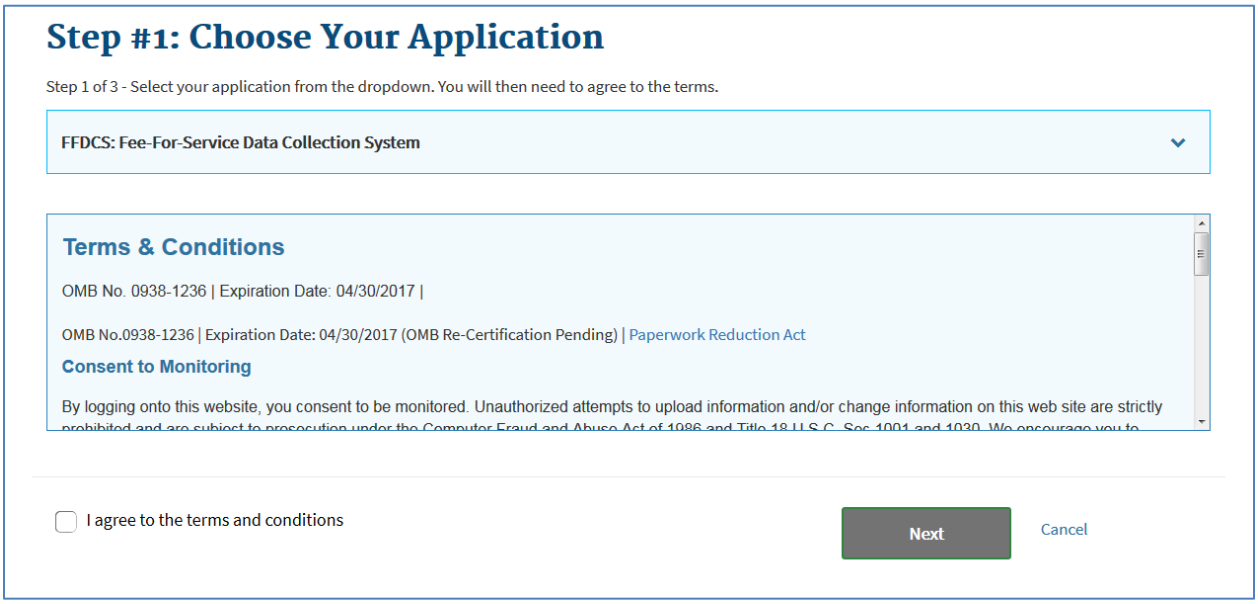
   The “Step #1: Choose Your Application” page opens, as shown in Figure 2-2.

Figure 2-2: Step #1: Choose Your Application Page

3. Select “FFSDCS: Fee-For-Service Data Collection System” from the dropdown list.

   The “Terms and Conditions” page opens, as shown in Figure 2-3.

Figure 2-3: Terms and Conditions Page



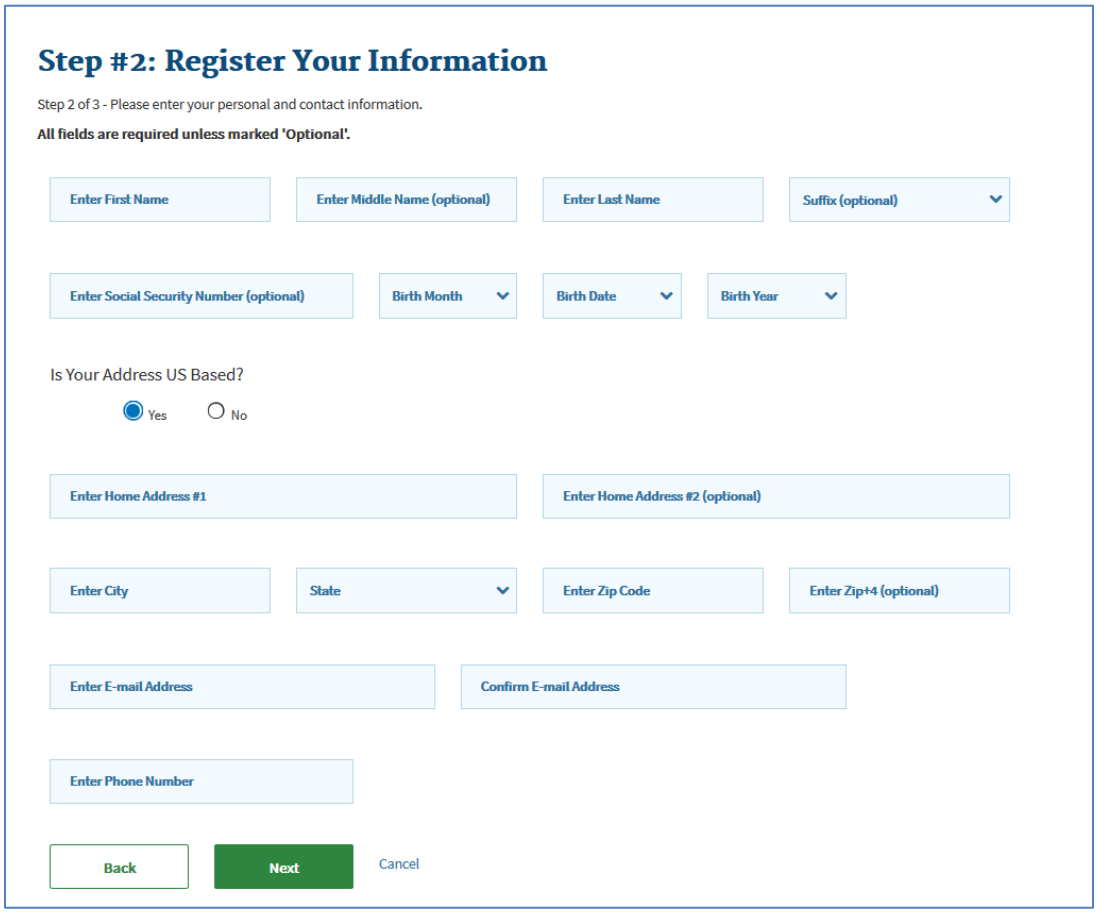
Note: Read through the Terms and Conditions on the page. The page states that you consent to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it is only used to uniquely identify the new user who is registering with the application. The page provides links to the *HHS Rules of Behavior* and the *CMS Privacy Act Statement*.

4. If you agree to the terms and conditions, click the corresponding check box and click on the **Next** button.

   Note: Users must agree to the terms and conditions to continue the registration process.

   The “Step #2: Register Your Information” page opens, as shown in Figure 2-4.

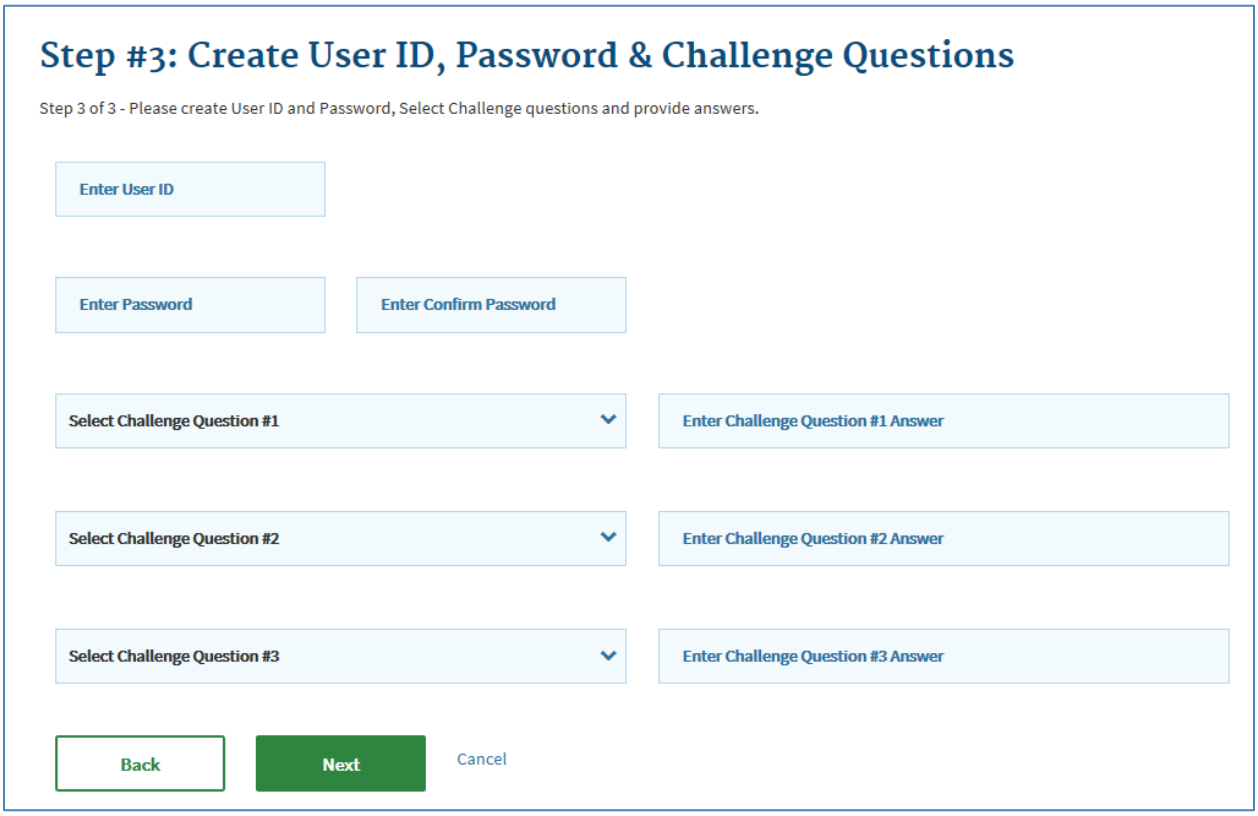
Figure 2-4: Step #2: Register Your Information Page



5. Enter your personal information in the required fields which are indicated by an asterisk (the additional fields are optional but may be required for further identity verification) and click on the **Next** button.

   The “Step 3: Create User ID, Password & Challenge Questions” page displays as shown in Figure 2-5.

Figure 2-5: Step #3: Create User ID, Password & Challenge Questions Page



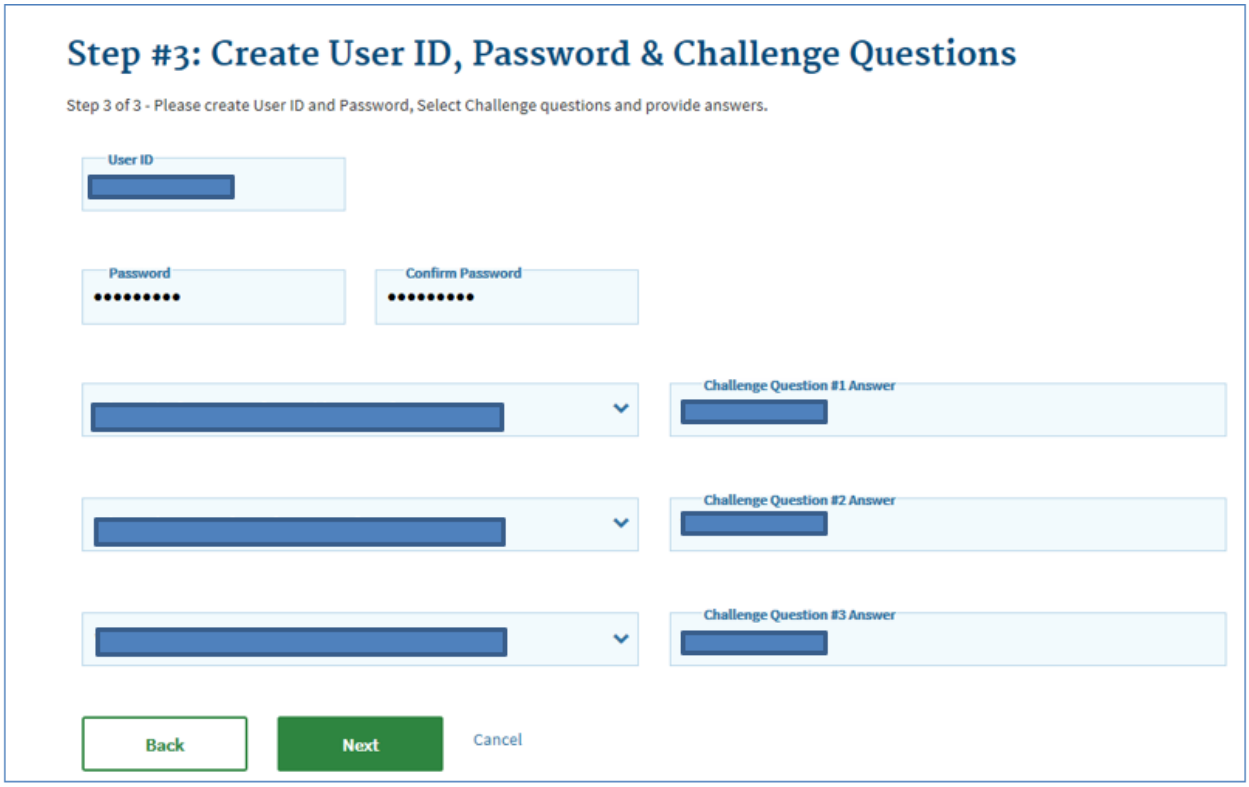
6. Enter your desired User ID in the “User ID” field. The User ID must be a minimum of 6 and a maximum of 74 alphanumeric characters. Allowed special characters are dashes (-), underscores (_), apostrophes (‘), @ and periods (.).
7. Enter your desired password in the “Password” field. The CMS Portal password must conform to the following CMS Acceptable Risk Safeguards (ARS) Password Policy:
    a. Be changed at least every sixty (60) days;
    b. Be a minimum of eight (8) and a maximum of twenty (20) characters;
    c. Be changed only once every 24 hours;
    d. Contain at least one (1) letter, one (1) number, and (1) special character;
    e. Contain at least one (1) uppercase and one (1) lowercase letter;
    f. Not contain your User ID;
    g. Be different from your previous six (6) passwords.
    h. Not contain commonly used words; and
    i. The following special characters may not be used: ? < > ( ) ‘ “ / \ &
8. Re-enter your desired password in the “Confirm Password” field.

    Note: The passwords must match before you can continue.

9. Select a Security Question from each of the three (3) dropdown lists for which the answer is known.
10. Enter the answers to the Security Questions in the corresponding “Answer” fields.

    The fields populate as shown in Figure 2-6.

Figure 2-6: Step #3: Create User ID, Password & Challenge Questions Page Populated

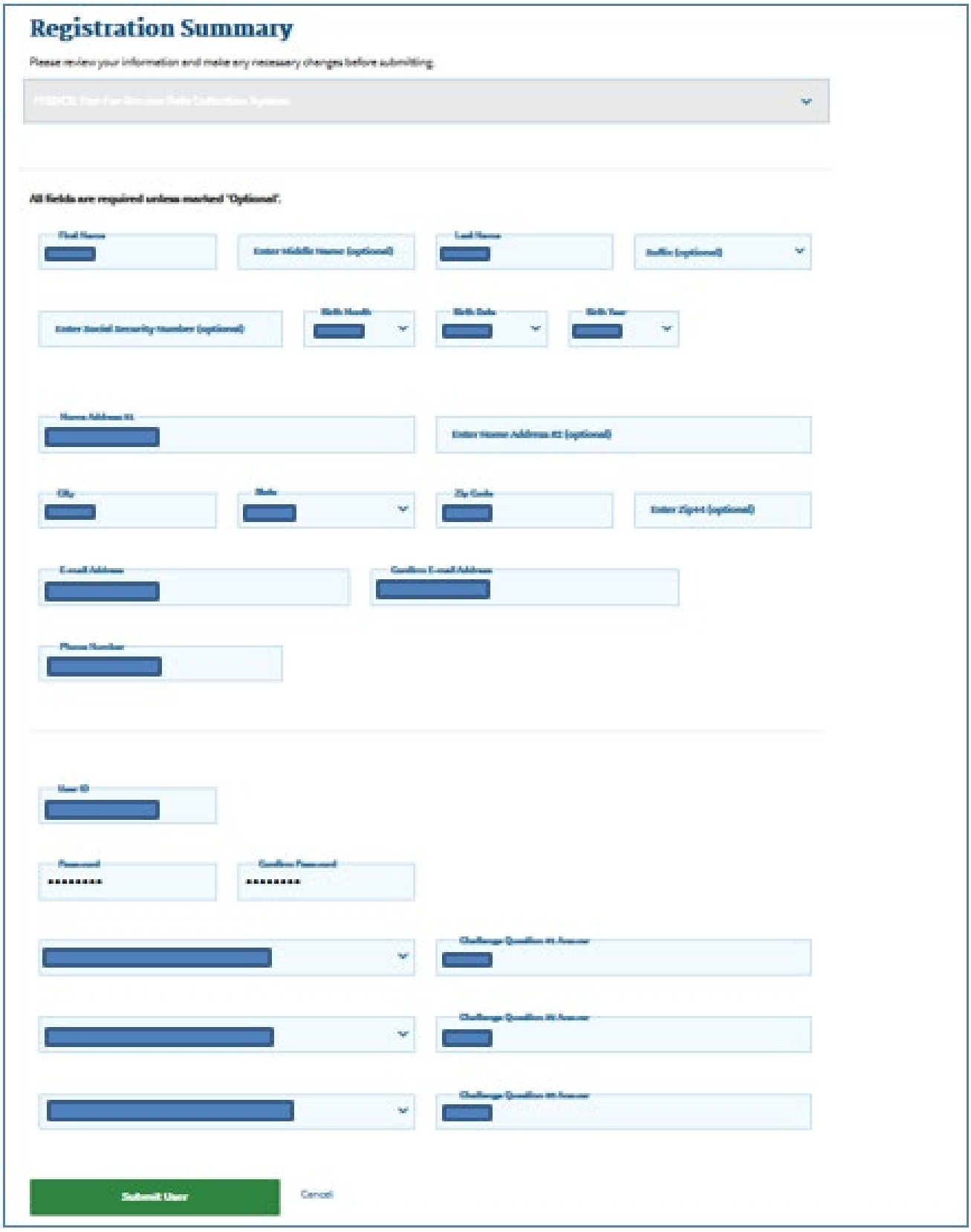


11. Click on the **Next** button to complete the registration process.

    Note: You may click on the **Cancel** button to exit out of the registration process. New information or changes entered will not be saved.

    The “Registration Summary” screen displays as shown in Figure 2-7.

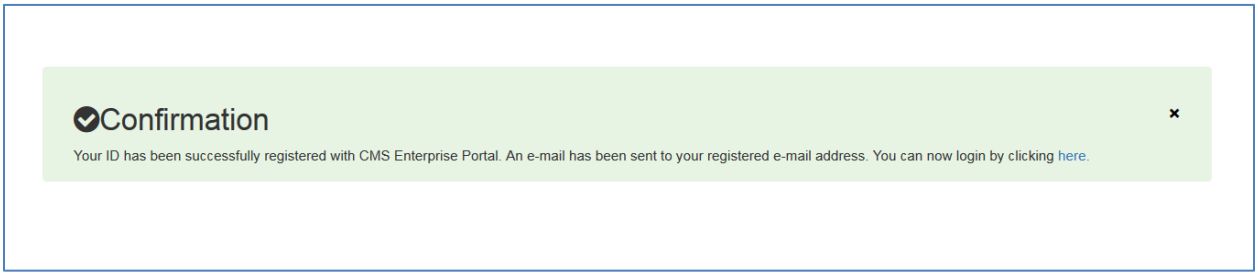
Figure 2-7: Registration Summary Page



12. Review, your information, make any necessary changes, and click on the **Submit User** button to complete the registration process.

    A “Confirmation” message displays as shown in Figure 2-8.

Figure 2-8: Confirmation Message



13. Please wait at least 5 minutes before logging on to the CMS Portal with your new EIDM user ID and password.

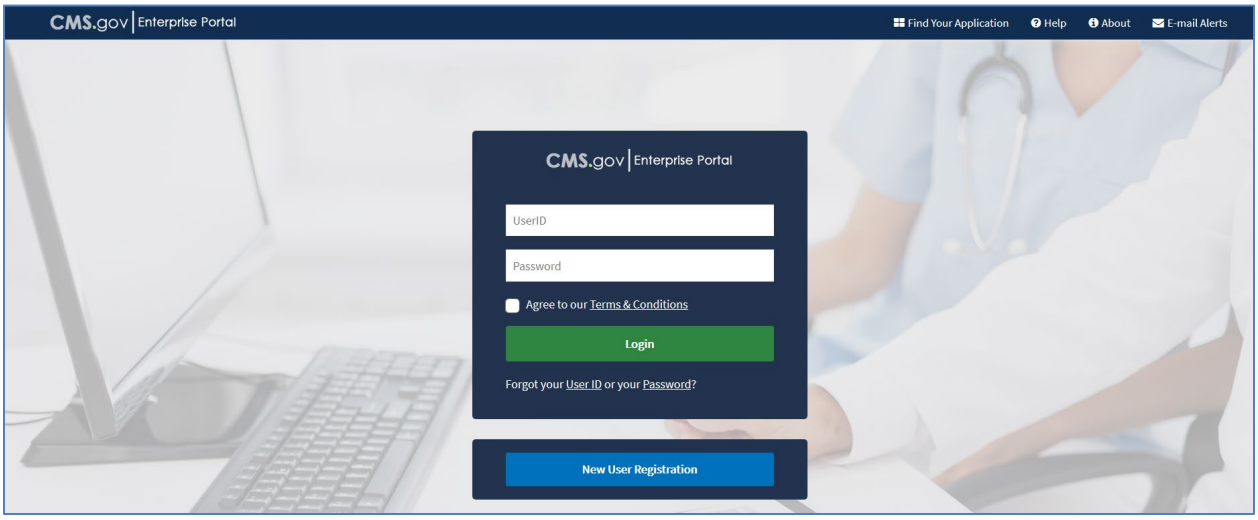
2.1.2 Requesting ASP Application Access

Perform the following steps to request access to the ASP Application:

1. Enter the address for the CMS portal (https://portal.cms.gov/wps/portal/unauthportal/home/) into your web browser and click on the **Enter** button.

   The CMS Enterprise Portal Home Page is shown in Figure 2-9.

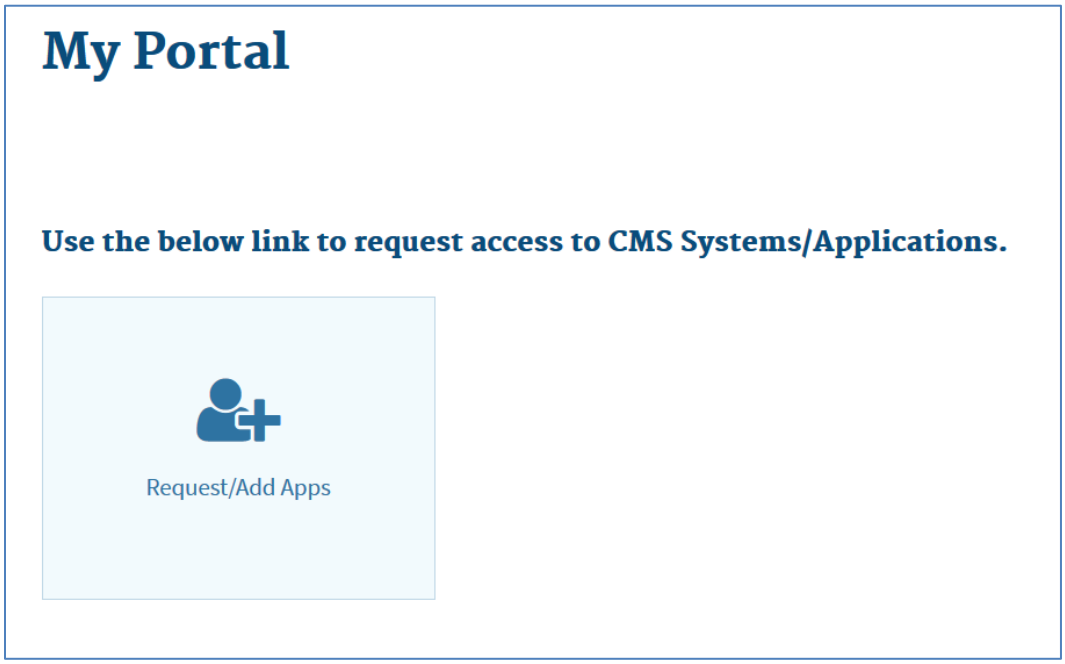
Figure 2-9: CMS Enterprise Portal Home Page



2. Enter your UserID and Password and click on the **Login** button.

   The “My Portal” page displays as shown in Figure 2-10.

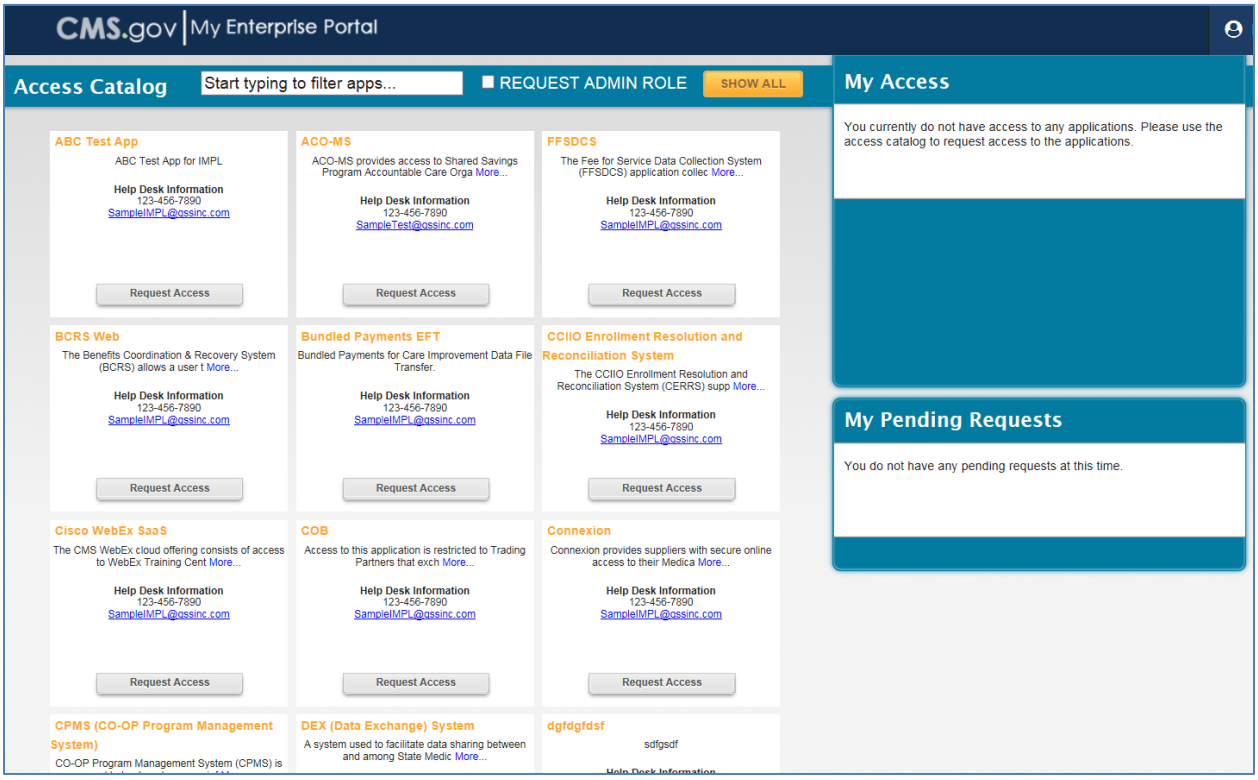
Figure 2-10: My Portal Page



3. Click on **Request/Add Apps**.

   The “Access Catalog” page displays as shown in Figure 2-11.

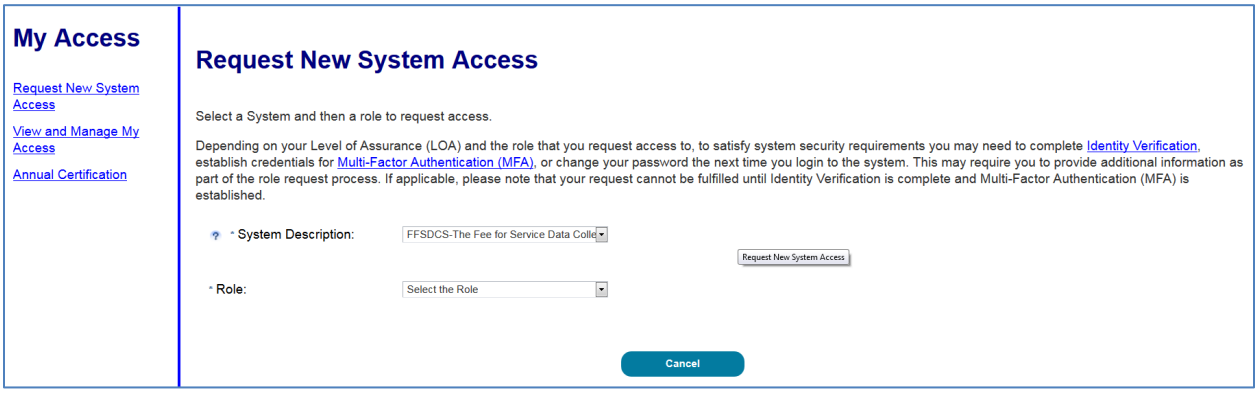
Figure 2-11: Access Catalog Page



4. Click on the **Request Access** button in the “FFSDCS” section.

   The “Request New System Access” page displays as shown in Figure 2-12.

Figure 2-12: Request New System Access Page



5. There are two roles that are applicable for ASP quarterly data submission:

   a. ASP Submitter (who can only submit data; if you are the Submitter, select the “ASP End User” role).

   b. ASP Certifier (who can only certify data)

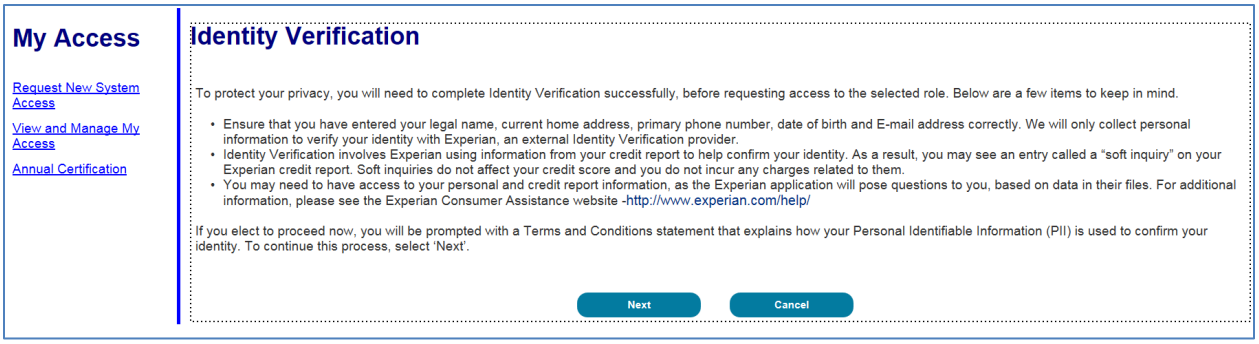
   If your role is to submit data, click on the “Role” dropdown list and select **ASP End User**.

   If your role is to certify, click on the “Role” dropdown list and select **ASP Certifier**.

6. If desired, enter any notes to the approver, and click on the **Submit** button.

   The “Identify Verification” page displays as shown in Figure 2-13.

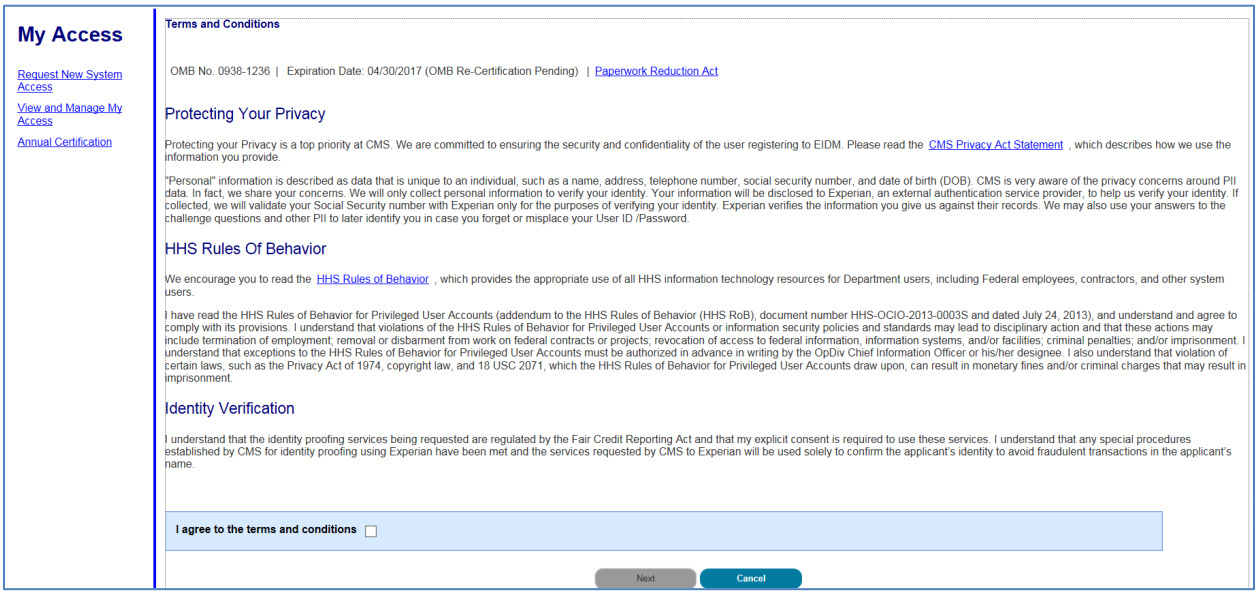
Figure 2-13: Identify Verification Page



7. Review the information and click on the **Next** button.

   The “Terms and Conditions” page displays as shown in Figure 2-14.

