HEALTH PLAN MANAGEMENT SYSTEM

FORMULARY SUBMISSION MODULE & REPORTS TECHNICAL MANUAL

JUNE 26, 2007

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INTRODUCTION

Since Contract Year (CY) 2006, the Health Plan Management System (HPMS) has provided various utilities to support the submission, review, and approval of the Bid and Formulary Submission for organizations offering the Medicare Part D benefit. As part of the overall Bid Submission process, an interface was originally established in CY 2006 to enable organizations to upload their Formulary submissions within HPMS. The CY 2007 HPMS Formulary Submission Module provided organizations with a series of enhancements and incorporated the use of a standard Formulary Reference File. The CY 2008 module includes updates to the Formulary Data Reference File, the Formulary File Format, Formulary Reports and new functionality for gap coverage and free first fill supplemental file submissions.

Using the HPMS Formulary Submission Module, the user is to submit one or more formulary files for a contract that contains all or a subset of drugs from the CMS provided Formulary Data Reference File. All subsequent resubmissions of a formulary file must be a complete resubmission of all proxy National Drug Codes (NDCs) in the formulary. That is, resubmitted formulary files should NOT include just the changes to the original formulary file submission, but rather an entire new version of the formulary file.

The CY 2008 HPMS Formulary Submission Module was made available to organizations beginning March 26, 2007. Formulary Submissions were due by 1:00 AM EDT on April 17, 2007. Initial review of CY 2008 formularies began April 17, 2007. It is anticipated that all formularies will be reviewed prior to the bid submission deadline of June 4, 2007, for CY 2008. It is highly recommended that organizations submit their formulary file(s) as early as possible during the upload time frame. Uploading earlier in this time frame will provide organizations with adequate time to address potential upload problems and submit corrected formulary file(s). An organization may resubmit their formulary as many times as necessary during the upload time frame, however, only the final successful submission will be processed for CMS review. Organizations implementing a drug formulary must provide a formulary file, along with the applicable supporting documentation (e.g. prior authorization attachment and step therapy attachment).

On June 5th, new functionality to support the submission of gap coverage and free first fill supplemental files will be released. Organizations must submit this supplemental information for each plan offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted their related bid(s). Details on the required file format and the steps for submitting these files can be found later in this document.

The CY 2008 Formulary Reports module provides reports that can be used to monitor the status of your formulary submission. The available reports include: Formulary/Bid Contact Report, Formulary Crosswalk Report, and the Formulary Status History Report.

This document provides information and instructions to:
- Submit New Formulary
- Revise Formulary

- Delete Formulary
- Submit Gap Coverage File
- Submit Free First Fill File
- Download Formulary Reference File
- Access Formulary File Examples
- Access/Generate Formulary and Supplemental File Reports
- Access the Technical Manual

GETTING STARTED

The **Health Plan Management System (HPMS)** is a web application hosted on an Extranet site that can be accessed via the Internet using a Secure Sockets Layer (SSL) Virtual Private Network (VPN).   You must have a valid CMS-issued User ID and password to log into the HPMS. To access the site via the Internet, go to: https://gateway.cms.hhs.gov.

> **Note:** The HPMS continues to be accessible by dial-up or T1/leased line via the Medicare Data Communications Network (MDCN). The URL for MDCN access is: https://32.90.191.19. Please contact your system administrator to determine if you can access the MDCN.

Step 1: Open the web browser (e.g., Internet Explorer) and enter the CMS SSL VPN gateway address https://gateway.cms.hhs.gov in the Address bar.

Step 2: Enter your User ID, Password and select HCFA.GOV from the Login Service drop down menu. Click the Logon button to proceed.

Step 3: Select the "HPMS" link to access the **HPMS Home Page**.
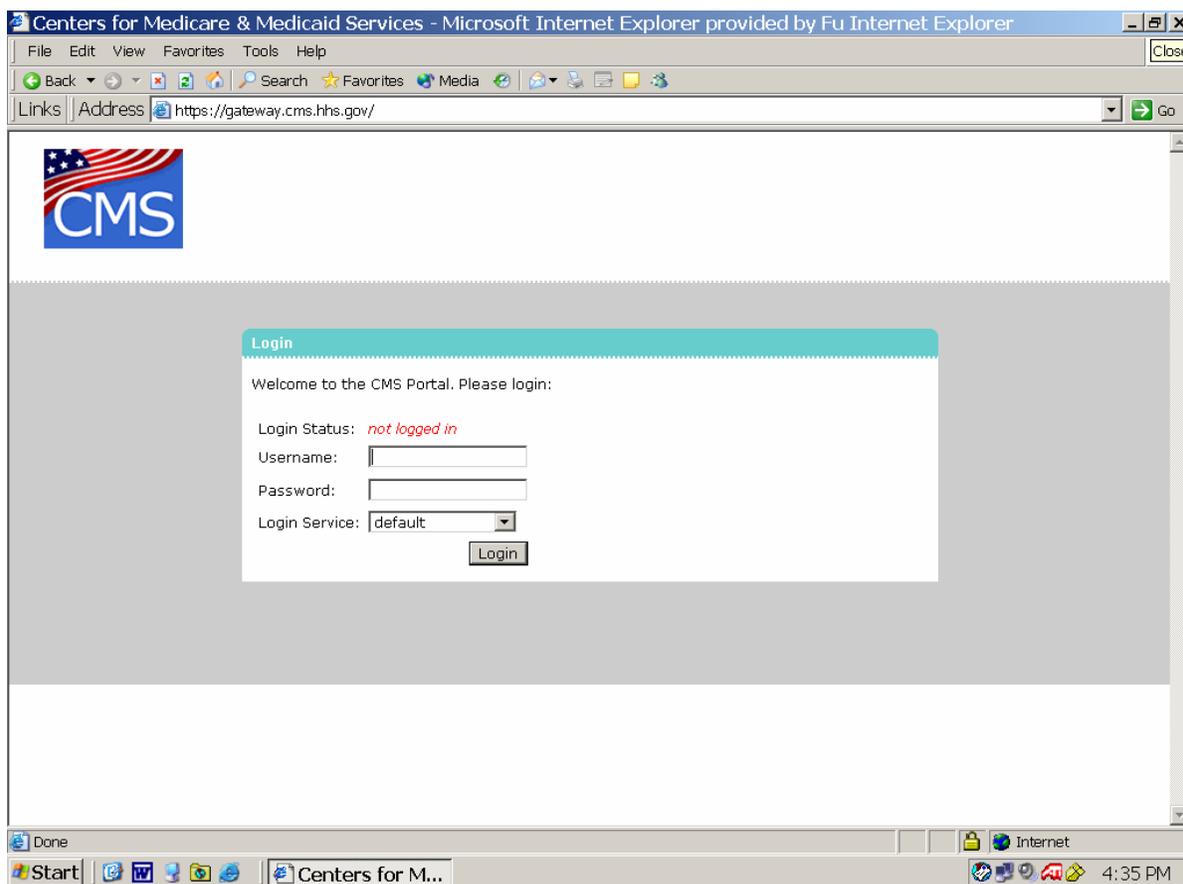
Step 4: Hover over the **Plan Formularies** link in the left-hand navigation bar to view the flyout menu. Select **Formulary Submission** to access the Formulary Submission module.
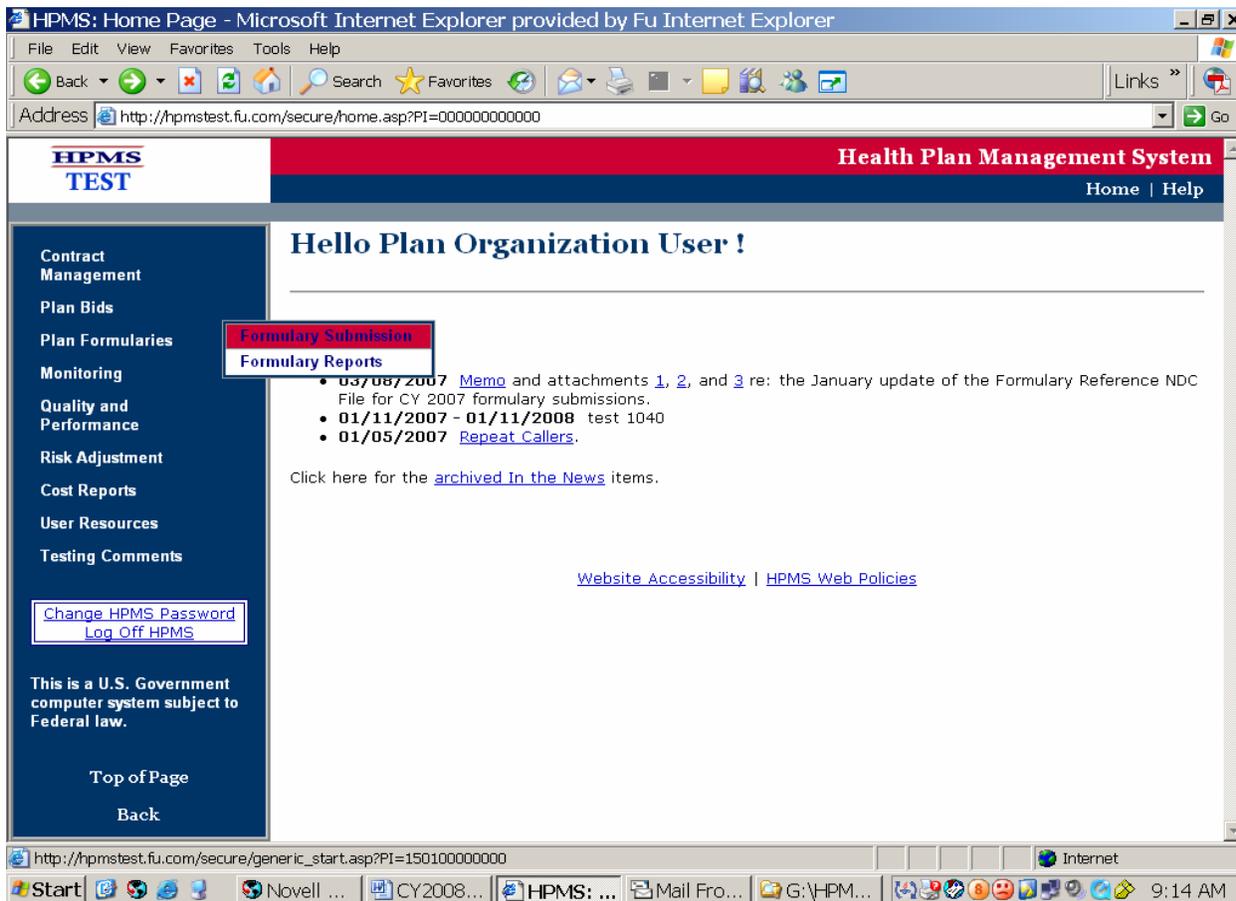
GENERAL INFORMATION

The formulary submission process contains a series of web pages that will collect information from the submitter. **Prior to beginning the submission process, you must ensure that the Formulary Contact information in the Contract Management module is completed.** You will not be able to submit a formulary for a contract that does not have this information. The Formulary Contact as well as the Formulary Upload Contact (the submitter) will receive all email notifications regarding the status of the formulary.

Once the formulary contact information is complete, you will step thru the Formulary Submission module to provide information on:

- **Associated Contracts** – Identify contract number(s) (H#, R#, S#, E#) that will be using the uploaded formulary.
- **Formulary Name** – Assign a name to your formulary. This name will be used only within the HPMS to identify the specific formulary submission (100 characters maximum).
- **Formulary Classification System** – Identify the formulary classification as United States Pharmacopeia (USP), American Hospital Formulary Service (AHFS), or a plan defined source.
- **Number of Cost Share Tiers** – Identify the maximum number of tiers in the formulary. This value must equal the highest tier value indicated in the submitted formulary file. Acceptable values are 1-10. This value must also match the tier information provided in the corresponding Plan Benefit Package (PBP).
- **Quantity Limits Requirements** – Indicate if there are drugs in the formulary that have quantity limit restrictions. Additionally, the formulary file must identify the drugs that have the quantity limit restrictions.
- **Specialty Pharmacies** – Indicate if there are drugs in the formulary that are only available at specialty pharmacies. Drugs with this restriction must be identified in the formulary file.
- **Prior Authorization Requirements** – Indicate if there are drugs in the formulary that require prior authorization. The formulary file must identify the drugs that require prior authorization and the organization must upload a supporting file detailing the prior authorization criteria.
- **Step Therapy Management Program** – Indicate if there are drugs in the formulary that require step therapy. The formulary file must identify the drugs that are part of the step therapy management program and the organization must upload a supporting file detailing the step therapy requirements.
- **Formulary Tier Information** – Specify information about each tier in the formulary.

The organization also should note that the formulary file must be created in an ASCII File Tab Delimited format and must contain one proxy NDC record for each drug offered within an organization's benefit plan(s). The record layout is provided in Appendix A: CY 2008 Formulary File Record Layout. Appendix B: Upload File Formats provides additional narrative instruction for completing your formulary file. It is imperative that the submission contains only those NDCs provided in the Formulary Reference NDC File. All other NDCs will be rejected by the HPMS Formulary Validation Process and the formulary submission will fail.

IMPORTANT NOTE: When uploading a new formulary, a unique 8-digit identifier will be assigned to each formulary submission. This ID will be prominently displayed on the HPMS screen. It is critical that the formulary upload user retain the Formulary ID for future reference. CMS will utilize this ID throughout the life cycle of the formulary.

SUBMIT NEW FORMULARY

The Submit New Formulary function should be used to submit a formulary for the first time. This process will create a formulary ID for the CY2008 formulary season in the following format: 00008xxx, e.g. 00008123. Please make note of the formulary ID as you will need this ID to submit subsequent updates to the formulary.

The process to submit a new formulary is as follows:

ASSOCIATE CONTRACTS TO FORMULARY

The Associate Contracts to Formulary page allows the user to associate one or more contracts to a formulary submission.

Step 1: Select CY 2008 from the Formulary Submission page.
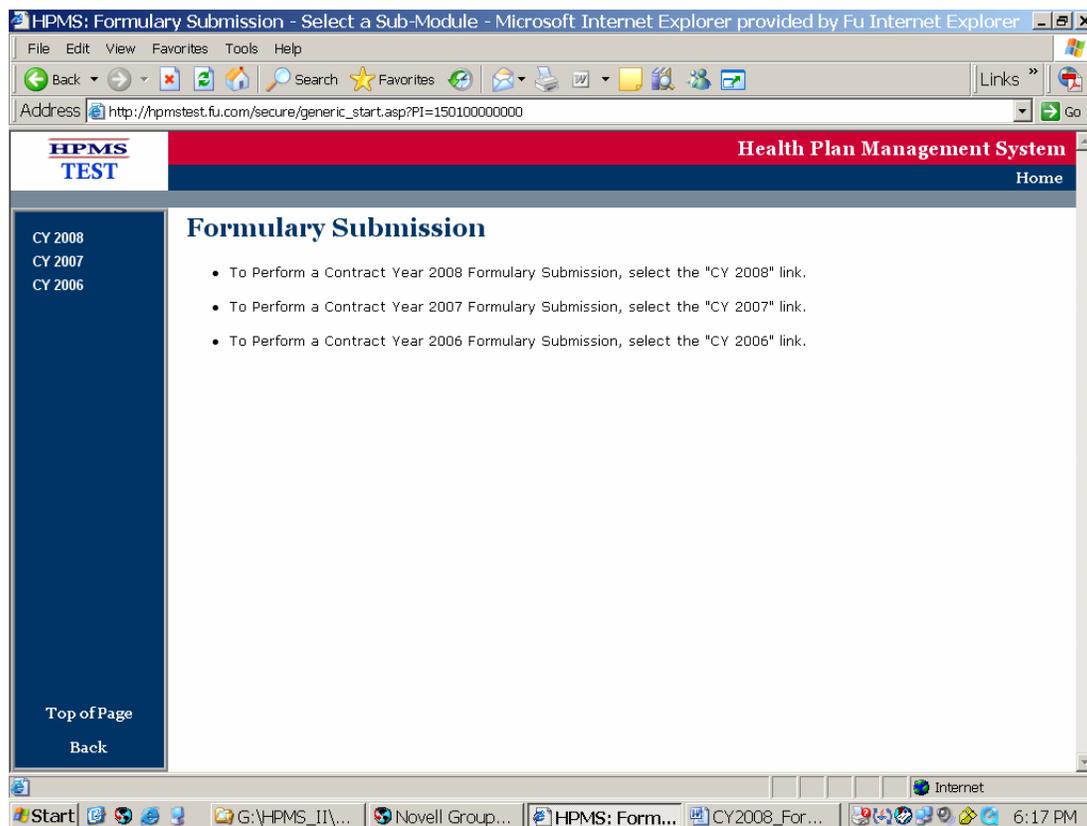
Step 2: Select **Submit New Formulary** from the 2008 Formulary Submission Start Page**.**
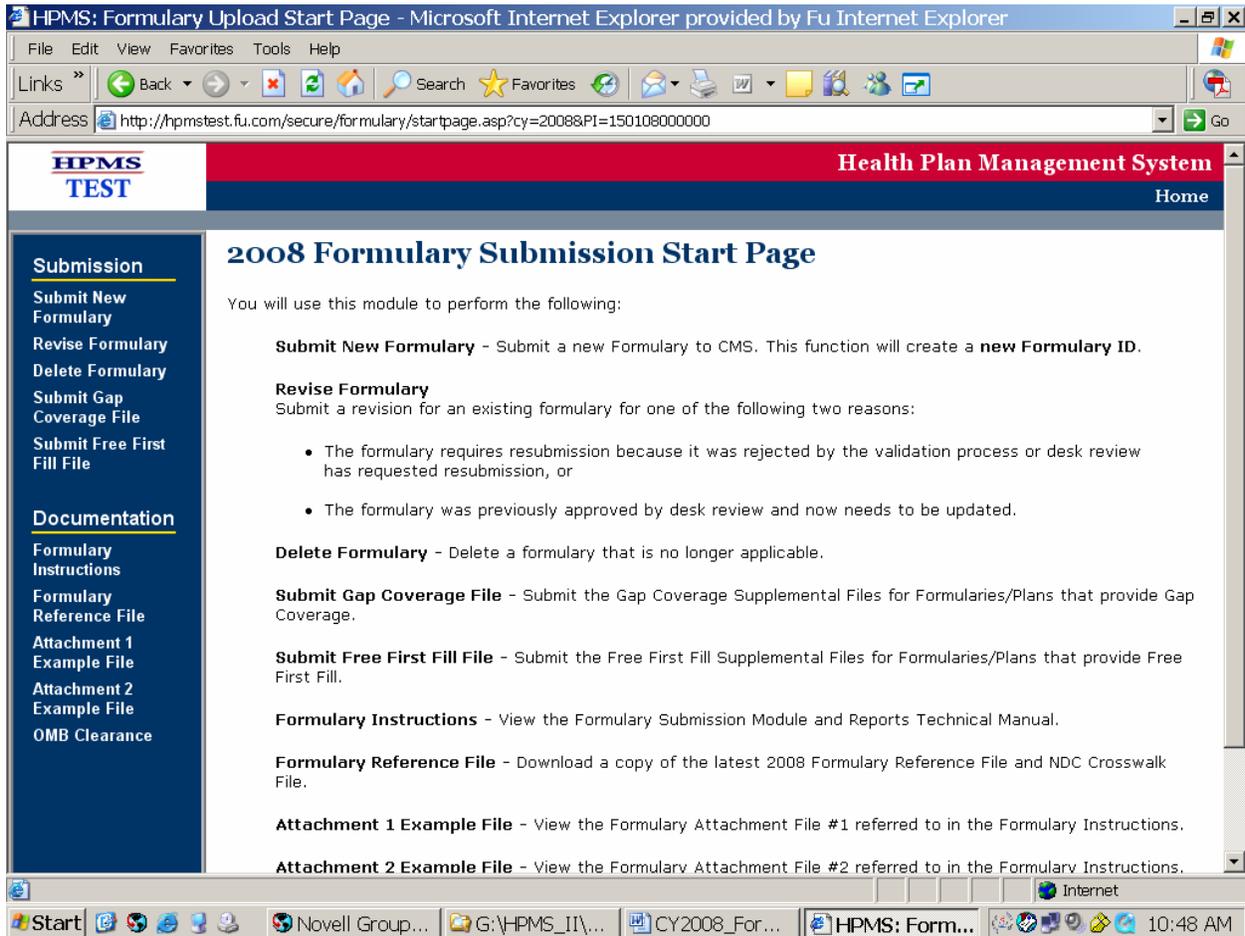
Step 3: Select one or more contracts on the Associate Contracts to Formulary page to associate with the new Formulary ID.

