Pharmacy Enterprise Customization System (PECS)

User Guide

Version 2.2

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Revision History

Date	Description of Change	Author Information
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05/04/2012	Added more information to Release Manager. Still needs better explanations of screen captures; added Null Drug Pairs write-up to Administrator Role (Julie's); added write-up on Quick Drug Pair Selection; added information about CCR5122 in User Guide in the Notification of Drug Pairs Needing Action for an Approved Drug-Drug Interaction section.	Marella Colyvas
5/04/2012	Clarified the "Also note: If you wish to put a Drug-Drug Interaction (DDI) . . ." statement at the end of the Notification of Drug Pairs Needing Action for the Approved Drug-Drug Interaction section.	Joanne Callahan
05/03/2012	Added explanation of Custom Update File in Release Manager section; updated definition of Administrator on pages 2 and 62 (added fact they can initiate null drug pair removal). Updated write-up on Quick Drug Pair Selection	Marella Colyvas
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4/6/2012	Edited and obtained new screen shots for Multiple DDI records to one FDB; attempted to write up Release Manager but need more information.	Marella Colyvas
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10/12/2010 CR 3391	Updated elements found in Enterprise Infrastructure Engineering (EIE) review for Operational Readiness Testing (ORT)	Marella Colyvas
4/14/2010	Baseline	Russell Chachula & Marella Colyvas

Table of Contents

Pharmacy Enterprise Customization System (PECS) Overview

Purpose

The Pharmacy Enterprise Customization System (PECS) is a Graphical User Interface (GUI) application that currently allows users to customize the contents of the following five business concepts:

- Drug-Drug Interaction
- Drug Pair
- Duplicate Therapy
- Dose Range
- Professional Monograph

The purpose of this user guide is to provide a general overview of the PECS application, as well as more detailed working information. It also provides reference material and task-based instructions for entering and approving Drug-Drug Interaction, Drug Pair, Duplicate Therapy, Dose Range, or Professional Monograph Customization Requests.

PECS Advantage

- All customizations will be performed at the national level to provide consistent order checks between facilities
- Use of First DataBank for drug interaction, duplicate therapy, and dosing data.
- More specificity in drug interaction order checks with the ability to include or exclude dose routes.
- More specificity in duplicate therapy order checks with FDB data.
- Weekly FDB updates with monthly customization updates.
- More frequent customization updates when needed.

Security Roles

The PECS application is accessible only by users signed directly into the VA network, or by users signed into the VA network via the RESCUE client. User authentication into the VA network is a precondition of PECS application access. Application authentication and authorization will be controlled by the VA Kernel Authentication and Authorization for J2EE (KAAJEE) security Application Programming Interface (API).

In order to log in to the application, each user must have a valid VistA account at a local or national facility, since KAAJEE delegates user authentication to VistA. At the application's login screen, users are prompted for their access and verify codes and will be allowed to select the VistA institution which issued their credentials*

Identity Management

Authorization is handled through the use of specific VistA security keys. PECS doesn't assign individual permissions to users. Instead, it defines a number of roles for its users (requestor, approver, release manager and administrator) and associates a set of permissions with each of them. These roles are mapped to security keys as follows.

PECS Role	VistA Security Key
Requestor	PSS_CUSTOM_TABLES_REQUESTOR
Approver	PSS_CUSTOM_TABLES_APPROVER
Release Manager	PSS_CUSTOM_TABLES_REL_MAN
Administrator	PSS_CUSTOM_TABLES_ADMIN

Depending on the permissions needed by a user, the appropriate role is determined and the corresponding key assigned to their account. The user provisioning process is part of the VistA system and is thus not documented here. Password changes, account activation/inactivation, etc., must be performed through VistA. Refer to the appropriate documentation for details on user account management

Following is a list of roles available within the application, and a description of what each role can do:

Requestor: Create a customization request, modify their own requests, and run, save, and export queries.

Approver: Create, review, approve, modify, delete or reject customization requests; run, save, and export queries, and run reports. An approver can review but cannot approve their own requests.

Release Manager: Can run queries and view detail records. A Release Manager can generate an incremental or full Custom Update file, or download an existing Custom Update.

Administrator: Can run queries and view detail records. In addition, Administrators can modify field settings for each concept type, add or delete users to/from the approver role, and initiate the process to remove drug pairs that contain a null routed generic drug.

Process Flow

Here is a process diagram depicting the process life cycle. It depicts the high-level business process from the point at which a new interaction is created to when a file is available to be loaded to production.

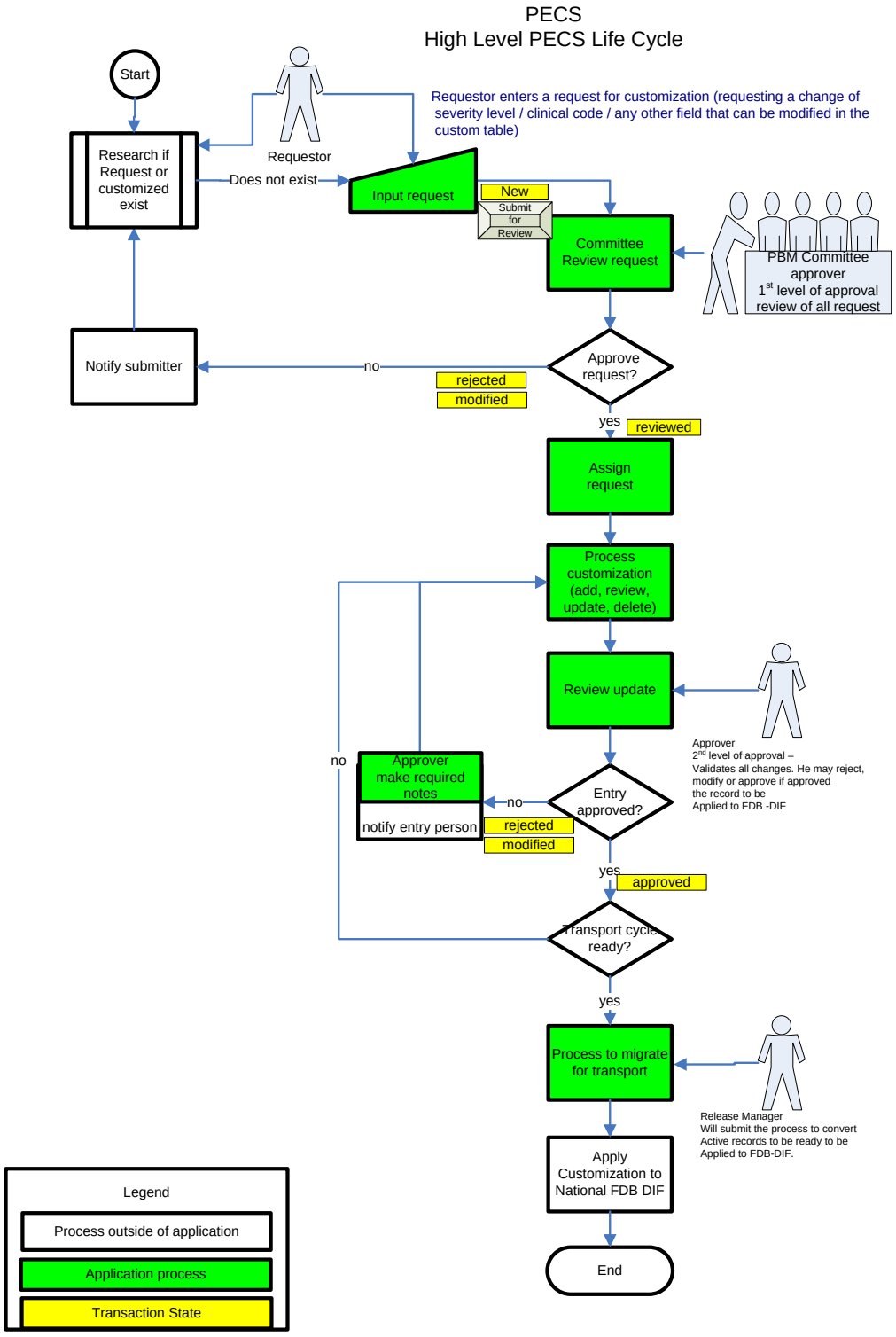


Figure 1: PECS Customization Life Cycle

Figure 1 shows the life cycle of a customization change from the Requestor entry to the point the record is ready to be sent to the production FDB Drug Information Framework (DIF) custom table. The updates and changes are made and maintained in a Staging Table. Records are not extracted until the Release Manager submits approved changes. Records are then formatted and placed in a directory where they will be updated to production. The process that updates these records uses software named DATUP.

Transaction Flow

The diagram below depicts the Action Statuses of a record's transition from creation to approval.