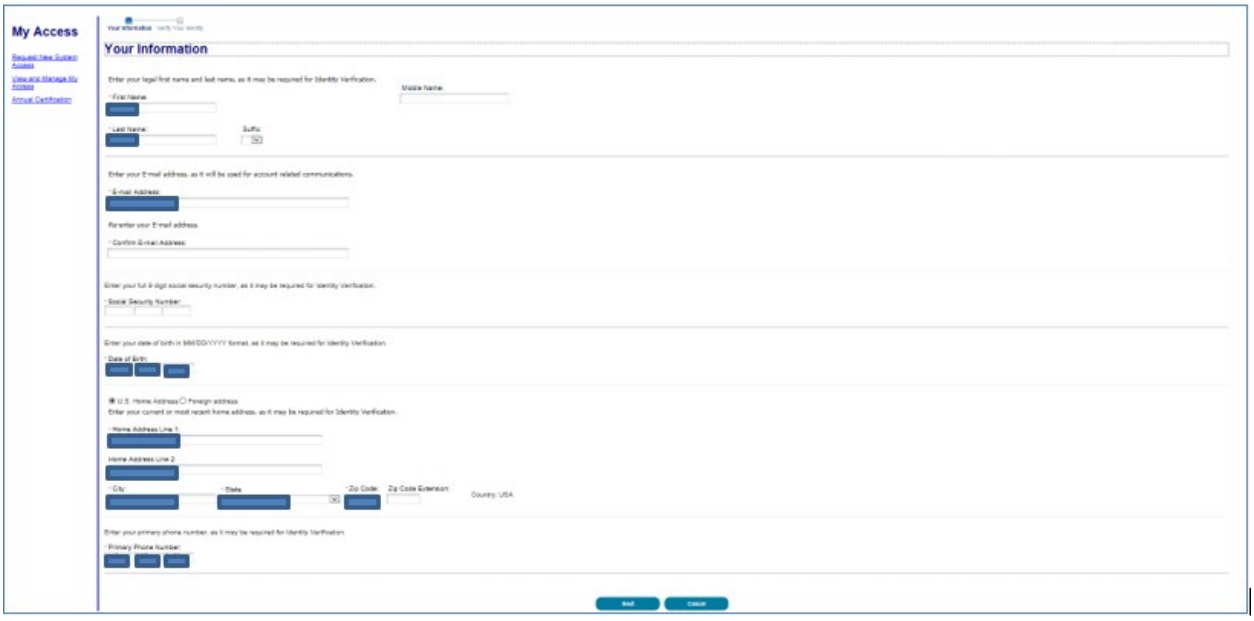
Figure 2-14: Terms and Conditions Page



8. Review the information, click in the box next to "I agree to the terms and conditions," and click on the **Next** button.

   The "Your Information" page displays as shown in Figure 2-15.

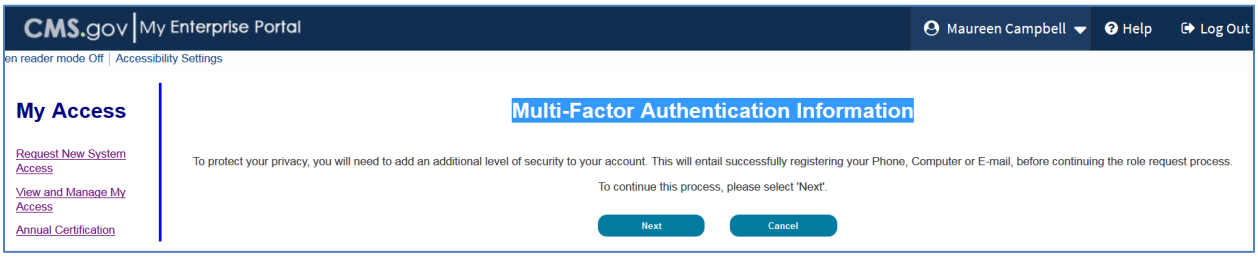
Figure 2-15: Your Information Page



9. Review your information, complete any additional required fields, and click on the **Next** button.

   The "Multi-Factor Authentication Information" page displays as shown in Figure 2-16.

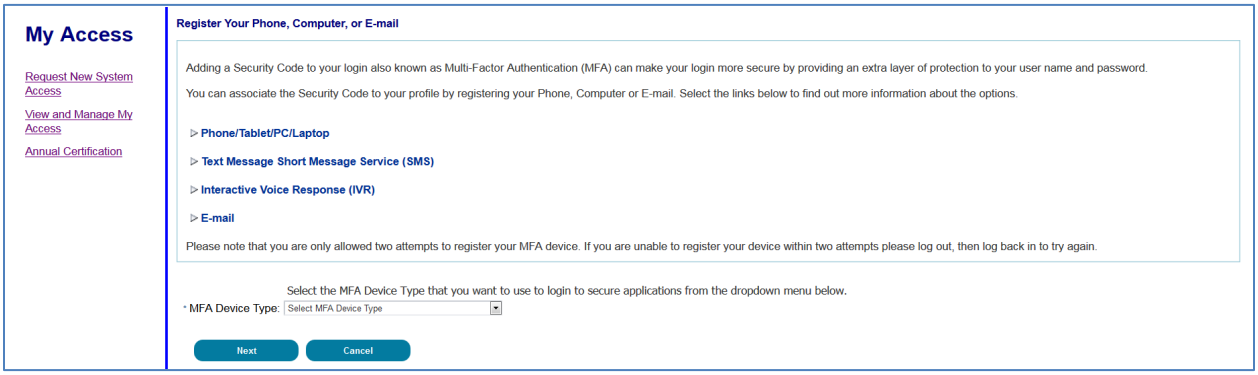
Figure 2-16: Multi-Factor Authentication Information



10. Click on the **Next** button.

    The “Register Your Phone, Computer, or Email” page displays as shown in Figure 2-17.

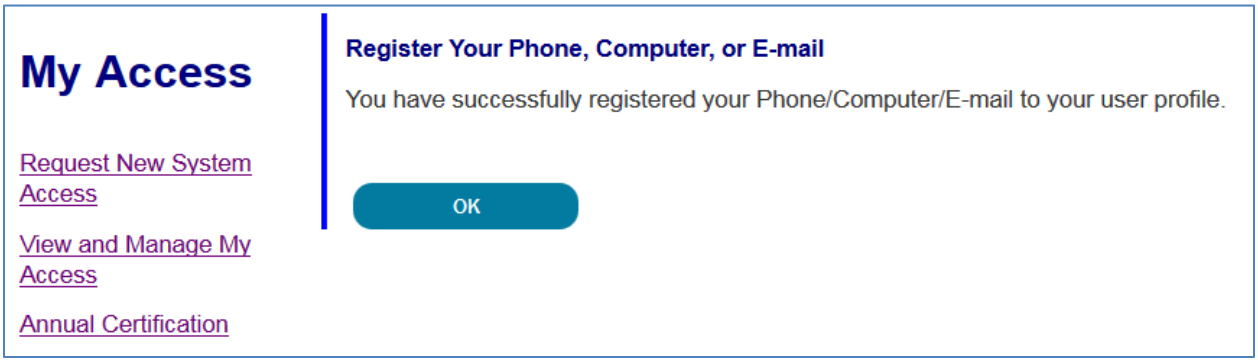
Figure 2-17: Register Your Phone, Computer, or Email Page



11. Select a device from the “MFA Device Type” dropdown list, enter any required information requested for the selected device, and click on the **Next** button.

    A message displays that your device has been registered successfully displays, as shown in Figure 2-18.

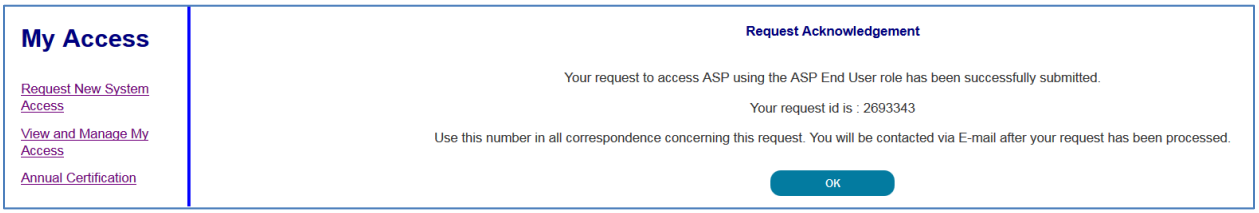
Figure 2-18: Successful MFA Registration Message



12. Click on the **OK** button.

    A “Request Acknowledgement” screen displays as shown in Figure 2-19.

Figure 2-19: Request Acknowledgement Page



13. Click on the **OK** button.

Note: After role submission, please wait up to 72 hours to receive an e-mail notification.

2.2 Points of Contact

2.2.1 Tier 1 Support – FFSDCS (ASP) Application Helpdesk

- Email: ASPHelpDesk@dcca.com
- Phone: 844-876-0765
  - 9AM-6PM Eastern, Non-Peak
  - 9AM-9PM Eastern, Peak
    - Jan 1st – Jan 31st
    - Apr 1st – Apr 30th
    - Jul 1st – Jul 31st
    - Oct 1st - Oct 31st
- Tier 1 Issue examples:
  - Account Unlock
  - Password Reset
  - Registration process questions
  - Policy Question escalations
  - System Availability escalations
  - Other

2.2.2 Tier 2 Support – CM Policy Support

- sec303aspdata@cms.hhs.gov
- Remedy/Service Now (SNOW) Service Tickets

2.2.3 Tier 3 Application/System Support (Data Computer Corporation of America [DCCA])

- Remedy/SNOW Service Tickets

2.2.4 Tier 4 Support

- Data Center SR Workflow

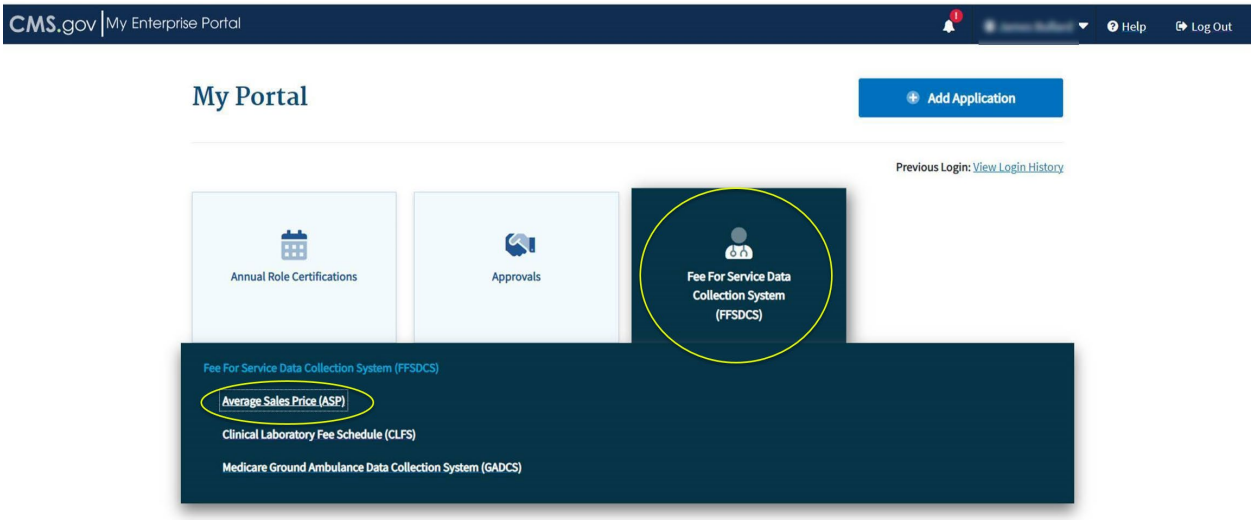
3. ASP Application Home Page

The ASP Application is comprised of numerous pages and pop-up windows to allow drug manufacturers to add, update, and view data entries (product data, financial data, certifications, re-statements, and compliance). The ASP Application uses a consistent layout across pages. The fields displayed on each page differ based on the type of user logged in and the privileges assigned to the user role for the logged in user. You can enter data into fields in the ASP Application unless the field displays with a gray background.

After logging into the CMS Enterprise Portal (https://portal.cms.gov/wps/portal/unauthportal/home/), you will see your My Portal page.

Click on the Fee For Service Data Collection System (FFSDCS) icon to show the selections. Then click on the first link Average Sale Price (ASP) [Figure 3-1].

Figure 3-1: My Portal Home Page



If the user is new to the application, the user is placed directly into the Home page (for Submitter [Figure 3-2] or Certifier [Figure 3-3]).

Figure 3-2: ASP Application Home Page – ASP Submitter

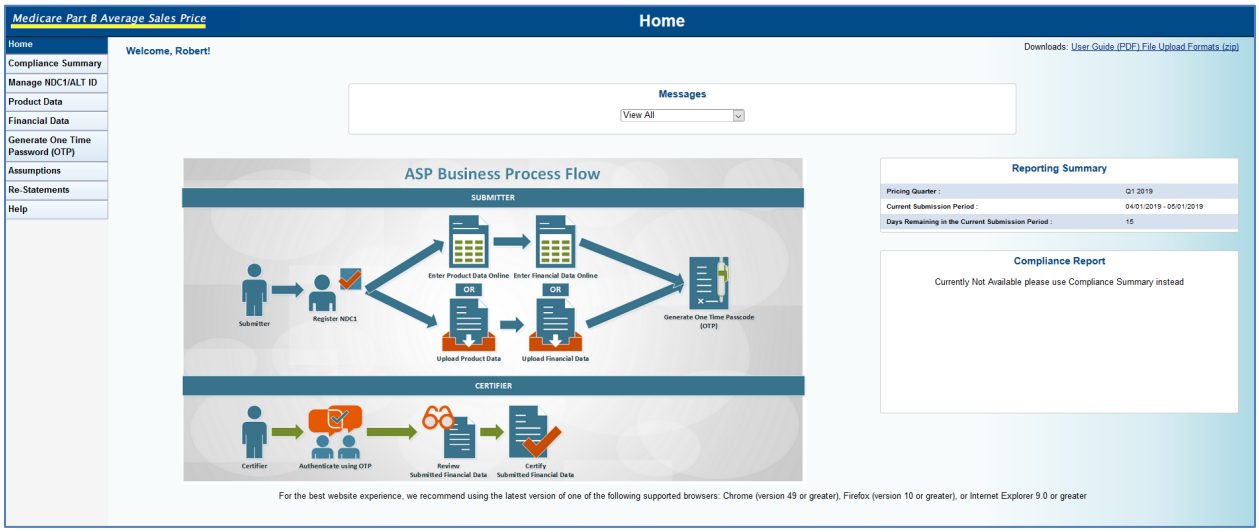
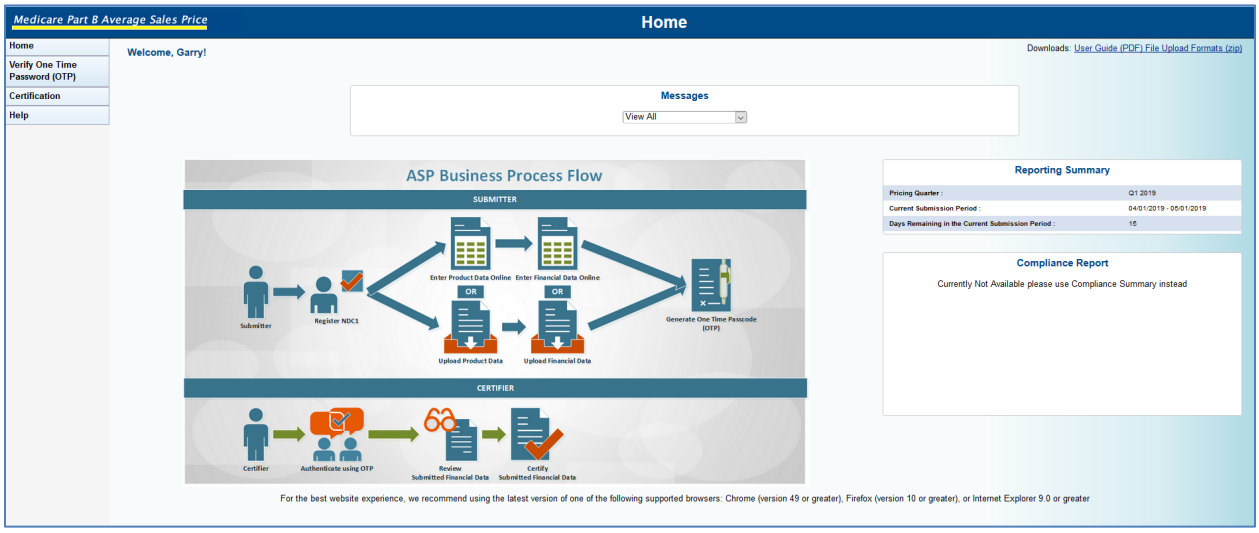


Figure 3-3: ASP Application Home Page – ASP Certifier



4. Manage NDC1/ALT ID - Submitter

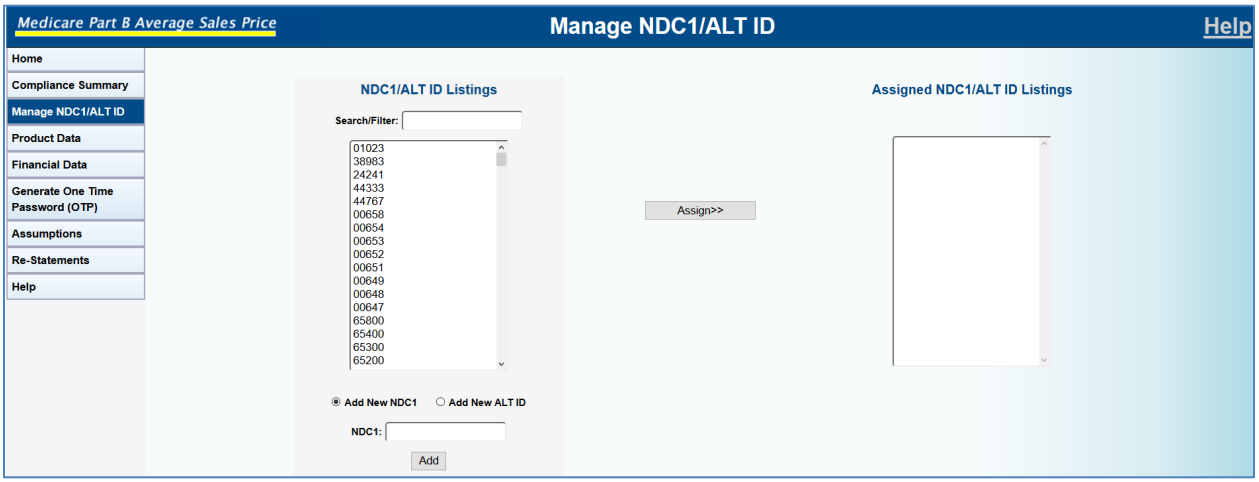
Before a labeler (Submitter) can begin submitting Product and Financial data for their respective labeler codes (NDC1/ALT ID), they are required to assign those labeler codes to their unique user account.

To assign NDC1 or Alternate ID codes, they must first be listed in the “NDC1/ALT ID Listings” list. If the NDC1 or Alternate ID is not on the list, you must add them to the list. Once on the list, they can then be assigned. Perform the following steps to manage NDC1s and Alternate IDs.

1. Click on **Manage NDC1/ALT ID** from the menu on the left side of the screen.

   The “Manage NDC1/ALT ID” screen displays with the global list visible, as shown in Figure 4-1.

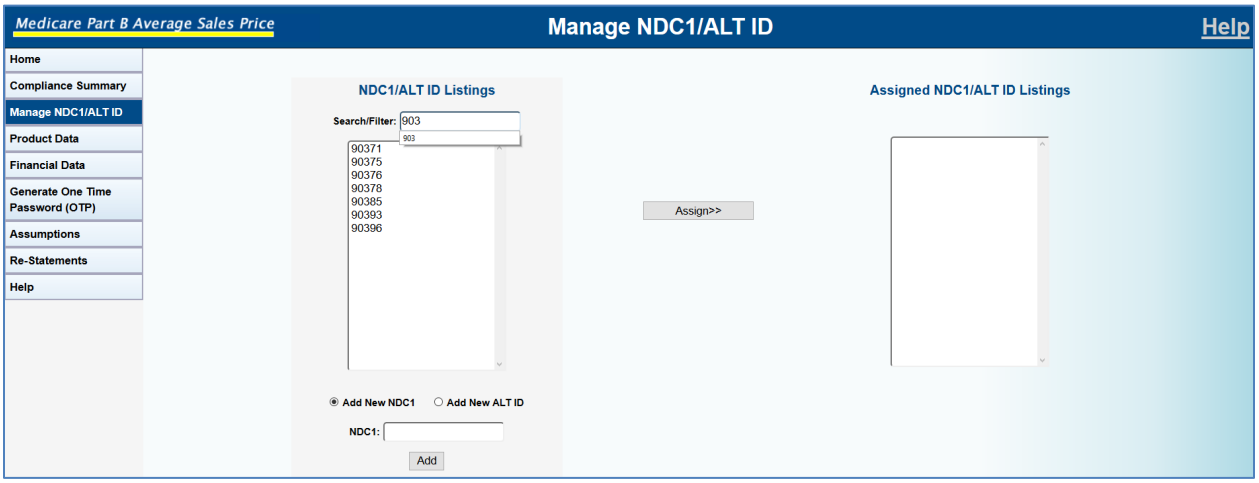
Figure 4-1: Manage NDC1/ALT ID Screen



2. To search for an NDC1, enter the partial or full NDC1 in the “Search/Filter:” field.

   The application filters the entered NDC1, as shown in Figure 4-2.

Figure 4-2: Manage NDC/ALT ID - Filter

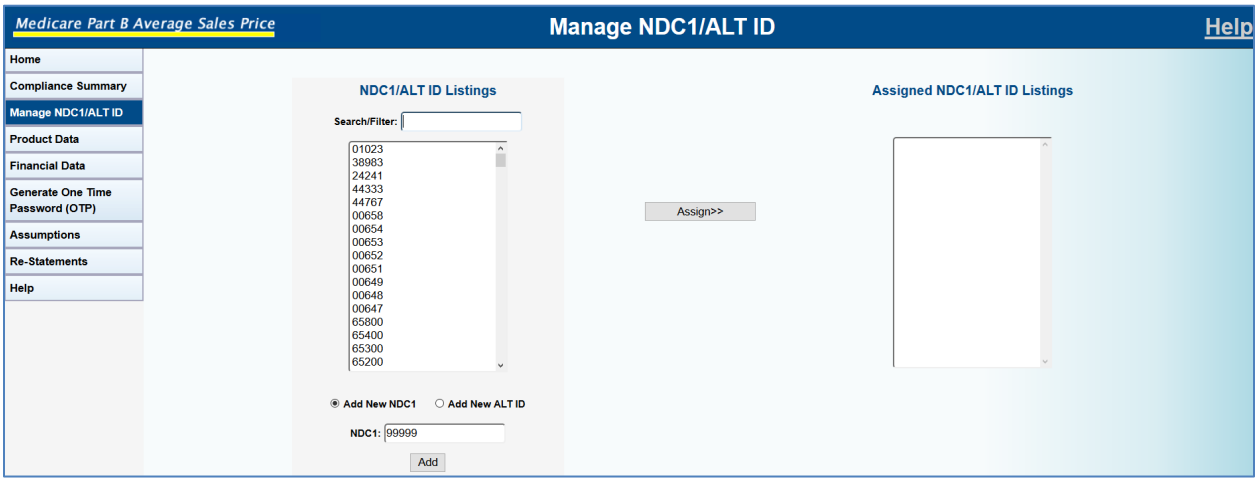


3. To add an NDC1 to the global list, click on the “Add New NDC1” radio button and enter your new NDC1 in the “NDC1:” field.

   Note: the NDC1 must be 5 digits.

   The “NDC1:” field is populated, as shown in Figure 4-3.

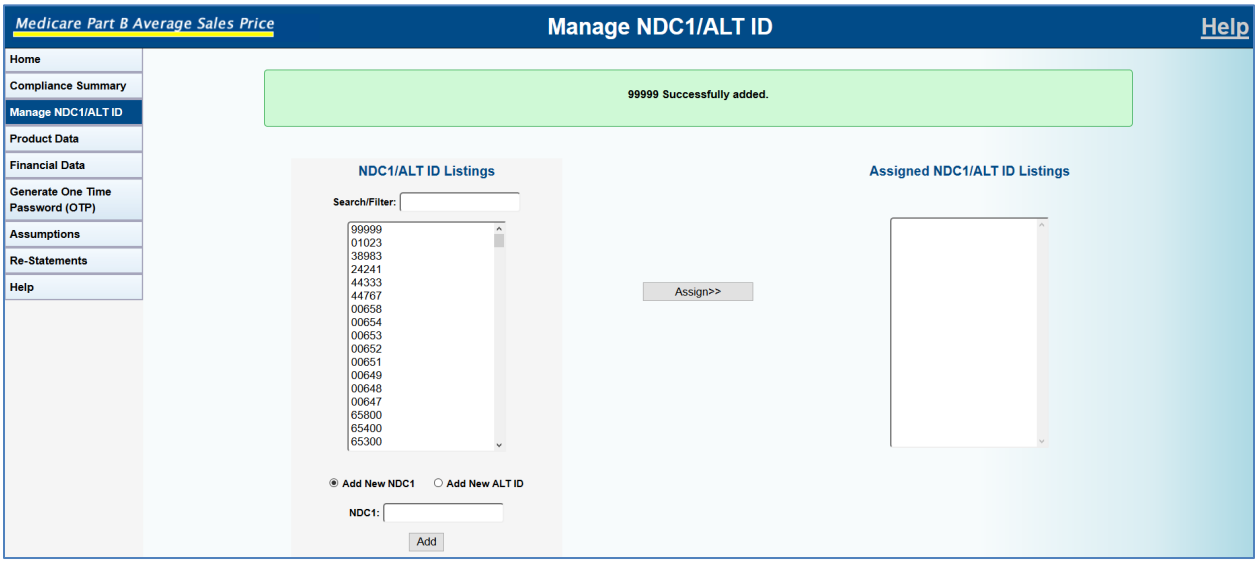
Figure 4-3: Manage NDC/ALT ID – NDC1 Field Populated



4. Click on the **Add** button.

   A message displays confirming that the new NDC1 was added successfully and the new NDC1 is listed at the top of the global list, as shown in Figure 4-4.

Figure 4-4: Manage NDC/ALT ID – NDC1 Saved Successfully

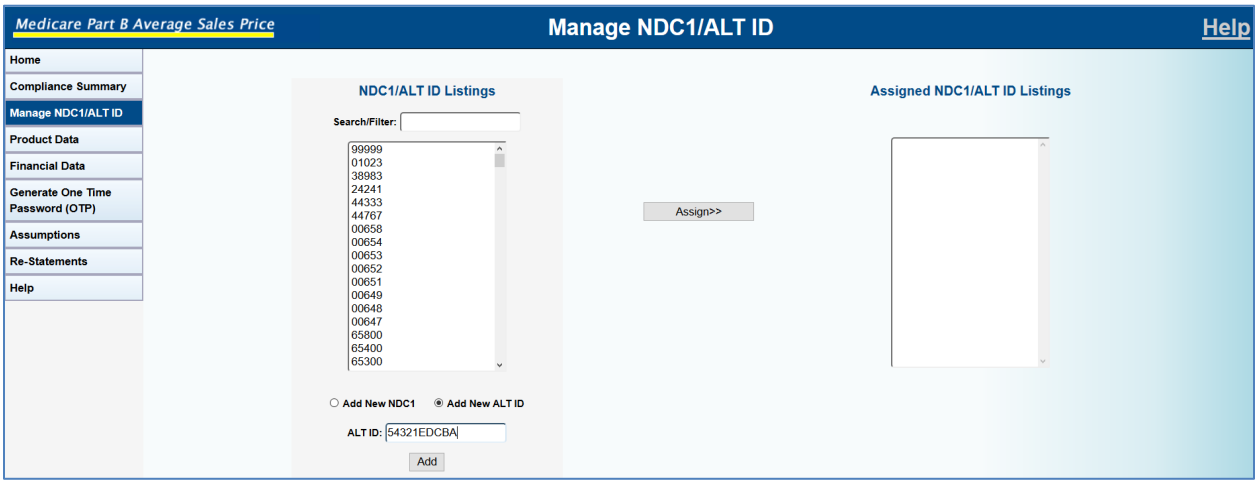


5. To add an Alternate ID to the global list, click on the “Add New ALT ID” radio button and enter your new Alternate ID in the “ALT ID:” field.

   Note: The ALT ID can be up to 23 alphanumeric characters including colon (:) period (.) and dash (-).

   The “ALT ID:” field is populated, as shown in Figure 4-5.

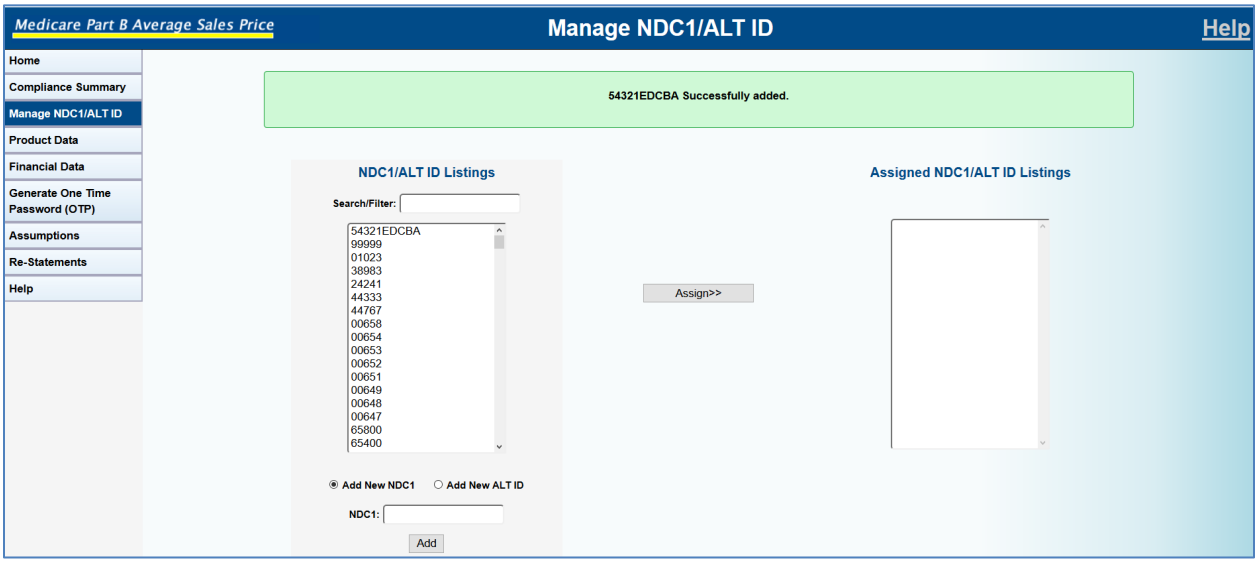
Figure 4-5: Manage NDC/ALT ID – ALT ID Field Populated



6. Click on the **Add** button.

   A message displays confirming that the new ALT ID was added successfully, and the new Alternate ID is listed at the top of the global list, as shown in Figure 4-6.

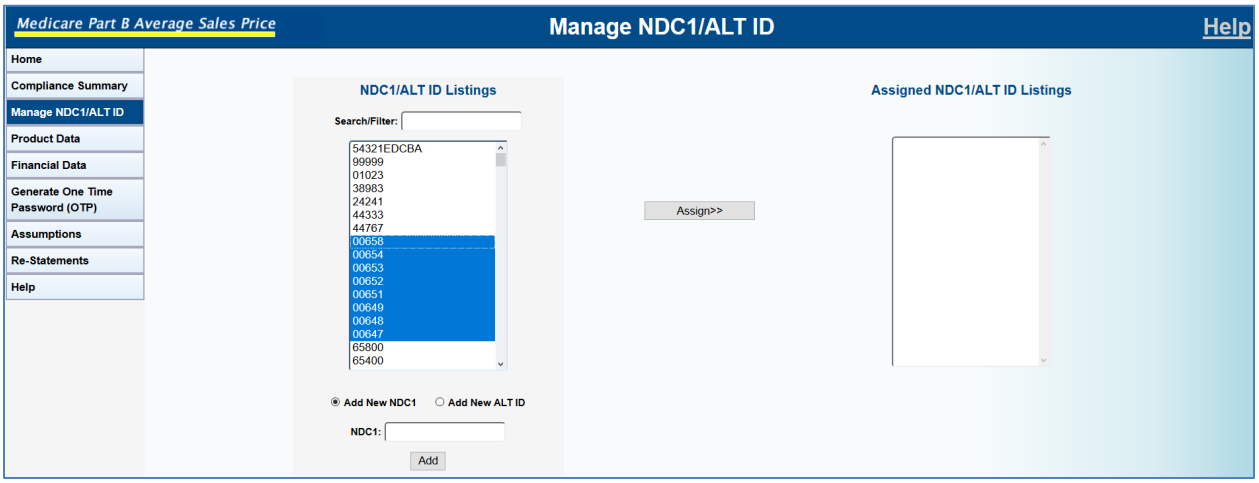
Figure 4-6: Manage NDC/ALT ID – ALT ID Saved Successfully



7. To assign NDC1s and ALT IDs, select one or more items from the “NDC1/ALT ID Listings” field.

   The selected item(s) are highlighted, as shown in Figure 4-7.