IMPORTANT NOTE: Prior to contract bid approval, selecting or deselecting the checkbox beside a contract can update the contract-to-formulary association. Once a contract bid is approved, the contract-to-formulary association selections can no longer be deselected.

Step 4: Select the **"Next" button** to confirm the Contract Associations and move on to the Formulary Information page.

FORMULARY INFORMATION

The Formulary Information page collects information about the formulary submissions including: Formulary Name; Formulary Classification System; Number of Tiers; Quantity Limit status; Specialty Pharmacies status; Prior Authorization status; and Step Therapy status.

Step 1: Enter responses to all of the questions. All fields are required.

Step 2: Select the **"Next" button** to confirm your entries and move on to the Formulary Tier Information page.

FORMULARY TIER INFORMATION

The Formulary Tier Information page collects information about the tiers within the formulary. The page will automatically generate the number of tiers based on the information entered on the prior page. The tier information entered in the formulary submission module must correspond to the number of tiers that will be identified in the corresponding CY 2008 PBP software.

When developing the formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure should be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 should have a higher cost-share for beneficiaries than drugs in Tier 2.

IMPORTANT NOTE: A Specialty Tier is defined as a tier that includes drugs that are high cost and unique. Drugs within the Specialty Tier are exempt from tiering exceptions.

Step 1: For each tier, indicate the Tier Name, Specialty Tier designation, and Drug Types.

Step 2: Select the **"Next" button** to confirm your information and move on to the Upload Files page.

UPLOAD FILES

The Upload Files page allows the user to upload the Formulary File, Prior Authorization File, and Step Therapy File if required. The page will determine what needs to be uploaded based on your prior responses.

It is imperative that the files are in the following format:
Formulary File (See Appendices A and B for additional assistance) – ASCII Tab delimited text file, e.g. *formulary123*.txt
Prior Authorization – Microsoft Word file, e.g. *priorauth123*.doc
Step Therapy – Microsoft Word file, e.g. *steptherapy123*.doc

Step 1: Enter the name of the Formulary Text File (Tab delimited .txt only) in the "Formulary File" field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file.

Step 2: Enter the name of the Prior Authorization File (MS-Word only) in the "Prior Authorization File" field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file. If "No" was selected for the prior authorization question from the Formulary Information page, this field will not be displayed.

Step 3: Enter the name of the Step Therapy File (MS-Word only) in the "Step Therapy File" field. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file. If "No" was selected for the step therapy question from the Formulary Information page, this field will not be displayed.

Step 4: Select the **"Upload" button** to submit the files and to continue to the Verify Submission page. Please wait until the file transfer is complete before attempting to navigate further.

VERIFY SUBMISSION

The submitter must verify the information entered during the submission process to complete the upload and submit the information to CMS. If anything is incorrect, you may use the Back button to return to prior pages and correct the information.
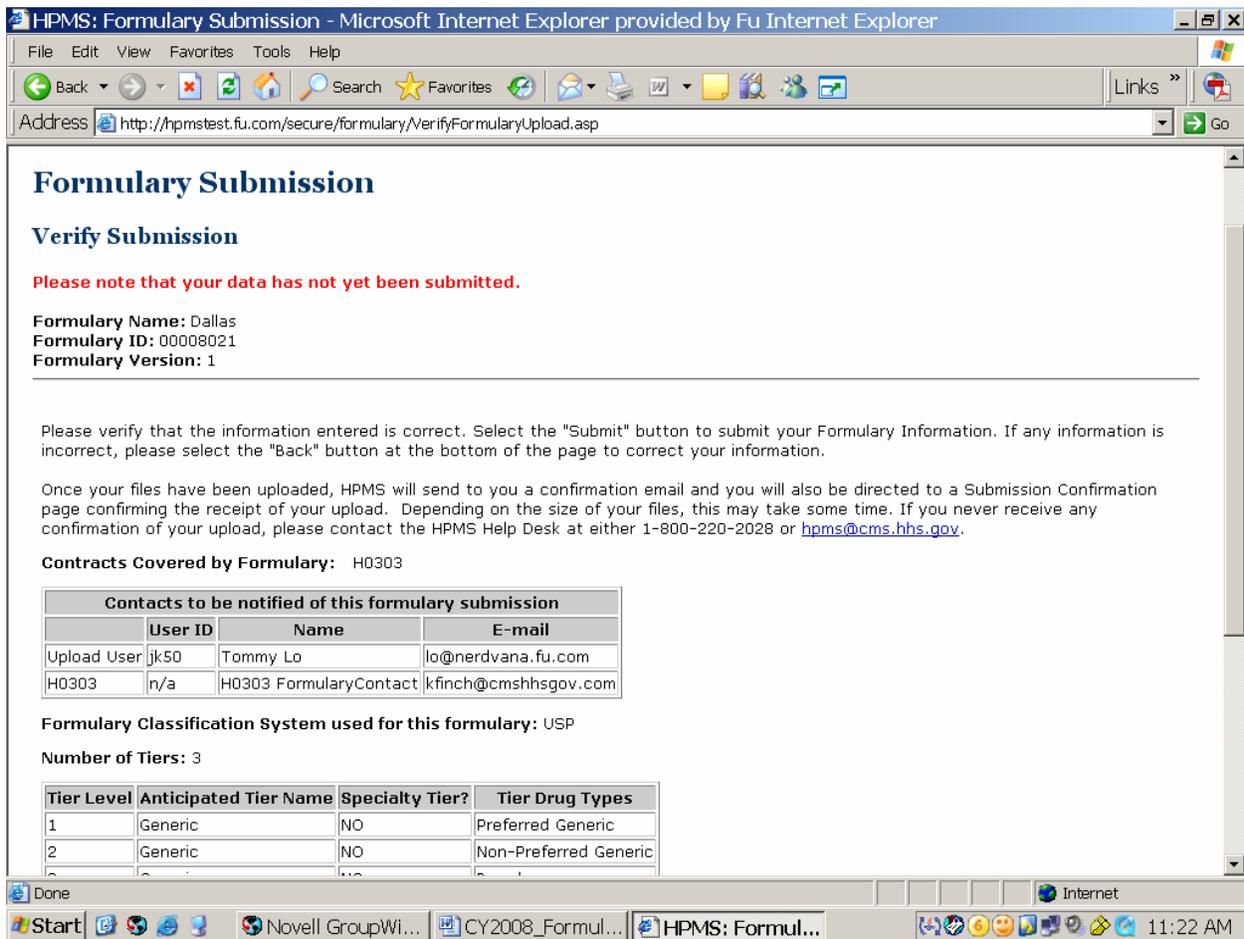
Step 1: Review the information for correctness.

Step 2:

Select the **"Submit" button** to send the submission to CMS for review. The Submission Confirmation page will display.

OR

Select the **"Back" button** to correct the information by returning to the appropriate pages.

SUBMISSION CONFIRMATION

The Submission Confirmation page provides a status of the successful upload and the unique Formulary ID assigned to your submission. This Formulary ID must be used for all subsequent resubmissions. This page will also generate an email to both the Formulary and the Formulary Upload Contact identified on this page acknowledging receipt of the submission and the assigned Formulary ID.

After receiving the uploaded formulary file the HPMS will perform a series of validation edits. At the close of the validation process, a second e-mail will be sent to the designated formulary contacts. This e-mail will either indicate that the formulary was successfully validated or it will identify errors detected during the validation process. If errors were detected the formulary submission will be rejected. The email will list a maximum of 200 errors message. You must correct the formulary and resubmit using the Revise Formulary function.

Step 1: Review the information and **MAKE NOTE OF YOUR ASSIGNED FORMULARY ID**.
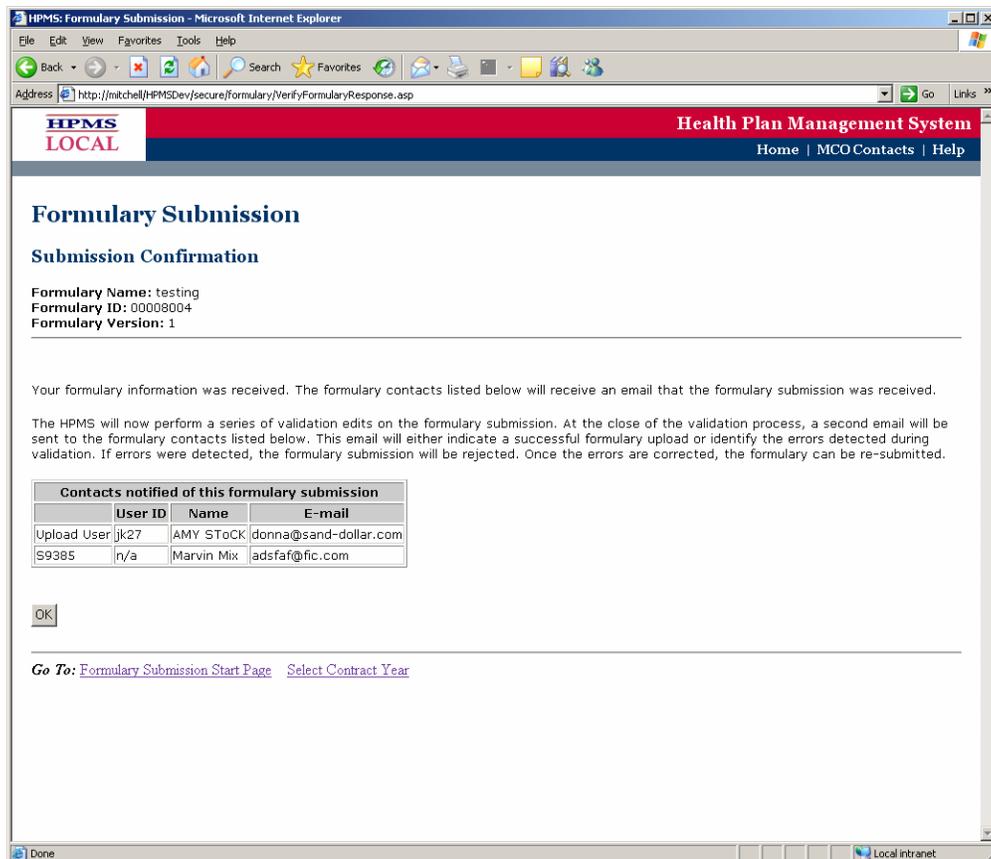
Step 2: Select the **"OK" button** to return to the Formulary Submission Start Page.

REVISE A FORMULARY

Use the Revise Formulary functionality to update existing formularies. You are only permitted to update a formulary that has a status of "Resubmission Requested" or "Rejected by Validation." Formularies that are "Approved" can be updated during the assigned monthly update windows. The user may indicate whether or not the Gap Coverage and/or Free First Fill Supplemental Files is required during this process.

The Formulary Resubmission–Select a Formulary page groups formularies into three categories:
- Resubmission – formularies that are eligible for resubmission either due to a validation failure or because a reviewer requested a resubmission.
- Updates – approved formularies that are eligible for resubmission during the scheduled monthly update window.
- In Process – formularies that are in desk review and are NOT eligible for resubmission.

Step 1: Select **Revise Formulary** from the 2008 Formulary Submission Start Page.

Step 2: Select a formulary you wish to update.

Step 3: Select the **"Update" button** to access the Formulary Resubmission's Associate Contracts to Formulary page.

Step 4: Respond to the questions as instructed in the **Submit New Formulary** section of the manual.

NOTE: The user may indicate if changes are required for the Gap Coverage Supplemental File and/or Free First Fill Supplemental File from the Formulary Resubmission – Upload Files page.

HPMS
DEV

Health Plan Management System

Home

Formulary Resubmission

Upload Files

Formulary Name: dmh aiken 2 new formularies v5
Formulary ID: 00008007
Formulary Version: 8

Step 1. Enter the name of the Formulary Text File (.txt) that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file.
Step 2. Please indicate if there are any changes to the previously uploaded copy of the Gap Coverage Supplemental File(s). If you indicate changes are not required, then the system will continue to use your previously uploaded Gap Coverage Supplemental data. If you indicate changes are required, then you will be prompted by email at a later time to upload the new files.
Step 3. Please indicate if there are any changes to the previously uploaded copy of the Free First Fill Supplemental File(s). If you indicate changes are not required, then the system will continue to use your previously uploaded Free First Fill Supplemental data. If you indicate changes are required, then you will be prompted by email at a later time to upload the new files.
Step 4. Enter the name of the Prior Authorization File that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file. The Prior Authorization File must be a MS Word File.
Step 5. Enter the name of the Step Therapy File that you would like to upload. If you are unsure of the file name and/or location, click on the "Browse" button to locate the file. The Step Therapy File must be a MS Word File.
Step 6. Click on the "Upload" button to send the file to HPMS.
Step 7. Wait until the file transfer is complete. Your browser will automatically be directed to the appropriate page once the file(s) are received.
Step 8. You will be directed to a verification page. The verification page allows you to confirm that your formulary information is correct before your data is submitted.

FORMULARY FILE

Select Formulary File for upload: [   ] Browse...

GAP COVERAGE SUPPLEMENTAL FILES
○ **This Formulary does not require changes to the previously uploaded copy of the Gap Coverage Supplemental File(s).**
○ **This Formulary requires changes to the Gap Coverage Supplemental File(s).**

FREE FIRST FILL SUPPLEMENTAL FILES
○ **This Formulary does not require changes to the Free First Fill Supplemental File(s).**
○ **This Formulary requires changes to the Free First Fill Supplemental File(s).**

PRIOR AUTHORIZATION FILE
⦿ **Use previously uploaded copy of the Prior Authorization File   View Previous File**
○ **Select Prior Authorization File for upload:**

STEP THERAPY FILE
⦿ **Use previously uploaded copy of the Step Therapy File   View Previous File**
○ **Select Step Therapy File for upload:**

Back   Upload

Go To: Formulary Submission Start Page   Select Contract Year

DELETE FORMULARY

The **Delete Formulary** functionality allows the user to delete existing formularies that have never been approved.   You should only delete a formulary if you are certain that it is obsolete. Eligible formularies are listed under the heading "Resubmissions – Available for deletion." The page also provides a list of formularies that are "Approved" or "In Process" for user reference. You cannot delete these formularies.

Step 1: Select **Delete Formulary** from the 2008 Formulary Submission Start Page**.**

Step 2: Select the formulary you wish to delete and click the Delete button.