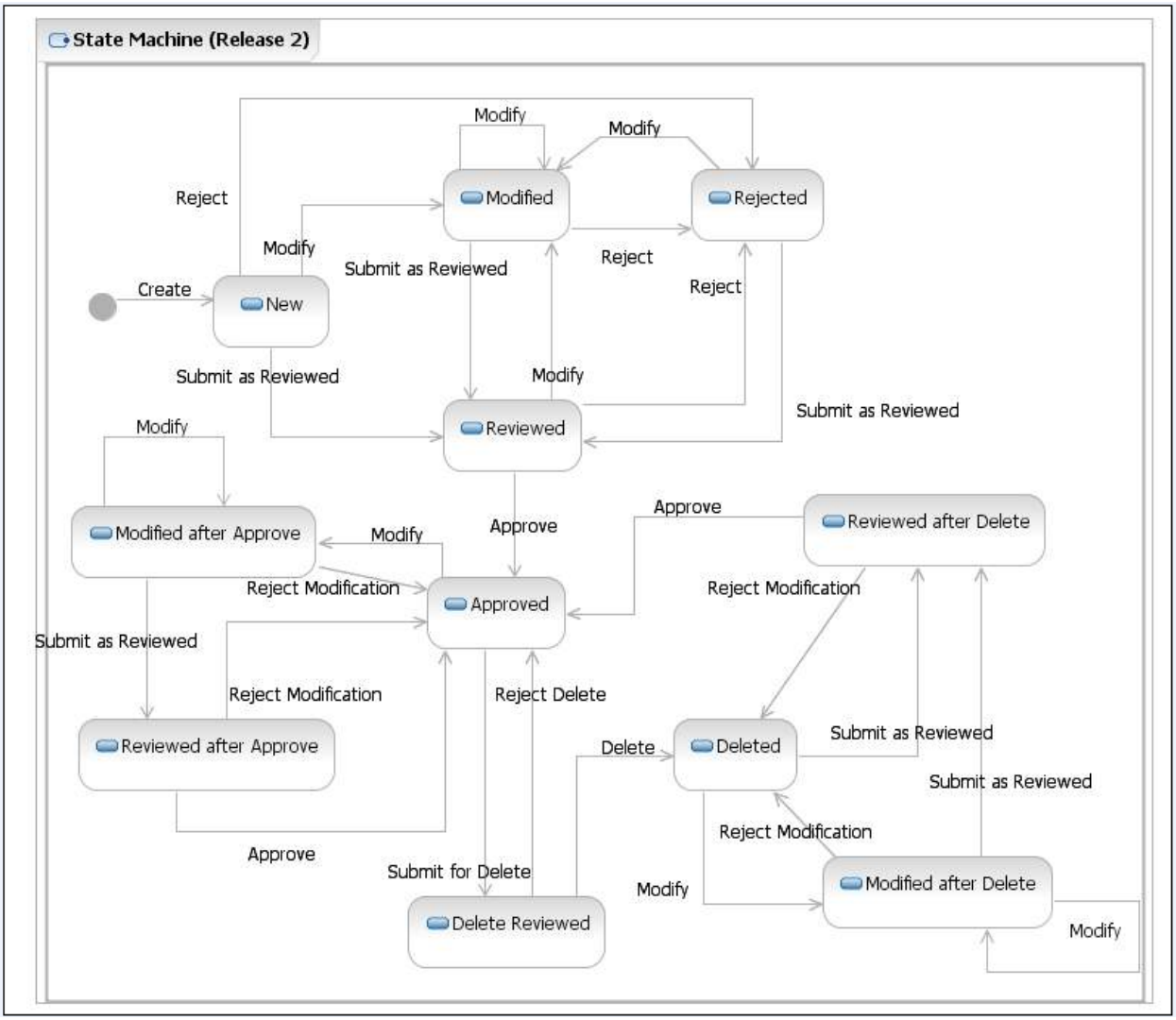


Figure 2: Action Statuses

Action Statuses

This list displays the different Action Statuses a VA customized record may go through as it steps through the approval workflow within PECS. Note that only seven of the following eleven states are displayed in the user interface - in other words, some of this information is "behind-the-scenes." It is included here as information only.

New - A new customization request has been created. If a user has the appropriate authority, they may modify the request (Modified) to be completed at a later point. Then, if they have the proper authority, they may submit the request as reviewed (Reviewed).

Modified - A user can make changes to their own New requests. The record will remain Modified until a user with the proper authority (Approver role) reviews the request and submits the request as Reviewed.

Modified After Approve - ***(displays as Modified)*** A user with the proper authority has requested a change in the Approved customization that requires another approval process.

Modified After Delete - ***(displays as Modified)*** A user with the proper authority has requested the deleted record be considered again for Approval with or without modifications. This requires another approval process.

Reviewed - This is the first stage of approval. A user with the proper authority (Approver role) reviews the new or modified customization request and submits it as Reviewed. The approver may also reject or modify the request. Note that an approver can review their own requests but not approve them.

Reviewed After Approve - ***(displays as Reviewed)*** Modifications were made to an approved record. A user with the proper authority (Approver role) reviews the request and submits it as Reviewed. The Approver may also reject the request, in which case the record returns to the Approved state, or they may modify it.

Reviewed After Delete ***(displays as Reviewed)-*** Modifications were made to a deleted record. A user with the proper authority (Approver role) reviews the request and submits it as Reviewed. The Approver may also reject the request, in which case the record returns to Deleted state, or they may modify it.

Rejected - The customization request is in a Rejected state. At this point the user may make changes, resubmit, or keep the transaction in the rejected state. All records that are rejected or not approved will remain in that state and will be available to the user for any future changes.

Approved – This is the second stage of approval. A user with the proper authority (Approver role) who did *not* submit the request as Reviewed will review the record and may approve, reject, or modify the request.

Delete Reviewed- The record remains active but a user with the proper authority (Approver role) has requested deletion of an existing approved customization.

Deleted – A user in the Approver role who did *not* submit the request for Deletion may delete the customization. If an Approver confirms the deletion, the record will remain active for potential future modifications.

Customization Information

Here is information on the basic types of customization that can be done with PECS.

Drug-Drug Interaction and Professional Monograph

This diagram displays how a drug interaction is tied to drug pairs and professional monographs:

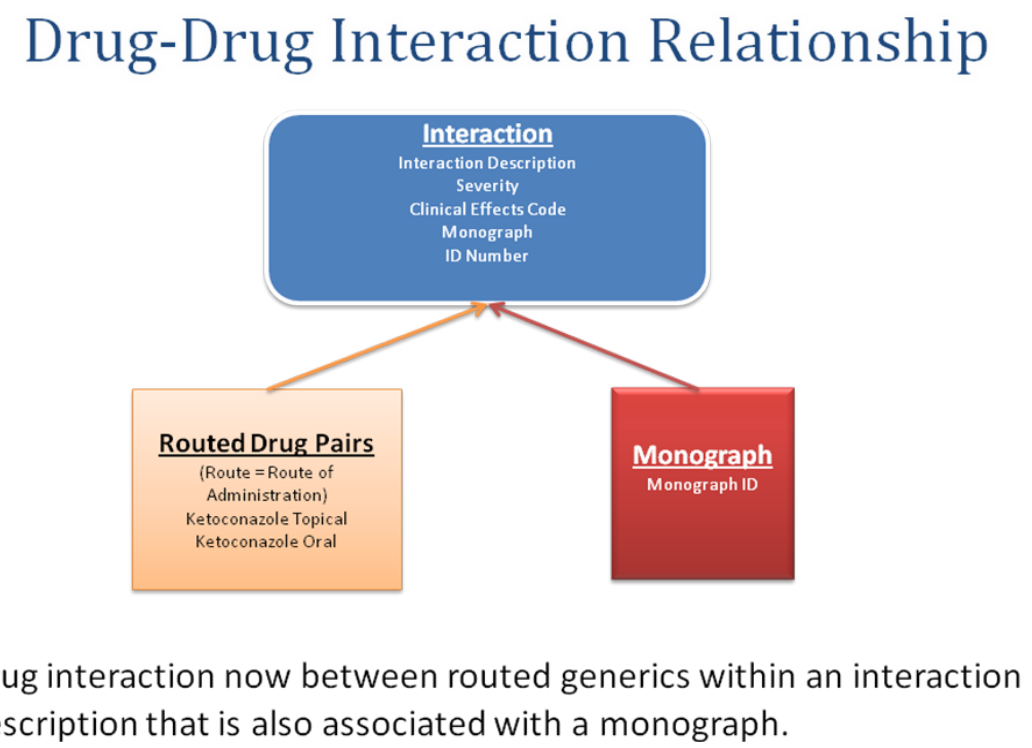


Figure 3: Drug-Drug Interaction Relationship

FDB Drug-Drug interaction severity levels:

1 = Contraindicated
2 = Severe
3 = Moderate
9 = Undetermined severity – Alternate therapy

Within the VA system, an FDB or VA Custom drug-drug interaction of severity level 1 will return a Critical order check and severity level 2 will return a Significant order check. Severity levels 3 and 9 will not return an order check.

Types of drug-drug interaction customizations include:

- Change in severity level
- Add or remove drug pairs
- Create drug interactions not found in FDB

Note: Due to the millions of possible drug pair combinations, you must be very specific on which two products are involved when reporting problems with the system.