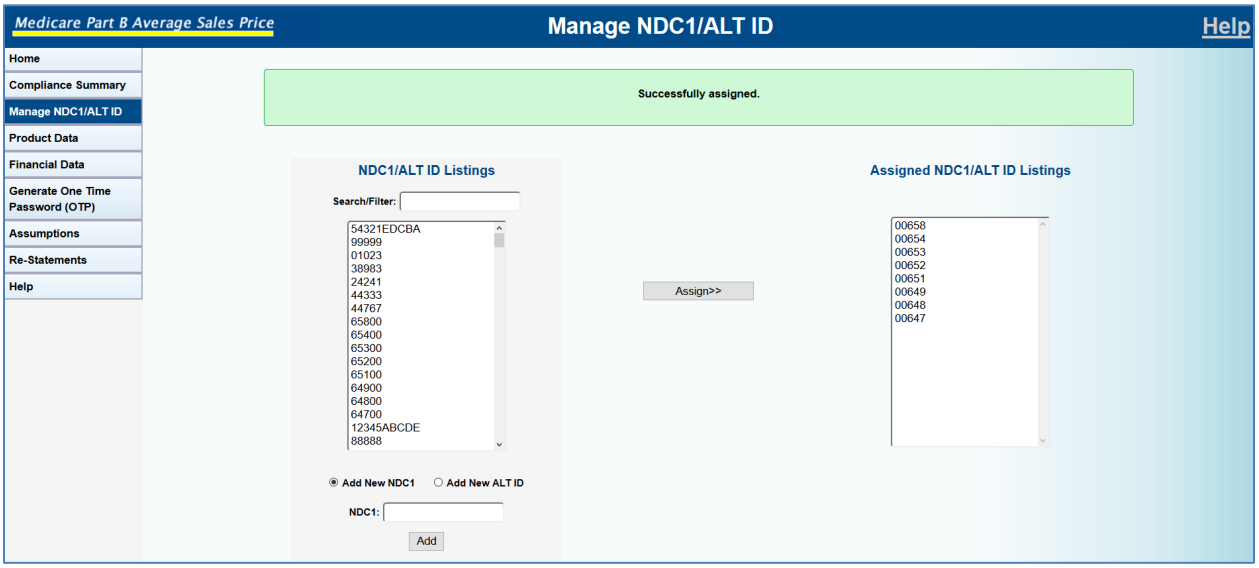
Figure 4-7: Manage NDC/ALT ID – Select NDCs/ALT IDs for Assignment



8. Click on the **Assign>>** button.

   A message displays stating that the items were successfully assigned. The selected item(s) appear in the “Assigned NDC1/ALT ID Listings” field, as shown in Figure 4-8.

Figure 4-8: Manage NDC/ALT ID – NDC1/ALT ID Assigned Successfully



5. Compliance Summary

5.1 Submitter

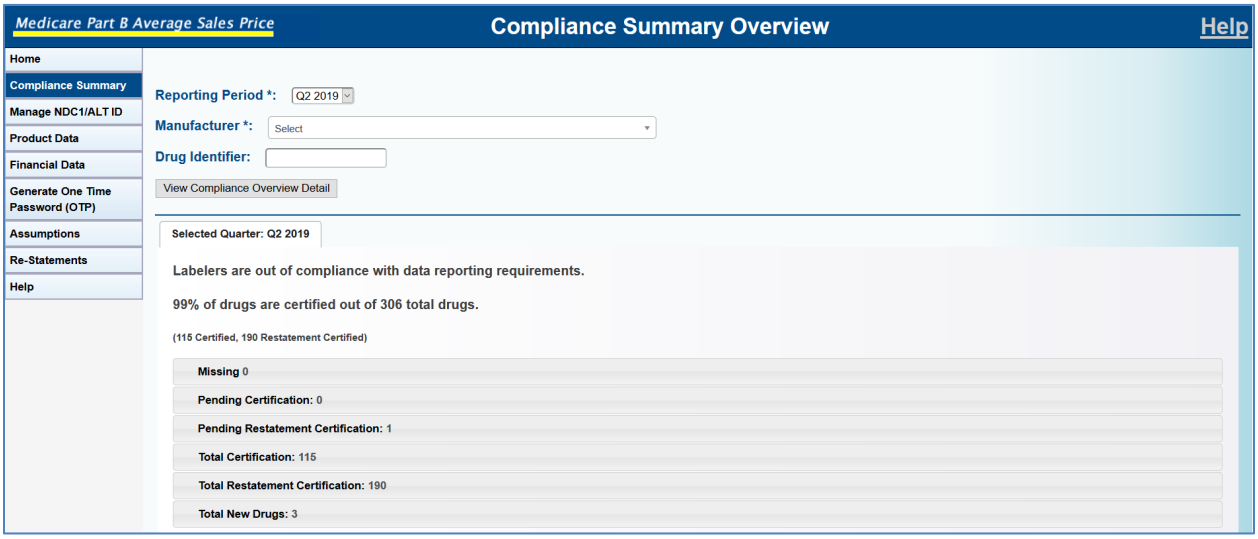
The Compliance Summary features allow Drug Manufacturers to view whether their drugs are in compliance with the drug submission reporting requirements. Drug Manufacturers can access a compliance summary for all drugs using the Compliance Summary menu tab.

1. From the menu on the left side of the page, click on **Compliance Summary**.

   The “Compliance Summary Overview” page displays with the current reporting period as the default, as shown in Figure 5-1.

   Note: The “Compliance Summary Overview” screen lists the compliance summary for all manufacturers assigned to a Submitter by default.

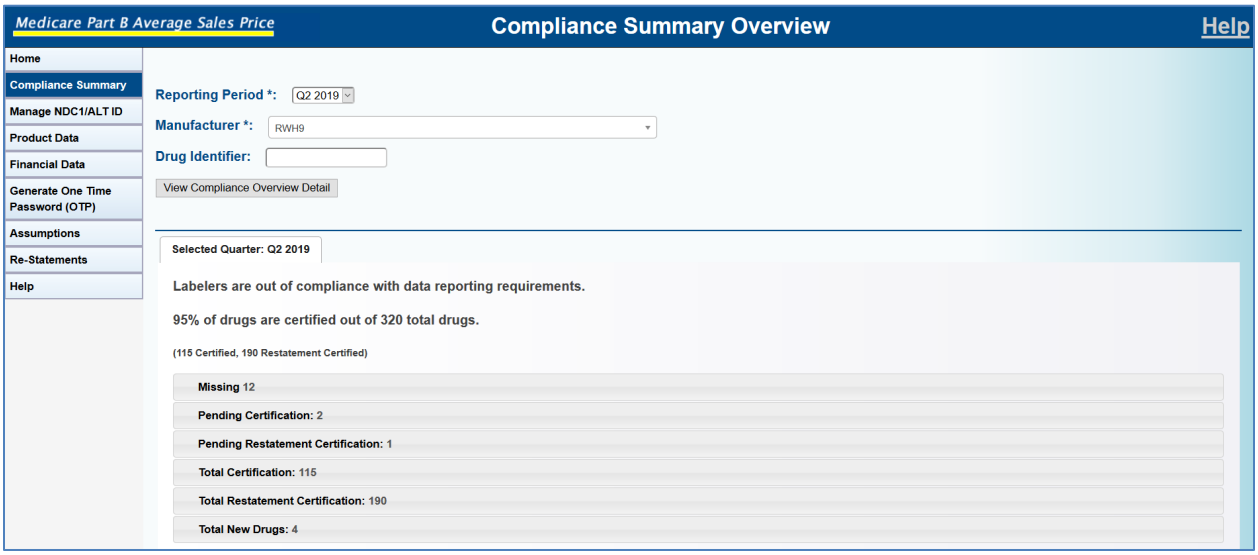
Figure 5-1: Compliance Summary Overview Page: Submitter



2. Select the desired reporting period from the “Reporting Period” dropdown list (required), the desired manufacturer from the “Manufacturer” dropdown list (required), the labeler code from the dropdown list (optional), and either a full or partial drug identifier (optional), and click on the **View Compliance Overview Detail** button to display the summary report.

   The summary results display for the selected manufacturer for the selected reporting period as shown in Figure 5-2.

Figure 5-2: Manufacturer's Compliance Summary Report: Submitter



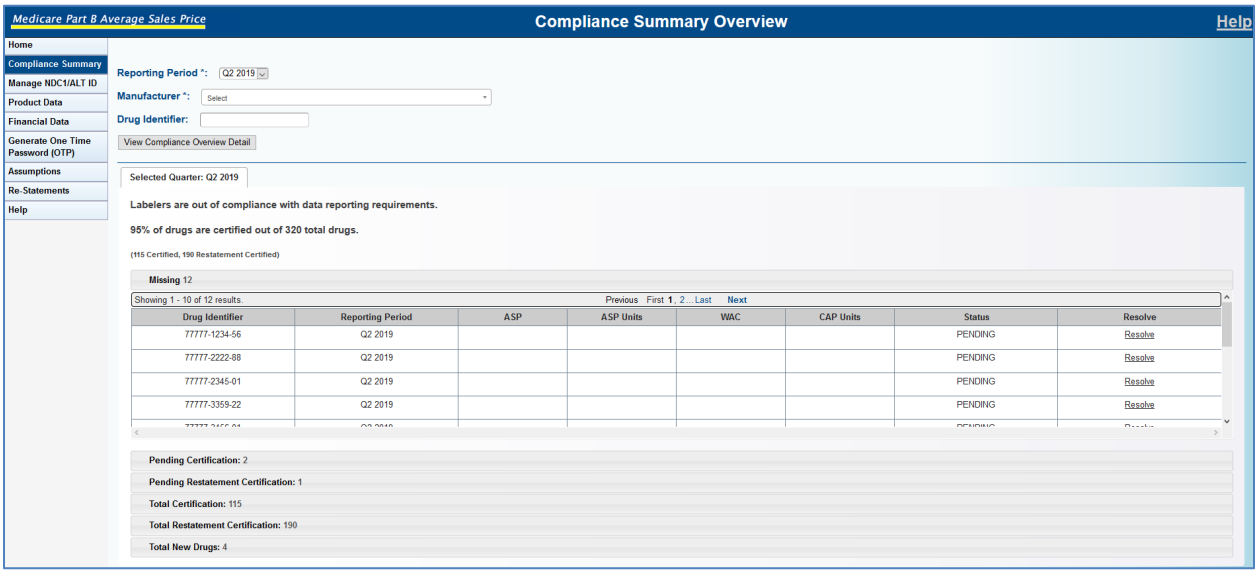
The Compliance Summary Overview screen displays statements whether or not the Drug Manufacturer is within compliance for the reporting period. Also listed is the percentage of drugs assigned to the user that are certified for the selected reporting period:

- Missing (go to step 3)
- Pending Certification (go to Step 6)
- Pending Restatement Certification (go to Step 8)
- Total Certification (go to Step 10)
- Total Restatement Certification (go to Step 12)
- Total New Drugs (go to Step 14)

3. To view drugs that are not compliant because the financial data for the drug have not been submitted, click on the **Missing** panel.

   The "Missing" report displays, as shown in Figure 5-3.

Figure 5-3: Compliance Summary: Submitter - Missing



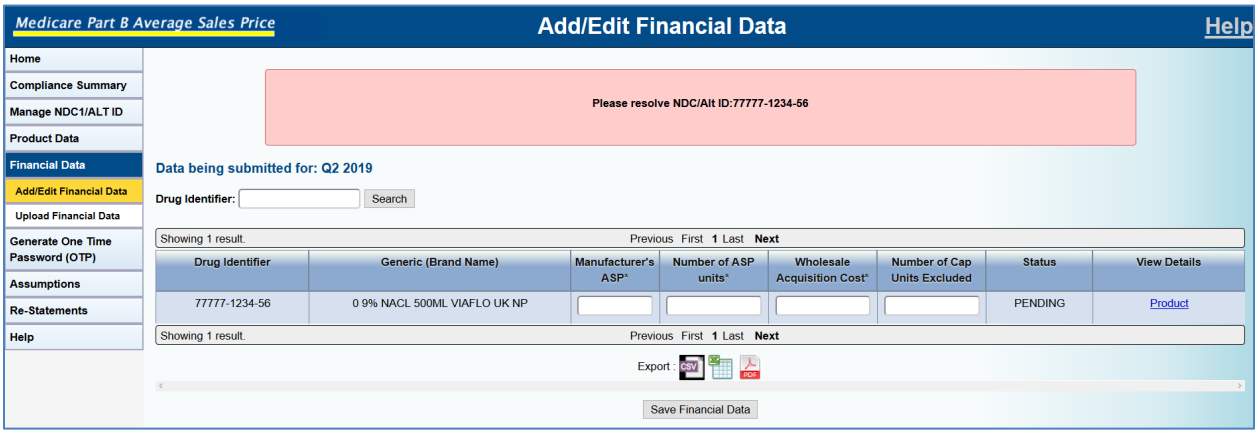
Drug Manufacturers have the ability to enter financial data by clicking on the “Resolve” link for the specific drug identifier.

4. Click on the **Resolve** link.

   The “Add/Edit Financial Data” screen displays for the drug identifier selected from the “Compliance Summary” screen, as shown in Figure 5-4.

   Note: If the reporting period selected is not the current reporting period, the “Add/Edit Restate Financial Data” screen displays.

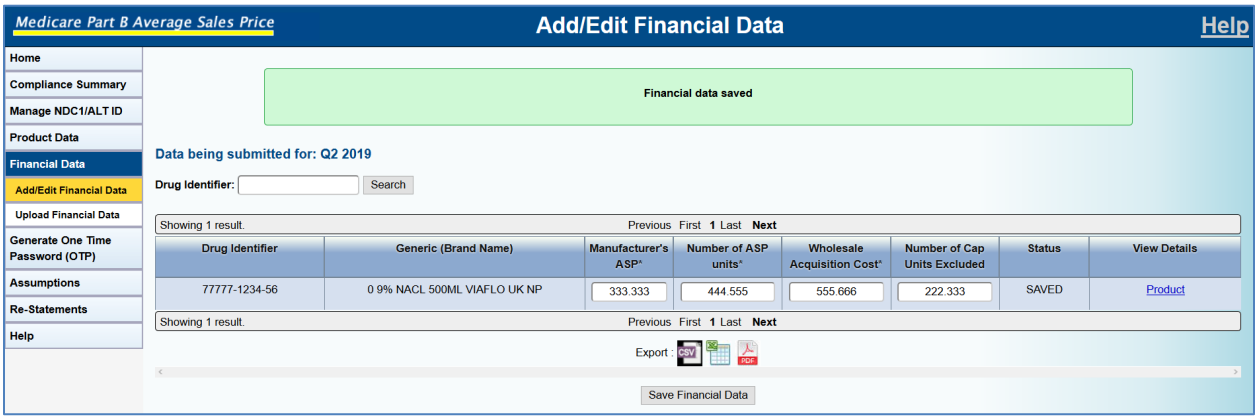
Figure 5-4: Compliance Summary: Submitter – Add/Edit Financial Data



5. Enter the missing financial data and click on the **Save Financial Data** button.

   A message displays stating that the financial data were saved successfully, as shown in Figure 5-5. The drug identifier status will now say “SAVED.”

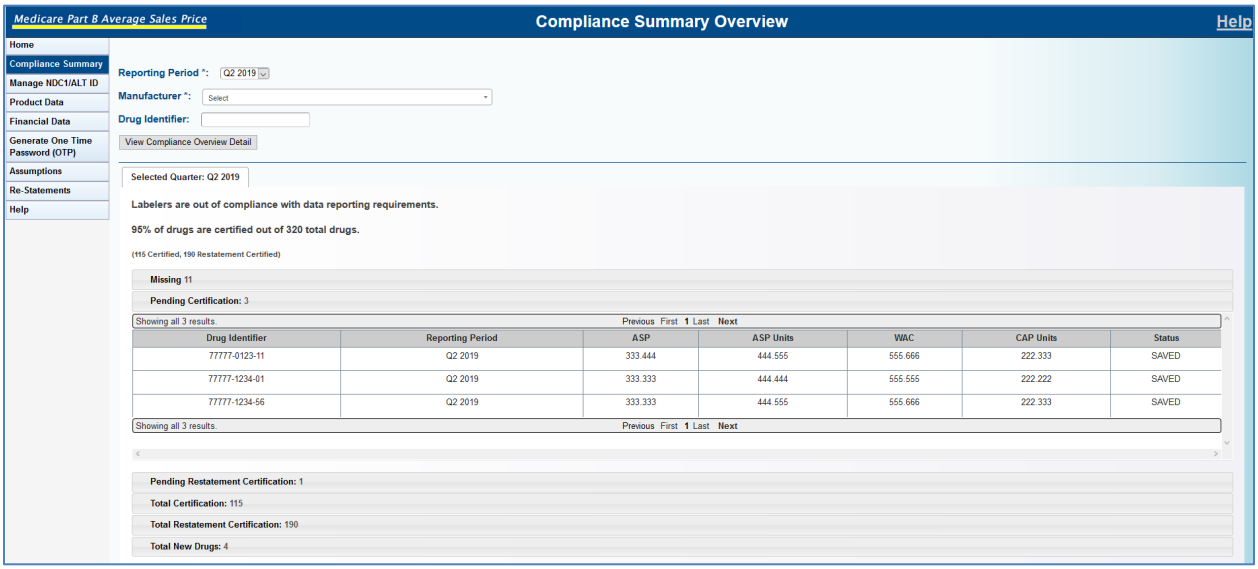
Figure 5-5: Compliance Summary: Submitter – Financial Data Saved Successfully



6. To view drugs that have saved financial data, but whose certifications are pending, click on the **Pending Certification** panel from the "Compliance Summary Overview" screen.

   The "Pending Certification" report displays, as shown in Figure 5-6.

Figure 5-6: Compliance Summary: Submitter – Pending Certification

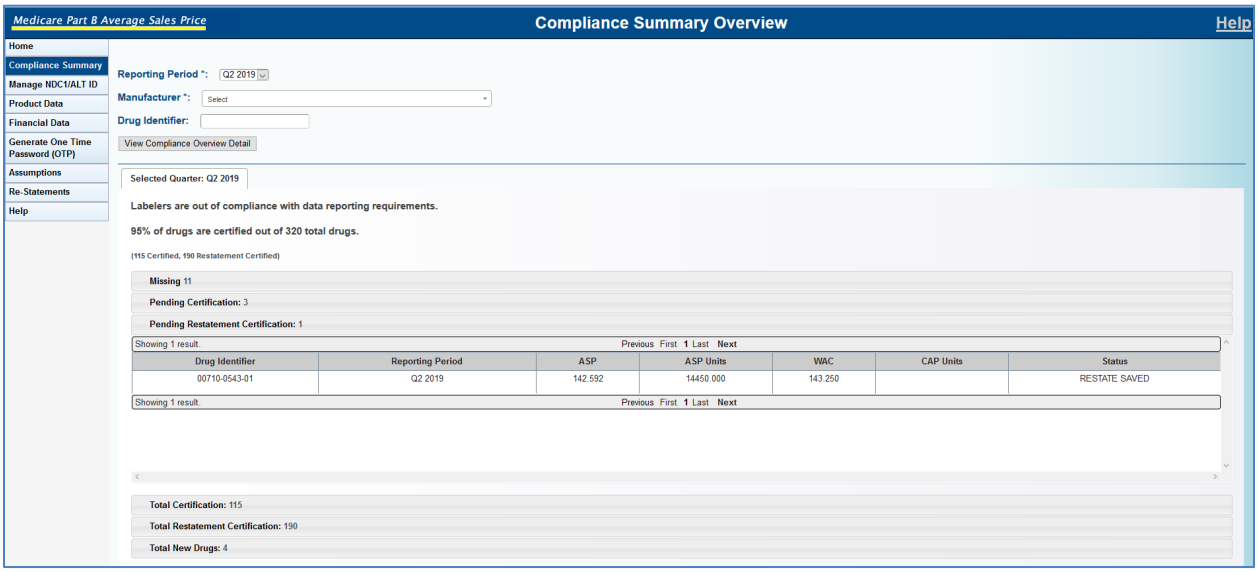


7. Click on the **Pending Certification** panel to hide the drug information that is pending certification.

8. To view drugs that have saved financial data that were restated but whose certifications are pending, click on the **Pending Restatement Certification** panel from the "Compliance Summary Overview" page.

   The "Pending Restatement Certification" report displays, as shown in Figure 5-7.

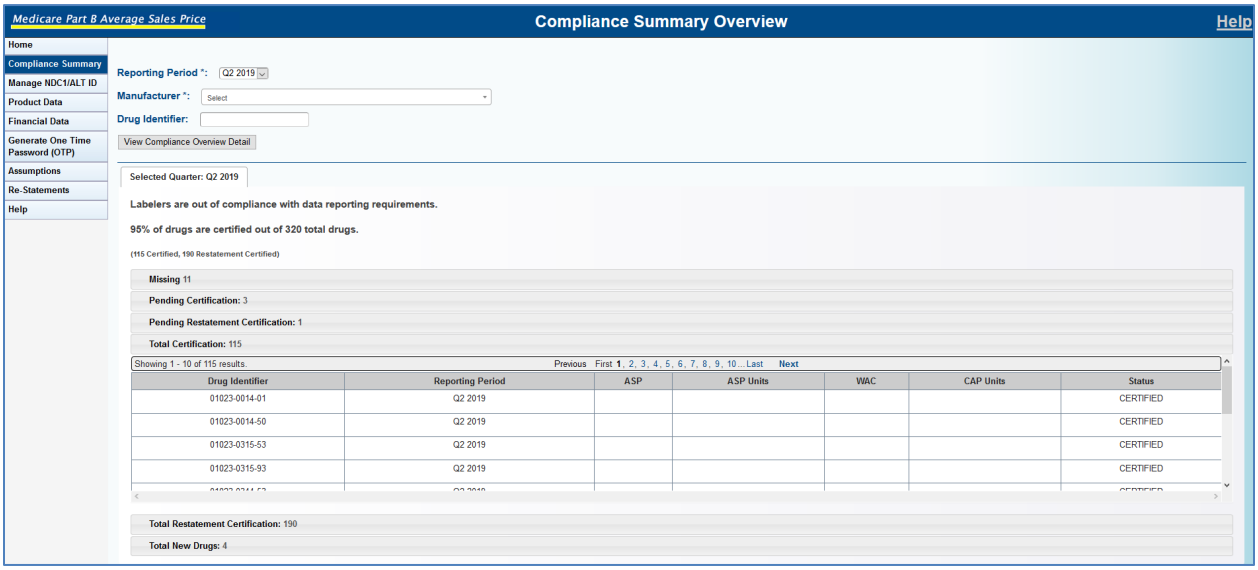
Figure 5-7: Compliance Summary: Submitter – Pending Restatement Certification



9. Click on the **Pending Restatement Certification** panel to hide the drug information that is pending restatement certification.
10. To view drugs that have been certified during the selected reporting period, click on the **Total Certification** panel from the “Compliance Summary Overview” page.

    The “Total Certification” report displays, as shown in Figure 5-8.

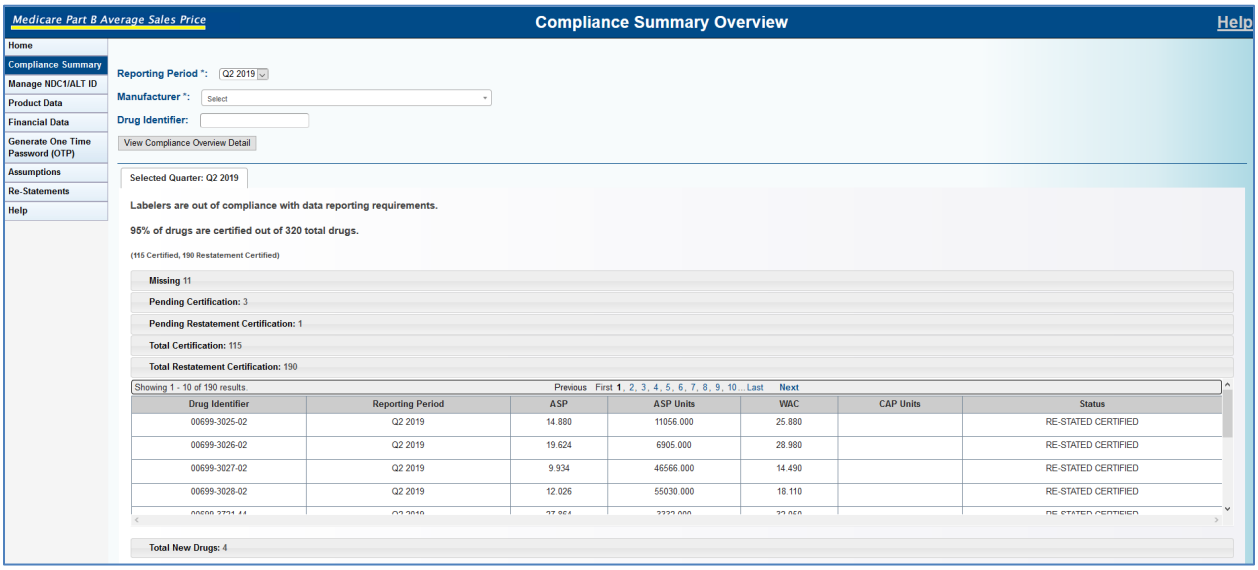
Figure 5-8: Compliance Summary: Submitter – Total Certification



11. Click on the **Total Certification** panel to hide the certified drug information.
12. To view the information for drugs that have been restated and certified, click on the **Total Restatement Certification** panel from the “Compliance Summary Overview” page.

    The “Total Restatement Certification” report displays, as shown in Figure 5-9.

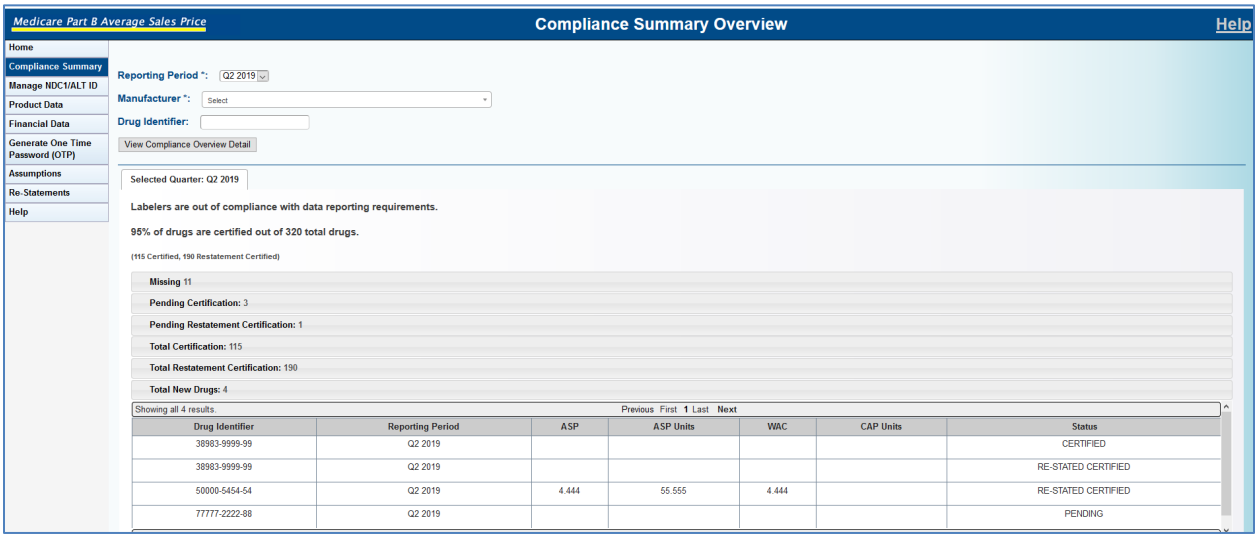
Figure 5-9: Compliance Summary: Submitter – Total Restatement Certification



13. Click on the Total Restatement Certification panel to hide the certified drug information.
14. To view the product and financial information for new drugs that have been certified or saved, click on the **Total New Drugs** panel.

    The “Total New Drugs” report displays, as shown in Figure 5-10.

Figure 5-10: Compliance Summary: Submitter – Total New Drugs



5.2 Certifier

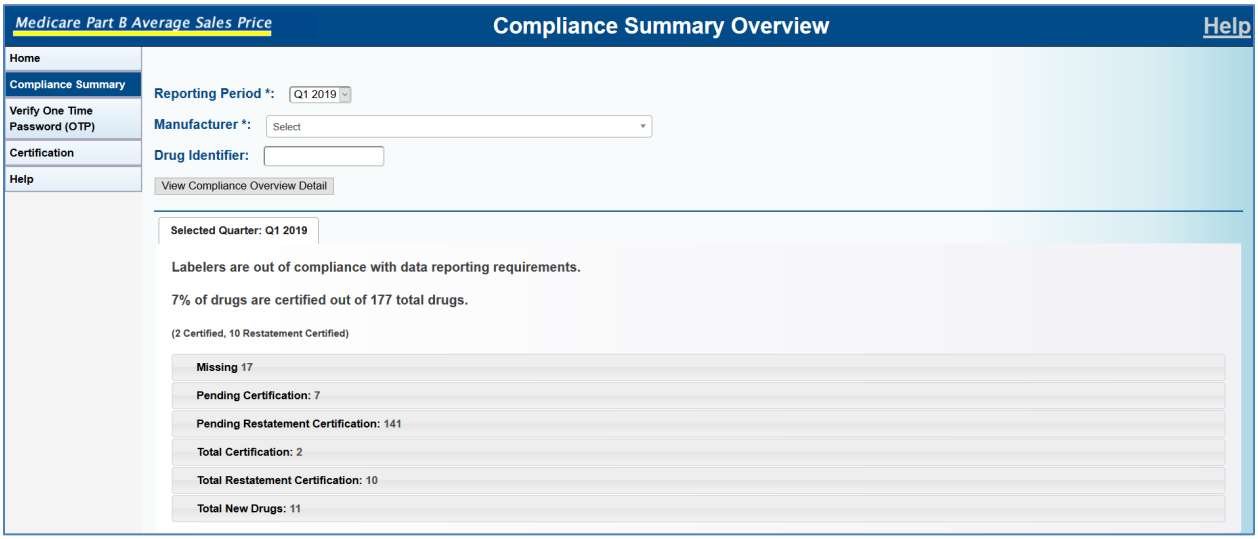
The Compliance Summary features allow Drug Manufacturers to view whether their drugs are in compliance with the drug submission reporting requirements. Drug Manufacturers can access a compliance summary for all drugs using the Compliance Summary menu tab.

1. From the menu on the left side of the page, click on **Compliance Summary**.

   The “Compliance Summary Overview” page displays.

Note: The “Compliance Summary Overview” screen lists the compliance summary for all manufacturers assigned as a default, as shown in Figure 5-11.

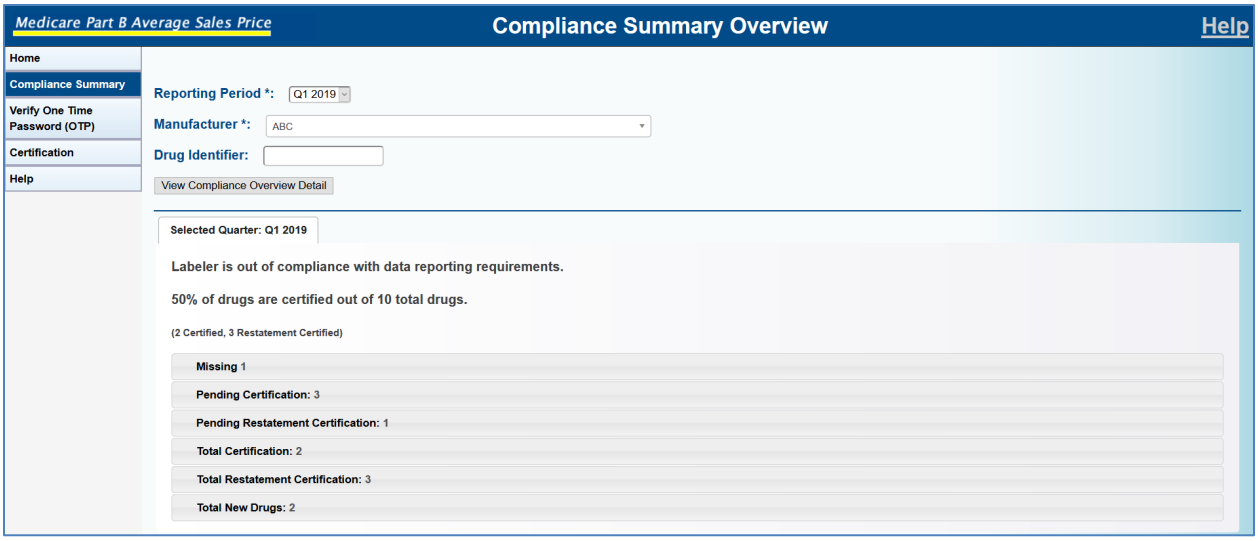
Figure 5-11: Compliance Summary Overview Page: Certifier



2. Select the desired reporting period from the “Reporting Period” dropdown list (required), the desired manufacturer from the “Manufacturer” dropdown list (required), the labeler code from the dropdown list (optional), and either a full or partial drug identifier (optional) and click on the **View Compliance Overview Detail** button to display the summary report.

   The summary results display for the selected manufacturer for the selected reporting period, as shown in Figure 5-12.

Figure 5-12: Manufacturer’s Compliance Summary Report: Certifier



The “Compliance Summary Overview” screen displays statements whether or not the Drug Manufacturer is within compliance for the reporting period. Also listed is the percentage of drugs assigned to the user that are certified for the selected reporting period.