Step 3: Review the page carefully and select the **"Delete" button** to finalize the deletion.
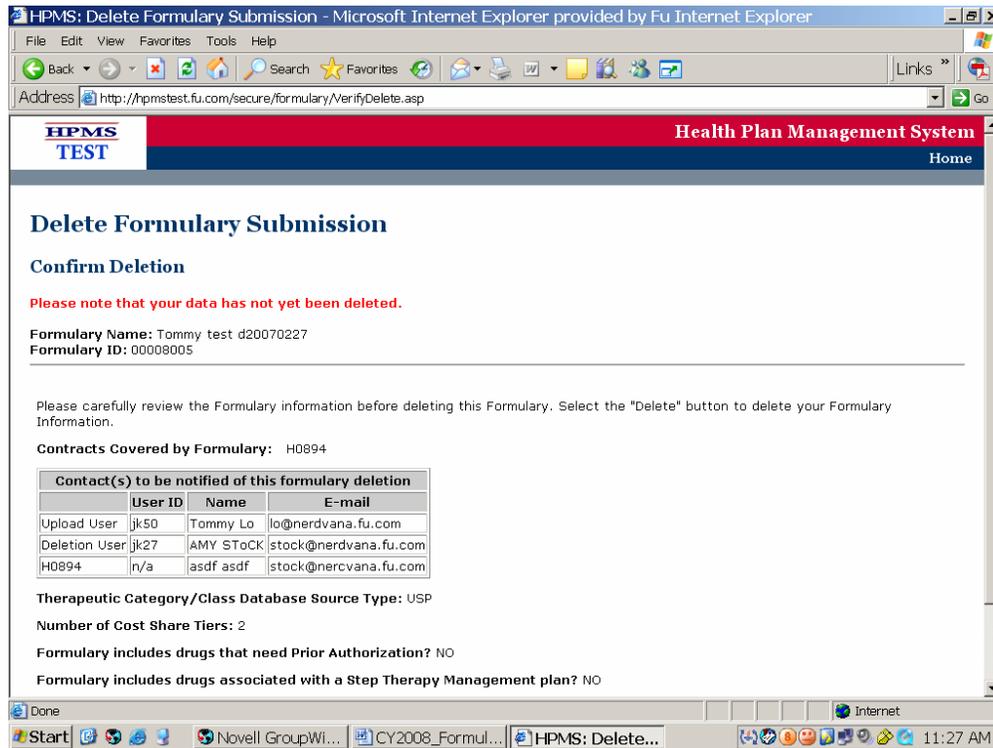
Step 4: Select the **"OK" button** to return to the Formulary Submission Start Page.
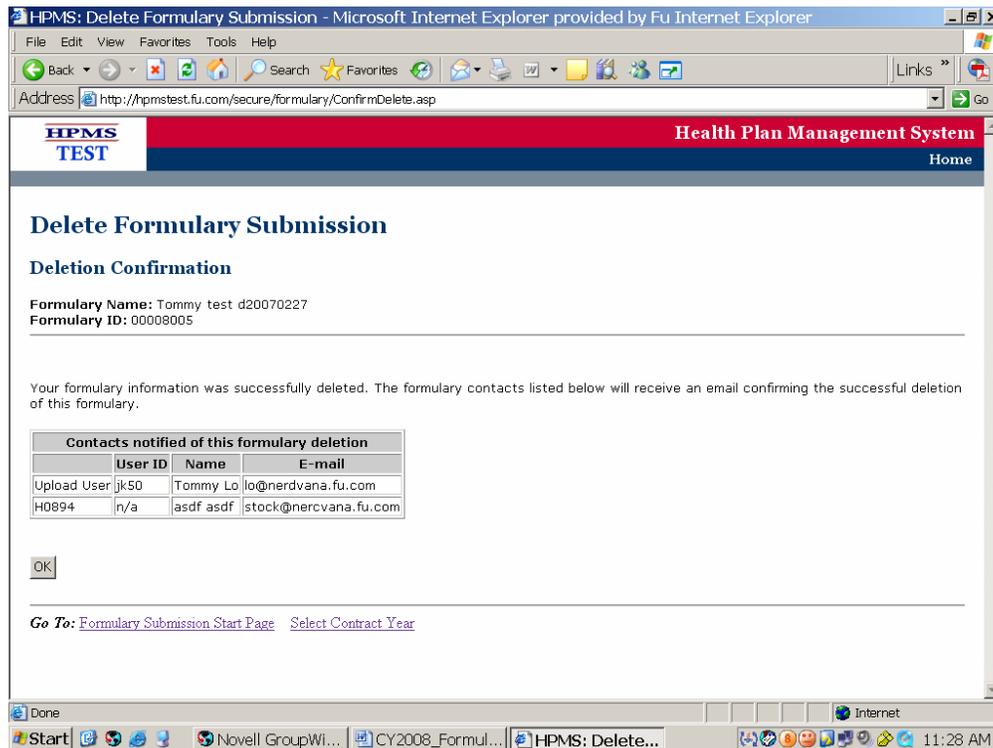
SUBMIT GAP COVERAGE FILE

The **Submit Gap Coverage File** functionality allows the user to upload their Gap Coverage file for a given formulary/plans.   If a bid submission indicated that a plan covers a part of a tier with the gap coverage benefit, the organization must submit the gap coverage information for the bid to be fully reviewed.   A supplemental file may be submitted for a formulary that is in "Approved" or "In Desk Review" status. The formularies that require a Gap Coverage File are listed on the Select a Formulary Page.

Please note that once you begin uploading the Gap Coverage files, you must repeat this process for all plans with a Gap Coverage file that are associated with the selected formulary. You cannot upload your files to HPMS until all plans are assigned to a Gap Coverage supplemental file.

Step 1: Select **Submit Gap Coverage File** from the 2008 Formulary Submission Start Page**.**

Step 2: Select the formulary for which you wish to upload a Gap Coverage File and click the "**Next" button**.

Step 3: **Enter the name of the Gap Coverage Supplemental file (.txt)** you wish to upload. If you are unsure of the filename and/or location, click on the Browse button to locate the file.

Step 4: Select the checkbox beside each contract/plan to associate a file and click the "Continue**" button**.

**Step 5:** Review the information for accuracy.

Step 6:

Select the **"Continue" button** to continue the Gap Coverage File submission process. The files will not be sent to CMS for review until all plans associated to the selected Formulary are assigned to a Gap Coverage Supplemental file.

OR

Select the **"Back" button** to correct the information by returning to the appropriate pages.
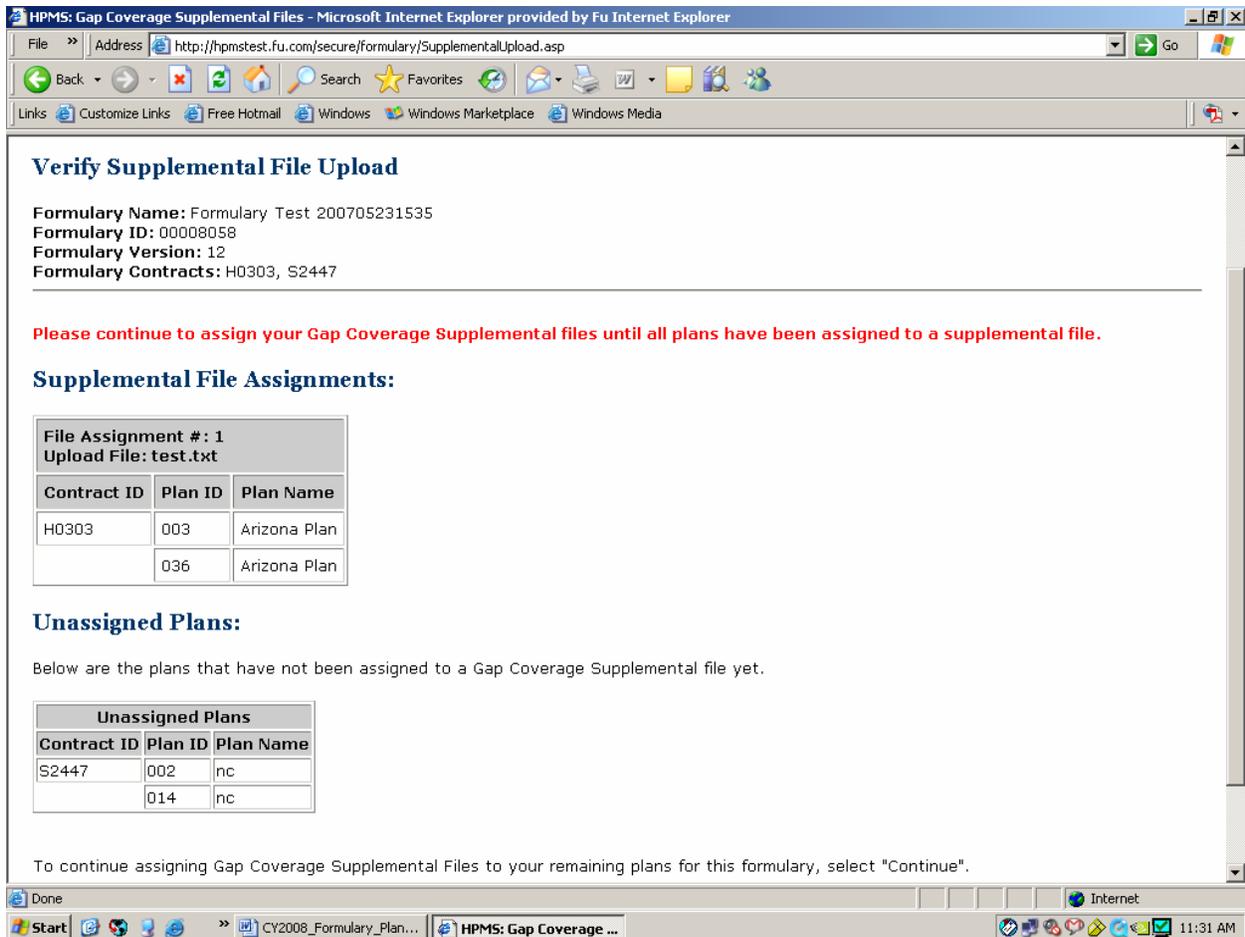
The user must repeat the Submit Gap Coverage process until all plans with supplemental coverage for the formulary are completed. The user continues to associate plans to Gap Coverage files on the Upload page and verifies data on the Verify Supplemental File Upload page.

Step 7: Review the information and click the "**OK**" **button** to return to the Gap Coverage Supplemental Files Select a Formulary page. The user may choose to continue the Gap Coverage file upload process or wait until a later time.

The Submission Confirmation page provides a status of the successful upload. This page will send an email to the contact identified on this page.

After receiving the uploaded Gap Coverage file, the HPMS will perform a series of validation checks. At the close of the validation process, a second email will be sent to the designated contact listed on this page. If errors were detected, the supplemental file submission will be rejected. You must correct the Gap Coverage file(s) and resubmit all of the file(s) using the Submit Gap Coverage File function.

SUBMIT FREE FIRST FILL FILE

The **Submit Free First Fill File** functionality allows the user to upload their Free First Fill file for a given formulary/plans. If a bid submission indicated that a plan offers Free First Fill, the organization must submit the free first fill information for the bid to be fully reviewed. A supplemental file may be submitted for a formulary that is in "Approved" or "In Desk Review" status. The formularies that require a Free First Fill file are listed on the Select a Formulary Page.

Please note, once you begin uploading the Free First Fill files, you must repeat this process for all plans with a Free First Fill file associated with the selected formulary. You cannot submit your files to HPMS for review until all plans associated to a formulary are assigned to a Free First Fill Supplemental file.

Step 1: Select **Submit Free First Fill File** from the 2008 Formulary Submission Start Page**.**

Step 2: **Select the formulary** for which you wish to upload a Free First Fill File and click the "**Next" button**.

Step 3: **Enter the name of the Free First Fill Supplemental File (.txt)** you wish to upload. If you are unsure of the filename and/or location, click on the Browse button to locate the file.

Step 4: Select the checkbox beside each contract/plan to associate a file and click the "**Continue**" button.
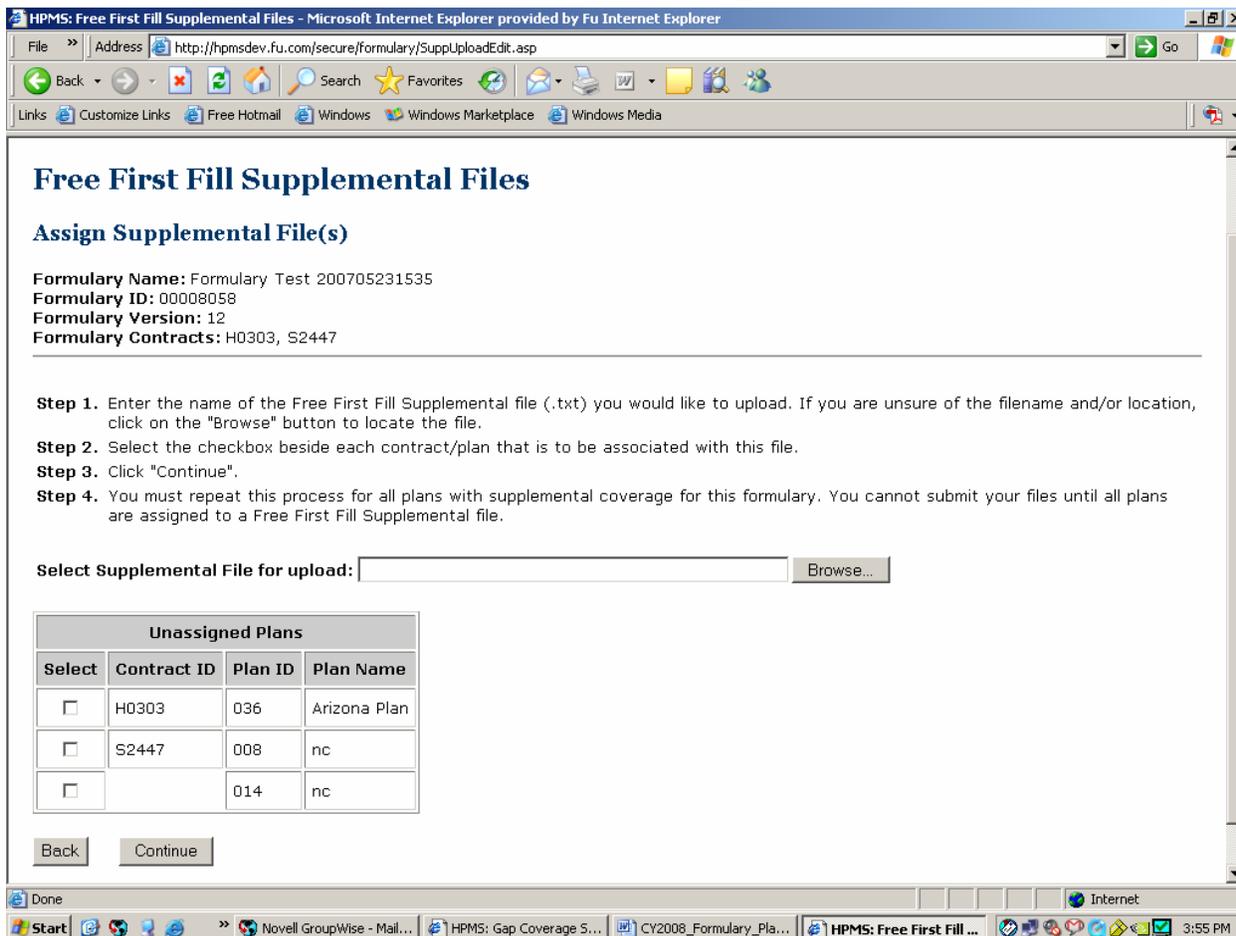
**Step 5:** Review the information for accuracy.

Step 6:

Select the **"Continue" button** to continue the Free First Fill File submission process. The files will not be sent to CMS for review until all plans associated to the selected Formulary are assigned to a Free First Fill Supplemental file.

OR

Select the **"Back" button** to correct the information by returning to the appropriate pages.
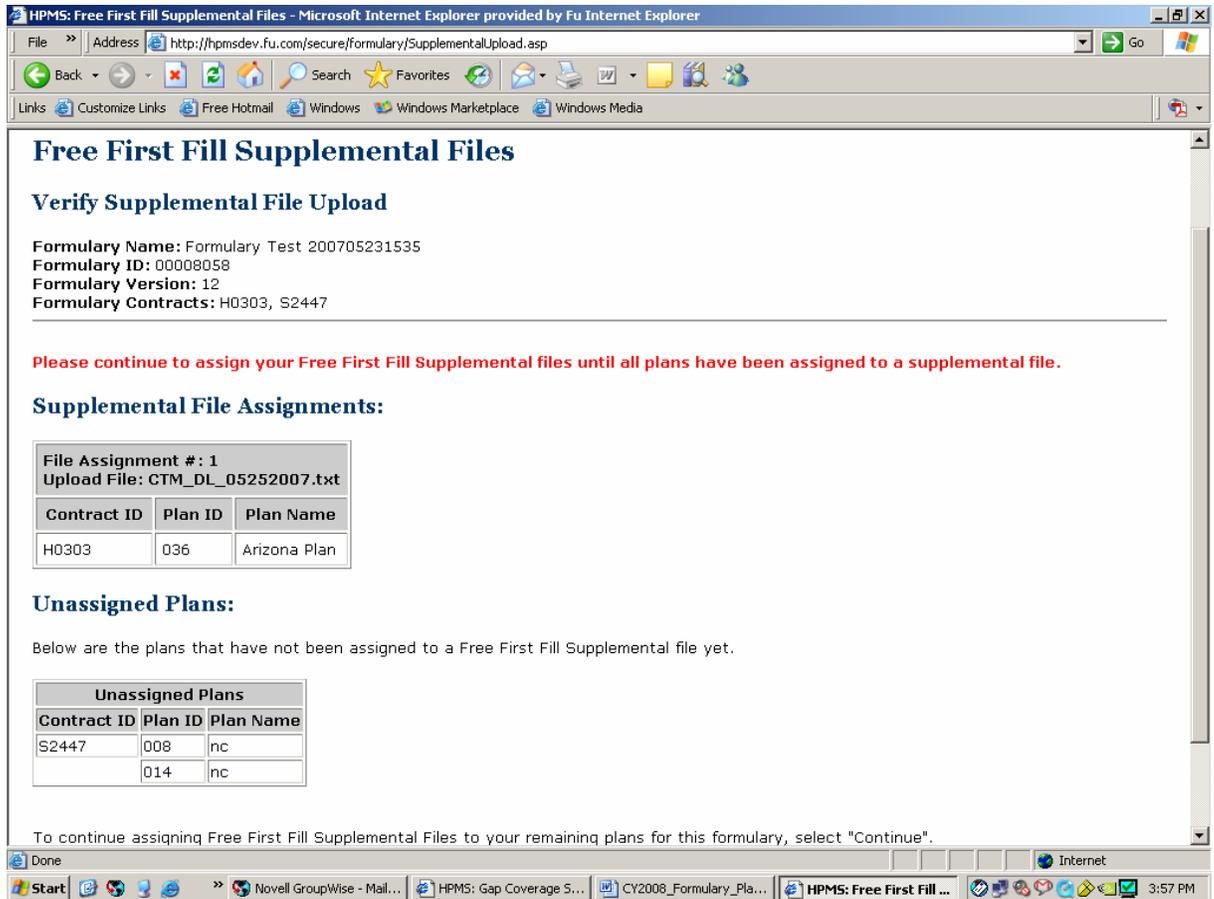
The user must repeat the Submit Free First Fill process until all plans with supplemental coverage for the formulary are completed. The user continues to associate plans to Free First Fill files on the Upload page and verifies data on the Verify Supplemental File Upload page.