Duplicate Therapy

The Duplicate Therapy concept allows you to specify the maximum number (0, 1, or 2) of duplicate therapy matches that can occur within a therapeutic class without creating an order check. A '0' duplicate allowance means only 1 medication from that therapeutic class can be on the patient profile without getting an order check (zero duplication). If a second drug from that class is added the provider gets the order check. If the allowance is '1', two drugs can be on the patient profile at once, the 3rd drug added would get the check (one duplication), etc.

The only type of Duplicate Therapy customization allowed is to increase or lower the duplicate therapy allowance for a therapeutic category.

Dose Range

Here is information about the Dose Range function:

- Dosing is based on the GCN Sequence Number (GCNSEQNO), a random number specific to all drug products with the same generic ingredient(s), route of administration, drug strength(s) and dosage form.
- Dosing is age-specific for most products. FDB has dosing for neonatal, infant, adolescent, adult, and geriatric. All ages are by days, for example, 18 years x 365= 6570 days.
- FDB also has indication-specific dosing, and dosing type. Examples of dosing type are loading, maintenance, single, initial.
- A typical product may have 30 or more dosing records when all variables are taken into consideration.
- The initial implementation of dosing order checks within VistA looks at the maximum single dose and daily dose range order checks using a common indicator.

PECS Button List

Here is a list of the buttons in PECS and their meanings. This list is alphabetical, not by window or function , as the buttons can display on many different windows and it depends upon user authority whether a button is visible.

- **Active** -- Displayed on the Query Result page. Opens an existing in-process request.
- **Add Default DRC Query** – Found on the Dose Range Advanced Query page. When selected, Concept Type Equal to 6 AND Age High in Days Greater than or Equal to 6570 is added to the query builder.
- **And** – Adds query criteria to a query that is being created for execution. This creates an "AND" clause with any other existing criteria.
- **Approve** – Moves the request from the Reviewed status into the Approved status.
- **Cancel** – Returns the user to the Home index page without saving any changes to the database for the request.
- **Clear Query** – Clears the Query Builder form of any previously entered data.
- **Customize** – Displayed on some pages to create a VA customization from an FDB record.

- **Edit** - Displays on the detail pages of all concepts where the record is in Read-only mode. This button allows users to edit a particular detail page if it is not already in use by another user.
- **Delete** – Moves the request from the Delete Reviewed status into the Deleted status.
- **Drug Pairs** – Retrieves a list of possible drug pairs from the FDB DIF database that are eligible to be added to the VA Custom Drug Interaction, and lists any existing custom drug pairs that the Drug Interaction may have.
- **Export**– Creates a file of the results of an executed query that can be downloaded and opened in the Microsoft Excel program.
- **Historical** – Displayed on the query result page. Opens a historic record as read-only.
- **Modify** – Moves a request from New, Modified, Rejected, Approved or Deleted into the Modified status. Writes any changes made to the request to the database, and leaves the status in the Modified status.
- **Open** – Displayed on the query result page. Opens an FDB record.
- **Open Blank Form**- Found under the FDB results when querying Both VA and FDB records in Drug-Drug Interaction, Professional Monograph or Dose Range. Navigates the user to a blank form.
- **Or** - Adds query criteria to a query that is being created for execution. This will create an "OR" clause with any other existing criteria.
- **Print Page** – Calls the browser's print page functionality.
- **Query** – Allows the user to submit a query to the system. If there are records that match the query parameters, they will be displayed in the results table.
- **Reject** – Moves the request from the New, Modified, or Reviewed status into the Rejected status. When records that are modified after approval or deletion are rejected, the record returns to the approved or deleted state.
- **Save Query** – Allows the user to save the executed query with a user-friendly name, available to be executed in the future.
- **Submit As Reviewed** – Moves the request from the New, Modified or Rejected status into the Reviewed status.
- **Submit For Delete** – Moves the request from the Approved status into the Delete Reviewed status.

Application Screens

Login

Instructions

The purpose of this screen is to provide an authorized user access to the system. Each user needs to select their site, then enter their current VistA access and verify codes,. which are their assigned/designated "user IDs" and passwords.

Note that authorization is handled through the use of specific VistA security keys. PECS doesn't assign individual permissions to users. Instead, it defines a number of roles for its users (requestor, approver, release manager and administrator) and associates a set of permissions with each of them. To see the list, refer to Identity Management on page 2.

Authentication Explanation

Application authentication and authorization is controlled by KAAJEE. Refer to VistA documentation for details on the user account maintenance.

If the response from the authentication request is successful via the KAAJEE API, KAAJEE returns a user profile object, which is used by the application to determine the user's role and permissions. On successful login, the system transfers the user to the Home page of the application.

Here is the login window:

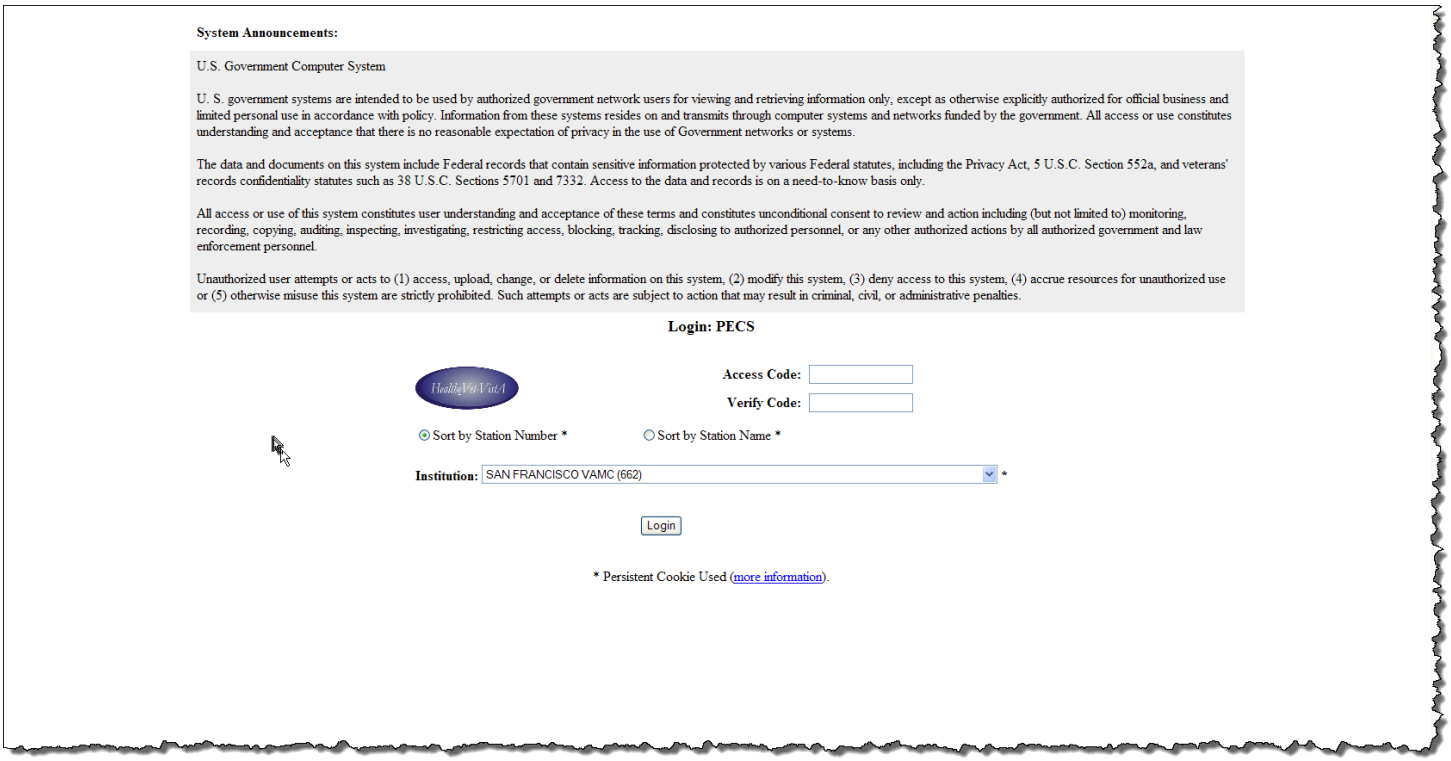


Figure 4: KAAJEE Login Screen

Home Page

The home page is the first page you see after logging in to the application. It provides information about when the last update to the First DataBank (FDB) database tables occurred and also when the last customization update file was created. The main purpose of the home page is to provide a count of the number of active customizations that you can access.

The Home page is organized into six panels. The display of a panel to the user is dependent upon the role of the user. Users in the "Requestor" role are shown only the "My Request History" panel. Users in the "Approver" role are shown all available panels.

The counts are organized by the action (Review/Approve/Delete) the user with the Approver role is assigned to perform on the customization records for each concept type (Drug-Drug Interaction, Professional Monograph, Duplicate Therapy, Dose Range, and Approved Drug-Drug Interactions with Pending Drug Pairs). The “Unassigned Requests” panel contains counts of records in the New, Modified, Reviewed, or Delete Reviewed status that are not assigned to a specific Approver, but need action taken to complete the request. Additionally, the Home page provides details on the status of any active customization records that the user may have entered into the system (My Request History). This allows the user to track their own requests through the approval process.