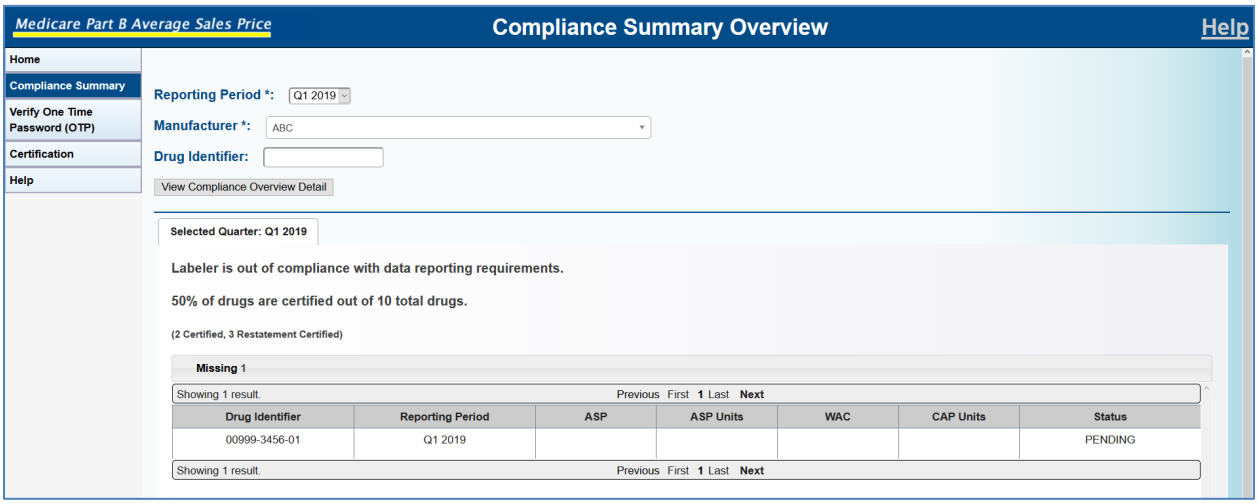
Drugs that are listed in the panels are:

- Missing (go to Step 3)
- Pending Certification (go to Step 6)
- Pending Restatement Certification (go to Step 8)
- Total Certification (go to Step 10)
- Total Restatement Certification (go to Step 12)
- Total New Drugs (go to Step 13)

3. To view drugs that are not compliant because the financial data for the drug have not been submitted, click on the **Missing** panel.

   The “Missing” report displays with the status of “PENDING,” as shown in Figure 5-13.

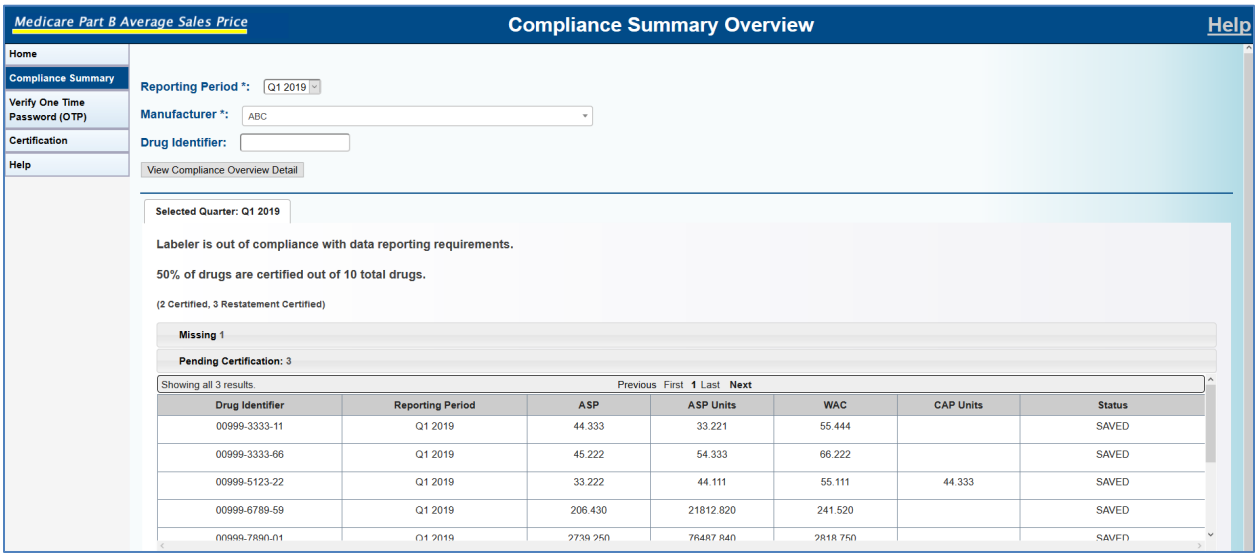
Figure 5-13: Compliance Summary: Certifier - Missing



4. Click on the **Missing** panel to hide the drug information that needs financial data.
5. To view drugs that have saved financial data but whose certifications are pending, click on the **Pending Certification** panel from the “Compliance Summary Overview” screen.

   The “Pending Certification” report displays, as shown in Figure 5-14.

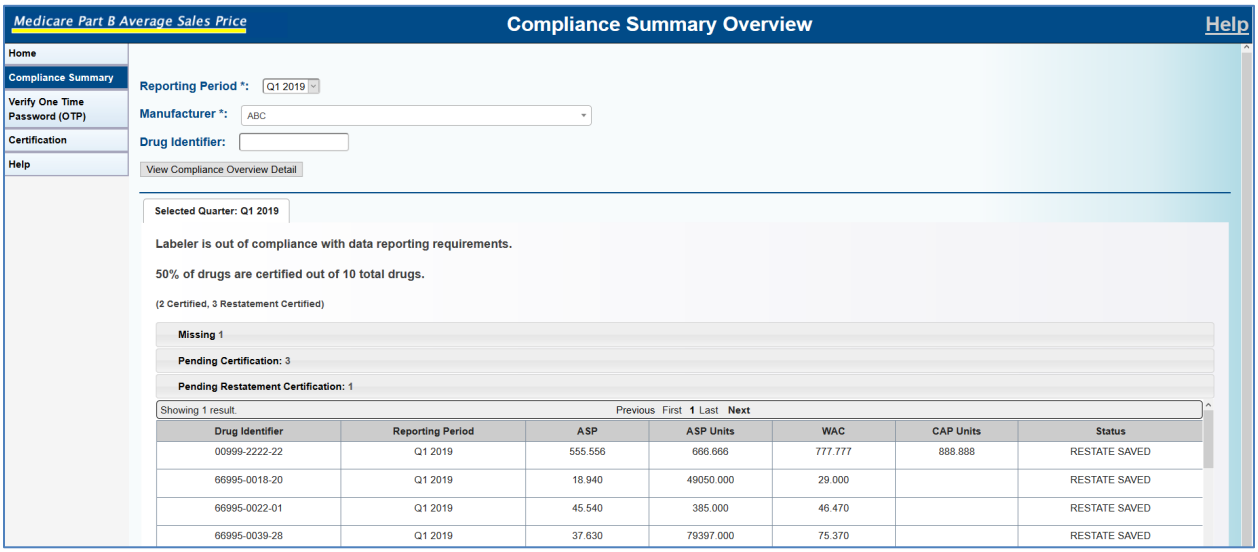
Figure 5-14: Compliance Summary: Certifier – Pending Certification



6. Click on the **Pending Certification** panel to hide the drug information that is pending certification.
7. To view drugs that have saved financial data that were restated but whose certifications are pending, click on the **Pending Restatement Certification** panel from the "Compliance Summary Overview" page.

   The "Pending Restatement Certification" report displays, as shown in Figure 5-15.

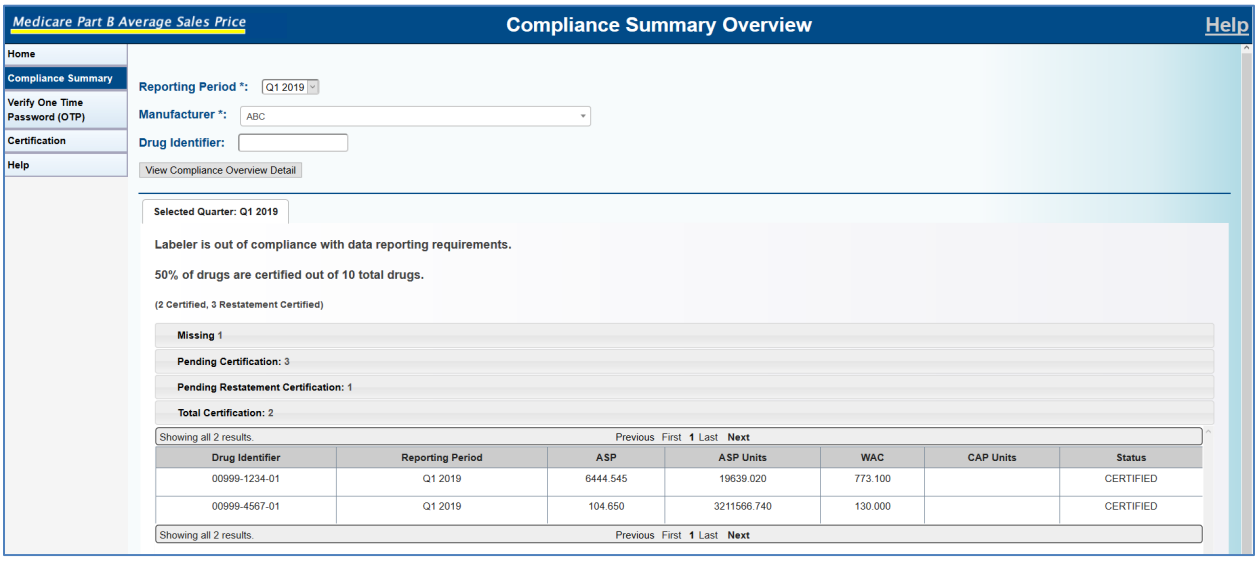
Figure 5-15: Compliance Summary: Certifier – Pending Restatement Certification



8. Click on the **Pending Restatement Certification** panel to hide the drug information that is pending restatement certification
9. To view drugs that have been certified during the selected reporting period, click on the **Total Certification** panel from the "Compliance Summary Overview" page.

   The "Total Certification" report displays, as shown in Figure 5-16.

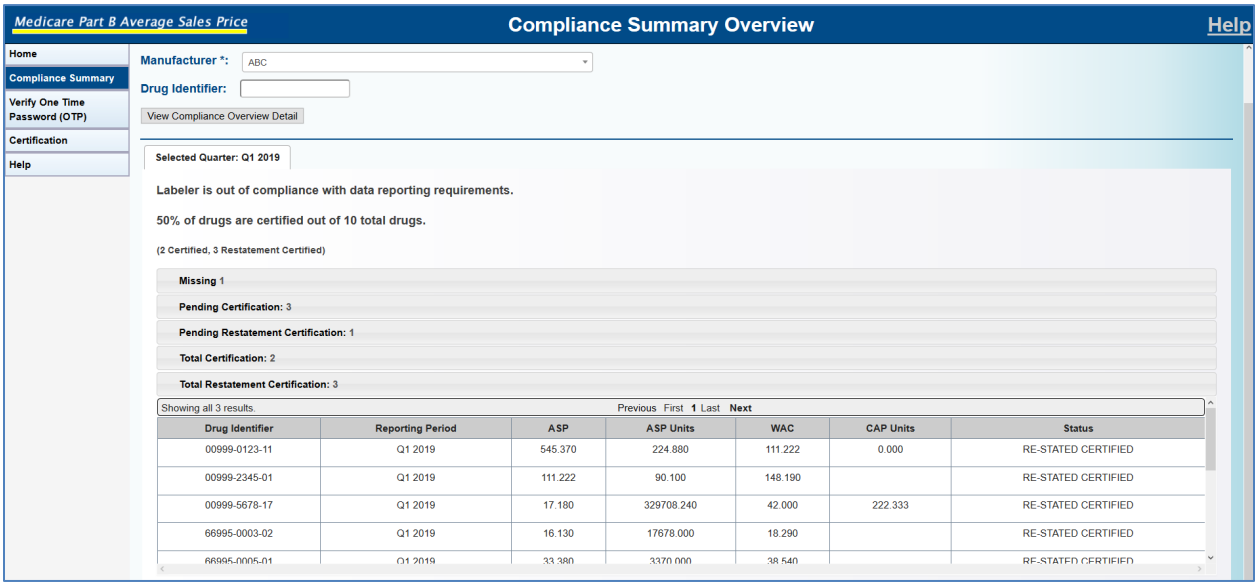
Figure 5-16: Compliance Summary: Certifier – Total Certification



10. Click on the **Total Certification** panel to hide the certified drug information.
11. To view the information for drugs that have been restated and certified, click on the **Total Restatement Certification** panel from the "Compliance Summary Overview" page.

    The "Total Restatement Certification" report displays, as shown in Figure 5-17.

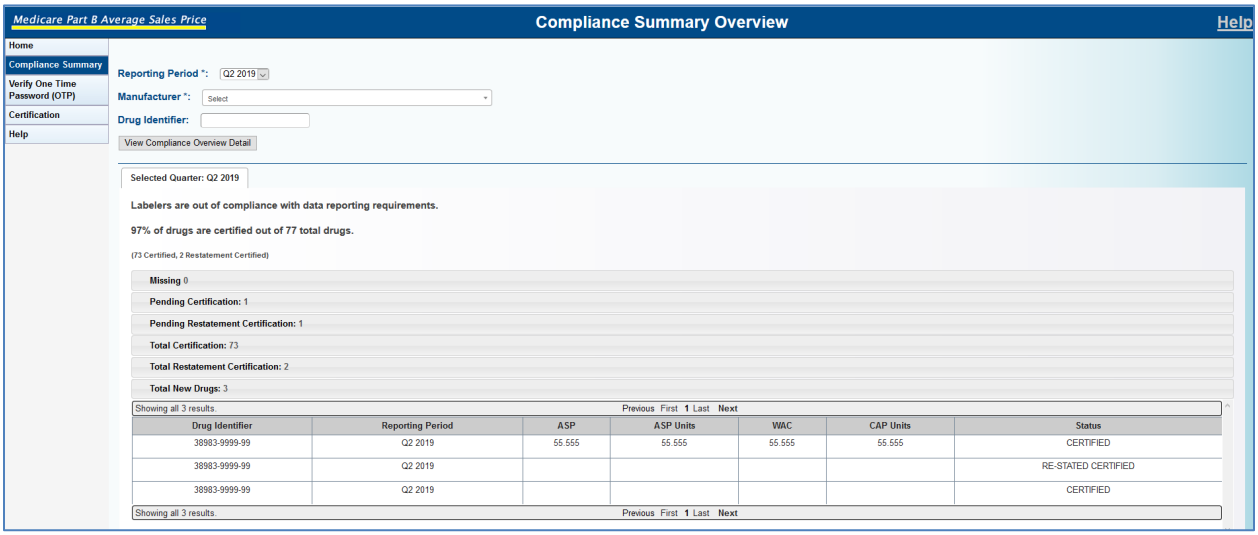
Figure 5-17: Compliance Summary: Certifier – Total Restatement Certification



12. Click on the **Total Restatement Certification** panel to hide the certified drug information.
13. To view the product and financial information for new drugs that have been certified or saved, click on the Total New Drugs panel from the "Compliance Summary Overview" page.

The “Total New Drugs” report displays, as shown in Figure 5-18.

Figure 5-18: Compliance Summary: Certifier – Total New Drugs



14. Click on the **Total New Drugs** panel to hide the certified drug information.

6. Product Data

Drug manufacturers are required to submit quarterly drug data to the ASP application for ASP pricing using a file transfer process or through online data entry. Drug data consists of product data and financial data. The following subsections detail the steps required to submit drug product data using online data entry and through approved file uploads.

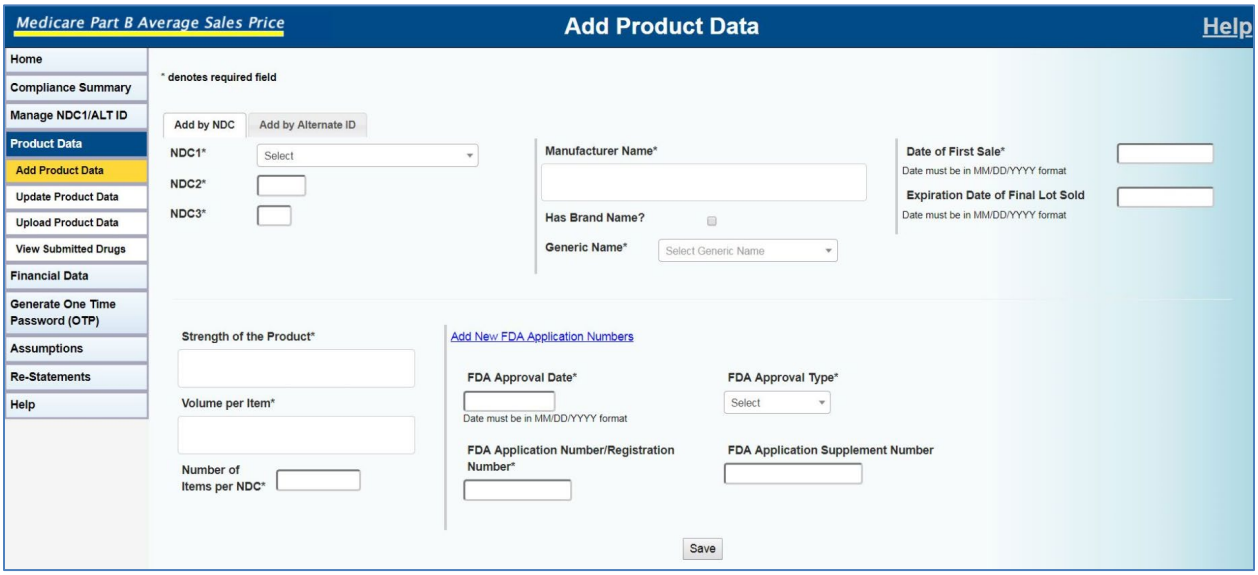
6.1 Add Product Data

Add Product Data allows drug manufacturers the ability to manually submit drug product data one at a time to CMS. To upload product data for multiple drugs at once from a file, skip to section 6.2.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Add Product Data**.

   The “Add Product Data” screen displays, as shown in Figure 6-1.

Figure 6-1: Add Product Data Screen



2. To add fields by NDC, select the “Add by NDC” tab and use the following requirements:

   Note: To add fields by Alternate ID, go to step 4.

   NDC1: dropdown

   Note: if the NDC1 desired is not in the dropdown list, click on **Manage NDC1/ALT ID** from the menu on the left side of the screen, and add and assign your NDC1.

   NDC2: numeric
   required
   4-digit entry

NDC3: numeric
required
2-digit entry

Manufacturer Name: required
limited to 250 characters

Note: When entering Product Data for the same Manufacturer more than once, be sure that the spelling is the same each time for that Manufacturer. If data were entered through "Upload Product Data," the spelling must match that as well.

Has Brand Name?: checkbox
optional

Brand Name: field is only displayed if the "Has Brand Name?" box is checked
required if "Has Brand Name?" box is checked
limited to 250 characters

Generic Name: dropdown list
required

New Generic Name: displayed only if selecting "Add New Generic Name" from the "Generic Name" dropdown list
required
limited to 250 characters

Date of First Sale: MM/DD/YYYY format
required
cannot occur before the FDA approval date
must occur prior to the "Current Reporting Period" start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per NDC: numeric
required
limited to 9 digits and 2 decimal places

FDA Approval Date: required
MM/DD/YYYY format
must be prior to "Current Reporting Period" start date

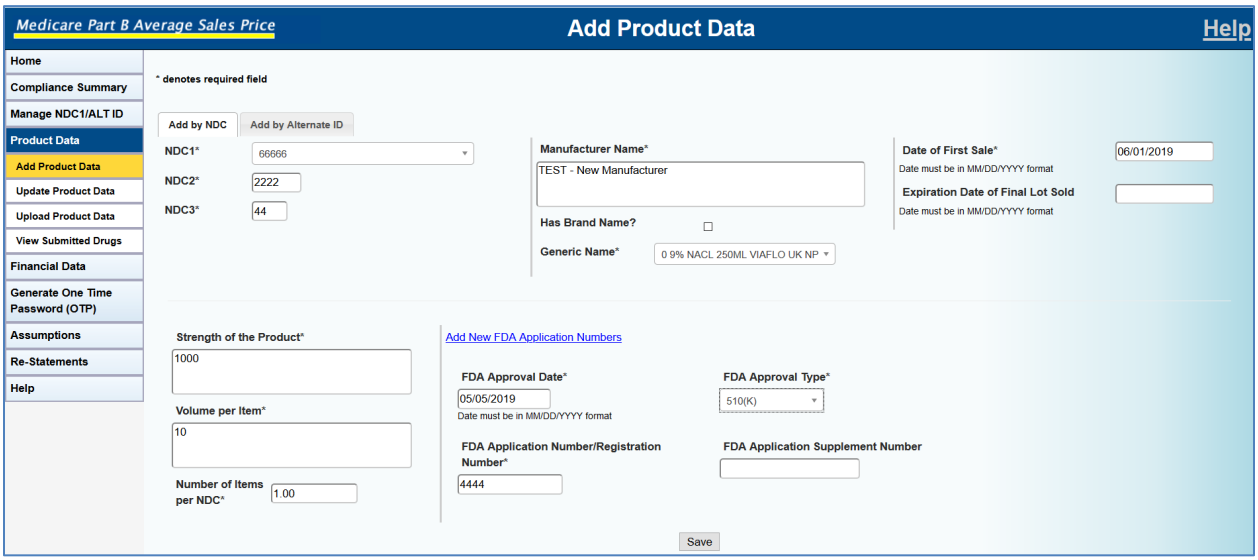
FDA Application Number/Registration Number: required
alphanumeric
up to 10 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

FDA Approval Type: required
dropdown list

FDA Application Supplement Number: alphanumeric
optional
up to 9 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The field windows populate with the entered data, as shown in Figure 6-2.

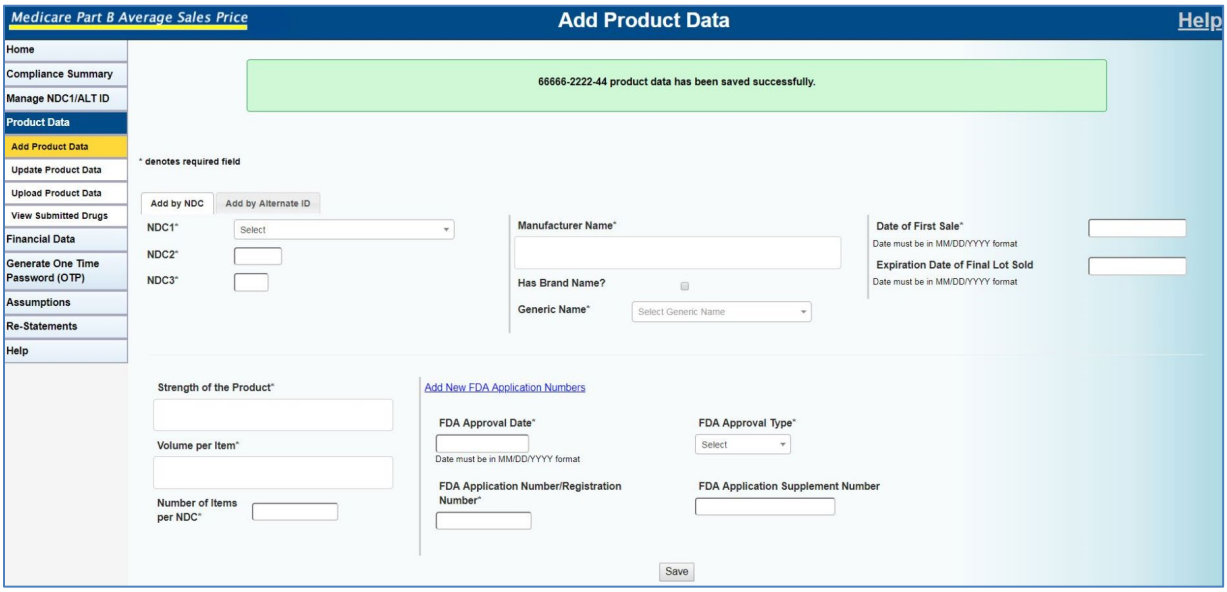
Figure 6-2: Add Product Data – Fields Populated



3. Click on the **Save** button.

   The screen displays the confirmation that the product submission has been successfully saved, as shown in Figure 6-3.

Figure 6-3: Add Product Data – Product Submission Saved Successfully



4. To add fields by Alternate ID, select the “Add by Alternate ID” tab, and use the following requirements:

   Alternate ID: required
   dropdown

   Note: if the Alternate ID you want to use is not in the dropdown list, you must click on **Manage NDC1/ALT ID** from the menu on the left side of the screen, and add and assign the Alternate ID.

   Manufacturer Name: required
   limited to 250 characters

   Note: When entering Product Data for the same Manufacturer more than once, be sure that the spelling is the same each time for that Manufacturer. If data were entered through “Upload Product Data,” the spelling must match that as well.

   Has Brand Name?: checkbox
   optional

   Brand Name: field is only displayed if the “Has Brand Name?” box is checked
   required if “Has Brand Name?” box is checked
   limited to 250 characters

   Generic Name: dropdown list
   required

   New Generic Name: only displayed when selecting “Add New Generic Name” from the “Generic Name” dropdown list
   required
   limited to 250 characters

Date of First Sale: MM/DD/YYYY format
numeric
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per Alternate ID: numeric
required
up to 9 digits allowed and 2 decimal places

FDA Approval Date: optional
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

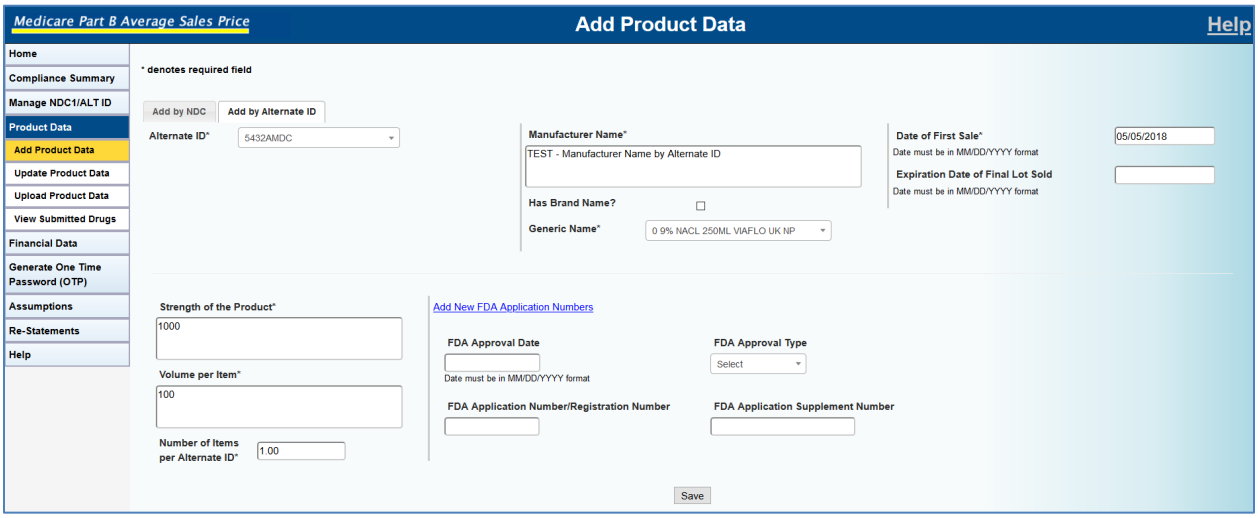
FDA Application Number/Registration Number: optional
alphanumeric
up to 10 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

FDA Approval Type: optional
dropdown list

FDA Application Supplement Number: alphanumeric
optional
up to 9 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The fields populate with the entered data, as shown in Figure 6-4.

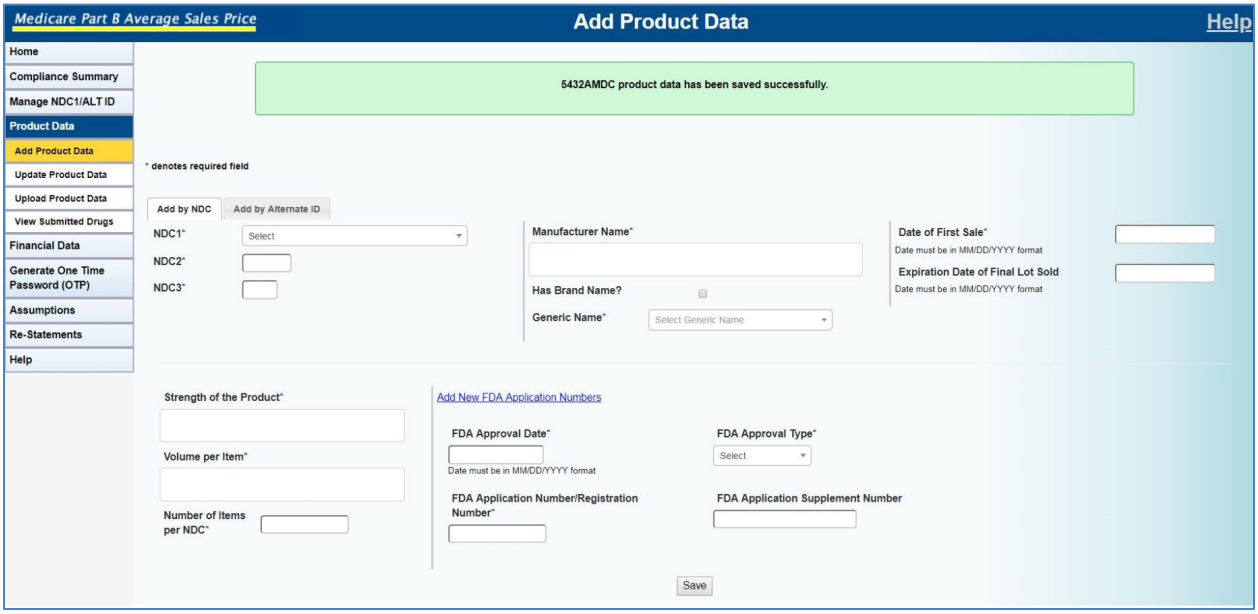
Figure 6-4: Add Product Data – Add Fields by Alternate ID



5. Click on the **Save** button.

   The screen displays the confirmation that the product submission has been successfully saved, as shown in Figure 6-5.

Figure 6-5: Add Product Data – Product Submission Saved Successfully



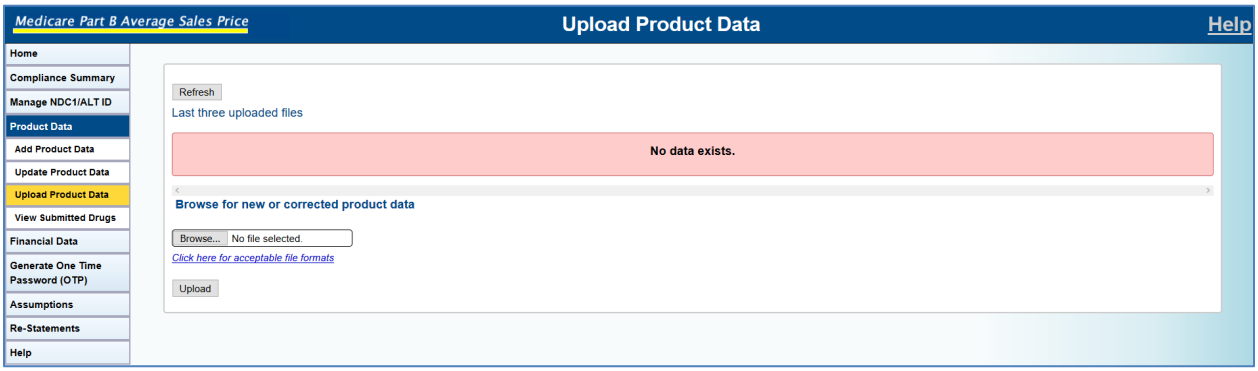
6.2 Upload Product Data

ASP provides drug manufacturers the ability to submit Medicare Part B drug data to CMS. Perform the following steps to upload drug product data using the file transfer process.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Upload Product Data**.

   The “Upload Product Data” screen displays, as shown in Figure 6-6.

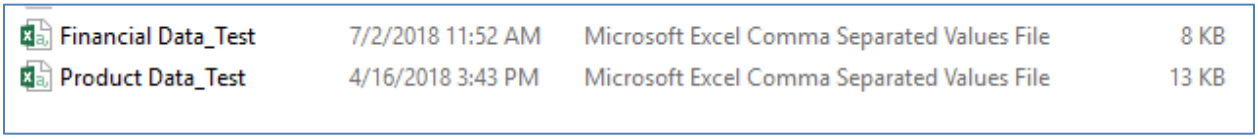
Figure 6-6: Upload Product Data Screen



2. To upload data, click on the **Browse…** button.

   The file directory opens, as shown in Figure 6-7.