Step 7: Review the information and click the "**OK" button** to return to the Free First Fill Files. Select a Formulary page. The user may choose to continue the upload process or wait until a later time.

The Submission Confirmation page provides a status of the successful upload. This page will send an email to the contact identified on this page.

After receiving the uploaded Free First Fill file, the HPMS will perform a series of validation checks. At the close of the validation process, a second email will be sent to the designated contact listed on this page. If errors were detected, the supplemental file submission will be rejected. You must correct the Free Fist Fill file(s) and resubmit the file(s) using the Submit Free First Fill function.

File   Edit   View   Favorites   Tools   Help

Links   »   Back ▼   ▼   ×   🔃   🏠   🔍 Search   ⭐ Favorites   🔅   🔅 ▼ 🖨 🔳 ▼ 🔳 🔍 🔅 🔳

Address   http://hpmsdev.fu.com/secure/formulary/ConfirmSuppUpload.asp   ▼ → Go

HPMS DEV   **Health Plan Management System**
                                                                                Home

Free First Fill Supplemental Files

Submission Confirmation

Formulary Name: Formulary Test 200705231615
Formulary ID: 00008060
Formulary Version: 1
Formulary Contracts: H9104

Your Free First Fill Supplemental file(s) have been successfully uploaded.

The HPMS will now perform a series of validation edits on the Free First Fill supplemental file submission. At the close of the validation process, a second email will be sent to the contact listed below. This email will either indicate a successful upload or identify the errors detected during validation. If errors were detected, the supplemental file submission will be rejected. Once the errors are corrected, the Free First Fill supplemental file(s) can be re-submitted.

Contact notified of Supplemental File(s) submission		
User ID	**Name**	**E-mail**
jk50	Tommy Lo	lo@nerdvana.fu.com

OK

Go To: Formulary Submission Start Page   Select Contract Year

Done   🌐 Internet

🏁 Start   🔳 🔳 🔳 🔳 🔳   🔳 Novell Gr…   🔳 G:\HPMS…   🔳 CY2008_…   🔳 HPMS: F…   🔳 gcfffscree…   🔳🔳🔳🔳🔳🔳   1:15 PM

FORMULARY AND SUPPLEMENTAL FILE REPORTS

The Formulary Reports functionality provides users access to a variety of formulary-related information to assist users in the formulary submission process. This section provides detailed information on the following reports:

- Formulary/Bid Contact Report
- Formulary Crosswalk Report
- Formulary Status History Report

The Formulary Reports are available from the Plan Formularies link on the HPMS Home Page.

Step 1: Hover over the **Plan Formularies** link in the left-hand navigation bar to view the flyout menu. Select **Formulary Reports** to access the Formulary Reports by Contract Year.

Step 2: Select the **CY 2008** link from the Formulary Reports page.
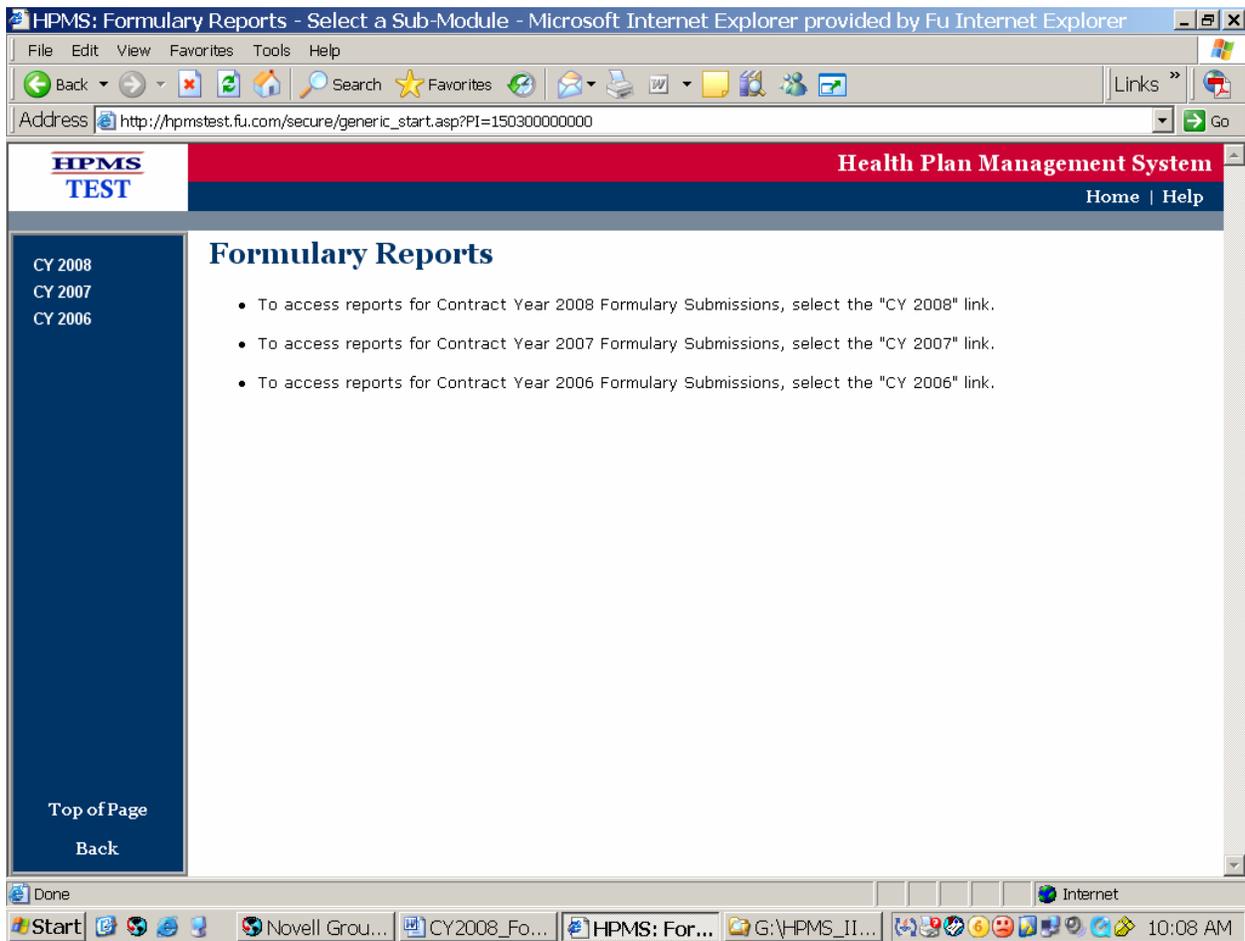
FORMULARY/BID CONTACT REPORT

The **Formulary/Bid Contact Report** provides contact information at the "Contract Level" and "Plan Level" for one or more contract(s). The report includes Name, Address, Phone Number, Fax Number, and Email Address for the following contract contacts:

- CEO;
- CFO;
- Medicare Compliance Officer;
- Marketing Contact;
- Bid Primary Contact; and
- Formulary Contact.

The Plan Level information displays the Plan ID, Name, Address, Phone Number, Fax Number, and Email Address for the following contacts:

- Bid Actuary Contact;
- Bid PBP Contact:
- Certifying Actuary – MA Bid; and
- Certifying Actuary – Part D Bid.

Step 1: Select "**Formulary/Bid Contact Report"** from the Contract Year 2008 – Select a Report page.
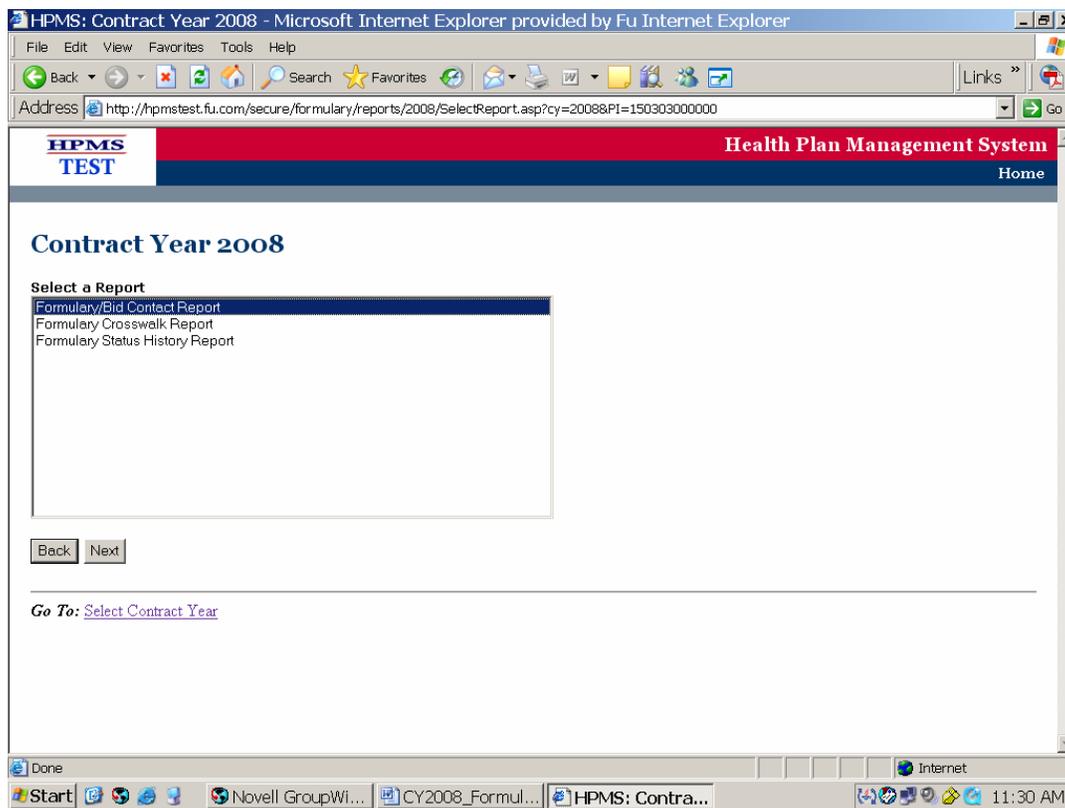
Step 2: Select the desired Contract Number(s) from the Formulary/Bid Contact Report selection criterion page and click on **Next.**
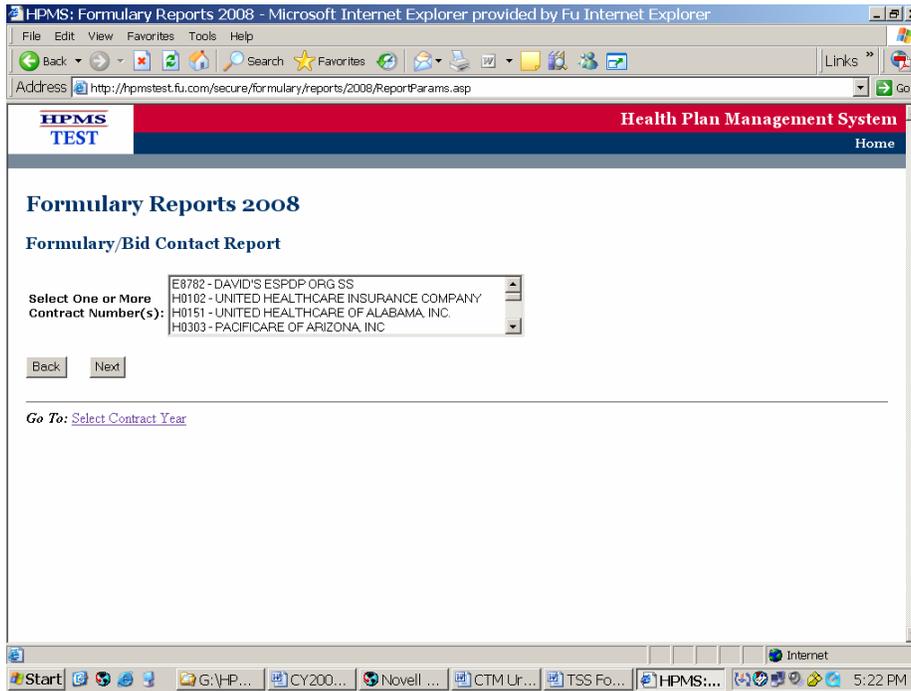
Step 3: View the details of the Formulary/Bid Contact Report.

IMPORTANT NOTE: If the information from the Formulary/Bid Contact Report is incorrect, please update the "Contact Information" in the HPMS **Contract Management Module**.
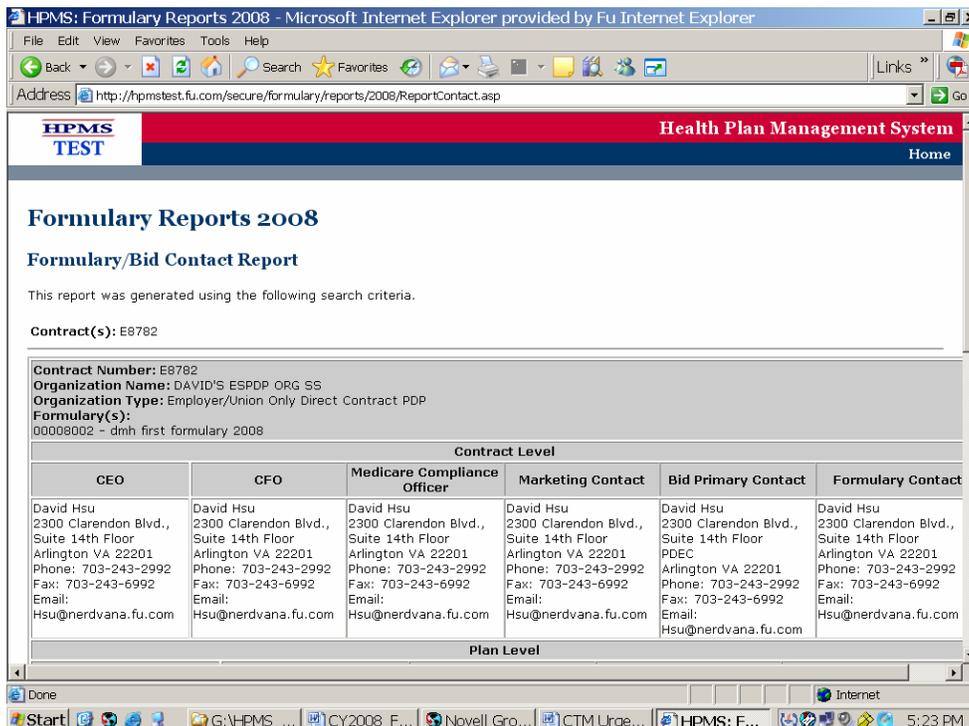
FORMULARY CROSSWALK REPORT

The **Formulary Crosswalk Report** displays information about which formularies are associated to a selected contract's plans. This report includes the Contract Number, Plan ID, Part D indicator, Formulary ID, and Formulary Status for a selected contract number(s). This report can be exported to Excel.