If you click the link to the number of records under each panel (if more than ‘0’), you are taken to the Advanced Query/Customization tab with the “Build a Query” panel displaying the fields, filters, and values that were queried against, in order to obtain the results showing in the "VA Table Results" panel. The ‘VA Table Results’ panel contains the active records that match the items for the count displayed on the Home page.

The bottom of the home page (and every page) also contains links to the various areas of the system, which are also accessible via the tabs at the top of every page.

The following window displays an example of what a user with the "Approver" role may see on the home page:

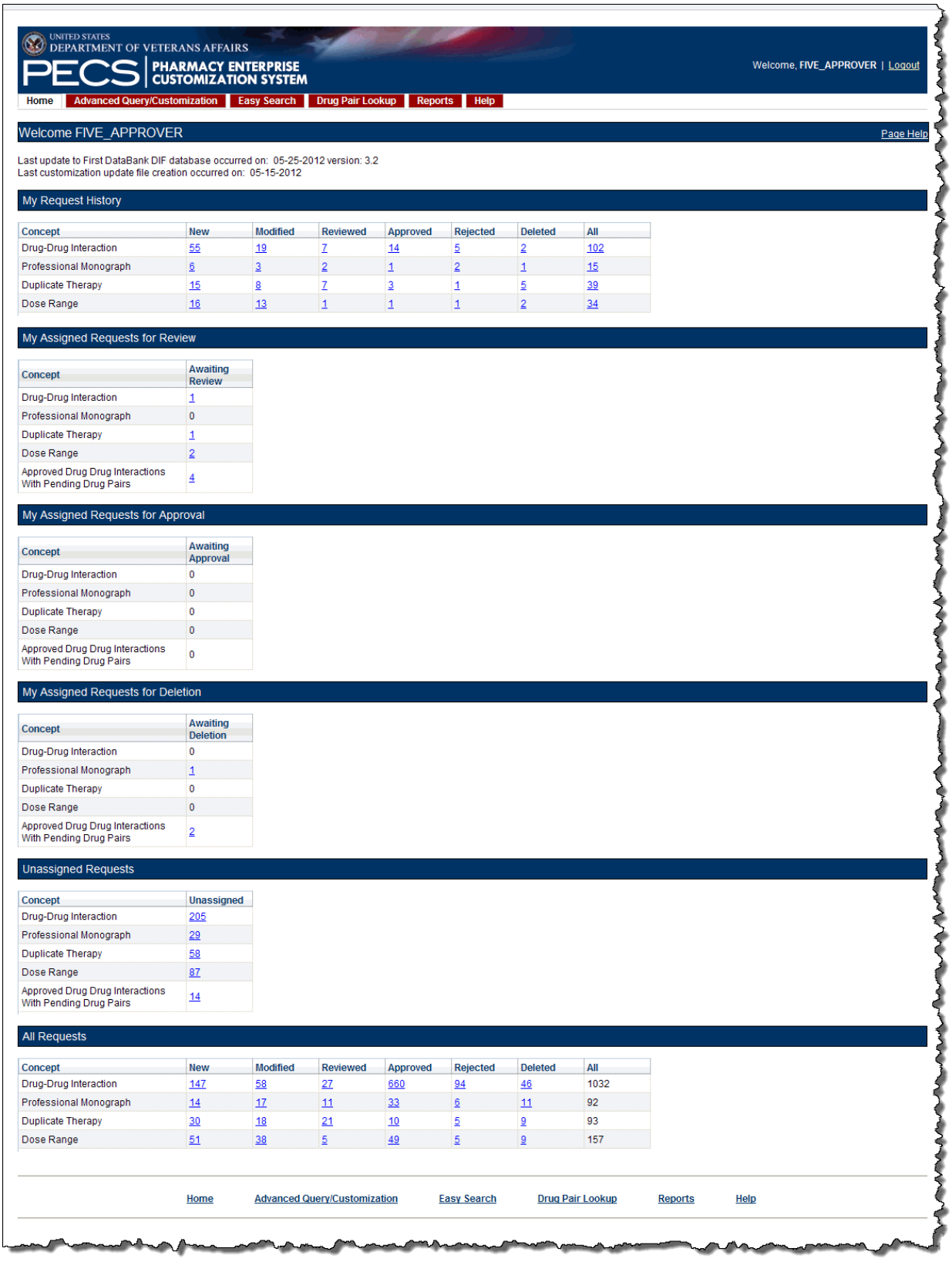


Figure 5: Home Page for Approver (All Available Panels)

This window displays an example of what a user with the “Requestor” role may see on the home page:

Figure 6: Home Page for Requestor

Drug Pair Lookup Page

If you have the proper authority, you can access the Drug Pair page by clicking the Drug Pair Lookup tab. It allows you to perform a quick query search on the most common elements.

On this page, you can perform a simplified query where a record search is performed from the FDB DIF and VA Custom tables. Simply enter filter data in any or all of the four entry fields (Drug A, Drug B, Interaction, or Severity Level Code). The resulting data is displayed under the VA Table Results and FDB Table Results panels. These consist of active customized Drug Pair records from the VA custom database (DB), which are available for modification, as well as their related Drug Pair records from the FDB DB from which they were customized.

Field names are as follows:

- Drug A - The name (or partial name) of one generic drug associated with an interaction.
- Drug B - The name (or partial name) of a second generic drug associated with an interaction.
- Interaction - An assigned drug interaction ID number or Description associated with the drug pair of Drug A and Drug B.
- Severity Level Code - Drop down list of available severity codes.