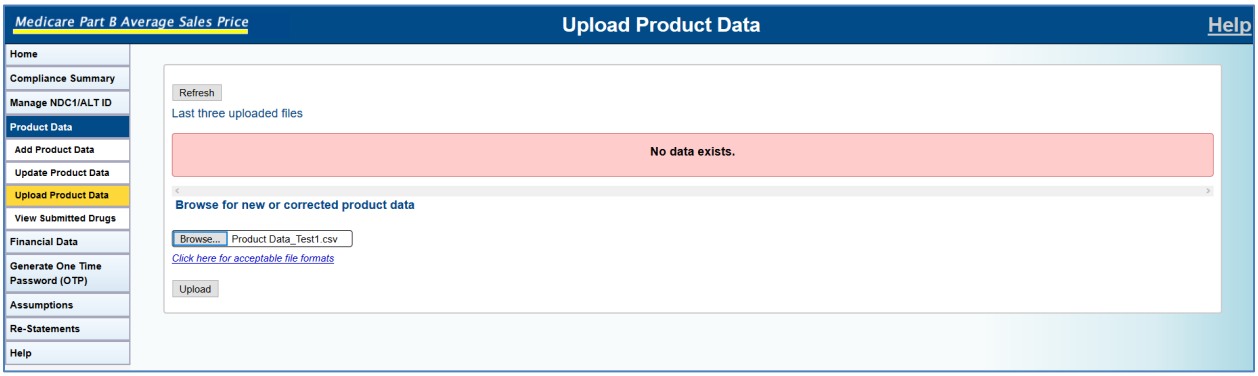
Figure 6-7: File Directory Window



3. Select a file and double-click on it.

   The “Browse…” field is populated, as shown in Figure 6-8.

Figure 6-8: Upload Product Data Browse Field Populated

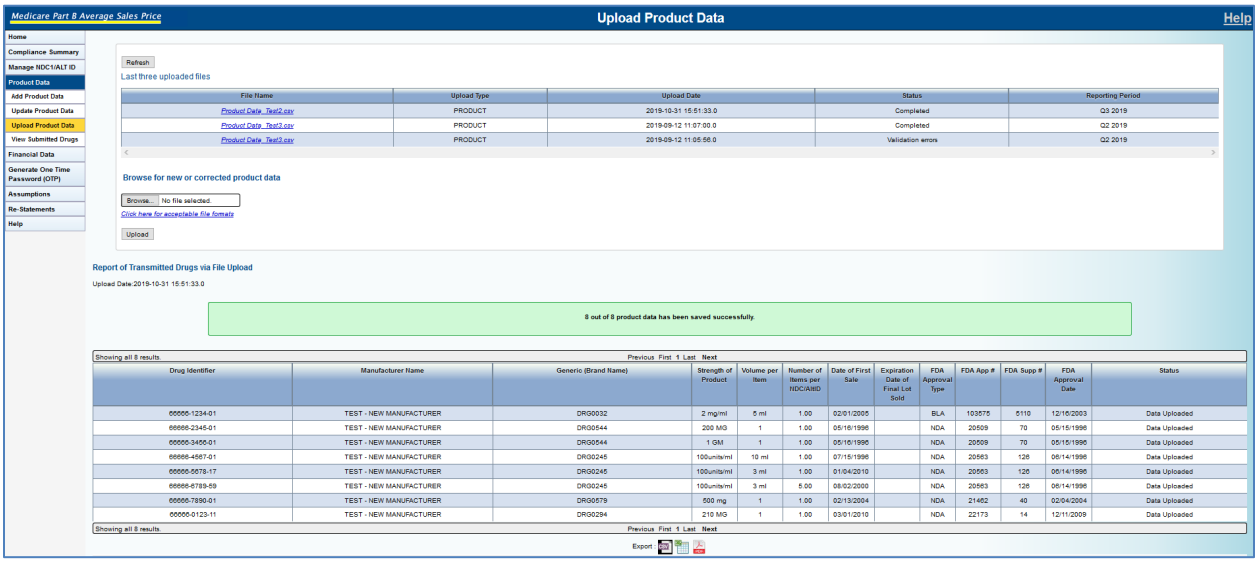


4. Click on the **Upload** button.

   A message displays confirming that the product data were saved successfully, and the drug data are listed, as shown in Figure 6-9.

   Note: ASP offers a “Refresh” button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say “Processing.” If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say “Completed.”

Figure 6-9: Upload Product Data Saved Successfully

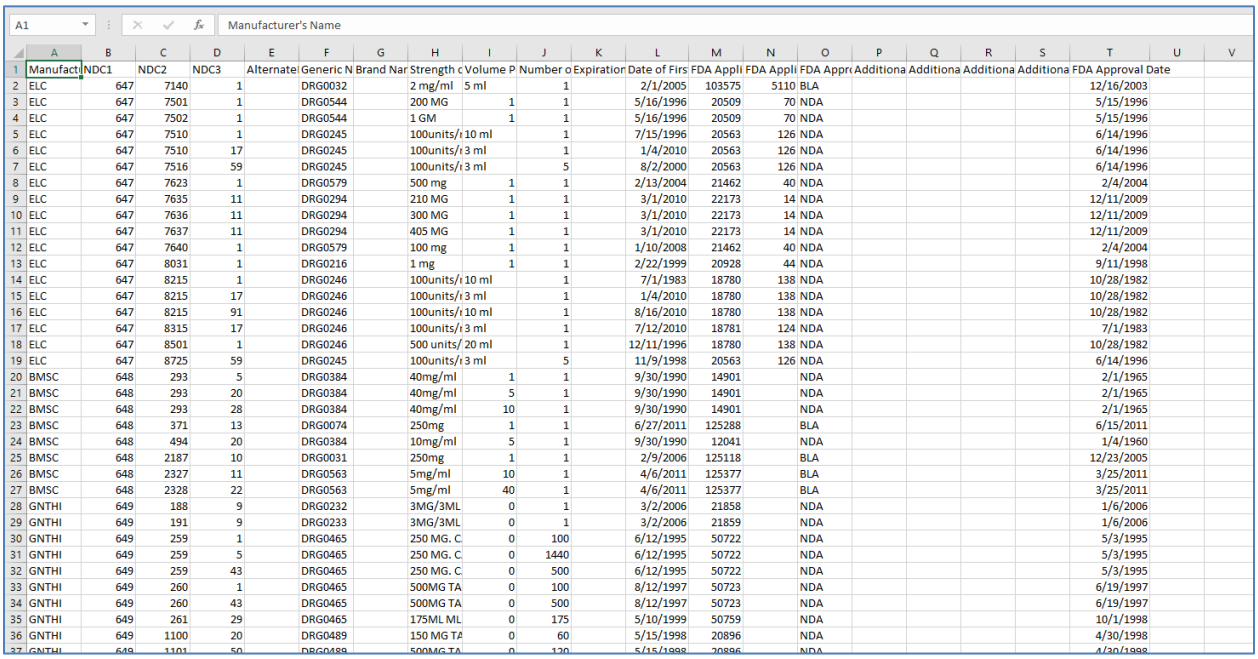


Note: Errors will be displayed in the “Status” column detailing what you will have to change in the Upload File.

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 0. To be certain of file column formatting, click on the “Click here for acceptable file formats” link, or follow the criteria below.

5. Open the “Upload Product” file, as shown in Figure 6-10.

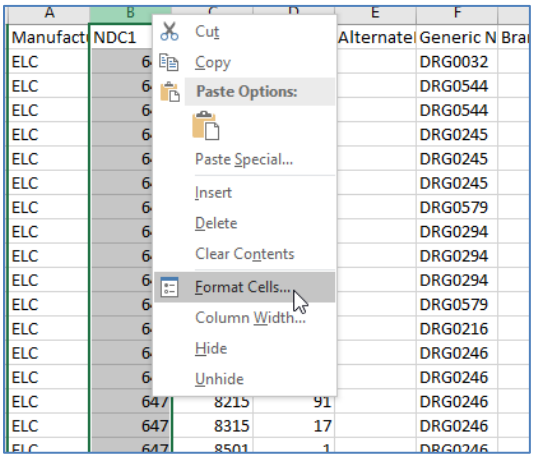
Figure 6-10: Upload Product File



6. To reformat a column, right-click on a column header.

   The “Column Editing” dropdown displays, as shown in Figure 6-11.

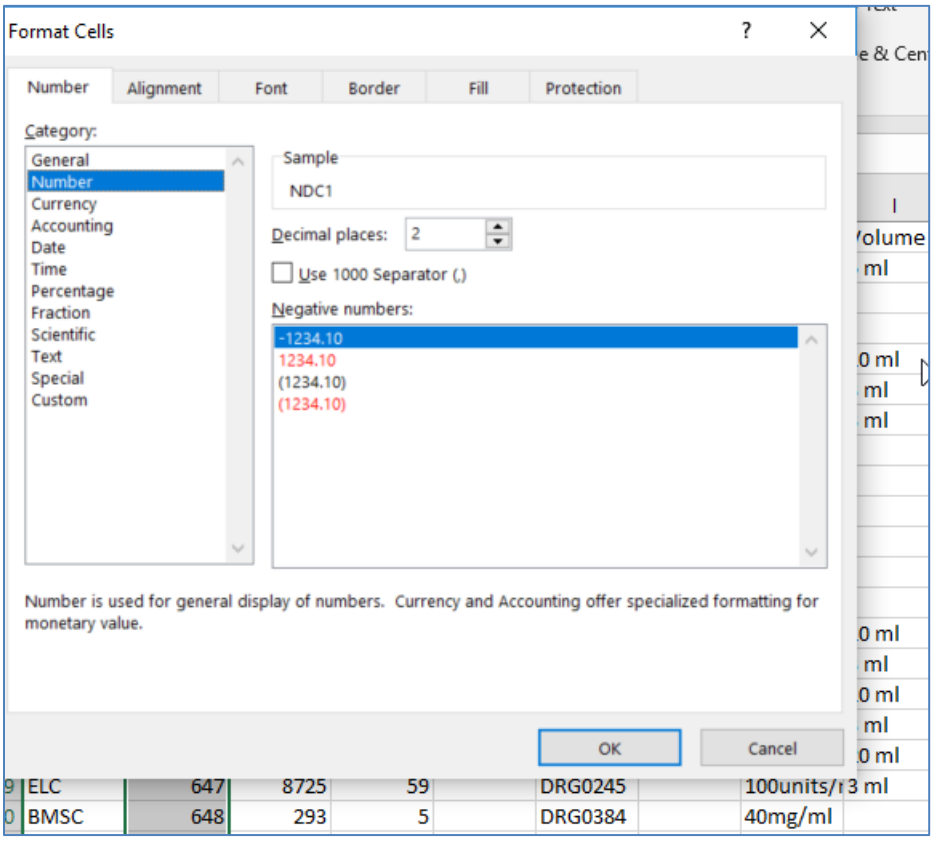
Figure 6-11: Upload Product Data Column Editing Dropdown



7. Select “Format Cells.”

   The “Format Cells” window displays, as shown in Figure 6-12.

Figure 6-12: Upload Product Data Format Cells Window

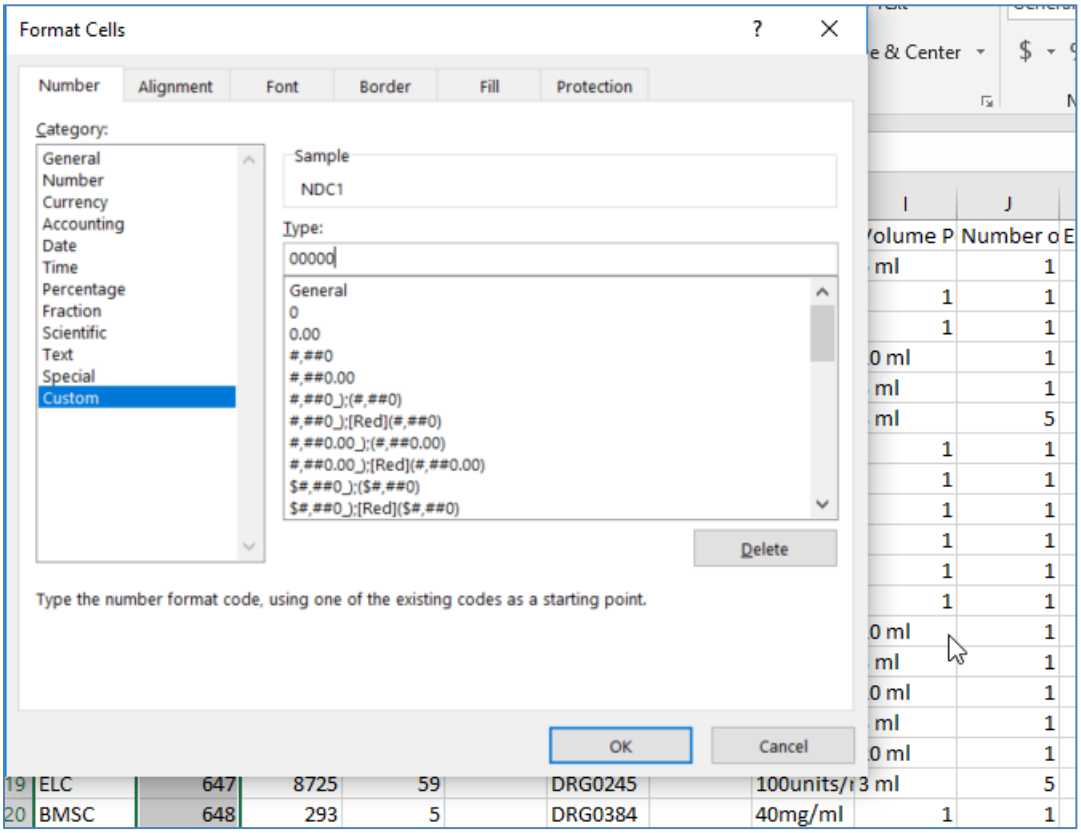


8. Make the following changes according to the below criteria:

Note: For NDC1, NDC2, and NDC3 columns, select “Number” and then “Custom.”

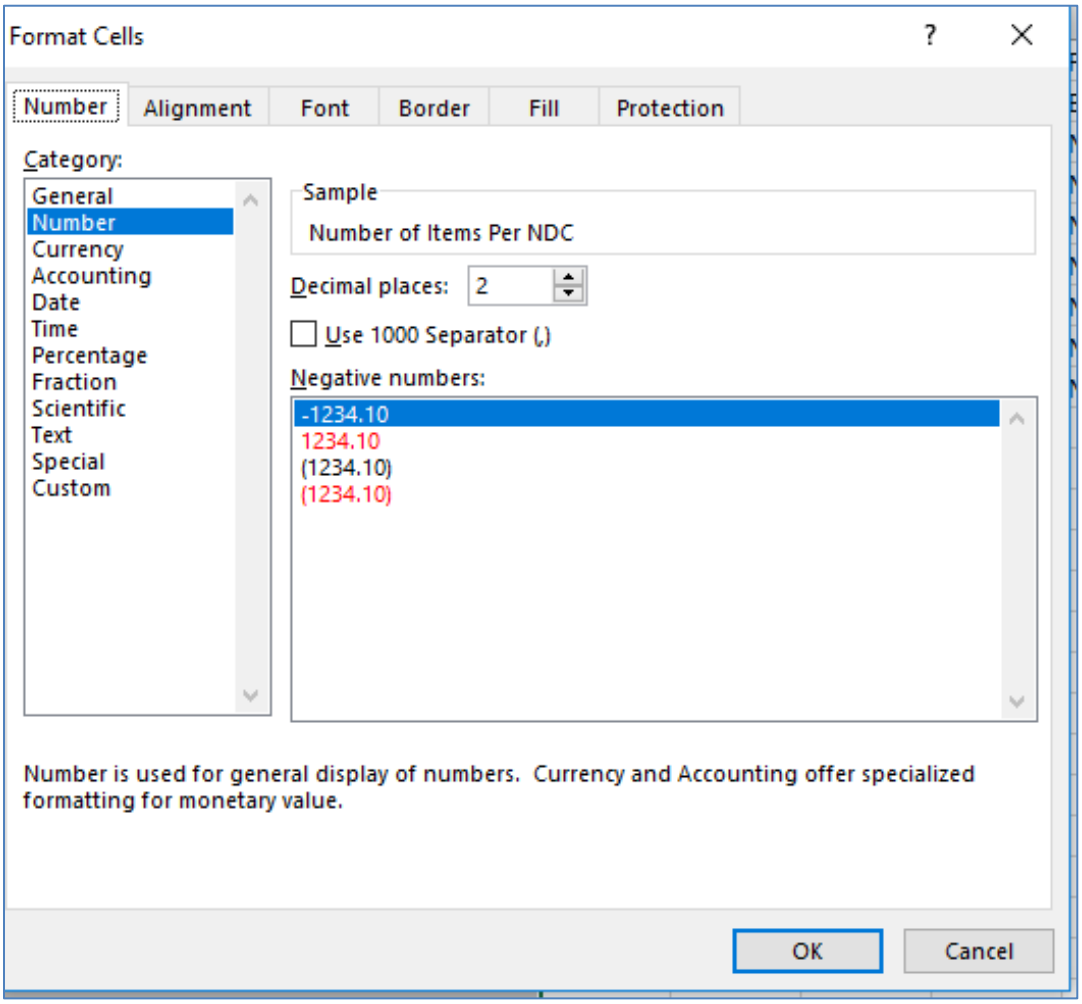
- NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 6 for any other column changes
- NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 6 for any other column changes
- NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 6 for any other column changes

Figure 6-13: Upload Product Data Format Cells Custom Editing Example



Note: For the Number of Items Per NDC column, select “Number” ensure the “Decimal places” field is set to 2, and then click on the **OK** button. Repeat from Step 6 for any other column changes, as shown in Figure 6-14.

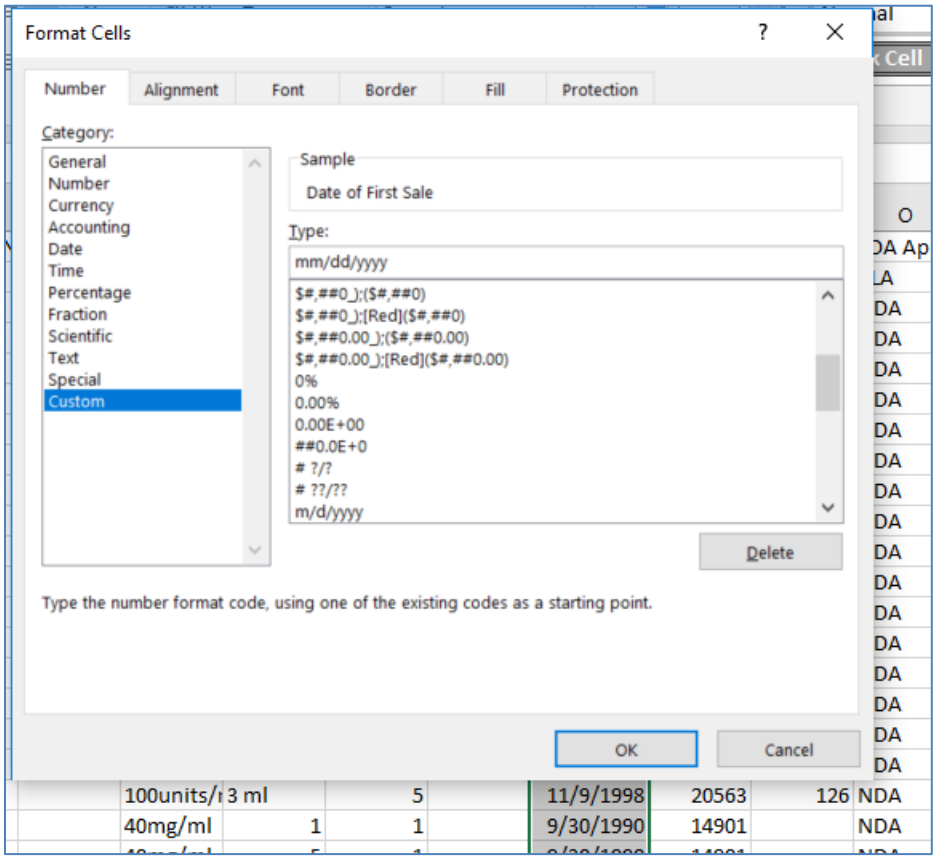
Figure 6-14: Upload Product Data Format Cells Custom Editing Example



Note: For the Expiration Date, Date of First Sale, and FDA Approval Date columns, select “Date” and then “Custom.”

- Expiration Date of Final Lot Sold: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes
- Date of First Sale: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes
- FDA Approval Date: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes

Figure 6-15: Upload Product Data Format Cells Date Custom Editing Example



9. Save the file and go back to Step 2.

   Note: Be sure that you do NOT change any of the column headers, as that will invalidate the upload.

   Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 0 through 8 again, before you resave the file.

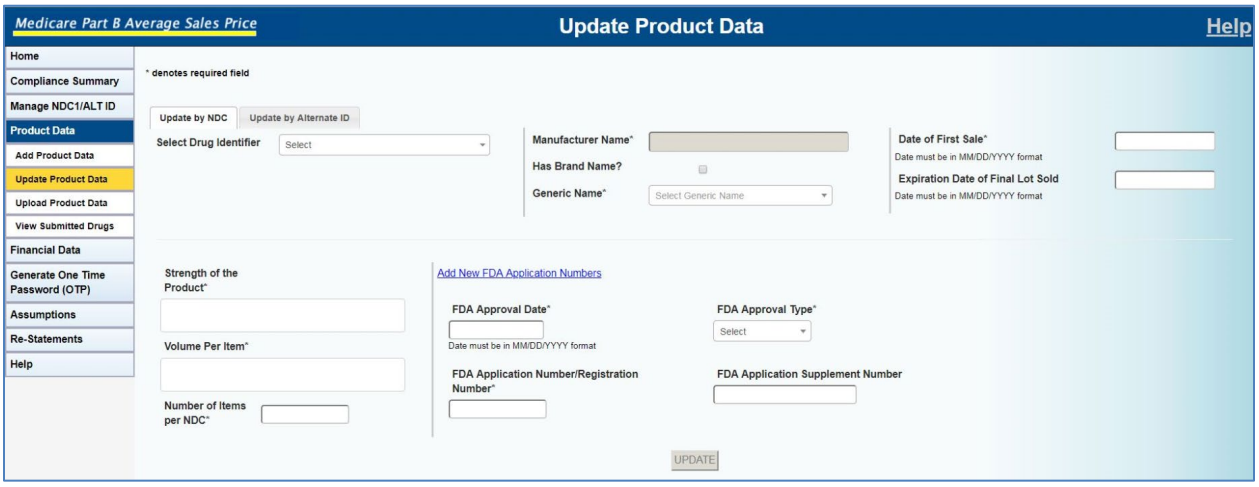
6.3 Update Product Data

Update Product Data allows drug manufacturers the ability to update drug product data to CMS.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Update Product Data**.

   The “Update Product Data” screen displays with the current reporting period showing, as shown in Figure 6-16.

Figure 6-16: Update Product Data Screen



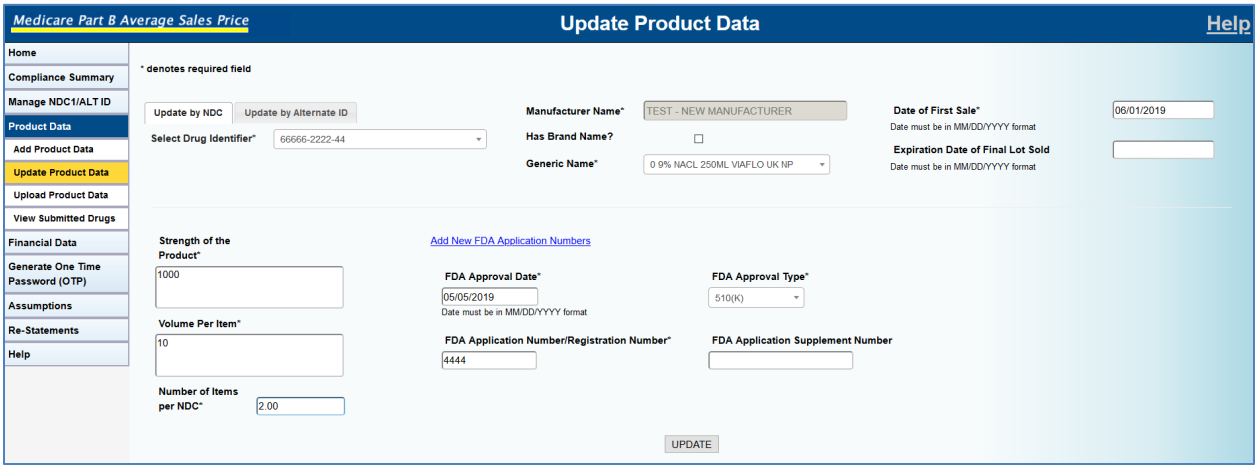
2. To update fields by NDC, select the “Update by NDC” tab.

   Note: To update fields by Alternate ID, go to step 6.

3. Select Drug Identifier: dropdown menu
   required

   All of the fields automatically populate, as shown in Figure 6-17.

Figure 6-17: Update Product Data Screen, Update by NDC Tab Fields Populated



4. Make any updates using the following criteria.

   Has Brand Name?: checkbox
   optional

   Brand Name: field is only displayed if the “Has Brand Name?” box is checked
   required if “Has Brand Name?” box is checked
   limited to 250 characters

   Generic Name: dropdown list
   required

New Generic Name: displayed only if selecting “Add New Generic Name” from the “Generic Name” dropdown list
required
limited to 250 characters

Date of First Sale: MM/DD/YYYY format
required
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per NDC: numeric
required
limited to 9 digits and 2 decimal places

FDA Approval Date: required
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: required
alphanumeric
up to 10 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

FDA Approval Type: required
dropdown list

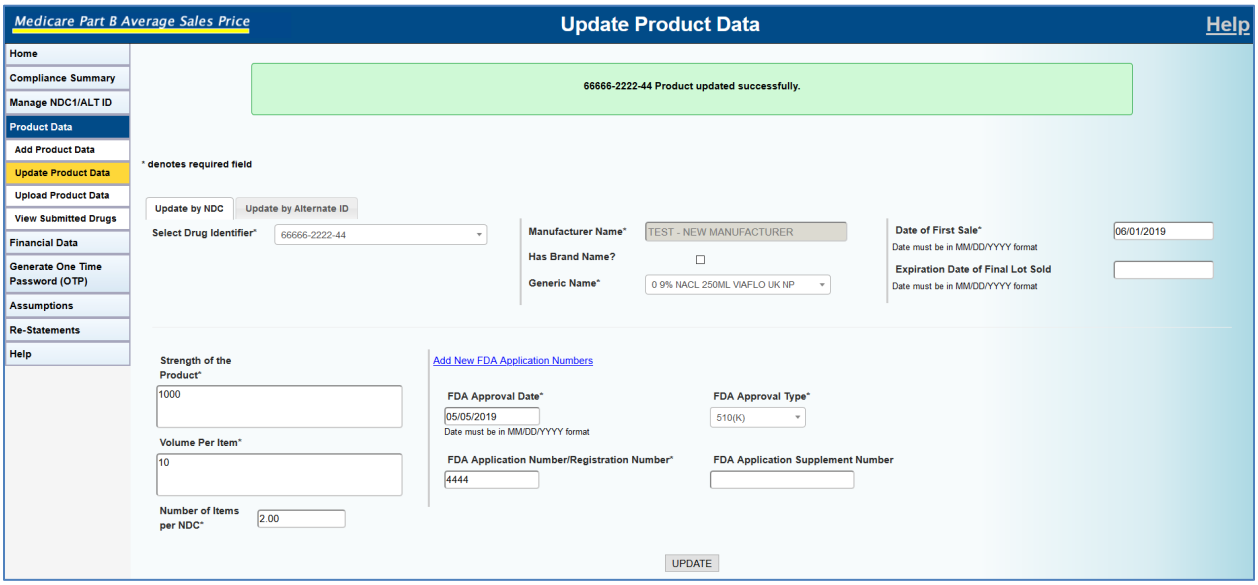
FDA Application Supplement Number: optional
alphanumeric
up to 9 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The fields populate with the entered data.

5. Click on the **UPDATE** button.

   The screen displays the confirmation that the product submission has been saved, as shown in Figure 6-18.

Figure 6-18: Update Product Data Screen – Update by NDC Saved Successfully



6. To update fields by Alternate ID, select the “Update by Alternate ID” tab, select an alternate ID from the dropdown list, and use the following requirements:

   Has Brand Name?: checkbox
   optional

   Brand Name: field is only displayed if “Has Brand Name?” box is checked
   required if “Has Brand Name?” box is checked
   limited to 250 characters

   Generic Name: dropdown list
   required

   New Generic Name: only displayed when selecting “Add New Generic Name” from the “Generic Name” dropdown list
   required
   limited to 250 characters

   Date of First Sale: MM/DD/YYYY format
   required
   cannot occur before the FDA approval date
   must occur prior to the “Current Reporting Period” start date

   Expiration Date of Final Lot Sold: MM/DD/YYYY format
   optional

   Strength of the Product: required
   limited to 500 characters

   Volume Per Item: required
   limited to 250 characters

Number of Items per Alternate ID: numeric
required
up to 9 digits and 2 decimal places

FDA Approval Date: optional
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: optional
alphanumeric
up to 10 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

FDA Approval Type: optional
dropdown list

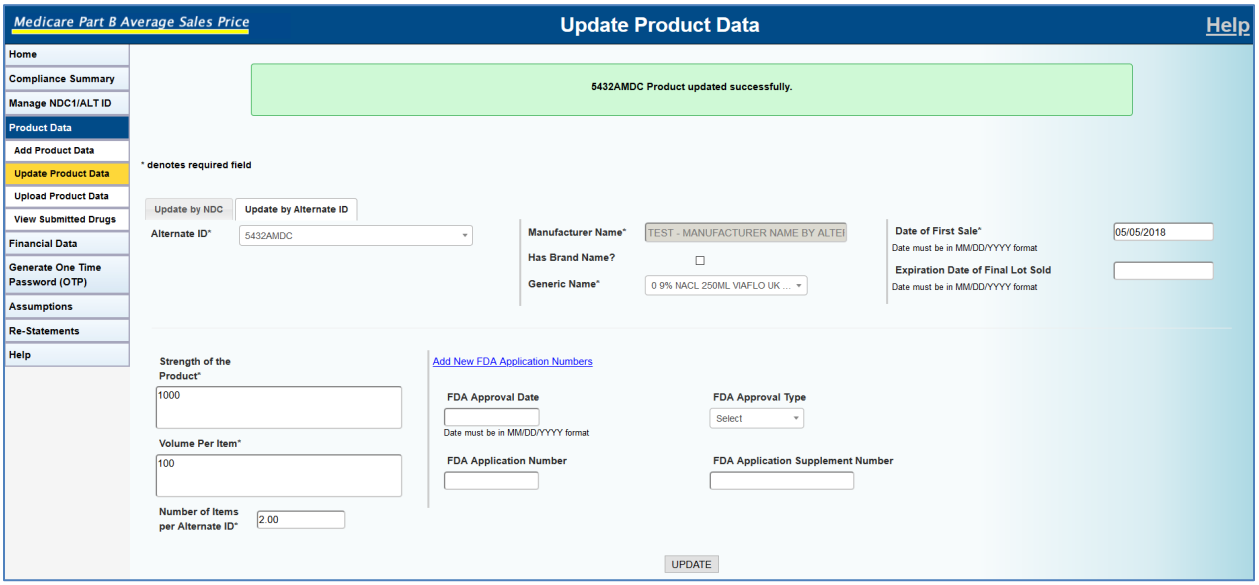
FDA Application Supplement Number: optional
alphanumeric
up to 9 characters
can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The fields populate with the entered data.

7. Click on the **UPDATE** button.

   The screen displays the confirmation that the product submission has been saved, as shown in Figure 6-19.

Figure 6-19: Update Product Data Screen – Update by Alternate ID Updated Successfully



6.4 View Submitted Drugs

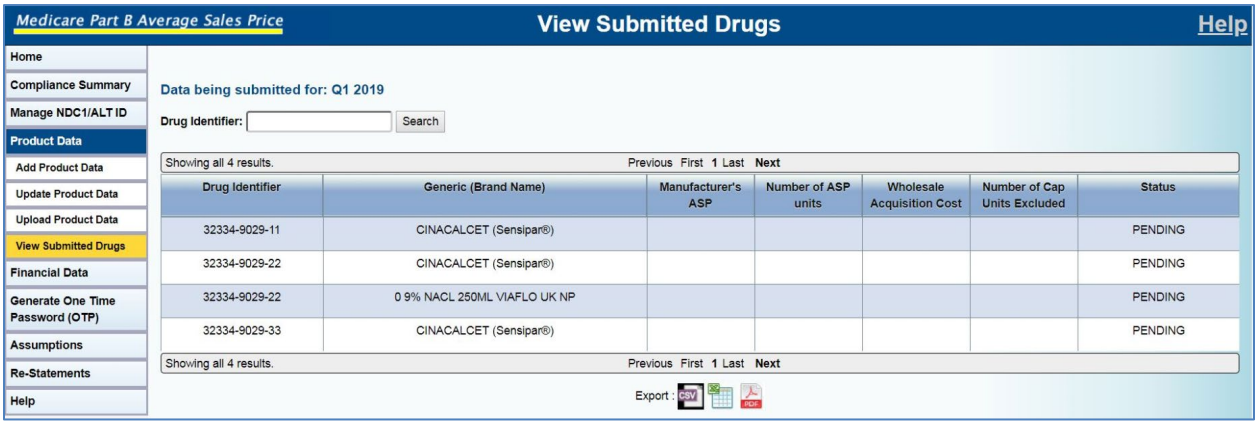
Drug manufacturers have the ability to view drug data that have been submitted during the current reporting period. Drug manufacturers cannot update or edit drug data using this feature.

Perform the following steps to view submitted drug data:

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **View Submitted Drugs**.

   The "View Submitted Drugs" window displays, as shown in Figure 6-20.

Figure 6-20: View Submitted Drugs Screen



This can be used to scroll through the list of drugs displayed on the "View Submitted Drugs" page in order to view submitted drug data and status. This can also be used to enter the "Drug Identifier" field and click on the **Search** button to filter the results to view a particular drug's data, using either a full or partial search of the drug identifier.