**Step 1:** Select **"Formulary Crosswalk"** from the Contract Year 2008 – Select a Report page.
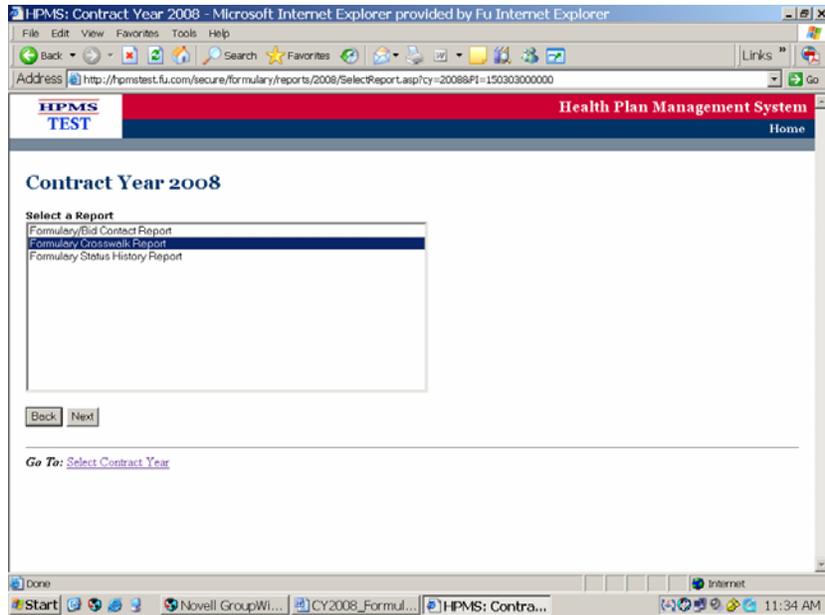
Step 2: Select the desired Contract Number(s) from the Formulary Crosswalk Report selection page.
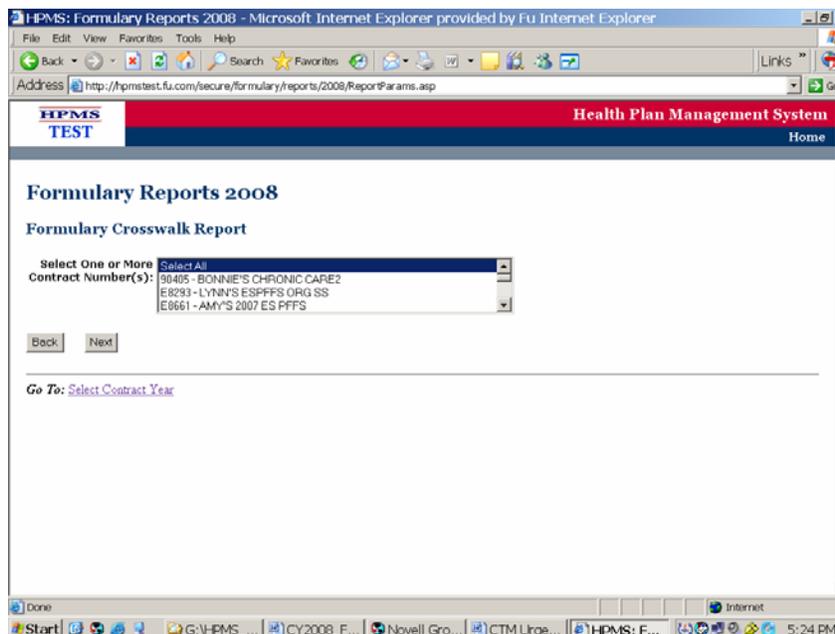
Step 3: View the details of the Formulary Crosswalk Report.
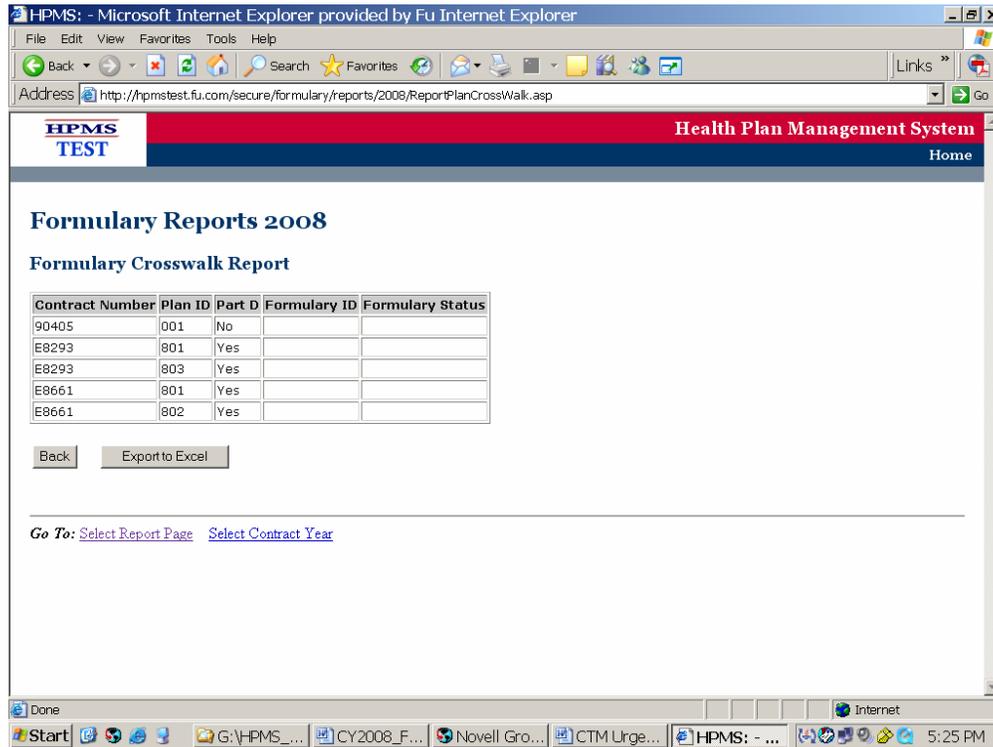
Step 4: Select the **"Export to Excel" button** to open/save the report in an Excel file if desired.
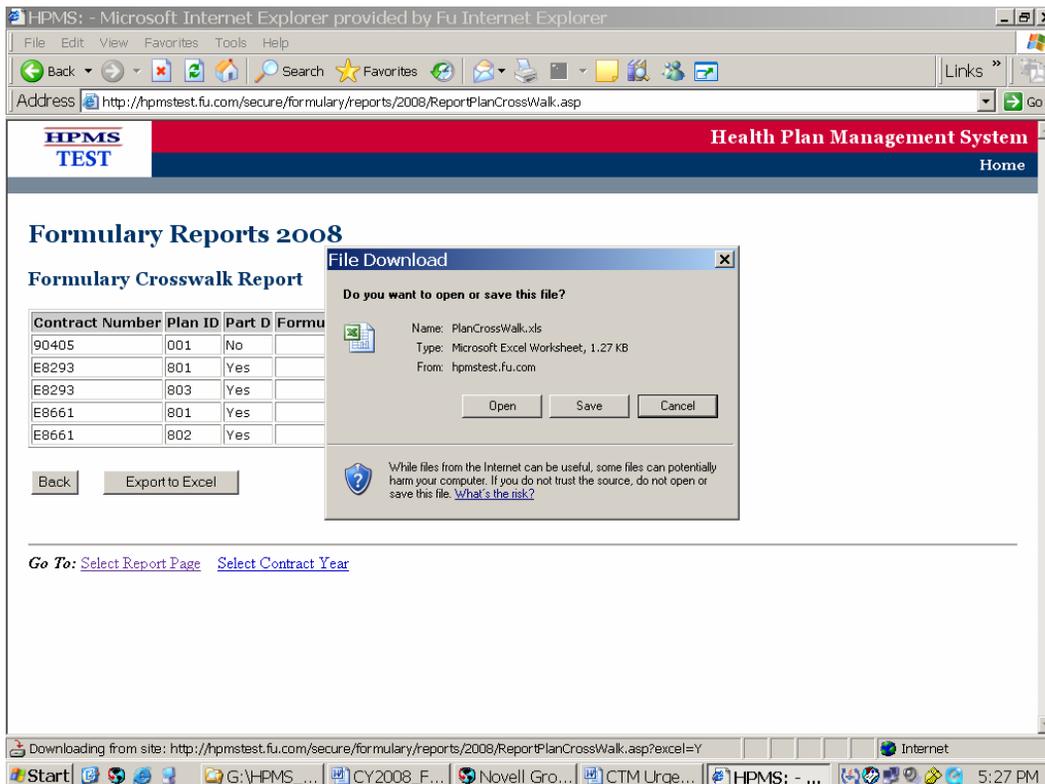
FORMULARY STATUS HISTORY REPORT

The **Formulary Status History Report** provides detailed status information on all versions for a given formulary ID. The report includes: Formulary ID; Formulary Version; Formulary Status; Version Deleted; Formulary Type; Comments; Last Approved Formulary Version; Last Approved Formulary Date; and Most Recent Formulary Submission Date. The information on the "Comments" column is from the Formulary Desk Review process. In addition, the user has a capability to access further information from the **Formulary NDC Report** and **FUT Email** pop-up pages.

The **Formulary NDC Report** displays information including: Number of Tiers (including Tier-related details), Effective Date, Quantity Limit, Database Resource, Prior Authorization, and Step Therapy Management. This pop-up page also allows the user to open/save the formulary attachments (Prior Authorization File and Step Therapy File), if applicable. Additionally, the user has a capability to view the contents of the formulary submission file.

The **FUT Email** pop-up page displays the email generated by the FUT validation process.

Step 1: Select **"Formulary Status History Report"** from the Contract Year 2008 – Select a Report page.
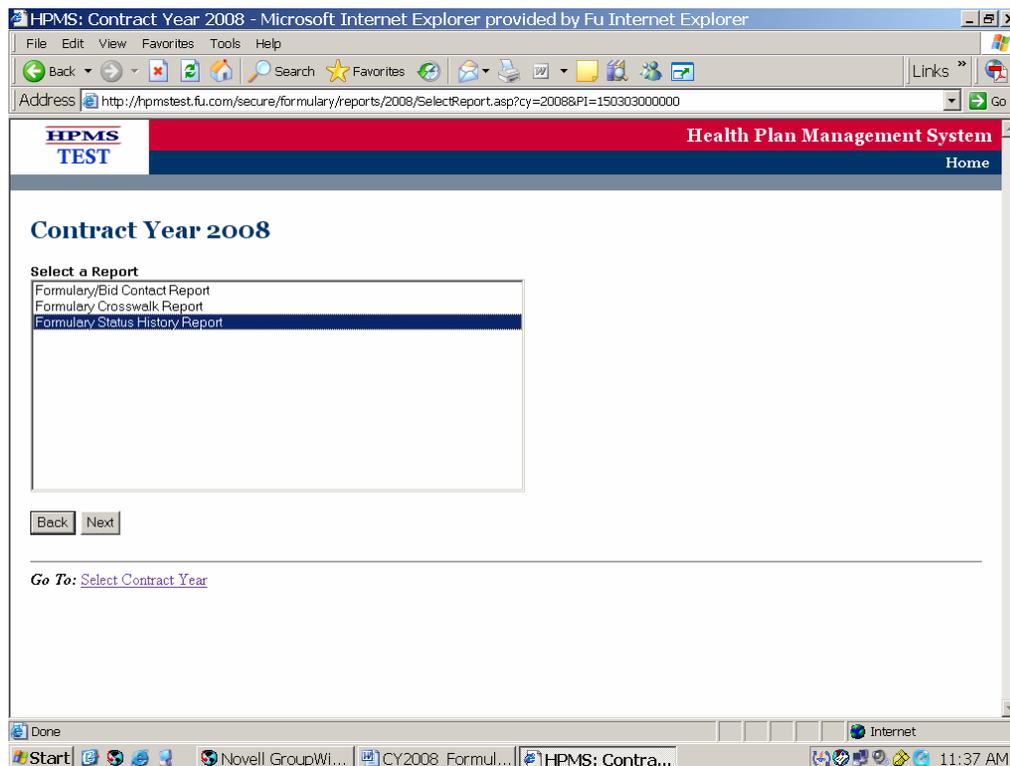
Step 2: Select the desired Formulary ID(s) from the Formulary Status History Report selection criterion page.
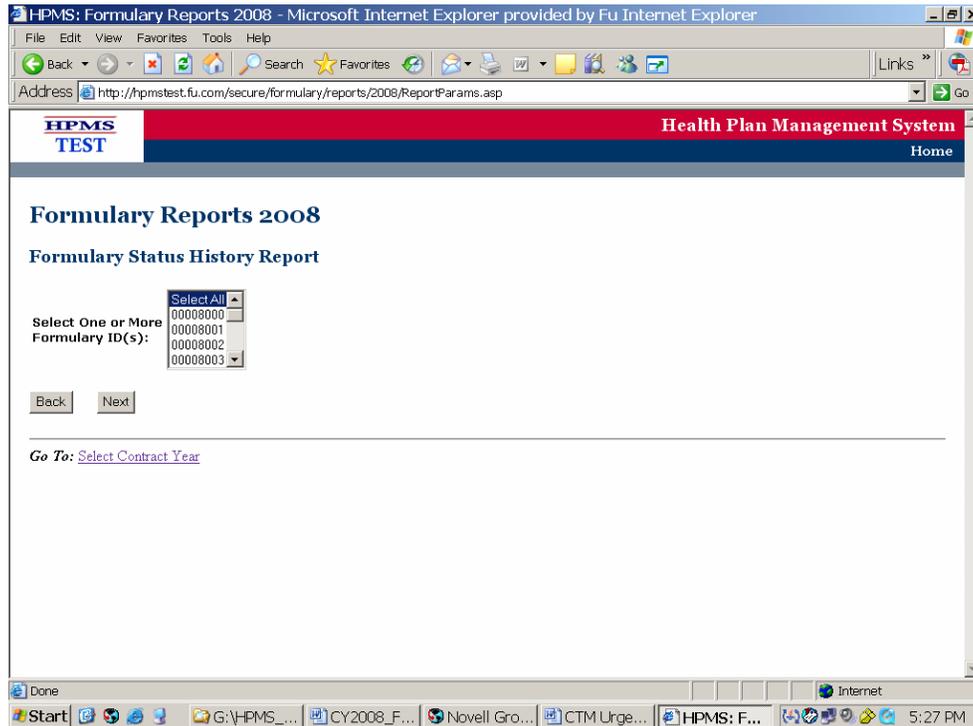
Step 3: View the details of the Formulary Status History Report.
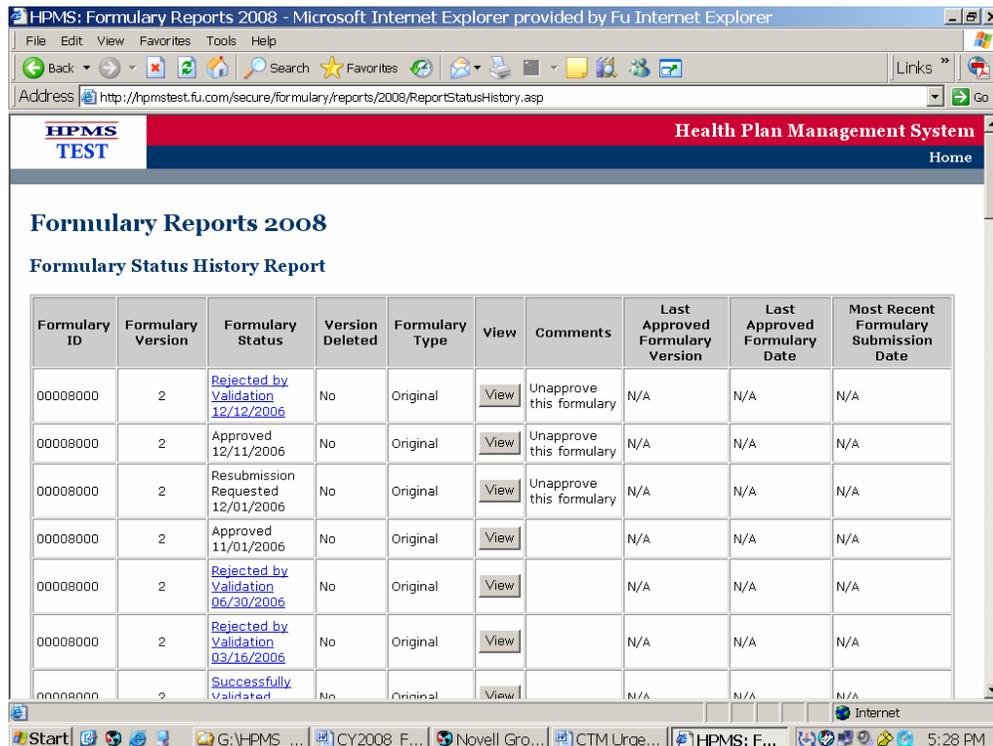
Step 4: Click on one of the available links in the Formulary Status column to view the Formulary Status History Report – **FUT Email** report for that specific version submission.

Step 5: Click on the **"View" button** to view the Formulary Status History Report – Formulary NDC Report.

Step 6: Click on the "Prior Authorization File" and/or "Step Therapy File" links to open/save the attachments (if submitted).

Step 7: Select the **"Click here to view contents of the formulary submission"** link to access the data contained in the formulary submission file.

STATUS HISTORY REPORT – GAP COVERAGE

The **Status History Report – Gap Coverage** provides detailed statuses of Gap Coverage submissions on versions for a given Formulary ID. The report includes Formulary ID, Formulary Version, Plans, Supplemental File Status, and View. In order to use the View button the Gap Coverage submission status cannot be "Rejected by Validation." If the status is "Rejected by Validation," the user is able to click on the link to view the email that contains the rejection details.

The View button allows the user to view the Gap Coverage to Contract ID and Plan Number association. The user can further view the NDC, Brand Name, Generic Name, Dosage Form, Strength, Route of Administration, and Cost Share Tier Value.