Figure 7: Drug-Drug Pair Query Window

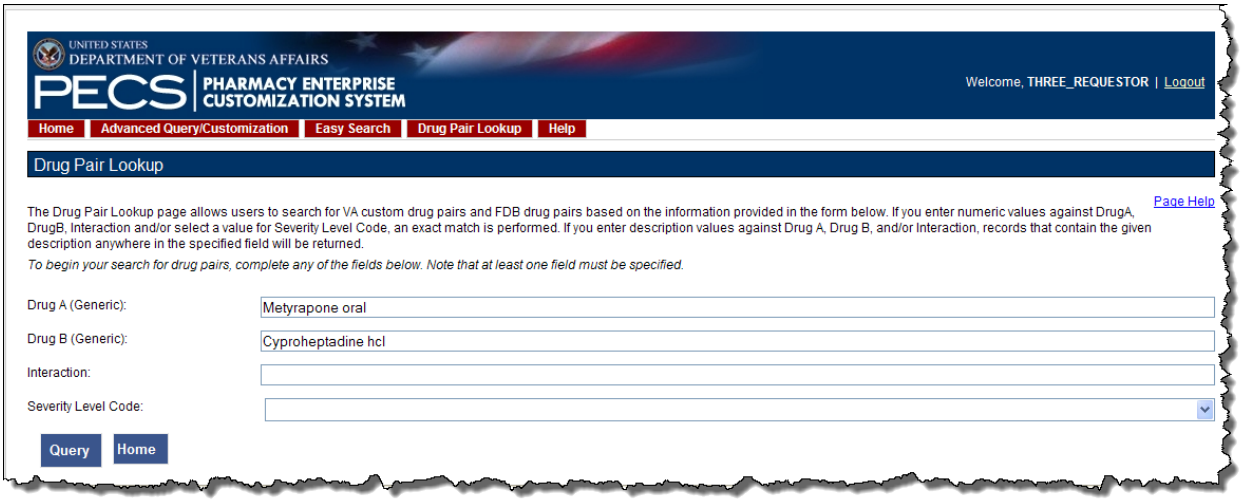


Figure 8: Sample Data

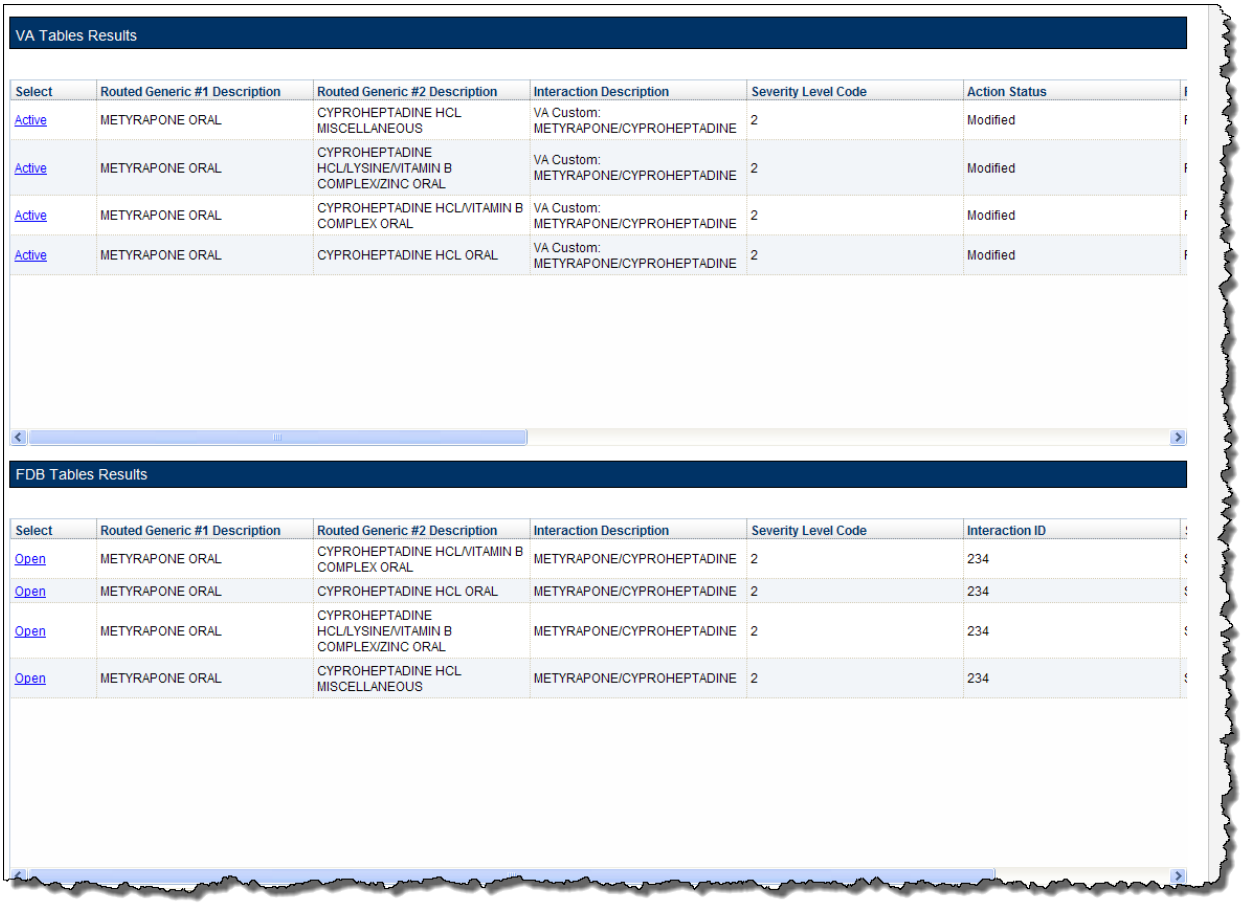
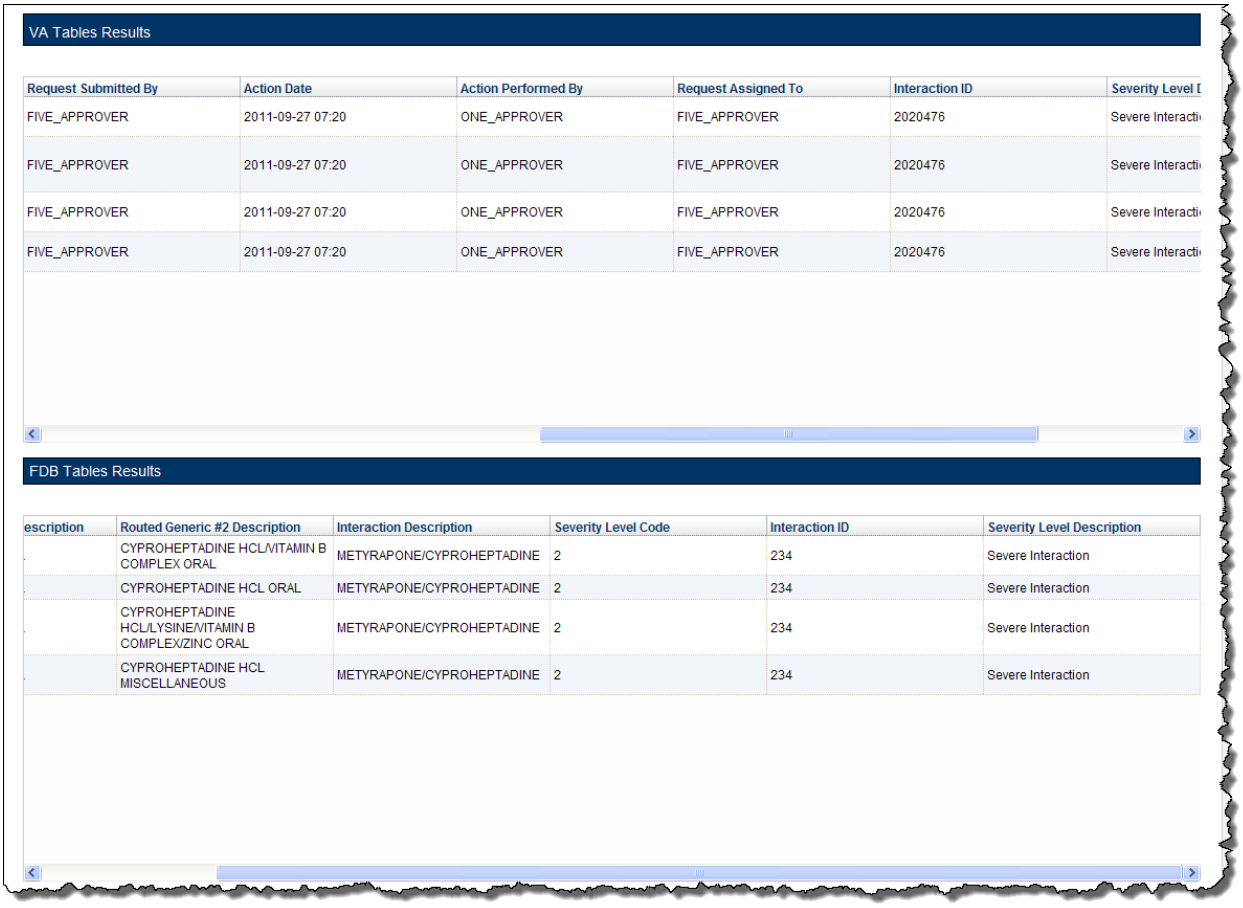


Figure 9: Drug Pair Query Result

Note that in this example, both the FDB table and VA Custom table contain more information that is found via the horizontal scroll bar:



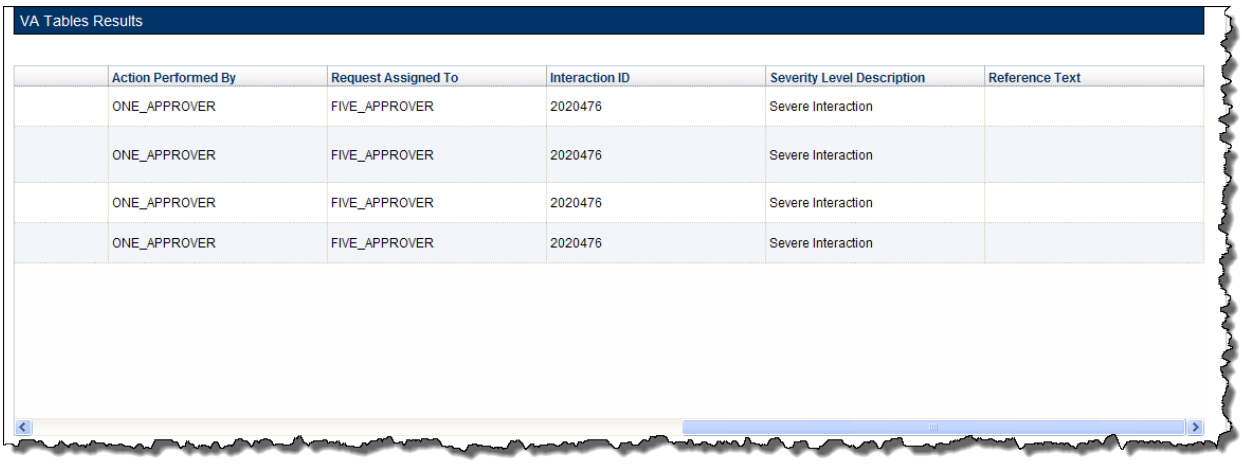
VA Tables Results

Request Submitted By	Action Date	Action Performed By	Request Assigned To	Interaction ID	Severity Level D
FIVE_APPROVER	2011-09-27 07:20	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interacti
FIVE_APPROVER	2011-09-27 07:20	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interacti
FIVE_APPROVER	2011-09-27 07:20	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interacti
FIVE_APPROVER	2011-09-27 07:20	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interacti

FDB Tables Results

escription	Routed Generic #2 Description	Interaction Description	Severity Level Code	Interaction ID	Severity Level Description
	CYPROHEPTADINE HCL/VITAMIN B COMPLEX ORAL	METYRAPONE/CYPROHEPTADINE	2	234	Severe Interaction
	CYPROHEPTADINE HCL ORAL	METYRAPONE/CYPROHEPTADINE	2	234	Severe Interaction
	CYPROHEPTADINE HCL/LYSINE/VITAMIN B COMPLEX/ZINC ORAL	METYRAPONE/CYPROHEPTADINE	2	234	Severe Interaction
	CYPROHEPTADINE HCL MISCELLANEOUS	METYRAPONE/CYPROHEPTADINE	2	234	Severe Interaction