7. Financial Data

Drug manufacturers are required to submit quarterly drug data to the ASP application for ASP pricing using a file transfer process or through online data entry. Drug data consists of product data and financial data. The following subsections detail the steps required to submit drug financial data using online data entry and through approved file uploads

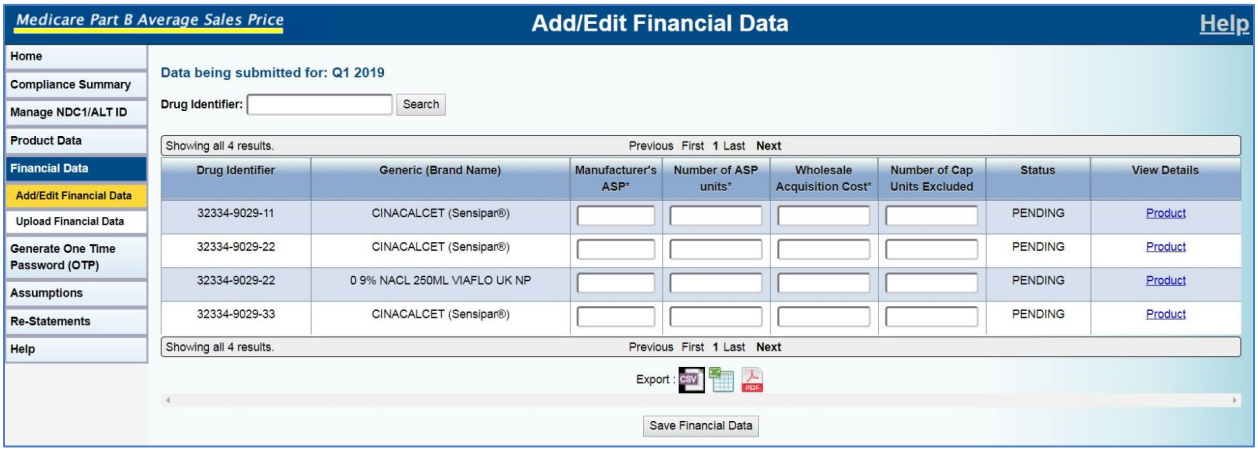
7.1 Add/Edit Financial Data

The ASP application provides the drug manufacturer the ability to submit Medicare Part B drug financial data to CMS. Perform the following steps to add drug financial data manually using the online data entry process. To upload financial data for multiple drugs at once from a file, skip to section 7.2.

1. Click on **Financial Data** from the menu on the left side of the screen, and then click on **Add/Edit Financial Data**.

   The “Add/Edit Financial Data” page displays a listing of the drugs, as shown in Figure 7-1.

Figure 7-1: Add/Edit Financial Data Screen



2. Scroll through the list of drugs displayed on the “Add/Edit Financial Data” page in order to locate the drug(s) needing financial data added or updated, or enter the drug identifier in the “Drug Identifier” field, and click on the **Search** button to filter the results.
3. Enter the Manufacturer’s ASP, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded in the respective fields, using the following criteria:

   Manufacturer’s ASP: numeric
   Must have three decimal places (i.e., XXXXXXXXXX.XXX).
   can be a positive number, a negative number, or be equal to 0.000

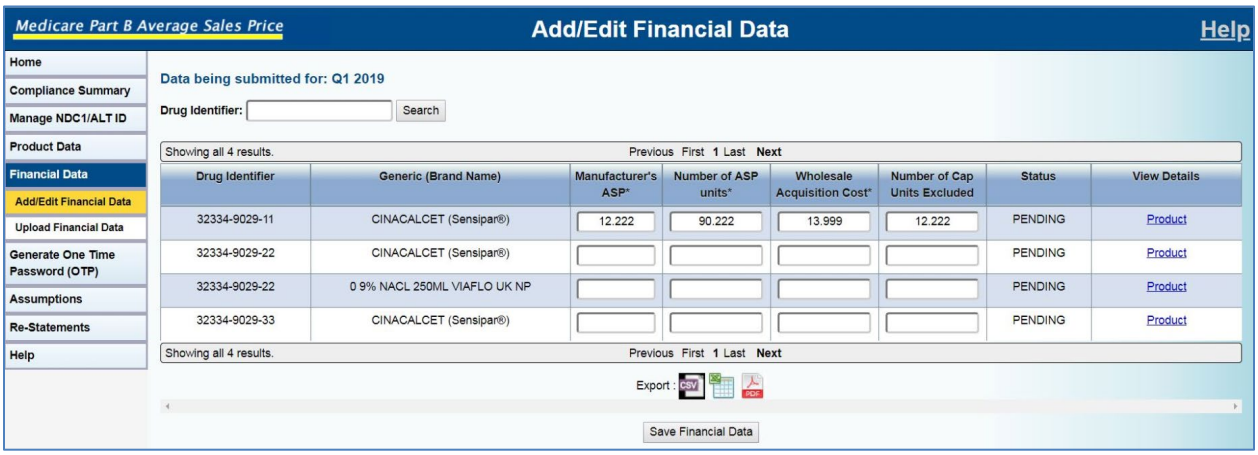
   Number of ASP units: numeric
   must have three decimal places (i.e., XXXXXXXXX.XXX).
   can be a positive number, a negative number, or be equal to 0.000

Wholesale Acquisition Cost: numeric
must have three decimal places (i.e., XXXXXXXXX.XXX).
can be a positive number, a negative number, or be equal to 0.000

Number of Cap Units Excluded: optional
numeric
must have three decimal places (i.e., XXXXXXXXX.XXX).
can be a positive number or be equal to 0.000

The fields populate, as shown in Figure 7-2.

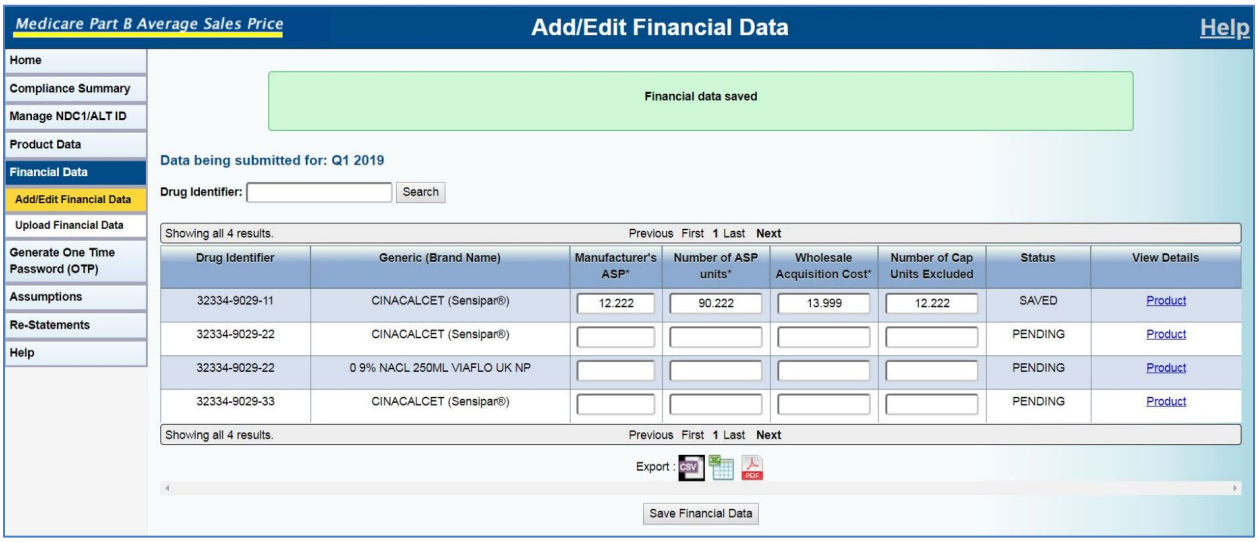
Figure 7-2: Add/Edit Financial Data Screen – Fields Populated



4. Click on the **Save Financial Data** button to add/update the Drug Identifier financial data.

   A message displays indicating that the Drug Identifier financial data have been saved to the ASP application and the status of the drug changes from “PENDING” to “SAVED,” as shown in Figure 7-3.

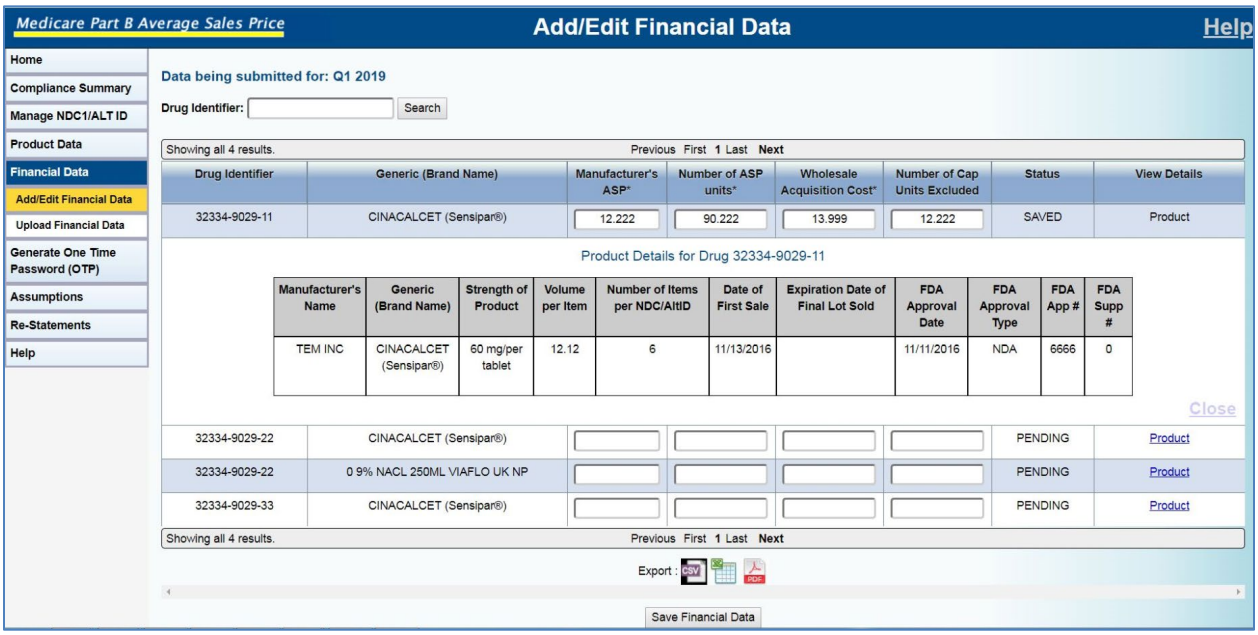
Figure 7-3: Add/Edit Financial Data Screen – Financial Data Saved



5. To view the product data for the Drug Identifier, click on the “Product” link in the “View Details” tab.

   The product data for the selected financial data display, as shown in Figure 7-4.

Figure 7-4: Add/Edit Financial Data Screen – Selected Financial Data



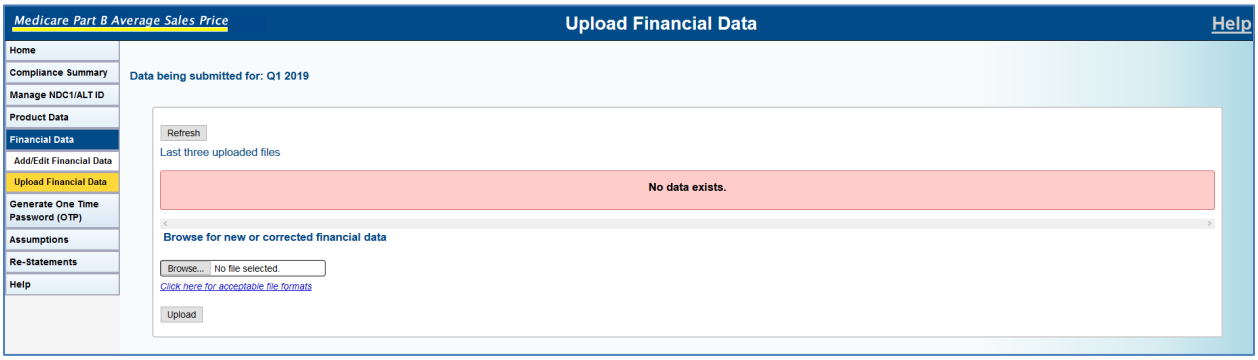
7.2 Upload Financial Data

ASP provides the drug manufacturer the ability to submit Medicare Part B financial data to CMS. Perform the following steps to upload drug financial data using the file transfer process.

1. Click on **Financial Data** from the menu on the left side of the screen, and then click on **Upload Financial Data**.

The “Upload Financial Data” screen displays, as shown in Figure 7-5.

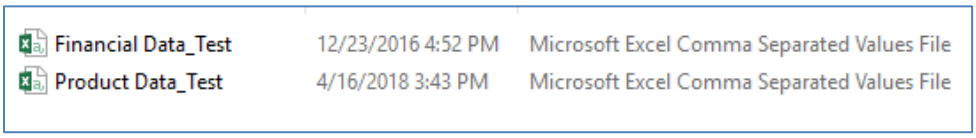
Figure 7-5: Upload Financial Data Screen



2. To upload data, click on the **Browse…** button.

   The file directory opens, as shown in Figure 7-6.

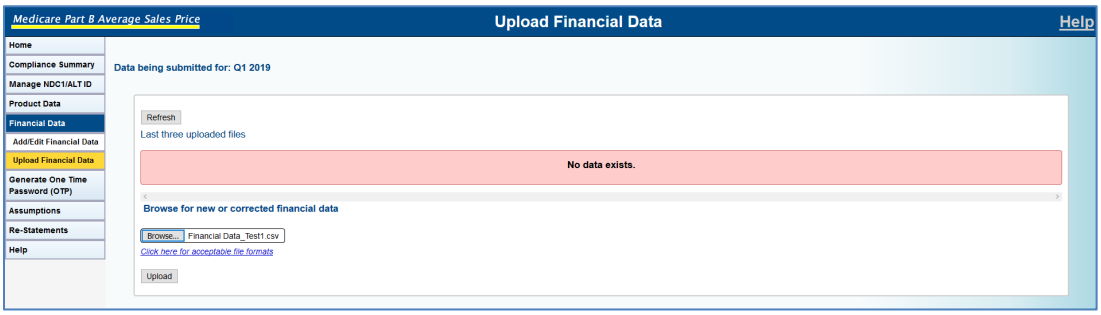
Figure 7-6: File Directory Window



3. Select a file and double-click on it.

   The “Browse…” field is populated, as shown in Figure 7-7.

Figure 7-7: Upload Financial Data Browse Field Populated

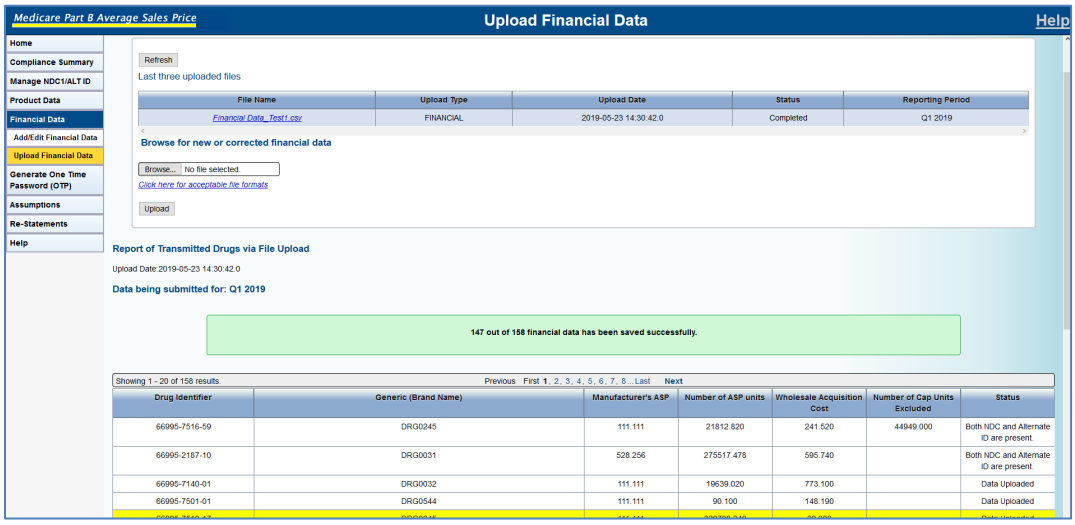


4. Click on the **Upload** button.

   A message displays confirming that the financial data were uploaded successfully, and the drug financial data are listed, as shown in Figure 7-8.

   Note: ASP offers a “Refresh” button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say “Processing.” If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say “Completed.”

Figure 7-8: Upload Financial Data Saved Successfully

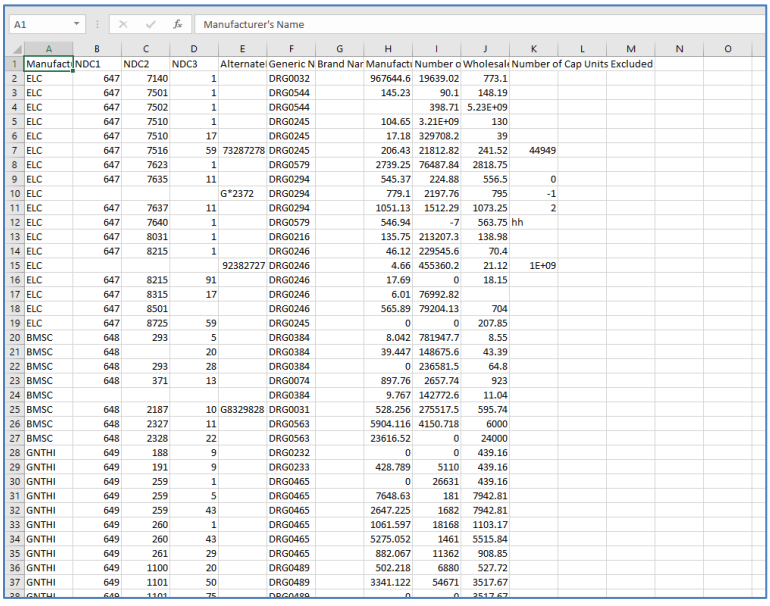


Note: Errors will be displayed in the “Status” column detailing what you will have to change in the Upload File.

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 5. To be certain of file column formatting, click on the “Click here for acceptable file formats” link, or follow the criteria below.

5. Open the “Upload Financial” file, as shown in Figure 7-9.

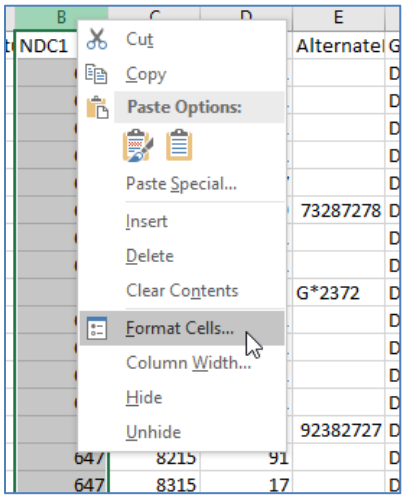
Figure 7-9: Upload Financial Data File



6. To reformat a column, right-click on a column header.

   The “Column Editing” dropdown displays, as shown in Figure 7-10.

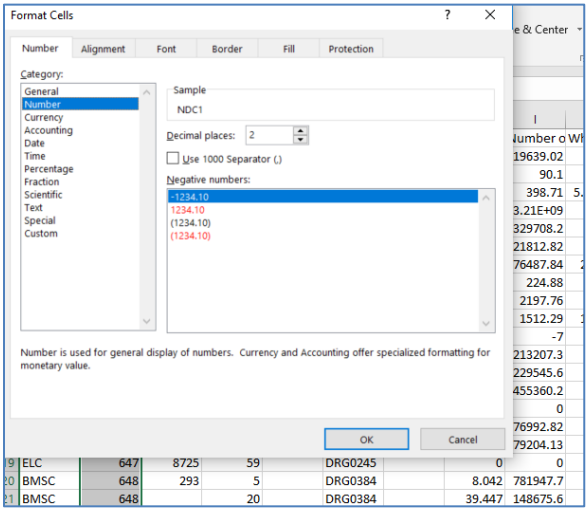
Figure 7-10: Upload Financial Data Column Editing Dropdown



7. Select “Format Cells.”

   The “Format Cells” window displays, as shown in Figure 7-11.

Figure 7-11: Upload Financial Data Format Cells Number Editing

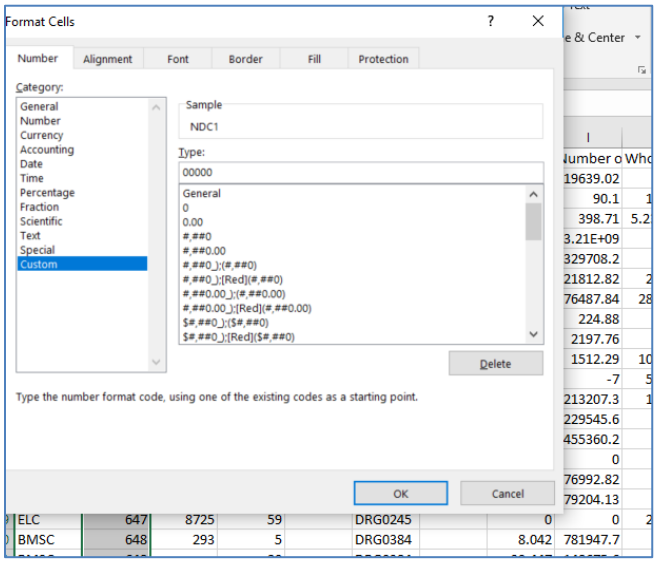


8. Make the following changes in the “Type” field according to the below criteria:

   Note: For NDC1, NDC2, and NDC3 columns, select “Number” and then “Custom.”

   - NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 7 for any other column changes
   - NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 7 for any other column changes
   - NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 7 for any other column changes

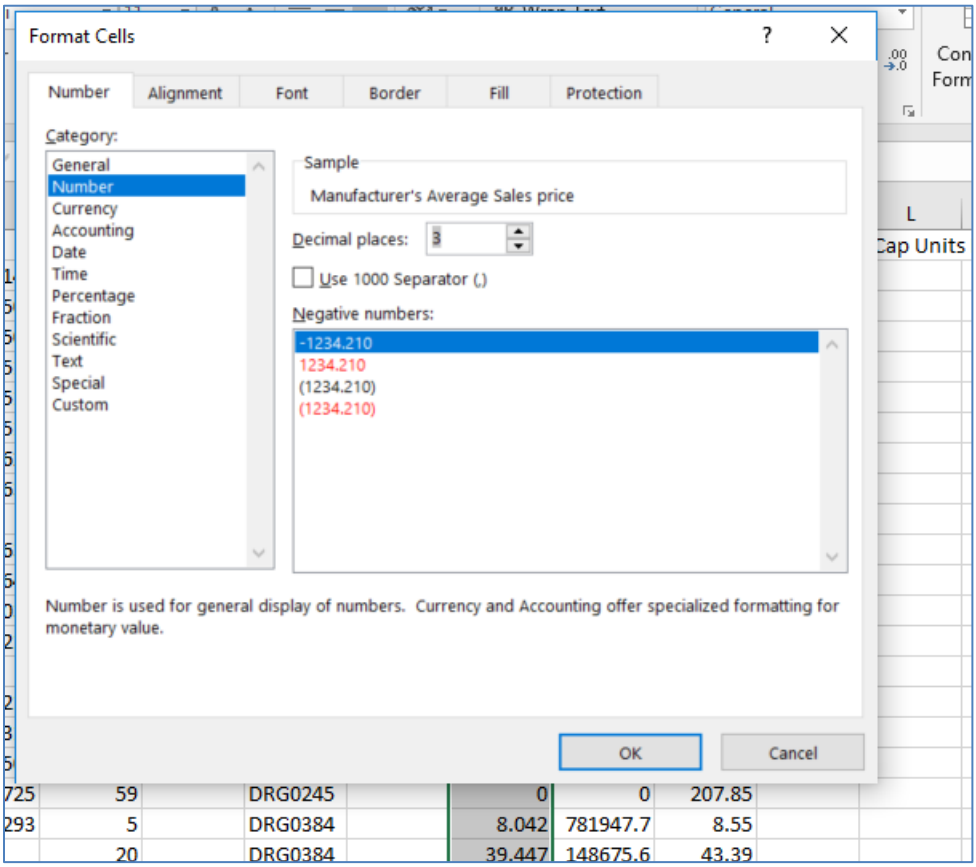
Figure 7-12: Upload Financial Data Format Cells Number Custom Editing Example



Note: For Manufacturer's Average Sales Price, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded, select "Number."

- Manufacturer's Average Sales Price: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of ASP Units: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes
- Wholesale Acquisition Cost: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of CAP Units Excluded: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes

Figure 7-13: Upload Financial Data Format Cells Number Editing Example



9. Save the file and go back to Step 2.

   Note: Be sure that you do NOT change any of the column headers, as that will invalidate the upload.

   Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 6 through 8 again, before you resave the file.

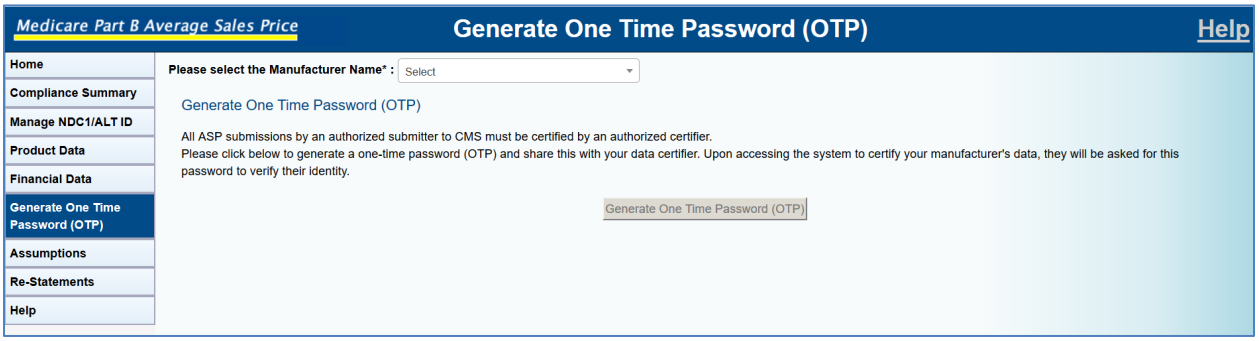
8. Generate One Time Password (OTP) - Submitter

Once the ASP Submitter successfully enters all the Product and Financial Data for the first time into the ASP application, the ASP Submitter can generate a One Time Password (OTP) for each Manufacturer Name. Once the OTP is generated, the ASP Submitter can provide the OTP to the Certifier. The OTP expires after 7 days of being generated. If the OTP expires, the ASP Submitter can generate another OTP and once again provide the OTP to the ASP Certifier. There can only be one active Certifier for a manufacturer. If the Certifier changes, the Submitter has to share a new OTP with the new Certifier.

1. Click on **Generate One Time Password (OTP)** from the menu on the left side of the screen.

   The “Generate One Time Password (OTP)” screen displays, as shown in Figure 8-1.

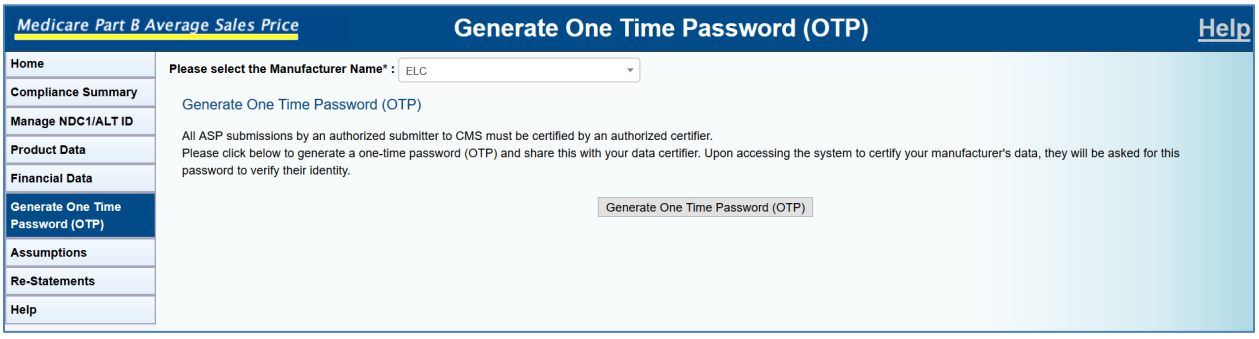
Figure 8-1: Generate One Time Password (OTP) Screen



2. Select a Manufacturer name from the “Please select the Manufacturer Name*:” dropdown list.

   The selected Manufacturer populates in the field, as shown in Figure 8-2.

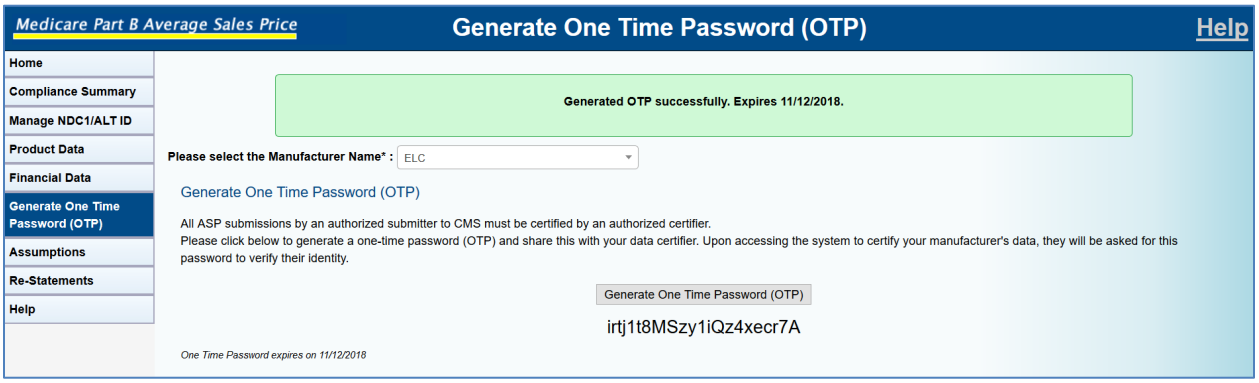
Figure 8-2: Generate OTP – Please select the Manufacturer name*: Field Populated



3. Click on the **Generate One Time Password (OTP)** button.

   The OTP displays and is available for 7 days, as shown in Figure 8-3.

Figure 8-3: OTP Generated Successfully



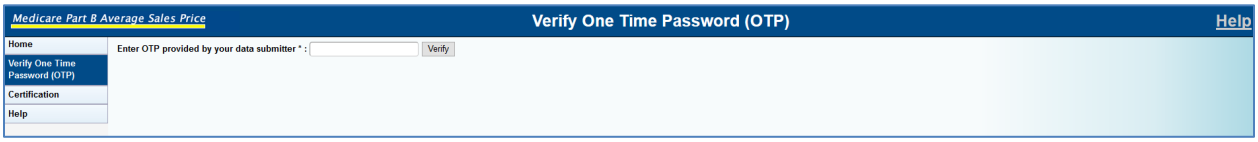
9. Verify OTP - Certifier

Once the ASP Submitter generates and provides an OTP for each Manufacturer Name to the Certifier, the Certifier must verify the OTP. The one-time password expires after 7 days of being generated. If the OTP expires, the ASP Submitter can generate another OTP and once again provide the OTP to the ASP Certifier.

1. Click on **Verify One Time Password (OTP)** from the menu on the left side of the screen.

   The “Verify One Time Password (OTP)” screen displays, as shown in Figure 9-1.

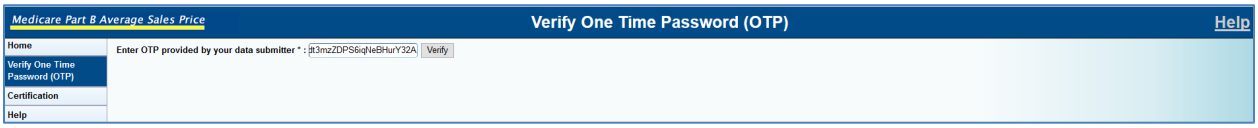
Figure 9-1: Verify One Time Password (OTP) Screen



2. Enter the OTP in the “Enter OTP provided by your data submitter*” field.

   The “Enter OTP provided by your data submitter*” field populates, as shown in Figure 9-2.

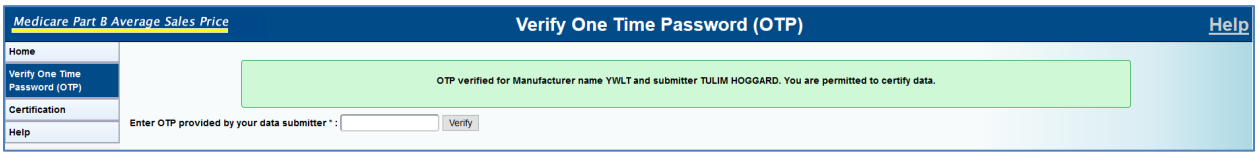
Figure 9-2: Verify OTP – Enter OTP provided by your data submitter*: Field Populated



3. Click on the **Verify** button.

   A message displays that the OTP has been verified and the data for that manufacturer are ready for certification, as shown in Figure 9-3.