Step 1: Select the **Bid Reports** link from the **Plan Bids** flyout menu from the HPMS Home Page.
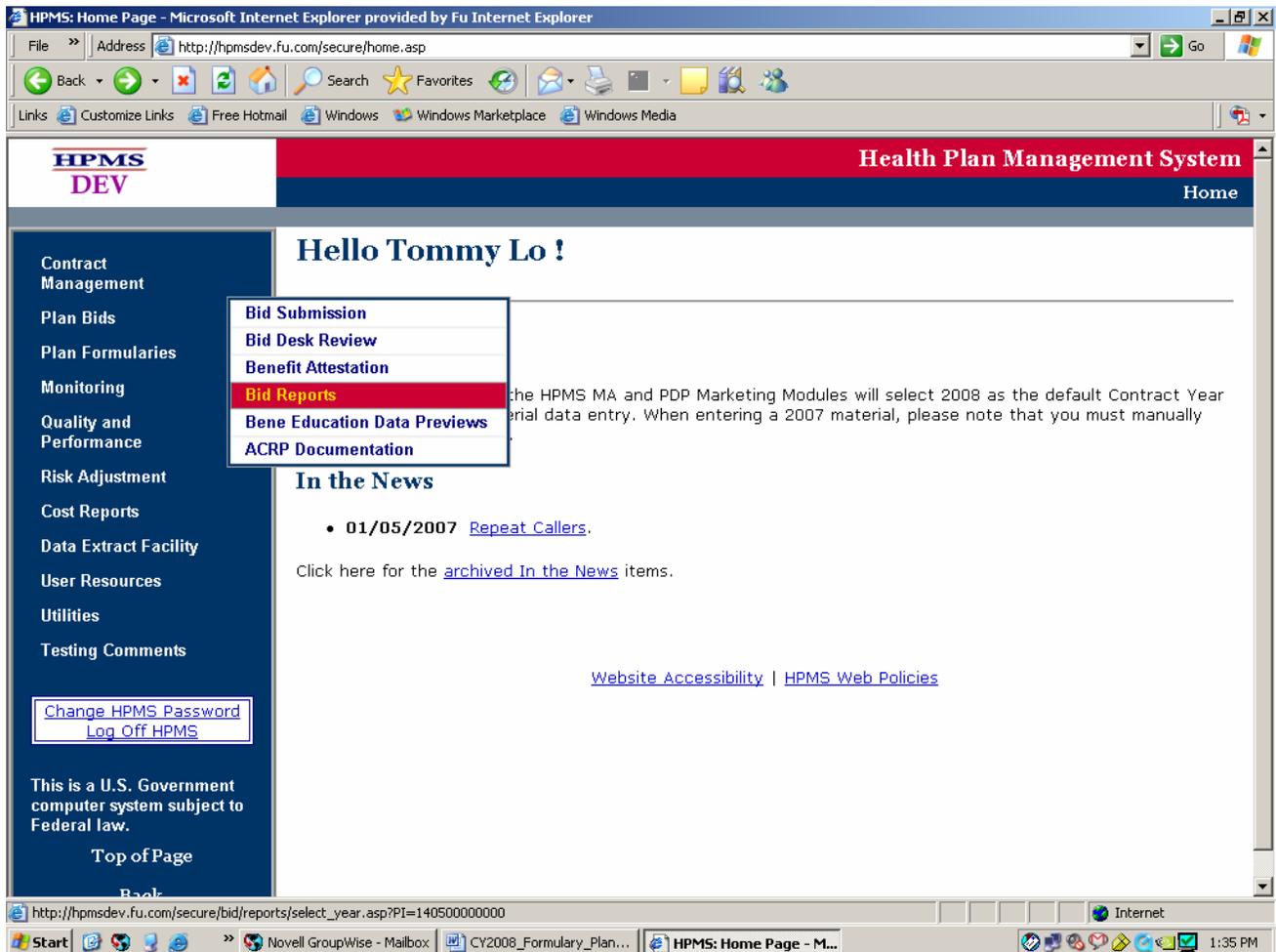
Step 2: Select **2008** from the **Select Contract Year** page and click **Next**.
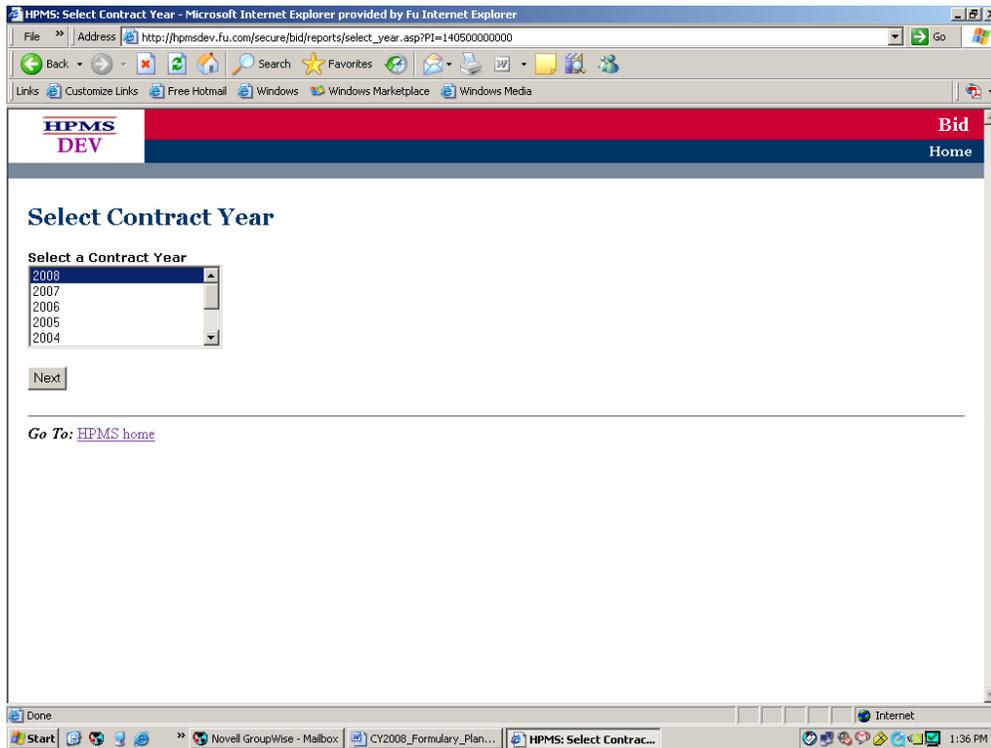
Step 3: Select **Status History Report – Gap Coverage** from the **Contract Year 2008 Select a Report** page and click **Next**.
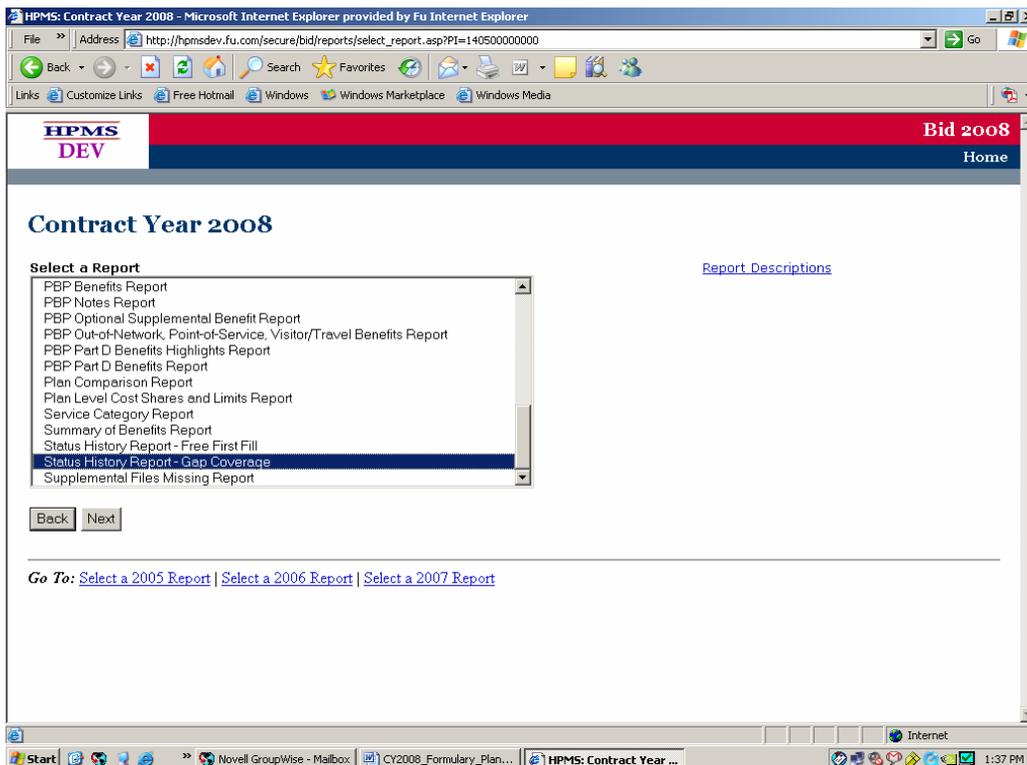
Step 4: Select the Contract ID(s) from the **Status History Report – Gap Coverage** contract selection page and click **Next**.
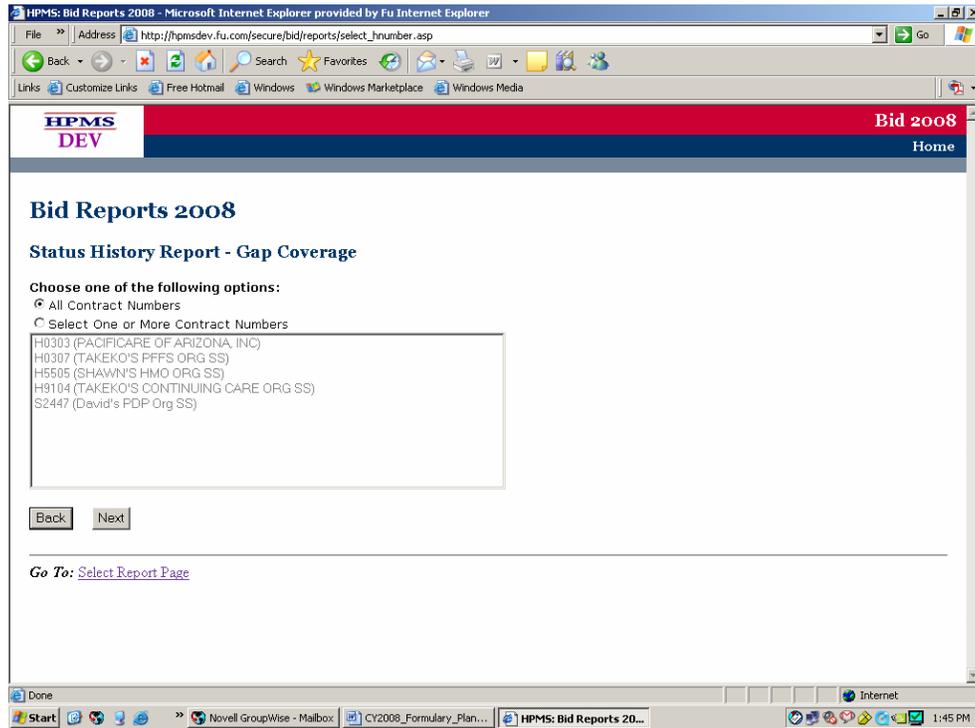
Step 5: Select a Plan(s) from the **Status History Report – Gap Coverage** plan selection page and click **Next**.
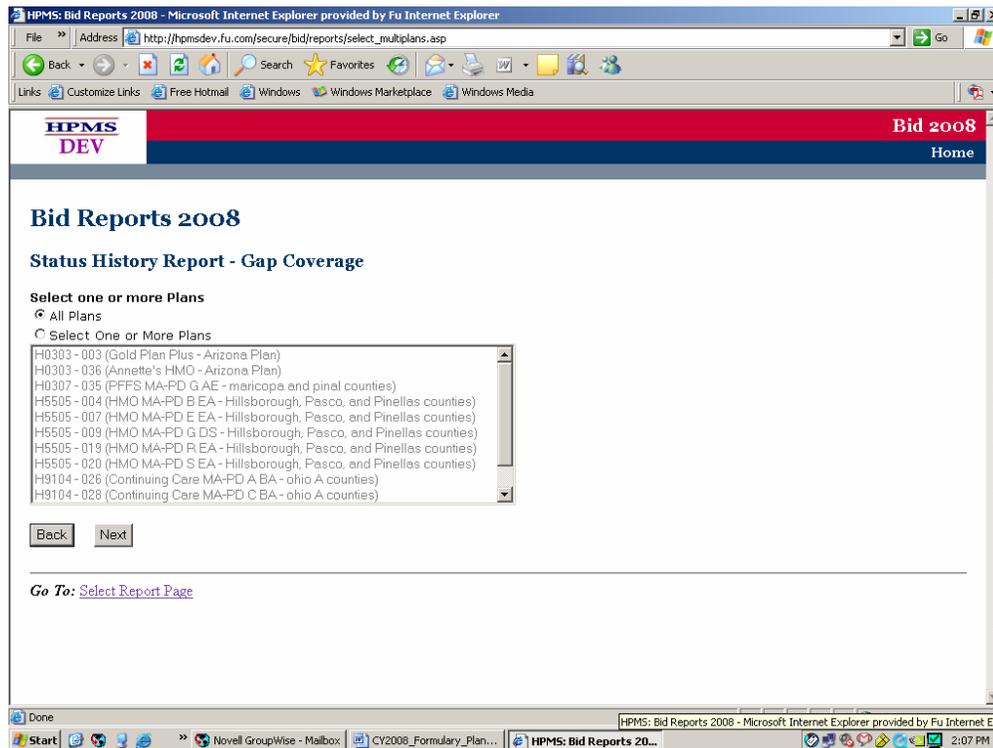
Step 6: Select a Formulary ID(s) from the **Status History Report – Gap Coverage** Formulary ID selection page and click **Next**.
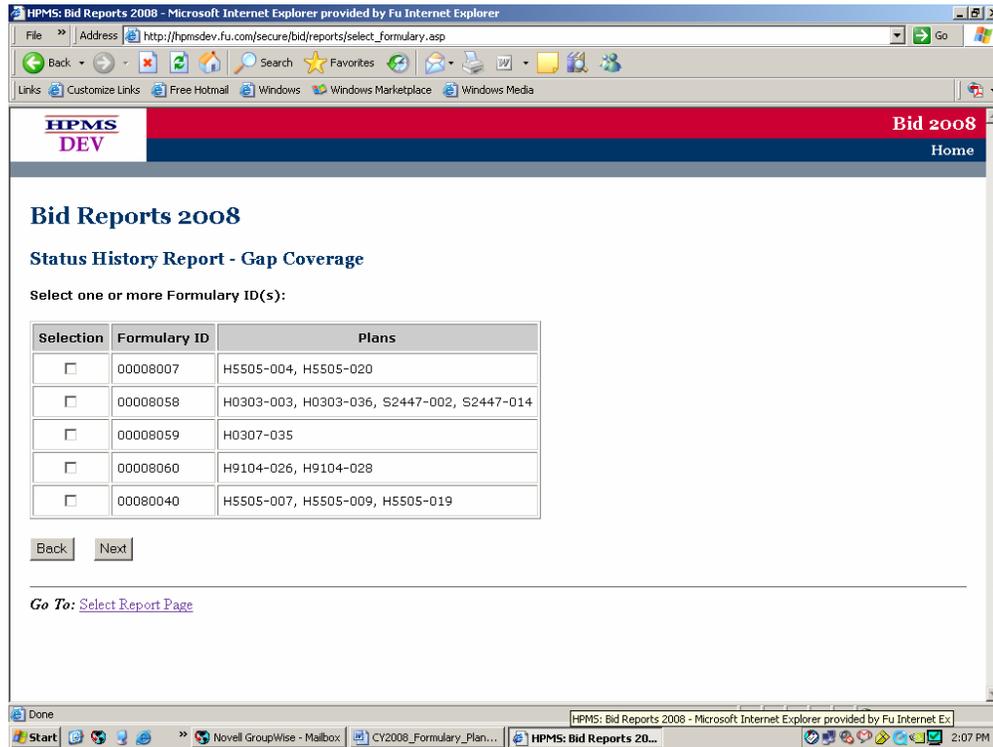
Step 7: View the **Status History Report – Gap Coverage** page.
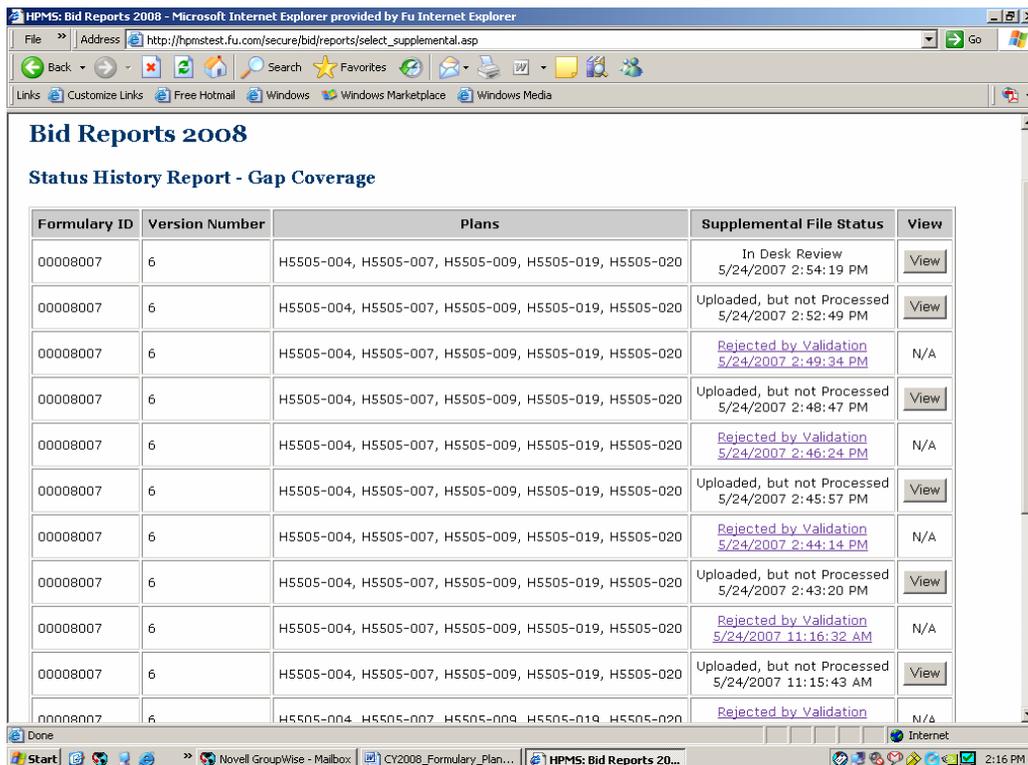
Step 8: Click on the **Rejected by Validation** link to view the **Rejection Email** pop-up page.
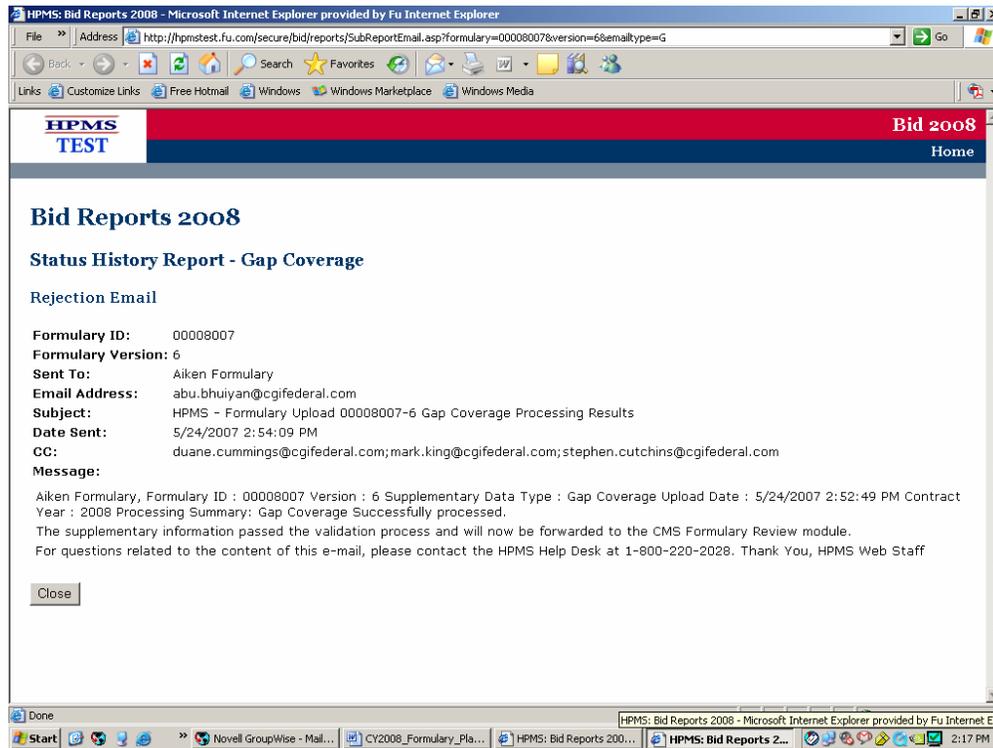
Step 9: Click the **View** button on the **Status History Report – Gap Coverage** page to view the **File to Plan ID Association** page.

Step 10: Click the **View** button to display the **Status History Report – Gap Coverage Detail** page.

STATUS HISTORY REPORT – FREE FIRST FILL

The **Status History Report – Free First Fill** provides detailed statuses of Free First Fill submissions on versions for a given Formulary ID. The report includes Formulary ID, Formulary Version, Plans, Supplemental File Status, and View. In order to use the View button the Free First Fill submission status cannot be "Rejected by Validation." If the status is "Rejected by Validation," the user is able to click on the link to view the email that contains the rejection details.