Figure 10: VA & FDB Tables, continued



VA Tables Results

	Action Performed By	Request Assigned To	Interaction ID	Severity Level Description	Reference Text
	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interaction	
	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interaction	
	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interaction	
	ONE_APPROVER	FIVE_APPROVER	2020476	Severe Interaction	

Figure 11: VA Table, continued

Note that you can move the columns in these tables and compare different fields side-by-side. Click the heading and drag and drop it:

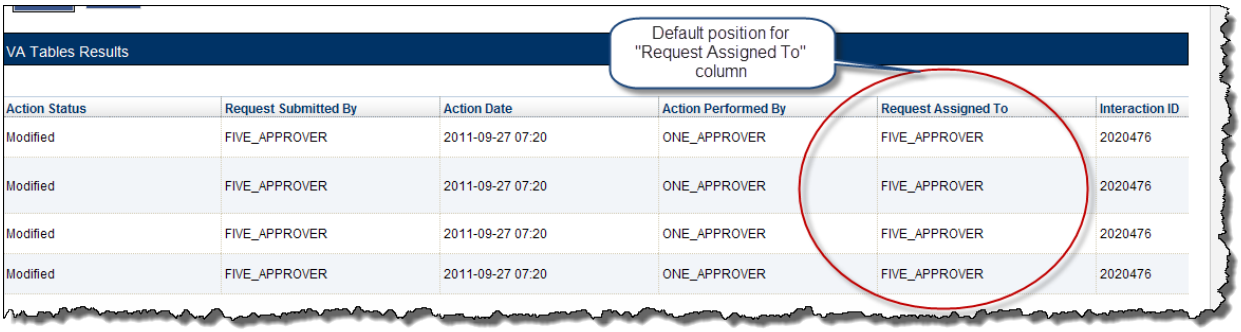


Figure 12: Default Position of "Request Assigned To"

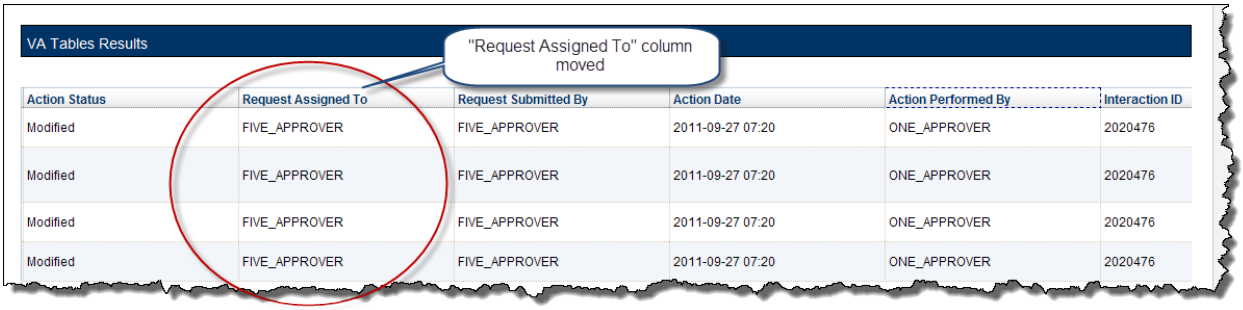


Figure 13: Re-positioned "Request Assigned To" Column

Advanced Query/Customization Page

The Advanced Query / Customization page is used to access customization records from either the FDB Standard table, the VA Custom tables, or both at the same time. This allows you to research existing records, make customizations, or export data.

Accessing the Advanced Query/Customization Page

The Advanced Query/Customization page allows you to retrieve records from either the FDB standard tables, custom tables, or both to research, make customization changes, or export data. The Advanced Query / Customization page can is accessed in one of two ways.

- Click the Advanced Query/Customization tab on the navigation bar near the top of the page. This will open a blank query.

Figure 14: Accessing the Advanced Query / Customization Page

- Click a link from one of the summary tables displayed on the Home tab. This will generate a query appropriate to the context of the link that was clicked. In the example below, a query displaying criteria to display the unassigned Drug-Drug Interaction records will be produced.

Figure 15: Access Advanced Query/Customization from the Home Tab

The Query Builder Panel

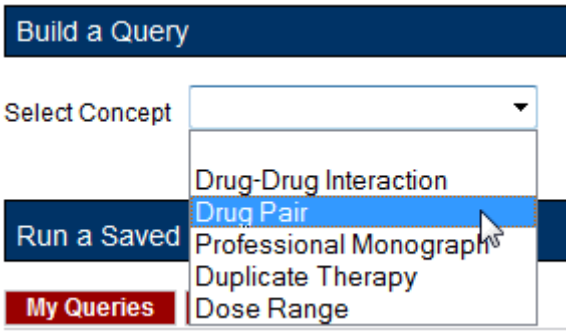
The Query Builder Panel on the Advanced Query/Customization page allows you to retrieve a specified set of records the VA Custom Tables, the FDB standard tables or Both in order to perform research, make customization changes, or export data. You can use it to create a new query, load a query you have previously saved, or load a query saved by another user.

How to Build a Query

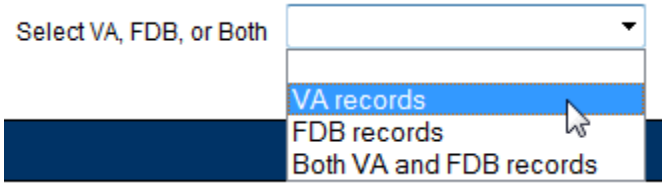
This is the Query Builder page, described above. From this page you can build your own query, run it, save it, run a saved query, or run another user's saved query.

To create a query

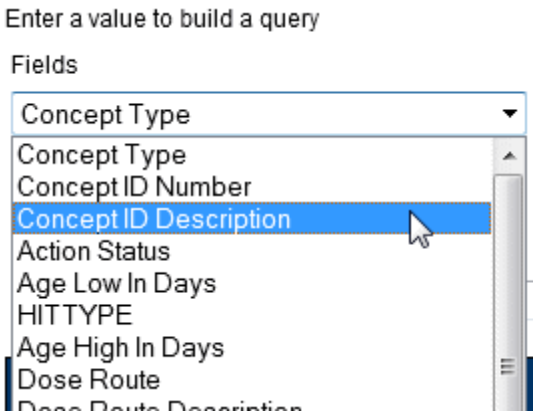
1. On the Advanced Query/Customization tab, select a Concept.



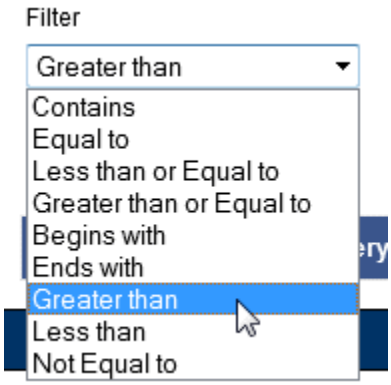
2. Select what data you want to view-- VA, FDB, or Both.



3. In the "Enter a value to build a query" area, select the Field you want to use as a query criteria. The available field options will be determined by the Concept you selected earlier.



4. Select the Filter you want to impose on the Field.



5. Enter a Value to use as your query criteria. The Value must be appropriate for the Field and Filter or an error will be generated. See Query Specifics for additional information.

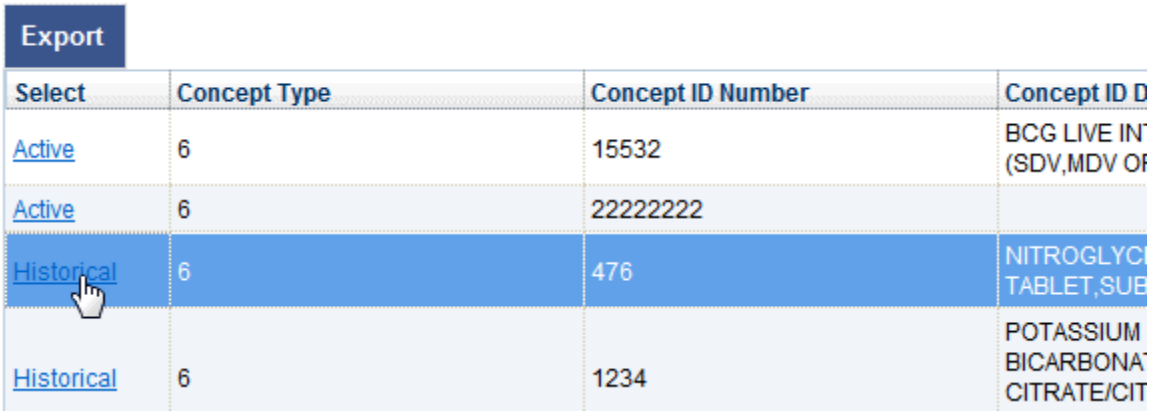
6. To add additional criteria to the query, make a selection from the And/Or list.