Figure 9-3: Verify OTP – OTP Verified Message



10. Assumptions

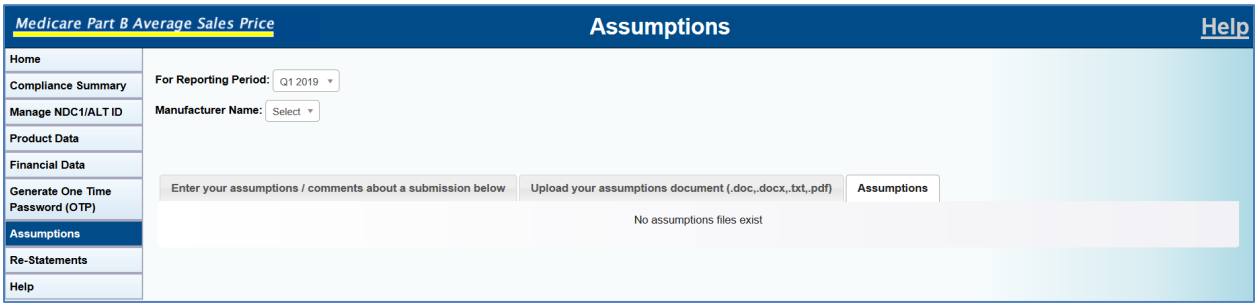
10.1 Assumptions - Submitter

Drug Manufacturers can submit comments regarding their certifications to CMS. These comments may be submitted for either the current or prior reporting periods. Perform the following steps to submit certification assumptions to CMS.

1. Begin by clicking on **Assumptions** button from the menu on the left side of the screen.

   The “Assumptions” page displays showing the current report period, as shown in Figure 10-1.

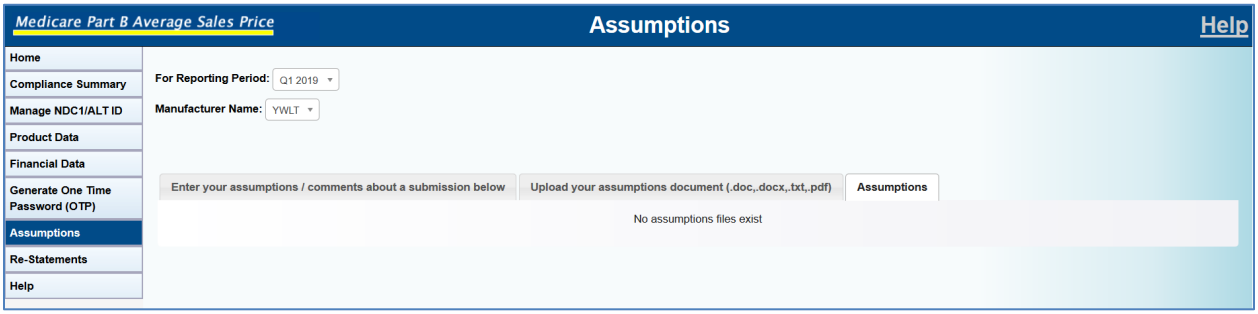
Figure 10-1: Assumptions Screen - Submitter



2. Select the desired reporting period from the “For Reporting Period” dropdown list and select the desired manufacturer name from the “Manufacturer Name” dropdown list.

   The “Assumptions” page is shown with the Manufacturer name populated, as shown in Figure 10-2.

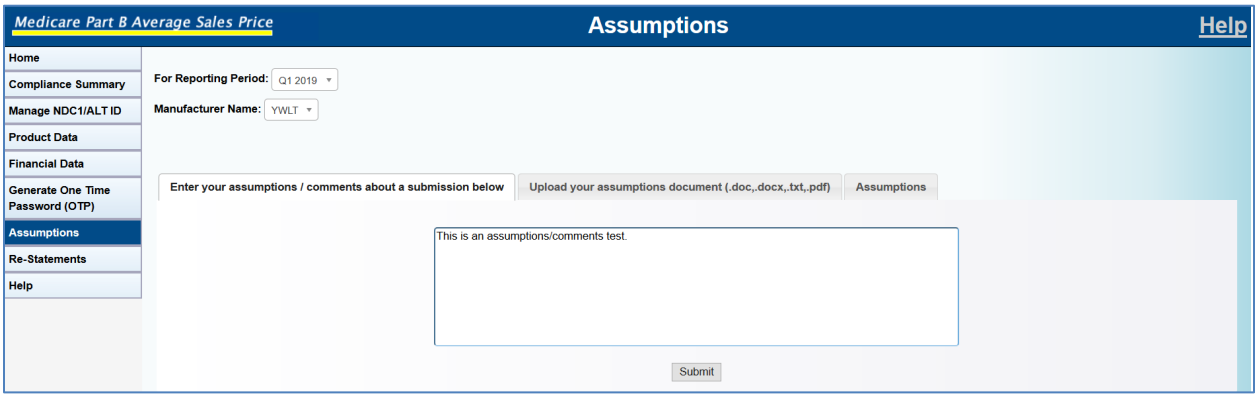
Figure 10-2: Assumptions – For Reporting Period Field Populated



3. Select the “Enter your assumptions / comments about a submission below” tab and enter your comment in the text field.

   The text field is populated, as shown in Figure 10-3.

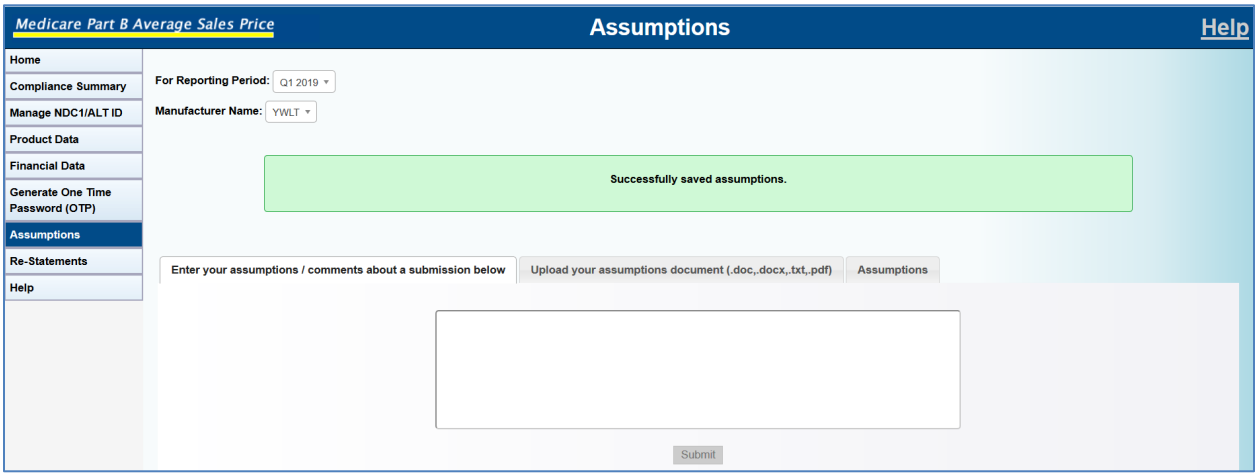
Figure 10-3: Assumptions – Comments Field Populated



4. Click on the **Submit** button.

   A message displays that the assumption has been successfully saved, as shown in Figure 10-4.

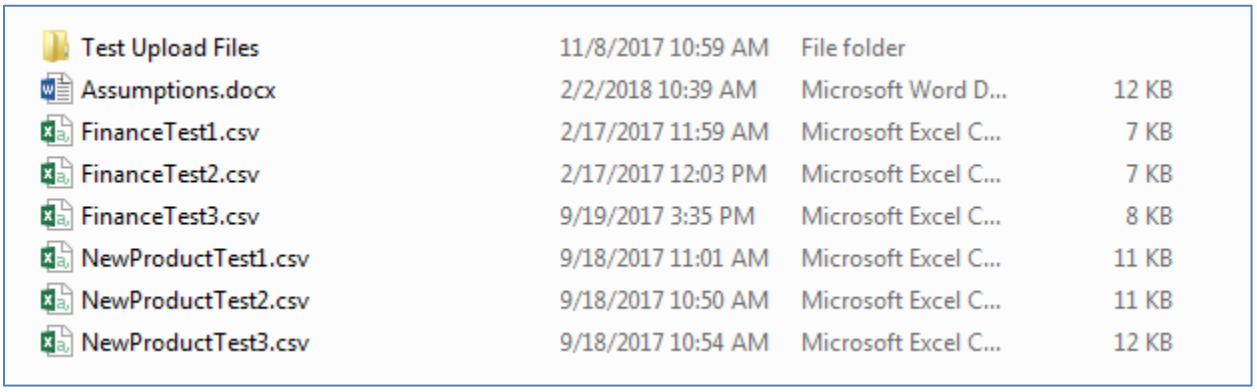
Figure 10-4: Assumptions Saved Successfully



5. To upload an assumption, select a Manufacturer Name, select the “Upload your assumptions document (.doc,.docx,.txt,.pdf)” tab, and click on the **Browse** button.

   The file directory window opens, as shown in Figure 10-5.

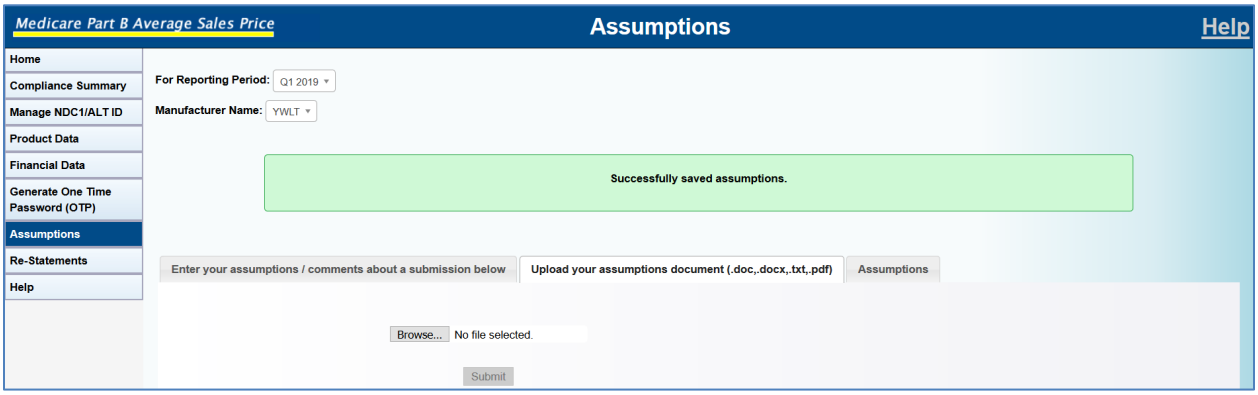
Figure 10-5: File Directory Window



6. Select the document to upload, and click on the **Submit** button.

   A message displays that the assumption has been successfully saved, as shown in Figure 10-6.

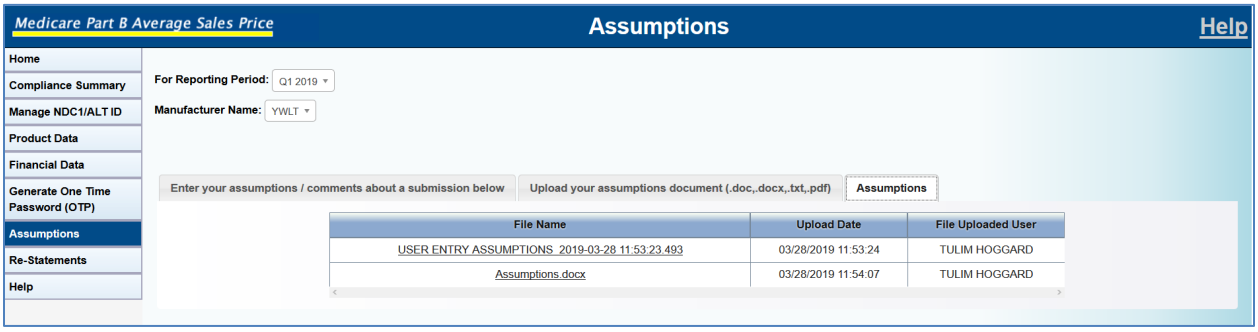
Figure 10-6: Assumptions Saved Successfully



7. To view assumptions that have been added, select a Manufacturer Name and click on the “Assumptions” tab.

   The added assumptions are listed, as shown in Figure 10-7.

Figure 10-7: Assumptions Listed



   The Assumptions can be viewed and opened by clicking the file link in the “File Name” column.

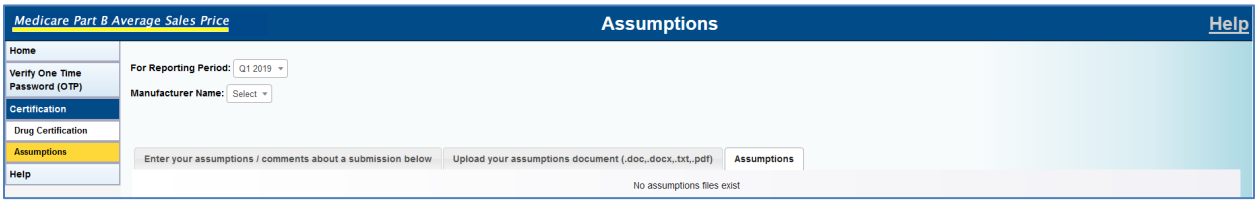
10.2 Assumptions – Certifier

Drug Manufacturers can submit comments regarding their certifications to CMS. These comments may be submitted for either the current or prior reporting periods. Perform the following steps to submit certification assumptions to CMS.

1. Begin by clicking on **Certification** from the menu on the left side of the screen, and then click on **Assumptions**.

   The "Assumptions" page displays showing the current report period, as shown in Figure 10-8.

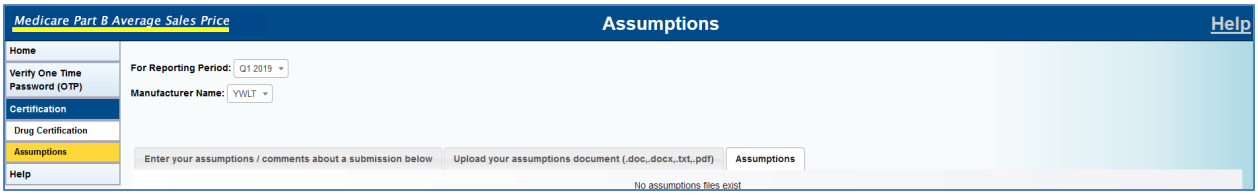
Figure 10-8: Assumptions Screen - Certifier



2. Select the desired reporting period from the "For Reporting Period" dropdown list and select the desired manufacturer name from the "Manufacturer Name" dropdown list.

   The "Assumptions" page is shown with the Manufacturer name populated, as shown in Figure 10-9.

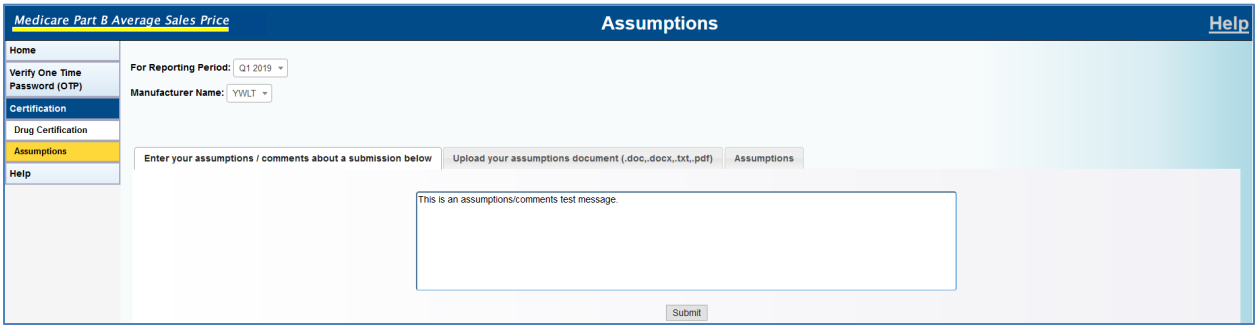
Figure 10-9: Assumptions – For Reporting Period Field Populated



3. Select the "Enter your assumptions / comments about a submission below" tab and enter your comment in the text field.

   The text field is populated, as shown in Figure 10-10.

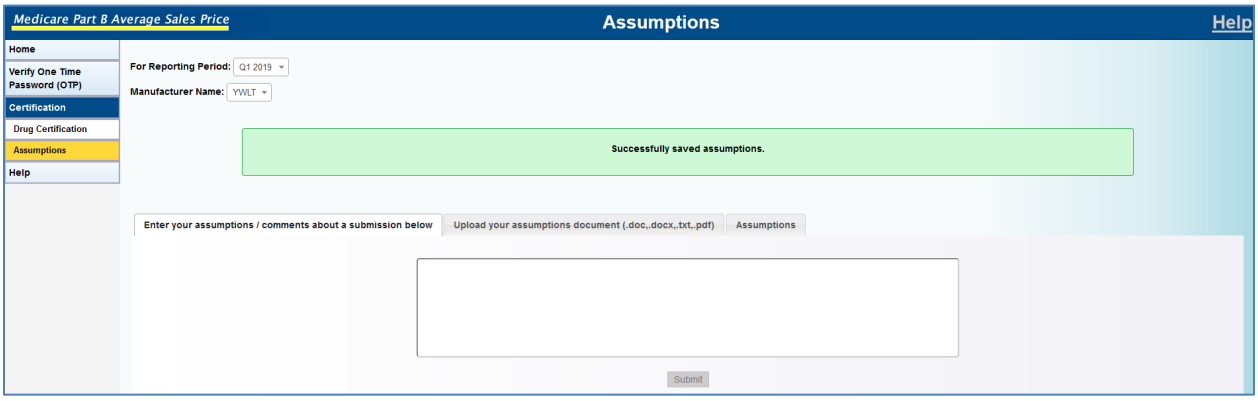
Figure 10-10: Assumptions – Comments Field Populated



4. Click on the **Submit** button.

   A message displays that the assumption has been successfully saved, as shown in Figure 10-11.

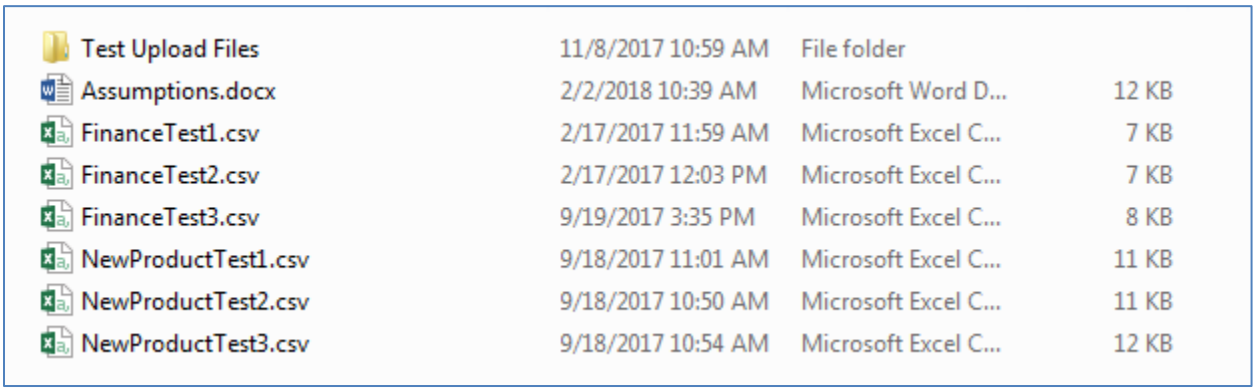
Figure 10-11: Assumptions Saved Successfully



5. To upload an assumption, select a Manufacturer Name, select the “Upload your assumptions document (.doc,.docx,.txt,.pdf)” tab, and click on the **Browse** button.

   The file directory opens, as shown in Figure 10-12.

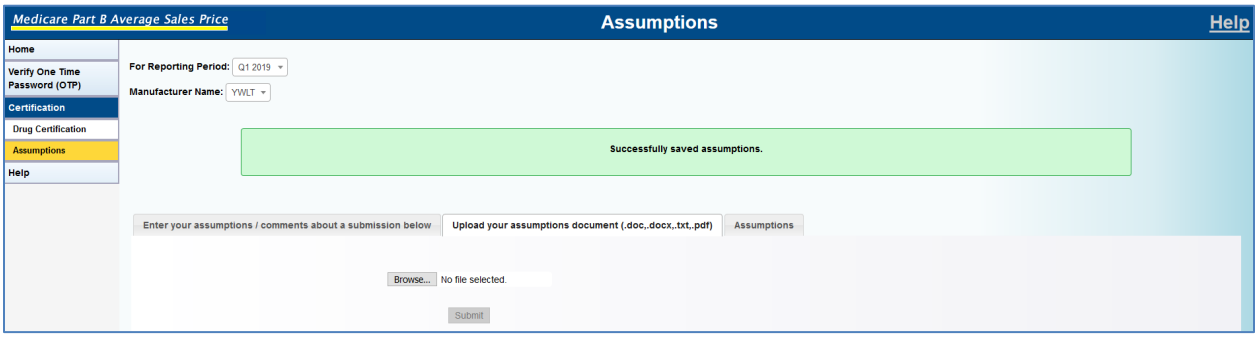
Figure 10-12: File Directory Window



6. Select the document to upload, and click on the **Submit** button.

   A message displays that the assumption has been successfully saved, as shown in Figure 10-13.

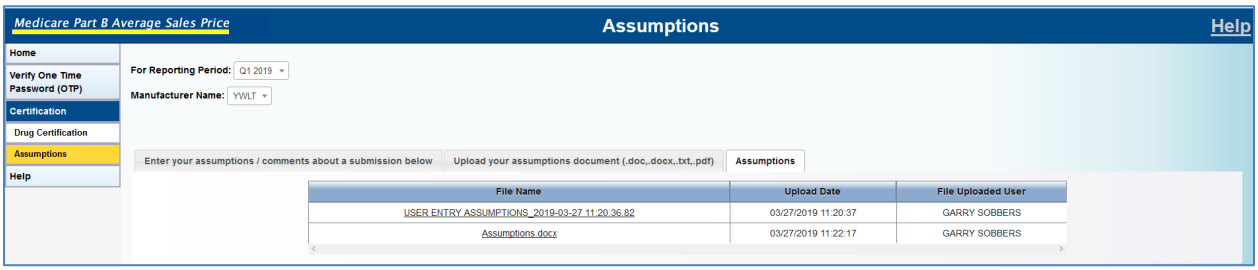
Figure 10-13: Assumptions Saved Successfully



7. To view assumptions that have been added select a Manufacturer Name and select the "Assumptions" tab.

   The added assumptions are listed, as shown in Figure 10-14.

Figure 10-14: Assumptions Listed



   The Assumptions can be viewed and opened by clicking the file link in the "File Name" column.

11. Re-Statements

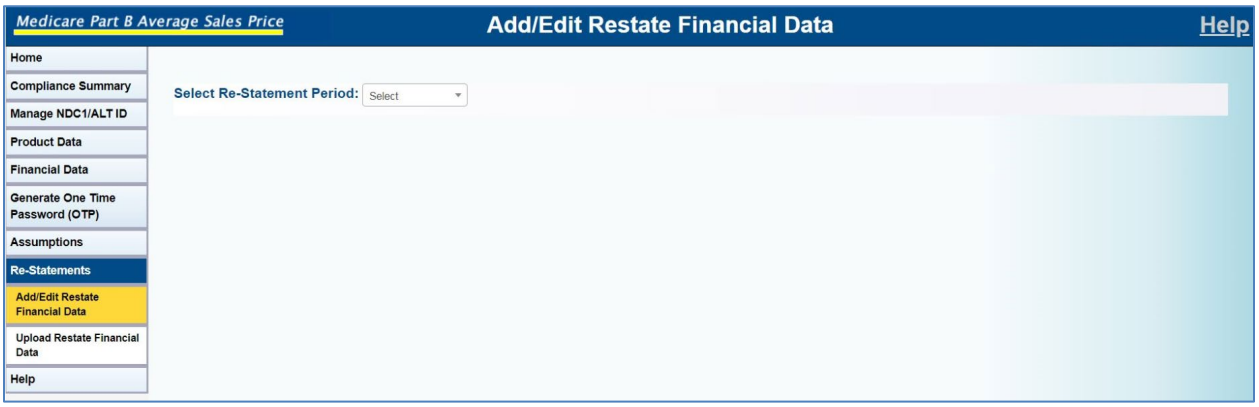
11.1 Add/Edit Restate Financial Data

The ASP application provides the drug manufacturers the ability to restate Medicare Part B drug financial data to CMS. Perform the following steps to restate the drug financial data manually using the online data entry process.

1. Click on **Re-Statements** from the menu on the left side of the screen, and then click on **Add/Edit Restate Financial Data**.

   The "Add/Edit Restate Financial Data" screen displays, as shown in Figure 11-1.

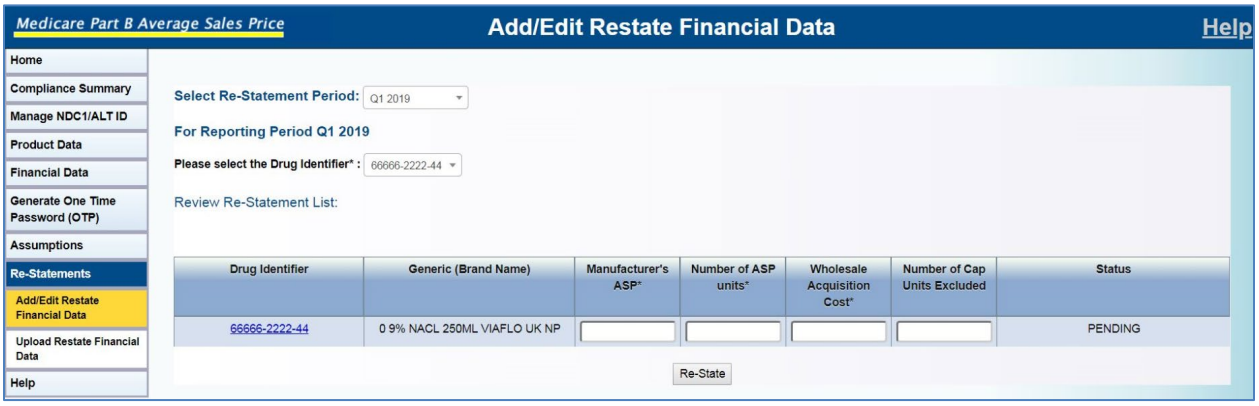
Figure 11-1: Add/Edit Restate Financial Data Screen



2. To add or edit data, select a reporting period from the dropdown menu in the "Select Re-Statement Period:" field and select a drug identifier.

   The "Select Re-Statement Period:" and "Please select the Drug Identifier*:" fields populate, as shown in Figure 11-2.

Figure 11-2: Add/Edit Restate Financial Data – Select Re-Statement Period and Drug Identifier



3. Add or edit the Manufacturer's ASP, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded in the respective fields, using the following criteria:

Manufacturer's ASP: numeric
must have three decimal places (i.e., XXXXXXXXXX.XXX).
can be a positive number, a negative number, or be equal to 0.000

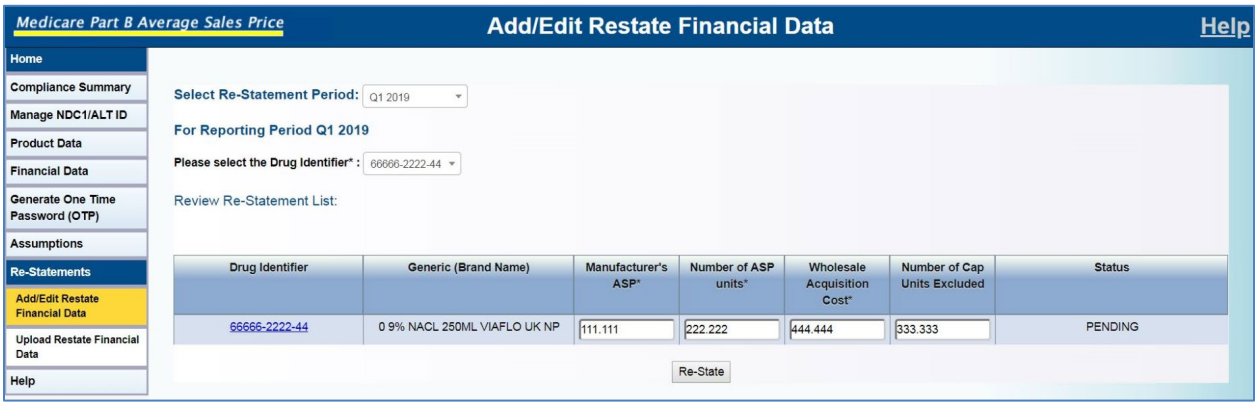
Number of ASP units: numeric
must have three decimal places (i.e., XXXXXXXXX.XXX).
can be a positive number, a negative number, or be equal to 0.000

Wholesale Acquisition Cost: numeric
must have three decimal places (i.e., XXXXXXXXXX.XXX).
can be a positive number, a negative number, or be equal to 0.000

Number of Cap Units Excluded: optional
numeric
must have three decimal places (i.e., XXXXXXXXX.XXX).
can be a positive number or be equal to 0.000

The fields populate, as shown in Figure 11-3.

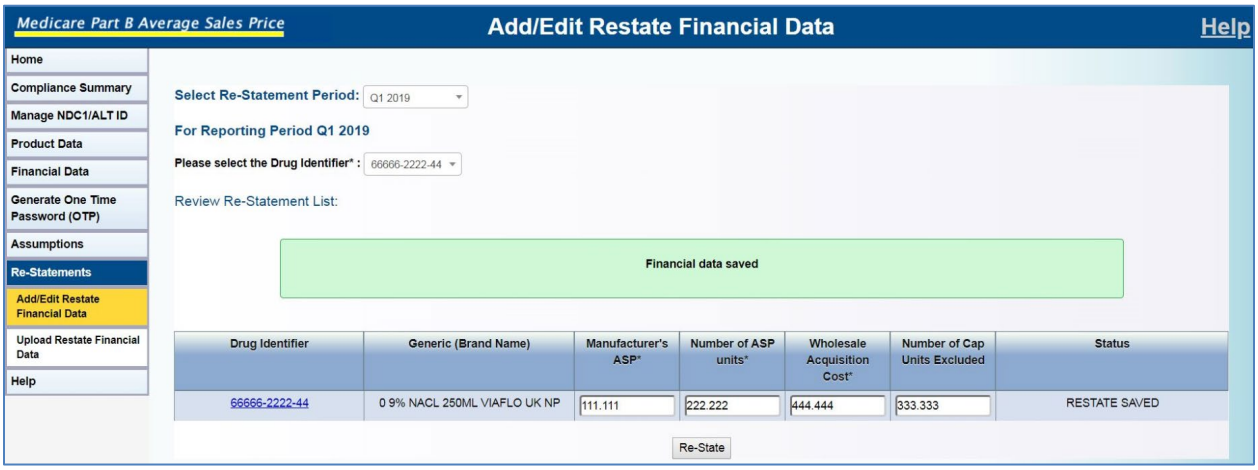
Figure 11-3: Add/Edit Restate Financial Data – Add/Edit Data



4. Click on the **Re-State** button.

   A message displays stating that the financial data have been saved, as shown in Figure 11-4.

Figure 11-4: Add/Edit Restate Financial Data – Data Saved Successfully



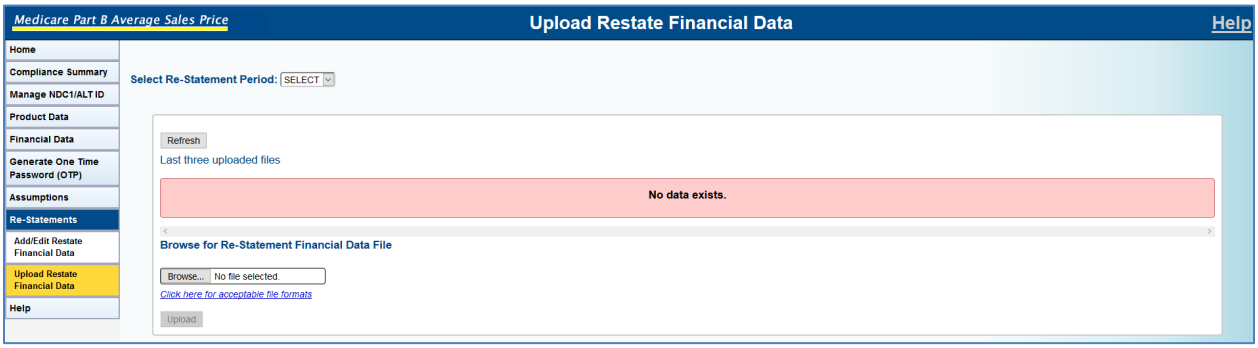
11.2 Upload Re-State Financial Data

ASP provides drug manufacturers the ability to restate Medicare Part B financial data to CMS. Perform the following steps to upload financial data using the file transfer process.

1. Click on **Re-statements** from the menu on the left side of the screen, and then click on **Upload Restate Financial Data**.

   The “Upload Restate Financial Data” screen displays, as shown in Figure 11-5.

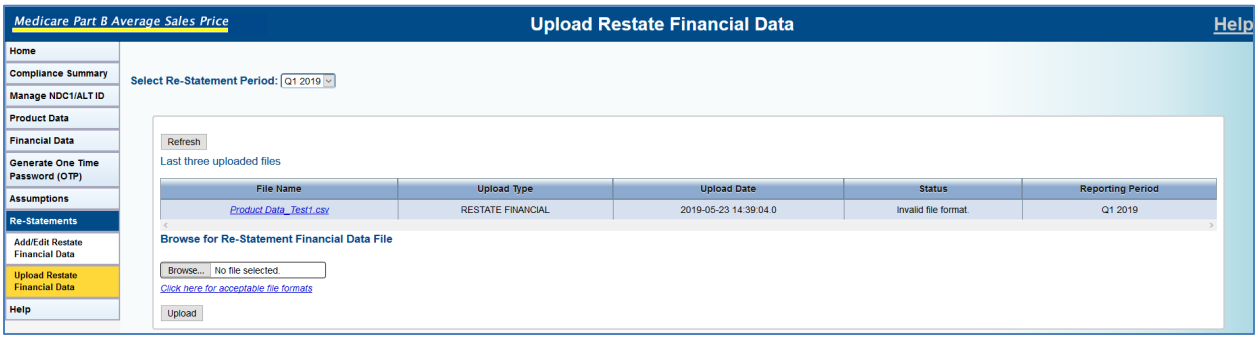
Figure 11-5: Upload Restate Financial Data Screen



2. To upload data, select a reporting period from the dropdown menu in the “Select Re-Statement Period:” field.

   The “Select Re-Statement Period:” field populates, as shown in Figure 11-6.