The View button allows the user to view the Free First Fill to Contract ID and Plan Number association. The user can further view the NDC, Brand Name, Generic Name, Dosage Form, Strength, Route of Administration, and Cost Share Tier Value.

Step 1: Select the **Bid Reports** link from the **Plan Bids** flyout menu from the **HPMS Home Page**.
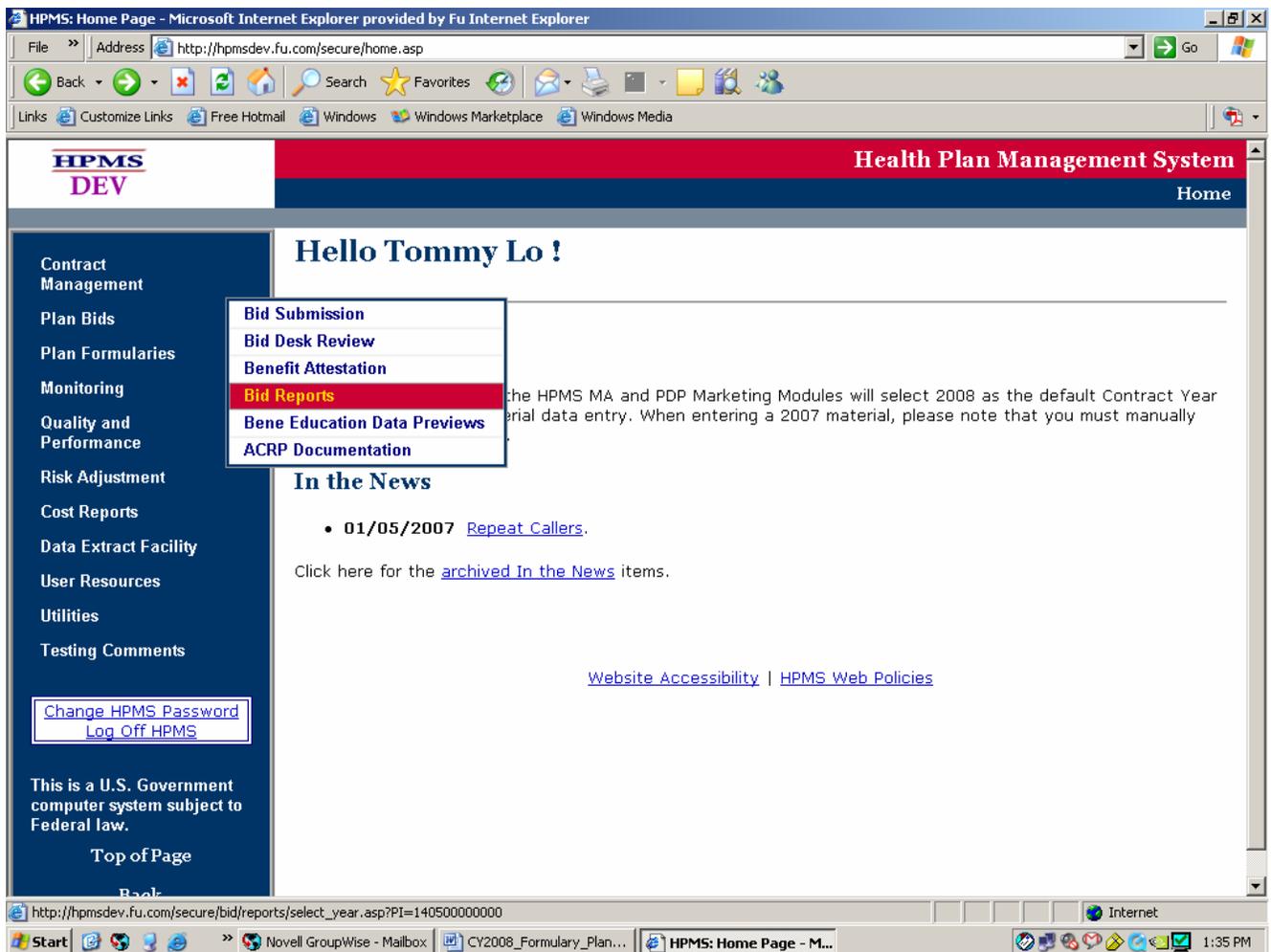
Step 2: Select **2008** from the **Select Contract Year** page and click **Next**.
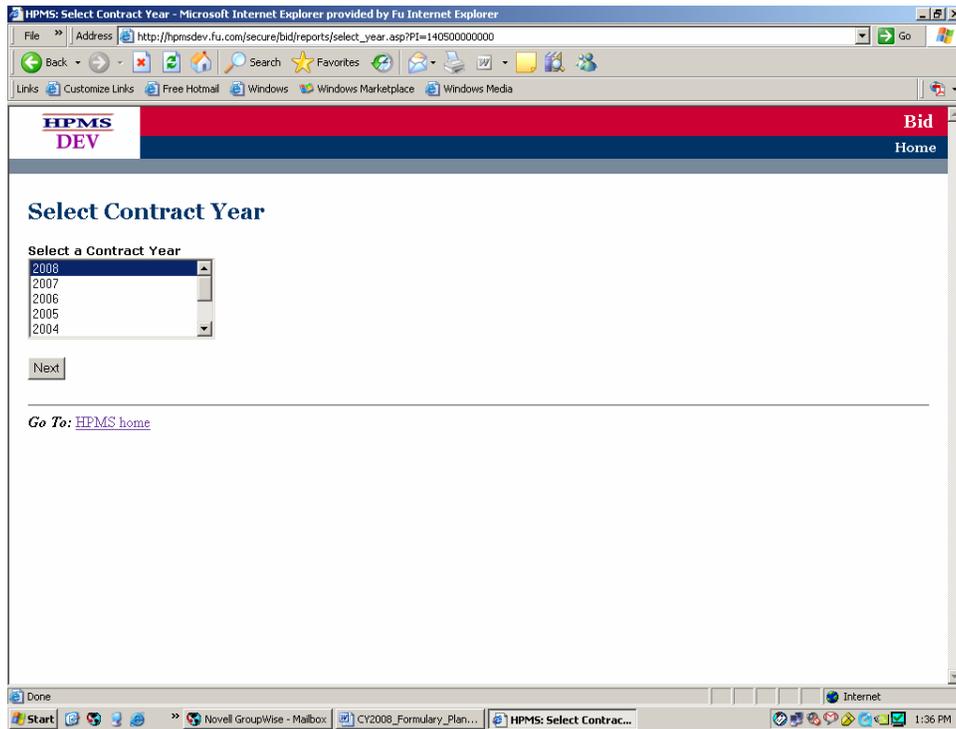
Step 3: Select **Status History Report – Free First Fill** from the **Contract Year 2008 Select a Report** page and click **Next.**
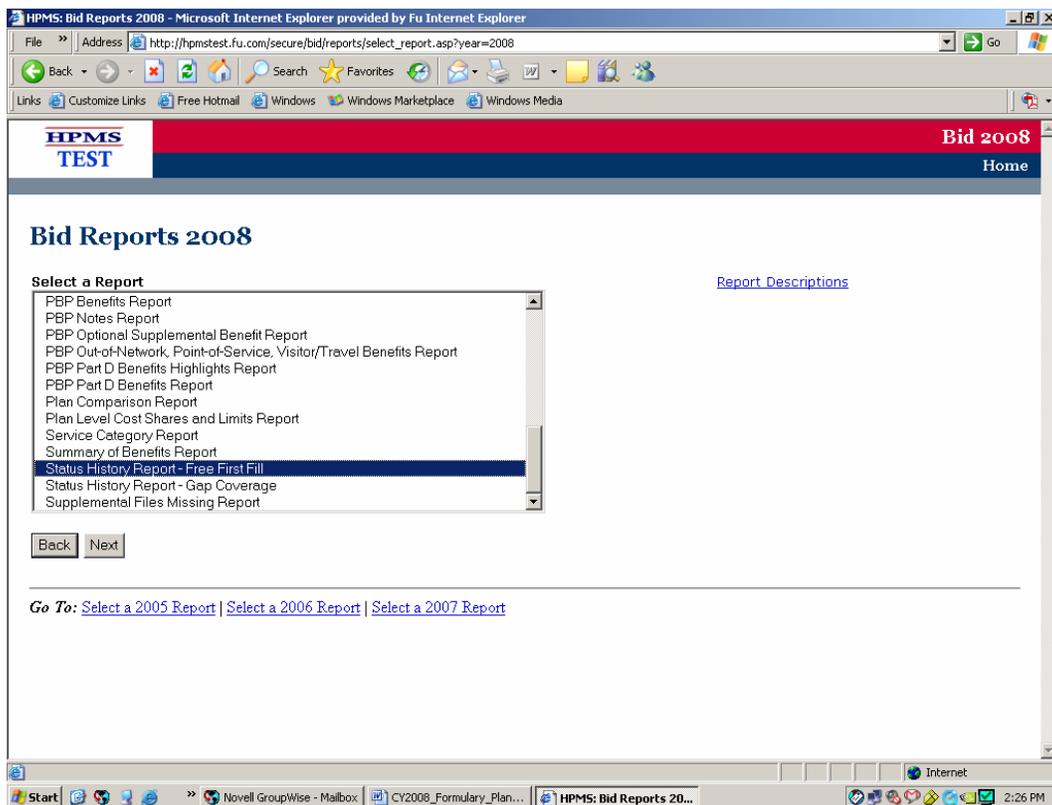
Step 4: Select the **Contract ID** from the **Status History Report – Free First Fill** contract selection page and click **Next**.
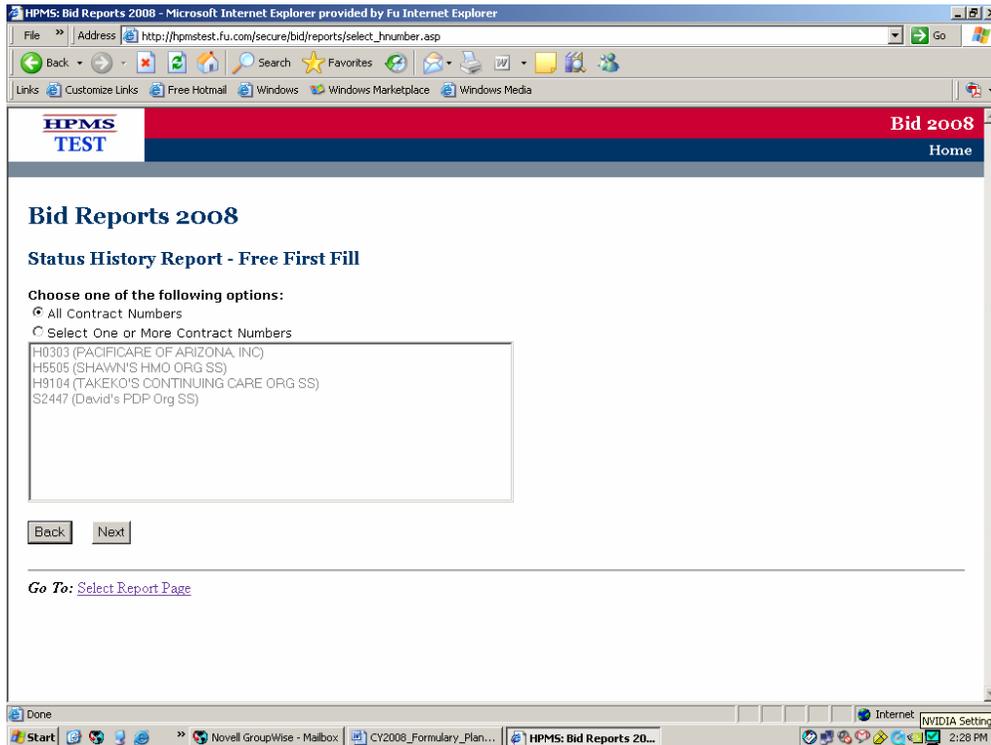
Step 5: Select a plan(s) from the **Status History Report – Free First Fill** plan selection page and click **Next**.
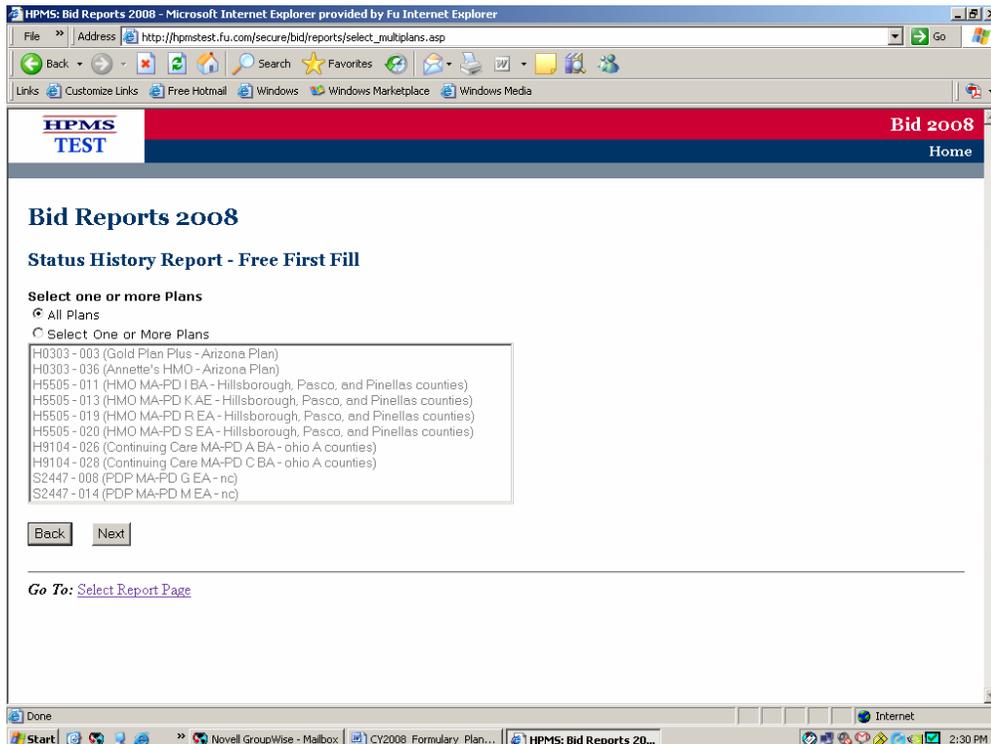
Step 6: Select a **Formulary ID(s)** from the **Status History Report – Free First Fill** Formulary ID selection page and click **Next**.
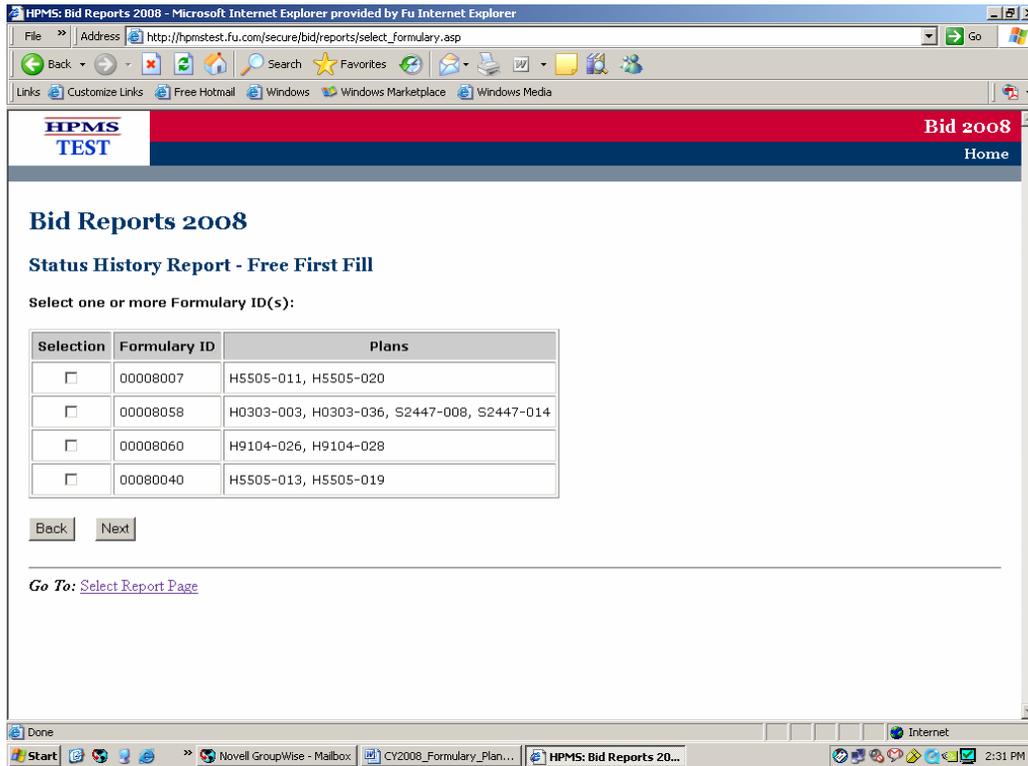
Step 7: View the **Status History Report – Free First Fill** page.
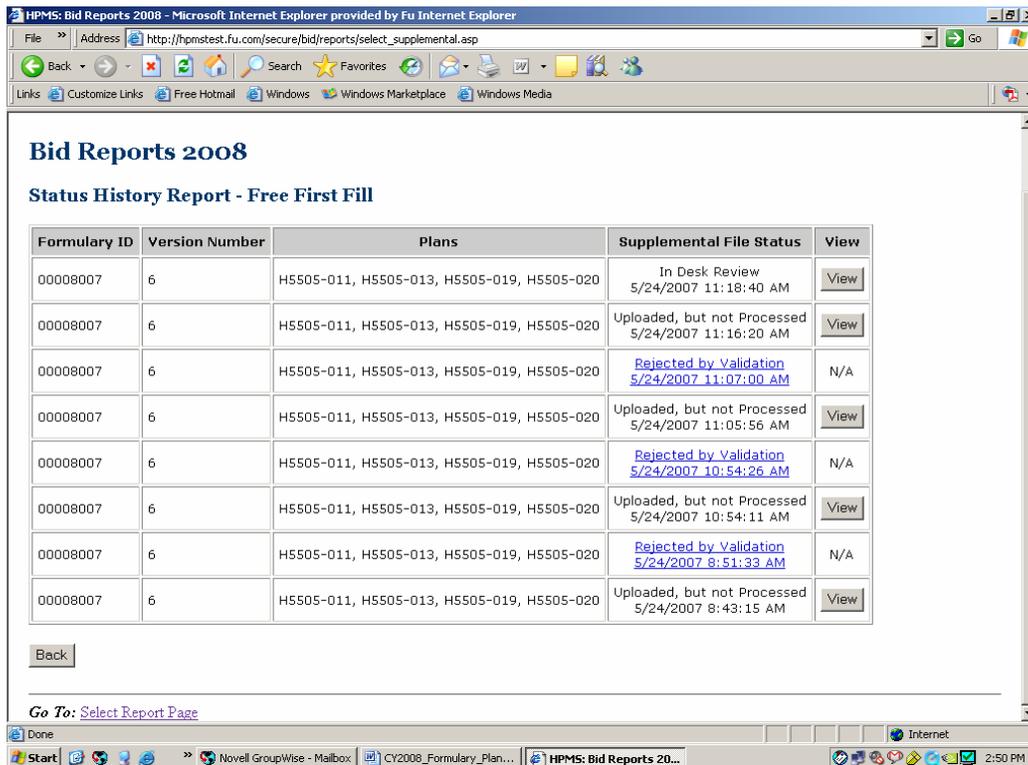
Step 8: Click on the **Rejected by Validation** link to view the **Rejection Email** pop-up page.
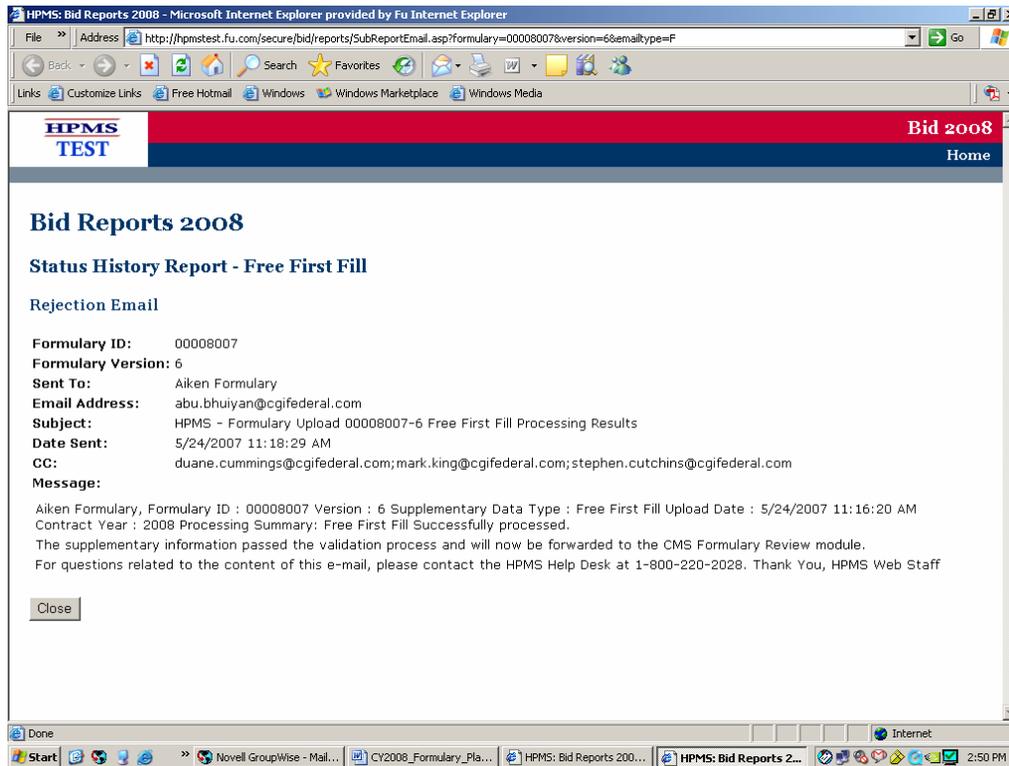
Step 9: Click the **View** button on the **Status History Report – Free First Fill** page to view the **File to Plan ID Association** page.