- AND indicates the results must match the new criteria and all the AND-connected criteria above it
- OR indicates that the results must match either the new criteria or the AND-connected criteria above it. See And/Or Usage Examples for additional information.

7. To include Historical Records in the query, select the Include Historical Records check box.

8. When all criteria have been added, click the Query button. The results will display below the query panel.

9. To see details of the record, select the link in the Select column.



And/Or Usage Example

To see approved records with an interaction description equal to "anti" or "Lido", build the query as follows:

Field	Filter	Value	And/Or
Interaction description	Equals	anti	And
Status	Equals	approved	Or
Interaction description	Equals	Lido	And
Status	Equals	approved	

If you build the query below, you will get approved records with an interaction description = "Anti", but you will get all records with an interaction description of "Lido", regardless of status.

Field	Filter	Value	And/Or
Interaction description	Equals	anti	And
Status	Equals	approved	Or
Interaction description	Equals	Lido	

Query Specifics

- Use the YYYY-MM-DD date format for searching date fields within a query
- Date values can only use the following filters::
    - Equal to
    - Less than or Equal to
    - Greater than or Equal to
    - Greater than
    - Less than

Save a Query

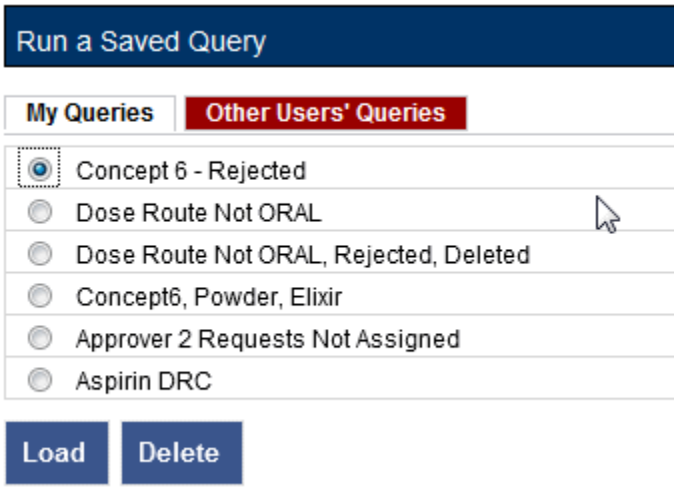
PECS allows you to save a complete query so that you and other PECS users can run a specific query without having to re-build it every time. This feature is not available to users with the Requestor role.

Note: the state of the Historical Records check box will not be saved with the query; if desired, it must be re-selected after the query is loaded at run-time.

To save a query

1. Create a query in the Build A Query panel. See Build A Query for additional information.
2. Enter a name for the query in the Query Name field. The name must contain at least five characters and cannot be longer than 64 characters.
3. Click Save Query.

4. The saved query will appear in the My Queries list.



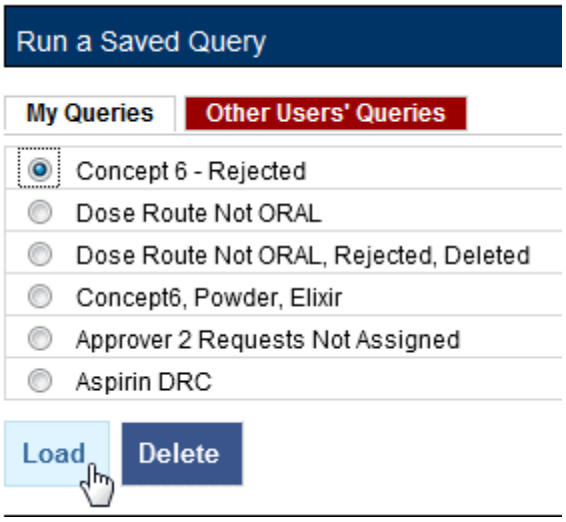
Run a Saved Query

PECS allows you to run a previously saved query with the same Concept and content (VA, FDB, or Both). You can run queries that you have saved or those that other users have saved.

To run a saved query

1. On the Advanced Query/Customization tab, select a Concept.
2. Select what data you want to view-- VA, FDB, or Both.
3. In the Run a Saved Query sub-panel, select either My Queries or Other Users's Queries, then select the query you want to run.

4. Click the Load button. This will add the components of the saved query to the Build a Query panel.



5. Click the Query button to run the query. You may also select additional criteria to alter or enhance the saved query.

Delete a Saved Query

You can delete queries you have created and saved. Note that the delete operation is immediate; you will not be warned that the query is about to be deleted and there is no undo option.

To delete a Saved Query

1. On the Advanced Query/Customization tab, select a Concept.
2. Select what data you want to view-- VA, FDB, or Both.
3. In the Run a Saved Query sub-panel, select My Queries; you cannot delete a query that was created by another user, then select the query you want to delete.
4. Click the Delete button. The query is deleted.

Rename a Saved Query

A saved query can be renamed by loading it then adding a different name in the Query Name field.

To rename a saved query

1. On the Advanced Query/Customization tab, select a Concept.
2. Select what data you want to view-- VA, FDB, or Both.
3. In the Run a Saved Query sub-panel, select My Queries; you cannot rename a saved query created by another user.
4. Enter a new the Query Name field.
5. Click Save Query. The new query name will appear in the My Queries list in place of the original query.

Sort Query Results

You can change the sort order of results of your query by clicking on the column headings in the display grid. Clicking once will display the records in ascending order (A to Z, 1-2-3 etc.) based on the contents of the column of the header you clicked; clicking a second time display the records in descending order (Z to A, 3-2-1, etc.). A small arrow indicates the direction of the current sort.

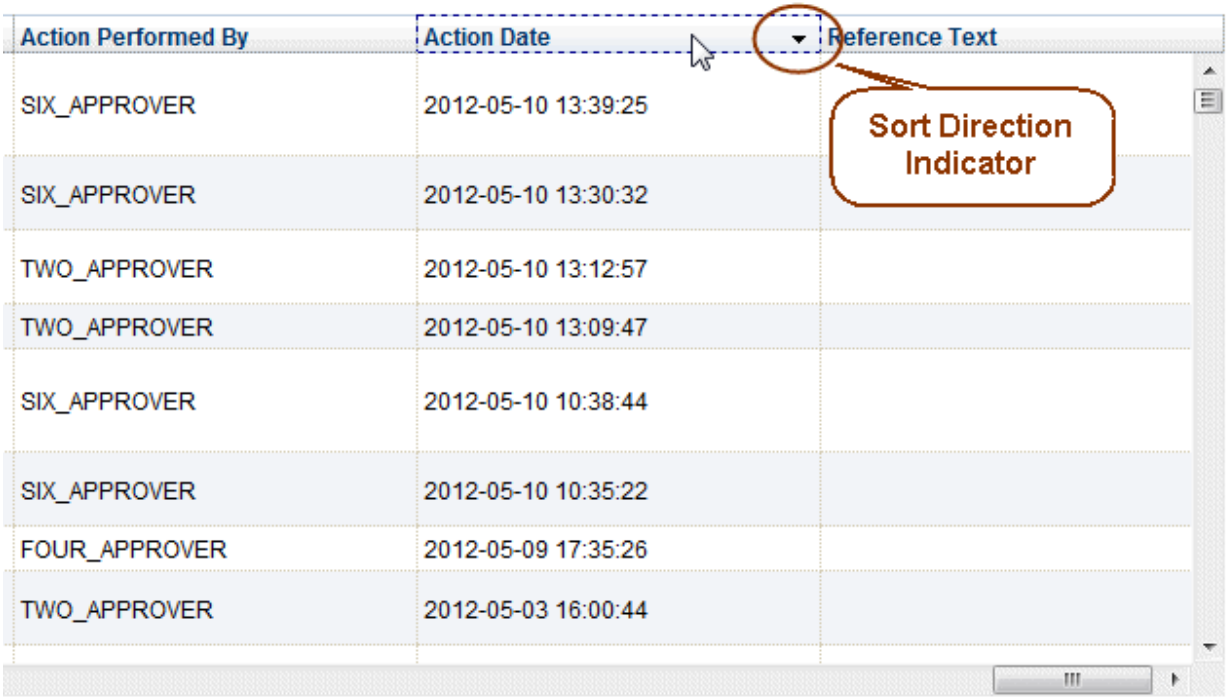


Figure 16: Sorting Query Results

For VA records, the default sort order is by the 'Action Date' value, from newest to oldest. This puts the VA Customizations that have been updated most recently at the top of the returned list. By default, FDB records are displayed in the order they appeared in the update file sent by FDB. However, they can be re-sorted by clicking a column header.

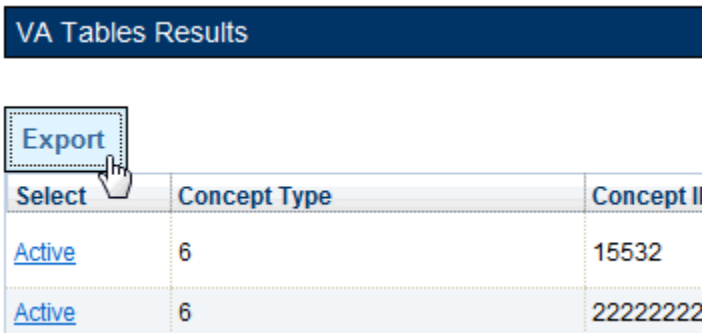
Note: Due to technical database restrictions, not all fields can be used to determine the sort order. For example, Concept ID Description on a Dose Range query cannot be used to sort the query results. Clicking these columns will have no result and the current sort order will be retained.