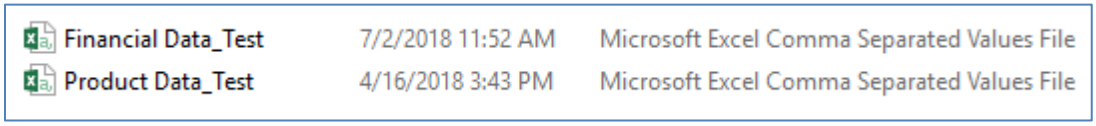
Figure 11-6: Upload Restate Financial Data Screen – Select Re-Statement Field Populated



3. Click on the **Browse** button.

   The file directory opens, as shown in Figure 11-7.

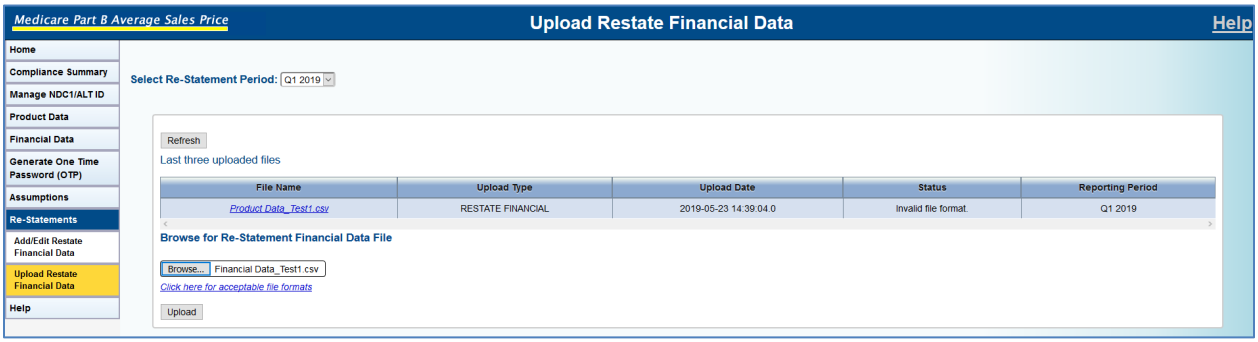
Figure 11-7: File Directory Window



4. Select a file in the appropriate format and double-click on it.

   The “Browse” field is populated, as shown in Figure 11-8.

Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated

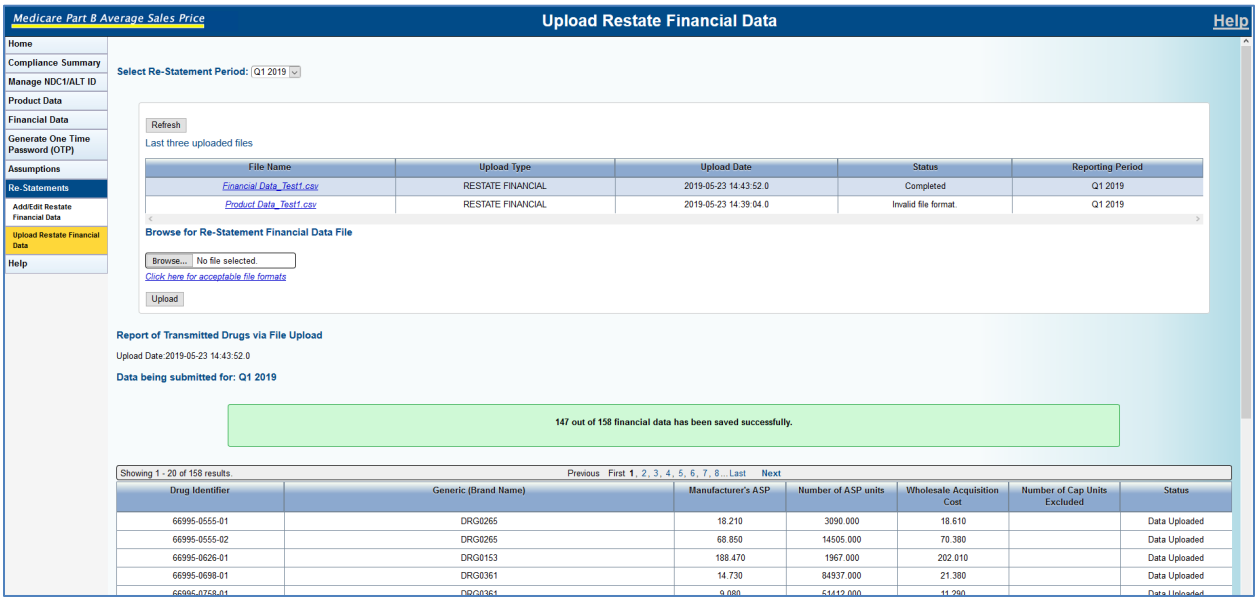


5. Click on the **Upload** button.

   A message displays confirming that the financial data were saved successfully, and the financial data are listed, as shown in Figure 11-9.

   Note: ASP offers a “Refresh” button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say “Processing.” If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say “Completed.”

Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully

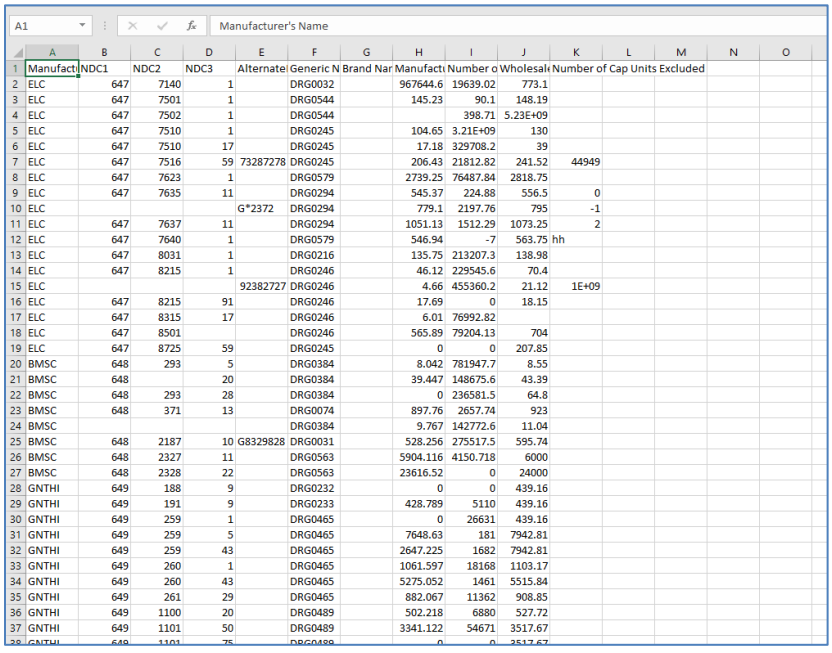


Note: Errors will be displayed in the "Status" column detailing what you will have to change in the Upload File.

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 6. To be certain of file column formatting, click on the "Click here for acceptable file formats" link, or follow the criteria below.

6. Open the "Upload Financial" file, as shown in Figure 11-10.

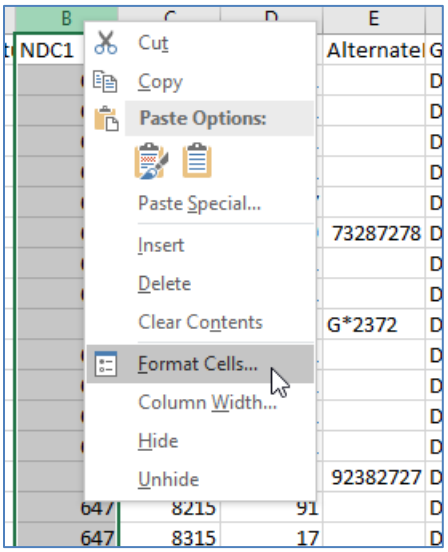
Figure 11-10: Upload Restate Financial Data File



7. To reformat a column, right-click on a column header.

   The “Column Editing” dropdown displays, as shown in Figure 11-11.

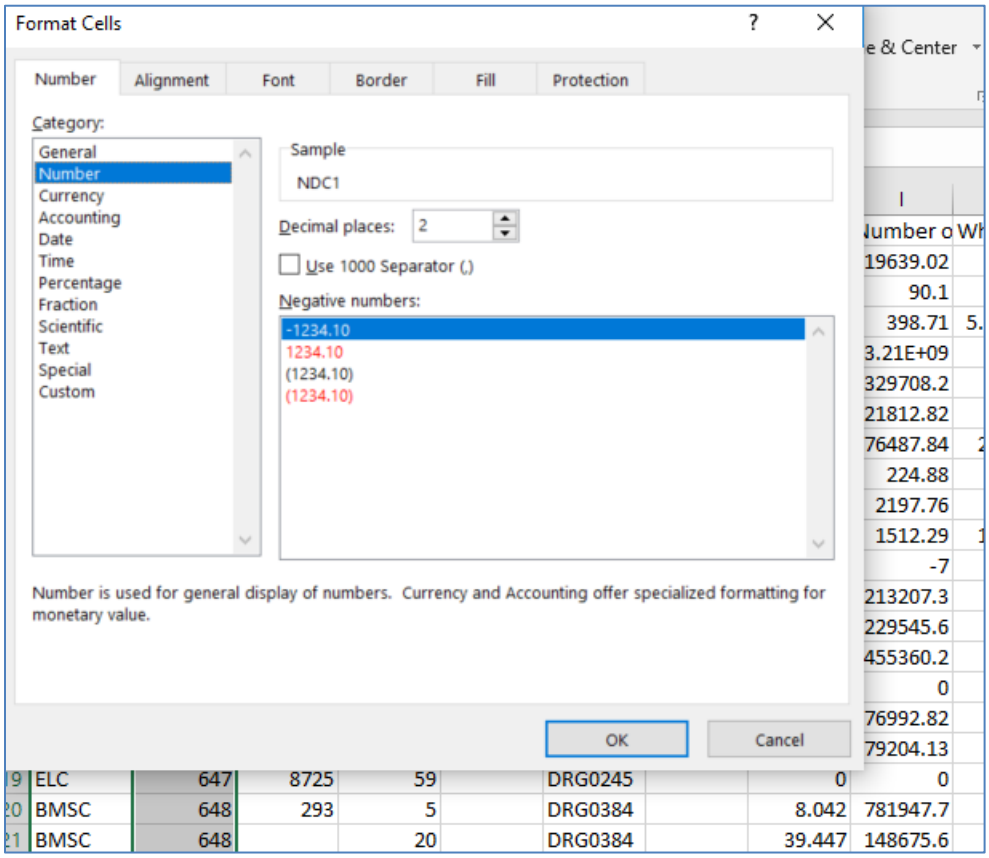
Figure 11-11: Upload Restate Financial Data Column Editing Dropdown



8. Select “Format Cells.”

   The “Format Cells” window displays, as shown in Figure 11-12.

Figure 11-12: Upload Restate Financial Data Format Cells Number Editing



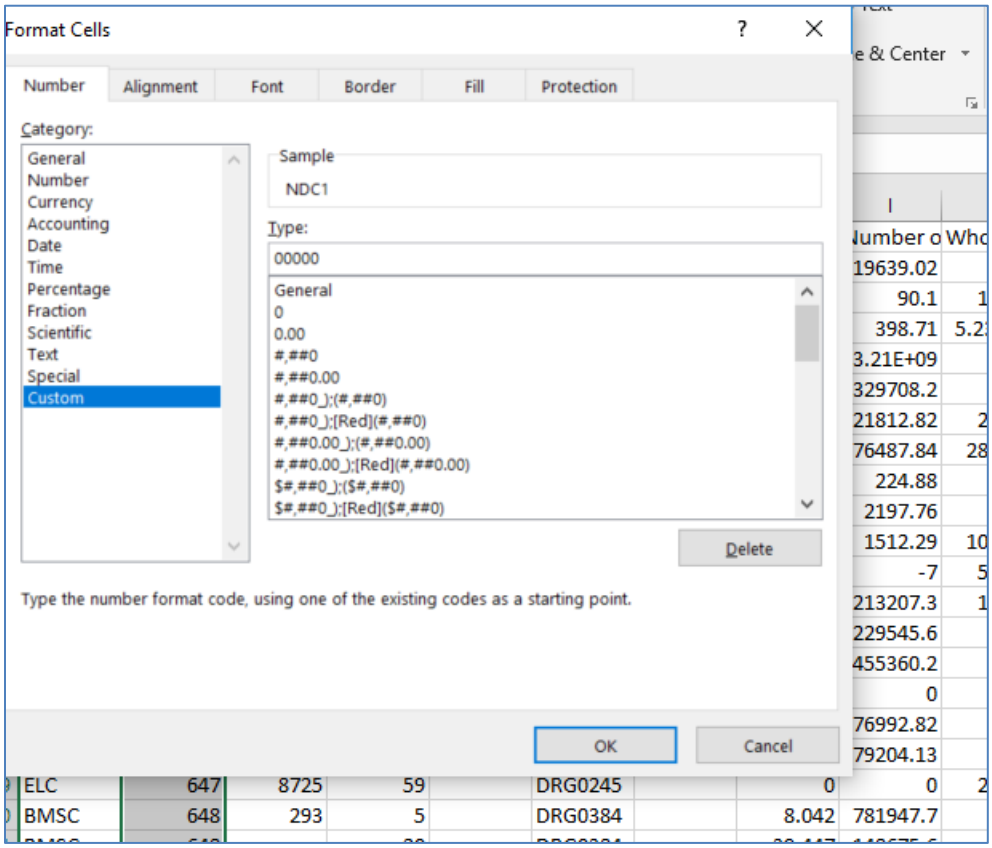
9. Make the following changes as shown in Figure 11-13 and Figure 11-14, in the “Type” field according to the below criteria:

   Note: For NDC1, NDC2, and NDC3 columns, select “Number” and then “Custom.”

   - NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 7 for any other column changes
   - NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 6 for any other column changes
   - NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 6 for any other column changes

     Example:

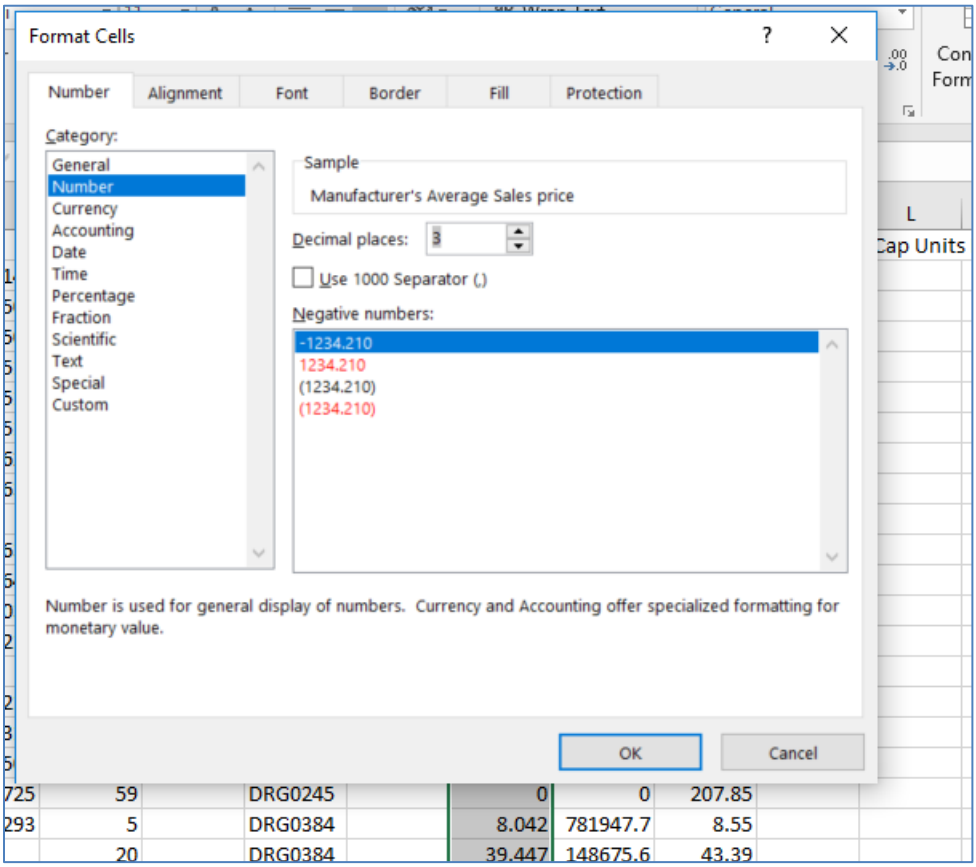
Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing Example



Note: For Manufacturer's Average Sales Price, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded, select "Number."

- Manufacturer's Average Sales Price: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 6 for any other column changes
- Number of ASP Units: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 6 for any other column changes
- Wholesale Acquisition Cost: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of CAP Units Excluded: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes

Figure 11-14: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully



10. Save the file and go back to Step 2.

Note: Be sure that you do NOT change any of the column headers, as that will invalidate the upload.

Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 6 through 8 again, before you resave the file.

12. Drug Certification

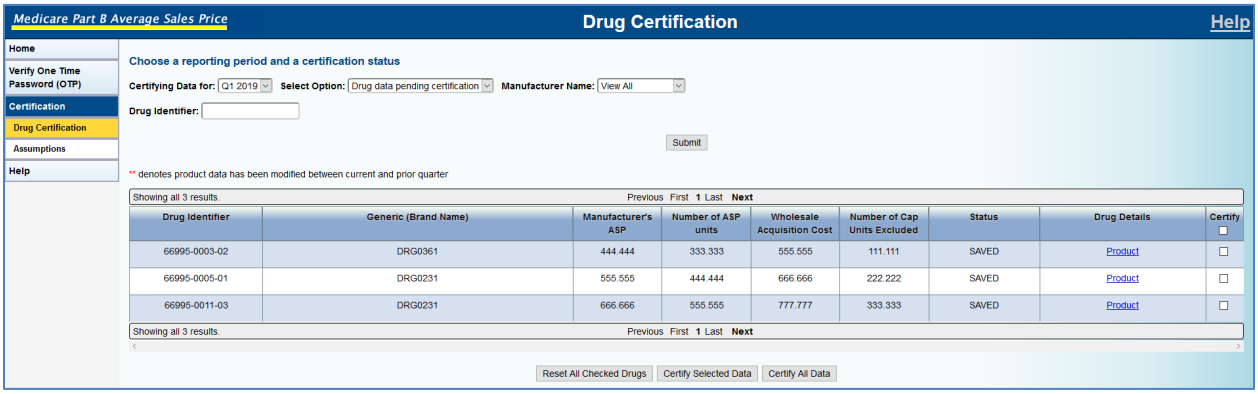
Drug certification is a process where a drug manufacturer certifies the accuracy of the drug data. In this section, data are selected and marked for immediate certification or later certification. Selection may be one drug product item, a list of drug items or all drug items pending certification for a manufacturer. The Drug Manufacturer gathers required quarterly drug data and submits it to the ASP application for ASP pricing. The Drug Manufacturer certifies that the data reported are correct.

With the appropriate user access, the ASP Application provides drug manufacturers the ability to certify the accuracy of drug data that have been previously submitted. This is for the Certifier to perform the following steps to certify drug data online.

1. Log into the application, click on **Certification** from the menu on the left side of the screen, and then click on **Drug Certification**.

   The “Drug Certification” screen displays, as shown in Figure 12-1.

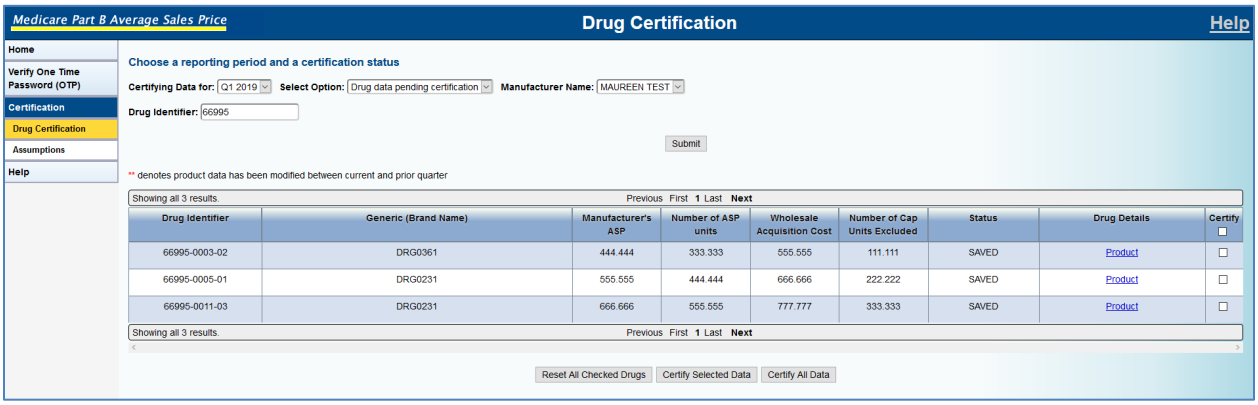
Figure 12-1: Drug Certification Screen



2. Select a Reporting Period from the dropdown list, a certification status, the manufacturer name (optional), and the drug identifier (optional), and click on the **Submit** button.

   The status for the drug information displays as “SAVED,” as shown in Figure 12-2.

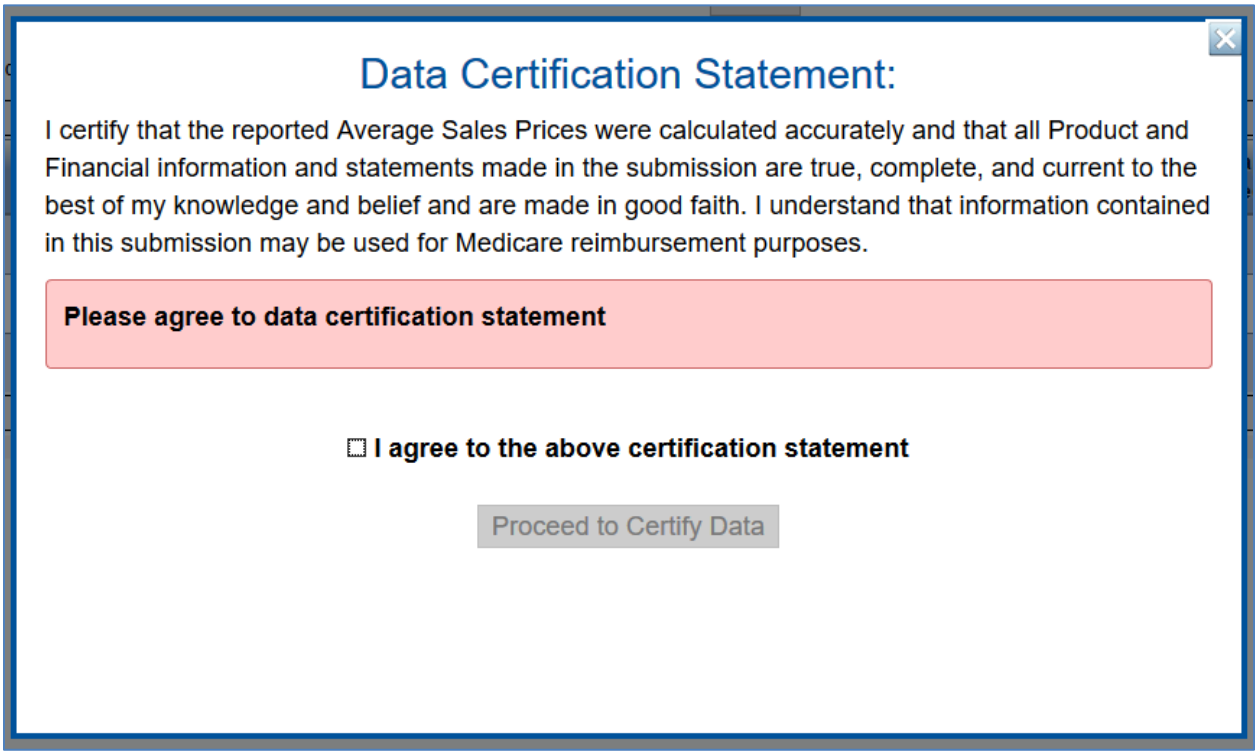
Figure 12-2: Selected Drugs to be Certified



3. Select the drugs to be certified by clicking the “Certify” check box of the individual drugs and clicking on the **Certify Selected Data** button, or by clicking on the **Certify All Data** button at the bottom of the page. If a drug is checked inadvertently, click on the **Reset All Checked Drugs** button to clear the “Certify” check boxes.

   A “Data Certification Statement” window displays, as shown in Figure 12-3.

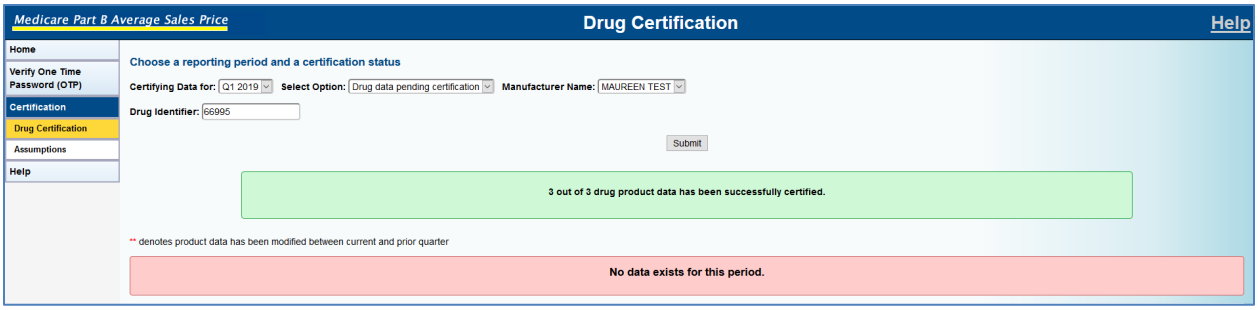
Figure 12-3: Data Certification Statement



4. Review the statement, click on the checkbox next to “I agree to the above certification statement,” and click on the **Proceed to Certify Data** button.

   A message displays stating that the data have been successfully certified, as shown in Figure 12-4.

Figure 12-4: Drug Information Successfully Certified



Appendix A: Record of Changes

Table A-1: Record of Changes

Version Number	Date	Author/Owner	Description of Change
1.0	03/23/2018	Maureen Campbell	Initial Release
1.1	04/26/2018	Maureen Campbell	Section 4.1: Add Product Data - Increased the requirements for “Strength of the Product” from 250 characters to 500 characters; made changes for requirements for “FDA Application Number,” “FDA Approval Type,” “FDA Approval Date,” and “Alternate ID.”
1.1	04/26/2018	Maureen Campbell	Section 4.3: Update Product Data - Increased the requirements for “Strength of the Product” from 250 characters to 500 characters; made changes for requirements for “FDA Application Number,” “FDA Approval Type,” “FDA Approval Date,” and “Alternate ID.”
1.1	04/26/2018	Maureen Campbell	Section 7.1: Restate Online - Increased the requirements for “Strength of the Product” from 250 characters to 500 characters; made changes for requirements for “FDA Application Number,” “FDA Approval Type,” and “FDA Approval Date.”
2.0	3/28/2019	Maureen Campbell	Globally: Changes to reflect changes in the application for Release 9
2.1	5/29/2019	Maureen Campbell	Section 5: Compliance Summary – Submitter – replaced section; Globally: changed FDA Application Number requirements from 9 digits to 10 digits; replaced most screenshots to reflect the absence of reporting period on the screens. Added Note about the Refresh button when uploading files. Increase Manufacture ASP and WAC digits increased from 6 to 10. Added Compliance Summary – Certifier and Assumptions – Certifier sections.
2.2	01/10/2023	Felicia Brown	Section 1 and 2.1: revised language
2.3	01/12/2023	Jenn Palmer	Added Appendix C, updated formatting, Added Figure 3-1 and corresponding instructions.

Appendix B: Acronyms

Table B-1: Acronyms

Acronym	Definition
ALT ID	Alternate Identification
AMP	Average Manufacturer Price
ARS	Acceptable Risk Safeguards
ASP	Average Sales Price
AWP	Average Wholesale Price
CAP	Competitive Acquisition Pricing
CHIP	Children's Health Insurance Program
CLFS	Clinical Laboratory Fee Schedule
CM	Center for Medicare
CMCS	Center for Medicaid and CHIP Services
CMS	Centers for Medicare & Medicaid Services
CSV	Comma-Separated Values
DAS	Division of Ambulatory Services
DCCA	Data Computer Corporation of America
EIDM	Enterprise Identity Management
ESRD	End Stage Renal Disease
EUA	Enterprise User Administration
FDA	Food and Drug Administration
FFS	Fee-for-Service
FFSDCS	Fee-for-Service Data Collection System
HHS	Health and Human Services
IVR	Interactive Voice Response
MFA	Multi-Factor Authentication
MMA	Medicare Modernization Act

Acronym	Definition
NDC	National Drug Code
OIG	Office of the Inspector General
OPPS	Outpatient Prospective Payment System
OTP	One Time Password
PII	Personally Identifiable Information
RIPD	Remote Identity Proofing
SMS	Short Message Service
SNOW	Service Now
URL	Uniform Resource Locator
WAC	Wholesale Acquisition Cost
XLC	eXpedited Life Cycle

Appendix C: Field Definitions

1. Table 1 contains the field definitions for drugs and biologicals reported on the NDC or CMS-specified unit level.

Most ASP reporting is done at the NDC level where the ASP corresponds to the amount of drug represented by that NDC. However, for a limited number of products, reporting at the NDC unit level is not appropriate and must be done at a CMS-specified unit level. A list of such drug products is maintained on the CMS website at: http://www.cms.gov/McrPartBDrugAvgSalesPrice/. For these drugs and biologicals, manufacturers will still submit ASP sales data for an NDC, but will do so on an ASP unit level specified in this list.

Table C-1: Field Definitions for Drugs and Biologicals

Field Name	Field Definition
Manufacturer's Name	The reporting manufacturer's name.
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC or UPC number) used when an 11 digit NDC is not available.
Manufacturer's Average Sales Price	ASP for a corresponding ASP unit rounded to 3 or more decimal places.
Number of ASP Units	The number of ASP units sold.
Wholesale Acquisition Cost (WAC)	The WAC for a corresponding ASP unit in effect on the last day of the reporting period. WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.

Field Name	Field Definition
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.
Strength of the Product	The dosage strength of one item (e.g.: 250 mg tablet, 20 mg/ml solution, 1 IU).
Volume Per Item	The amount in one item (ex: 10 ml in one vial, or 500 tablets in one bottle).
Number of Items Per NDC	The number of items in the 11-digit NDC (ex: if an NDC packaged as a box contains 4 vials, the number of items per NDC is 4).
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters. For ASP purposes, “at the end of utilization” means the manufacturer will not make sales of that NDC to any purchaser.
Date of First Sale	Report for NDCs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).
FDA Application Supplement Number	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration (FDA).
FDA Final Pre-Marketing Approval Date	This is the original date that the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).
FDA Approval Type	The type of FDA approval for the product.
Description of FDA Approval Type	If Other was specified in the column ‘FDA Approval Type,’ please specify the type.

2. Table 2 contains the field definitions for dermal grafting products.

Some dermal grafting products are not assigned an NDC. Instead, manufacturers identify them using product codes, which can be catalog numbers, Universal Product Codes (UPCs), or other unique identifiers. If an NDC is not available, the UPC or other unique identifier must be entered in the field “Alternate ID”. Manufacturers may not convert a UPC or other alternative identifier to an NDC format by adding zeros or removing numbers. Additionally, where the strength of a dermal grafting product must be described in units of area, manufacturers must report in units of square centimeters. Dermal grafting products that are sold in customized or irregularly shaped sheets must be quantified and reported using square centimeters. Other units of measure such as “square inches”, “each”, ”sheet”, etc are not acceptable. Dermal grafting products that are sold in powder, foam, or liquid form must be quantified and reported in metric measures such as grams, milligrams, or milliliters.

Table C-2: Field Definitions for Dermal Grafting Products

Field Name	Field Definition
Manufacturer's Name	The reporting manufacturer’s name.
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC number or UPC) used when an 11 digit NDC is not available.
Manufacturer's Average Sales Price	ASP rounded to 3 or more decimal places. Report the ASP per package, as identified by the NDC or alternate ID (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the ASP per box of five).
Number of ASP Units	Report the number of packages sold (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the number of boxes sold).

Field Name	Field Definition
Wholesale Acquisition Cost (WAC)	The WAC in effect on the last day of the reporting period. Report the WAC per package. WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.
Strength of the Product	For products sold in sheets: the total square centimeters in one item (ex: a 6cm x 8cm item is 48 sq cm).
Volume Per Item	Use this field for dermal grafting products that are reported in units of volume, for example liquids. Report the volume amount in one item, include the metric unit of measurement, such as cc or ml. Enter "1" for powders and sheets.
Number of Items Per NDC	The number of items in the 11-digit NDC or Alternative ID (ex: for an NDC or Alternate ID that has 5 grafts in a package, the number of items per NDC is 5).
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or Alternate ID when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means the manufacturer will not make sales of that NDC or Alternate ID to any purchaser.
Date of First Sale	Report for NDCs/Alternate IDs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).
FDA Application Supplement Number	The application supplement number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Number #1	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).

Field Name	Field Definition
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration (FDA).
FDA Final Pre-Marketing Approval Date	This is the original date the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).
FDA Approval Type	The type of FDA approval for the product.