Step 10: Click the **View** button to display the **Status History Report – Free First Fill Detail** page.

APPENDIX A: CY 2008 FORMULARY FILE RECORD LAYOUT

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Proxy NDC	CHAR NOT NULL Always Required	11	11-Digit National Drug Code	00000333800
Tier_Level_Value	CHAR NOT NULL Always Required	2	Defines the Cost Share Tier Level Value Associated with the drug. Assumption is that the drug is assigned to only one tier value. These values are consistent with the selection of tier value options available to data entry users in the Plan Benefit Package software. If no Tier Level Value applies, enter '1' as the value for this field.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Drug_Type_Label_Value	CHAR NOT NULL Always Required	1	Defines the Drug Type Label Value for the drug. Enter the label value for the Drug Type from the defined list of labels.	1 = Generic 2 = Preferred Generic 3 = Non-Preferred Generic 4 = Brand 5 = Preferred Brand 6 = Non-Preferred Brand
Quantity_Limit_Amount _YN	CHAR NOT NULL Always Required	1	Does the drug have a quantity limit restriction?	1 = Yes 0 = No
Quantity_Limit_Amount	NUM Sometimes Required	7	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount for a given number of days. The units for this amount must be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. If the drug does not have a quantity limit restriction, then leave this field blank.	1000.75

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
			The maximum logical number that will be accepted is "9999.99".	
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit.	60 (e.g. 9 pills every 60 days)
Prior_Authorization_YN	CHAR NOT NULL Always Required	1	Is prior authorization required for the drug?	1 = Yes 0 = No
Prior_Authorization_Group_Desc	CHAR Sometimes Required	100	Description of the drug's prior authorization group as it will appear on the submitted prior authorization attachment. The group name may represent a drug category or class or may simply be the name of the drug if no other grouping structure applies. If response to Prior_Authorization_YN = 0 (No), then leave this field blank.	Antiemetics
Specialty_Pharmacy_YN	CHAR NOT NULL Always Required	1	Does this drug have restricted access to certain specialty pharmacies?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR NOT NULL Always Required	100	Enter the name of the category for the drug. Note for CY 2008 this field is required for all drugs.	Analgesics
Therapeutic_Class_Name	CHAR NOT NULL Always Required	100	Enter the name of the class for the drug. Note for CY 2008 this field is required for all drugs.	Opioid Analgesics
Step_Therapy_YN	CHAR NOT NULL Always Required	1	Does step therapy apply to this drug? Note: Prerequisite (Step 1) drugs should also have a value of 1 in this field.	1 = Yes 0 = No
Step_Therapy_Type_Group_Num	NUM Sometimes Required	2	Enter the total number of step therapy drug treatment groups in which the drug is included. If response to Step_Therapy_YN = 0 (No), then leave this field blank. The maximum logical number that will be accepted is "99".	3

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
The remaining two fields described below should be repeated as a group or unit in the file. For example, for a given drug used in multiple Step Therapy programs, the values for Step_Therapy_Type_Group_Desc_1 = "CHF Therapy" and Step_Therapy_Type_Group_Step_1 = 4 should be included in adjacent columns in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_2 = "Angina Therapy" and Step_Therapy_Type_Group_Step_2 = 1 should be included in additional adjacent columns in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_3 = "CVD Therapy" and Step_Therapy_Type_Group_Step_3 = 5 should be included in additional adjacent columns in the file.				
Step_Therapy_Type_Group_Desc_X	CHAR Sometimes Required	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num If response to Step_Therapy_YN = 0 (No), then leave this field blank.	Step_Therapy_Type_Group_Desc_1 = "CHF Therapy" Step_Therapy_Type_Group_Desc_2 = "Angina Therapy" Step_Therapy_Type_Group_Desc_3 = "CVD Therapy"
Step_Therapy_Type_Group_Step_X	NUM Sometimes Required	2	Identifies the step number or level within the sequence for the Step Therapy Group. Field should be repeated in the record based upon the number of groups declared in Step_Therapy_Type_Group_Num AND in the same order as Step_Therapy_Type_Group_Desc_X If response to Step_Therapy_YN = 0 (No), then leave this field blank. The range of valid accepted values is 1 to 99. Note: Prerequisite (Step 1) drugs should have a value of 1 in this field.	Step_Therapy_Type_Group_Step_1 = 4 (e.g. Step 4 of 6) Step_Therapy_Type_Group_Step_2 = 1 (e.g. Step 1 of 3) Step_Therapy_Type_Group_Step_3 = 5 (e.g. Step 5 of 5)

APPENDIX B: UPLOAD FILE FORMATS

FORMULARY FILE INSTRUCTIONS

The formulary file must be created in an ASCII File Tab delimited format and contain one proxy NDC record for each drug offered with an organization's benefit plan(s). The Appendix A: Formulary File Record Layout is provided for your reference. Please note that only proxy NDCs provided in the CY 2008 Formulary Reference NDC File maybe uploaded. All other NDCs will be rejected by the HPMS Formulary Validation Process.

The following is a "field by field" description of how to structure your formulary file for upload into HPMS. Please note that every field is labeled either "Required," "Optional," or "Conditional." The conditional fields should be populated if the condition is met as outlined below. When an optional and/or conditional field is left blank, the blank must be represented by a tab delimiter.

The upload validation edits are explained in further detail within each field description. A formulary will be rejected if the validation edits are not met.

Field 1 – Proxy NDC:
REQUIRED: Each record should include an 11-digit proxy NDC associated with the formulary. The list of acceptable proxy NDCs can be found in the CY 2008 Formulary Reference NDC File. Proxy NDCs should only be entered once in this formulary file.

Field 2 – Tier_Level_Value:
REQUIRED: Enter the cost share tier level value associated with the drug. Include a value from 1 to 10 only. A number outside of this range will result in an upload error. If cost share tiering does not apply, include the value "1" in this field.

> **NOTE:** The maximum value entered for this field may NOT be greater than the value entered for the number of cost share tiers in the HPMS Formulary Submission Data Entry Web Interface. If these values are inconsistent an upload error will result.

Field 3 – Drug_Type_Label_Value:
REQUIRED: Enter a drug type label value associates with the drug. Include a value of 1 to 6 only. A number outside of this range will result in an update error.

Field 4 – Quantity_Limit_Amount_YN:
REQUIRED: This field should be set to a value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug has a restriction on the quantity that is available; otherwise set the value to 0 if there are no restrictions. Examples of quantity limits include the following:

- Simvastatin 80mg tablets - 30 tablets/30 days
- Risedronate 35mg tablets - 5 tablets/30 days
- Latanoprost 0.005% drops – 2.5 ml/30 days
- Albuterol HFA MDI – 17 grams/30days

Field 5 - **Quantity_Limit_Amount**:
CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_YN** field is 1, include the quantity limit unit amount. The unit amount for this field refers to unit values such as the number of tablets or the number of grams for the drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 9.

Field 6 - **Quantity_Limit_Days**:
CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_YN** field is 1, include the quantity limit day amount for this drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 60.

Field 7 – **Prior_Authorization_YN**:
REQUIRED: This value should be set to value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug requires prior authorization; otherwise set the value to 0 to indicate that a prior authorization is NOT required. NOTE: If the user selected **Yes** to the Prior Authorization question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 8 – **Prior_Authorization_Group_Desc:**
CONDITIONAL: If Prior Authorization value "YN" is 0, then leave this field blank. If Prior Authorization value "YN" is 1, then include the description of the drug's prior authorization group as it will appear on the Prior Authorization Attachment. The group name may represent a drug category or class or may be the name of the drug if no other grouping structure applies.

Field 9 – **Specialty Pharmacy_YN:**
REQUIRED: The value should be set to 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug has restricted access to certain specialty pharmacies; otherwise set the value to 0 to indicate that the drug is not restricted to certain specialty pharmacies.

NOTE: If the user selected "Yes" to the specialty pharmacy question in the HPMS data entry web interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent an upload error will result.

Field 10 – **Therapeutic_Category_Name**:
REQUIRED: Enter the name of the category for this drug.

Field 11 – **Therapeutic_Class_Name**:
REQUIRED: Enter the name of the class for this drug.

Field 12 – **Step_Therapy_Type_Group_YN**:
REQUIRED: This value should be set to a value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug is part of a Step Therapy Group; otherwise set the value to 0 to indicate that it is NOT part of a Step Therapy program.

> **NOTE**: If the user selected **Yes** to the Step Therapy question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 13 – **Step_Therapy_Type_Group_Num**:
CONDITIONAL. This field should include a value that indicates the number of step therapy drug treatment groups in which the drug is a member. The value included in this field may not exceed 2 digits in length.This field should contain a value if **Step_Therapy_Type_Group_YN** = 1 (Yes). If step therapy does not apply to a given drug, then leave this field blank by providing a tab delimiter.

Field 14 – **Step_Therapy_Type_Group_Desc_X**:
CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must provide a description of the step therapy drug treatment group. This field should be repeated in the drug record (in an additional column) based upon the number of groups declared in **Step_Therapy_Type_Group_Num**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter.

Field 15 – **Step_Therapy_Type_Group_Step_X**:
CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must include a value in this field that represents the unique step number within the sequence of steps for the treatment group identified in Field 12. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter. Prerequisite (Step 1) drugs should be indicated by a value of 1. This field should be repeated in the record (in an additional column) based upon number of groups declared in **Step_Therapy_Type_Group_Num** AND in the same order as **Step_Therapy_Type_Group_Desc_X**. For example, if an NDC has 3 step therapy treatment groups declared in the Step_Therapy_Type_Group_Num field, then three sets of values should be defined for Step_Therapy_Type_Group_Desc_X and Step_Therapy_Type_Group_Step_X as follows:

> **Step Therapy Treatment Group 1 Values –**
> Step_Therapy_Type_Group_Desc_1 = "CHF Therapy"
> And
> Step_Therapy_Type_Group_Step_1 = 4
>
> **Step Therapy Treatment Group 2 Values –**
> Step_Therapy_Type_Group_Desc_2 = "Angina Therapy"

And
Step_Therapy_Type_Group_Step_2 = 2

Step Therapy Treatment Group 3 Values –
Step_Therapy_Type_Group_Desc_3 = "CVD Therapy"
And
Step_Therapy_Type_Group_Step_3 = 5

PRIOR AUTHORIZATION FILE INSTRUCTIONS

If a formulary has prior authorization for one or more drugs, then the formulary upload submission must include an attachment that describes the specific prior authorization criteria. The criteria should be provided in MS-Word format.

> *Note:* This attachment should be written in Arial or Times New Roman font with font size of 10-12 point.

CMS requests that the prior authorization file be organized in the following format:

- Provide an initial summary page to organize the document, which should contain medication names (brand and/or generic) or medication classes that have prior authorization criteria (e.g. Proton pump inhibitors). These names must match the corresponding Prior Authorization Group Description entered on the formulary file. The medications or medication classes should be listed alphabetically with the associated page number. For example:

Summary Page	
Actiq	Page 1
COX-2 inhibitors	Page 2
Proton pump inhibitors	Page 3

- Following the summary page, each medication or medication class should be listed on the pages identified. For example:

  > Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Actiq, page 2 would contain the criteria for COX-2 inhibitors, and page 3 would contain the criteria for Proton pump inhibitors.

- If prior authorization criteria only applies to beneficiaries who are initiating the drug for the first time (i.e. "new starts"), this should be noted at the drug/class level where the prior authorization criteria is applicable. In addition, on the summary page, please denote with an asterisk the drugs or drug classes where a new start statement applies.

STEP THERAPY FILE INSTRUCTIONS

If a formulary has step therapy for one or more drugs, then the formulary upload submission must include an attachment that illustrates the detailed algorithms for all step therapy management programs in the formulary. The step therapy management algorithm file should be provided in MS-Word format.

>   *Note:* This attachment should be written in Arial or Times New Roman font with font size of 10-12 point.

CMS requests that the step therapy attachment be organized in the following format:

- Provide an initial summary page to organize the document, which should contain medication names (brand and/or generic) or medication classes that have step therapy criteria (e.g. Angiotension receptor blockers). These names must match the corresponding Prior Authorization Group Description entered on the formulary file. The medications or medication classes should be listed alphabetically with the associated page number. For example:

  >   Summary Page
  >   Angiotension receptor blockers   Page 1
  >   Proton pump inhibitors   Page 2

- Following the summary page, each medication or medication class should be listed on the pages identified. For example:

  >   Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Angiotension receptor blockers and page 2 would contain the criteria for Proton pump inhibitors.

- If step therapy criteria only applies to beneficiaries who are initiating the drug for the first time (i.e. "new starts"), this should be noted at the drug/class level where the step therapy criteria is applicable. In addition, on the summary page, please note with an asterisk (*) the drugs or drug classes where a new start statement applies.

SUPPLEMENTAL FILE INSTRUCTIONS

For each plan that offers Gap Coverage and/or Free First Fill, the organization must submit a supplemental file that defines the covered drugs. The file must be created in an ASCII File format and contain one proxy NDC record for each covered drug. The Supplemental File Record Layout is provided below for your reference. The supplemental file must only contain NDCs that exist in the associated formulary. If you include an NDC that is not part of the associated formulary, the file will be rejected by the HPMS Formulary Validation Process.

Note: If the plan offers gap coverage at the full tier level, you do not need to submit a supplemental file.

Gap Coverage and Free First Fill File Record Layout

Required File Format = ASCII File
Do not include a header record
Filename extension should be ".TXT"
One record per row

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Proxy NDC	CHAR NOT NULL Always Required	11	11-Digit National Drug Code	00000333800

APPENDIX C: CONTACT INFORMATION

Contact	Phone Number	Email Address
HPMS Technical Help Desk	1-800-220-2028	hpms@cms.hhs.gov
HPMS		
Julia Heeter	410-786-6198	julia.heeter@cms.hhs.gov
Ana Nunez-Poole	410-786-3370	ana.nunezpoole@cms.hhs.gov
Formulary Content & Review Guidelines		
Brian Martin	410-786-1070	brian.martin@cms.hhs.gov
Kady Flannery	410-786-6722	kathleen.flannery@cms.hhs.gov