Export Query Results

Query results for both VA and FDB records can be exported to an Excel spreadsheet file.

To export the query results

1. On the appropriate query results panel, click the Export button.



2. Select one of the following options from the dialog box:
   - Click Open to open the exported query in Excel.
   - Click Save to save the exported query to a location on your hard drive.
   - Click Cancel to abandon the export operation.

Query Errors

Running a query will sometimes return an error message.

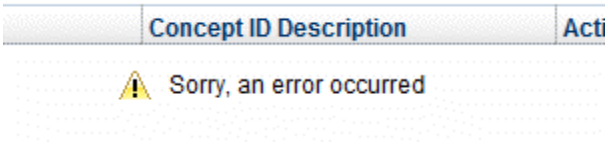


Figure 17: Query Error Message

In many cases, the error is caused by the query returning too many results which causes the database to time-out. Try re-writing the query with more specific criteria. For example, enter "Aspirin" as the Concept ID Description in a Dose Range query instead of "a" as the Concept ID Description. This will reduce the number of results and potentially prevent database time-outs. Rule of thumb: always be as specific as possible when creating a query.

An error may also appear if the selected Filter is not appropriate for the data type.

Special Dose Range Query Button

If you are performing a Dose Range Query, there is a special button that displays only on the Dose Range Query window for VA, FDB, or Both. It is a predefined search that enters a default Dose Range query. If you do not want to run the default, you can enter specific values yourself, then run your query.

Here are the predefined fields for this Dose Range Query:

- Concept type = 6 and
- AGEHIGHINDAYS >= (greater than or equal to) 6570

To run this query, simply press the Add Default DRC Query, then press Query. The results are shown below:

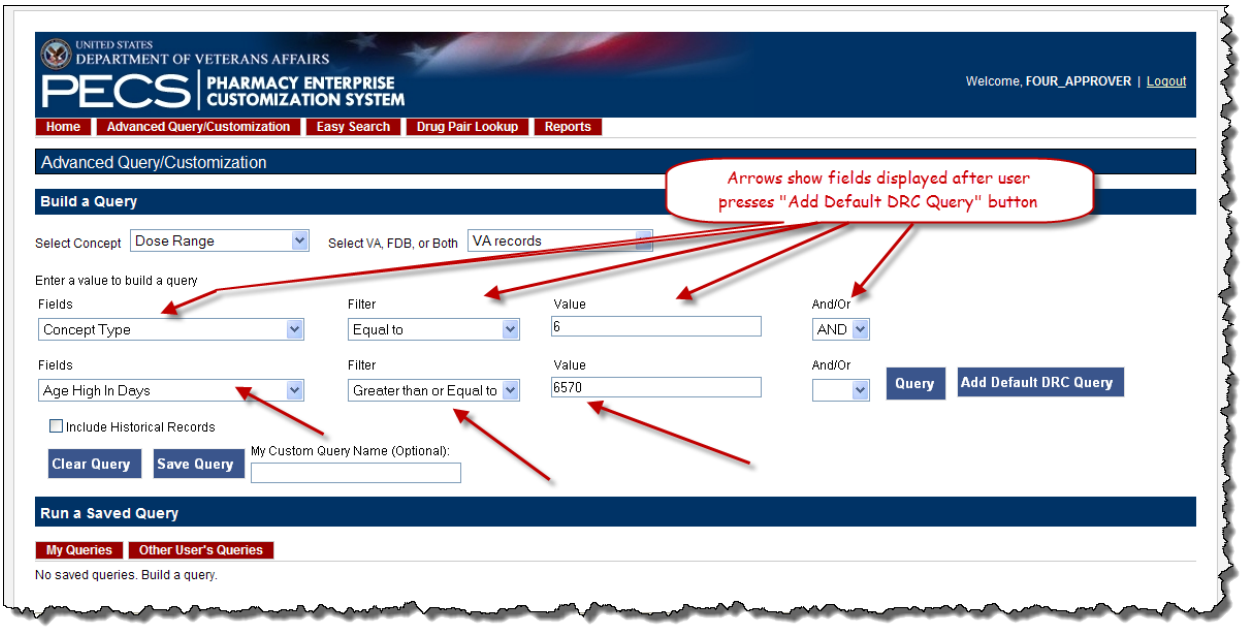


Figure 18: Default Dose Range Query Window

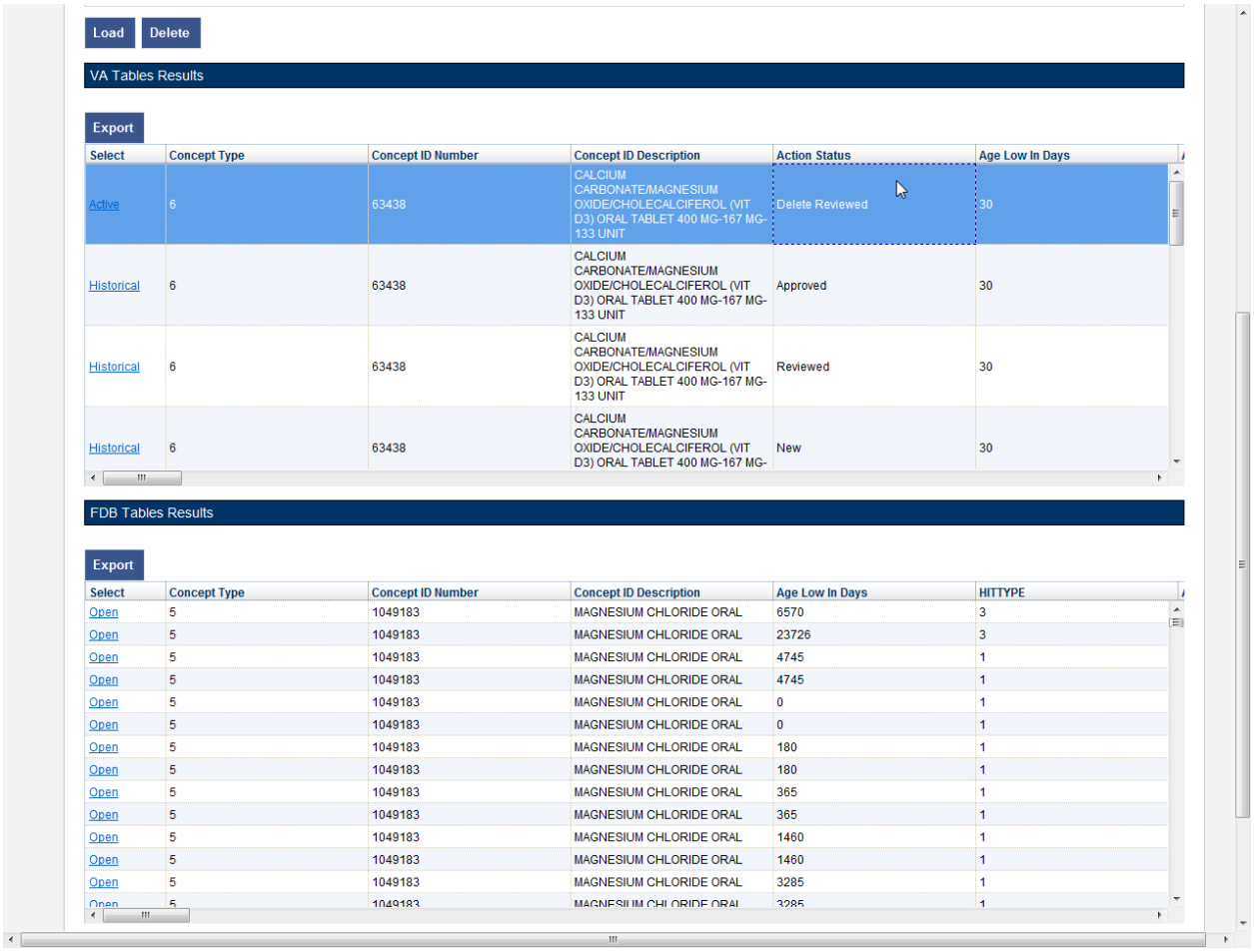


Figure 19: Results from Building a Dose Range Query with Default DRC Query

Panels You Can Modify

Following are example Dose Range, Professional Monographs, Duplicate Therapy, and Drug-Drug Interaction panels, shown in Read-Only mode, which is the default view. You can modify these panels only if:

1. You have the correct security permissions.
2. You have clicked the Edit button to bring up the record in Edit mode.
3. No other user is modifying the record at the same time (you will be notified if that is the case).

Note that shaded fields on any the detail pages in Edit mode cannot be modified.

Dose Range

Click the Edit Button to open the fields to edit the record. The view below is Read-Only.

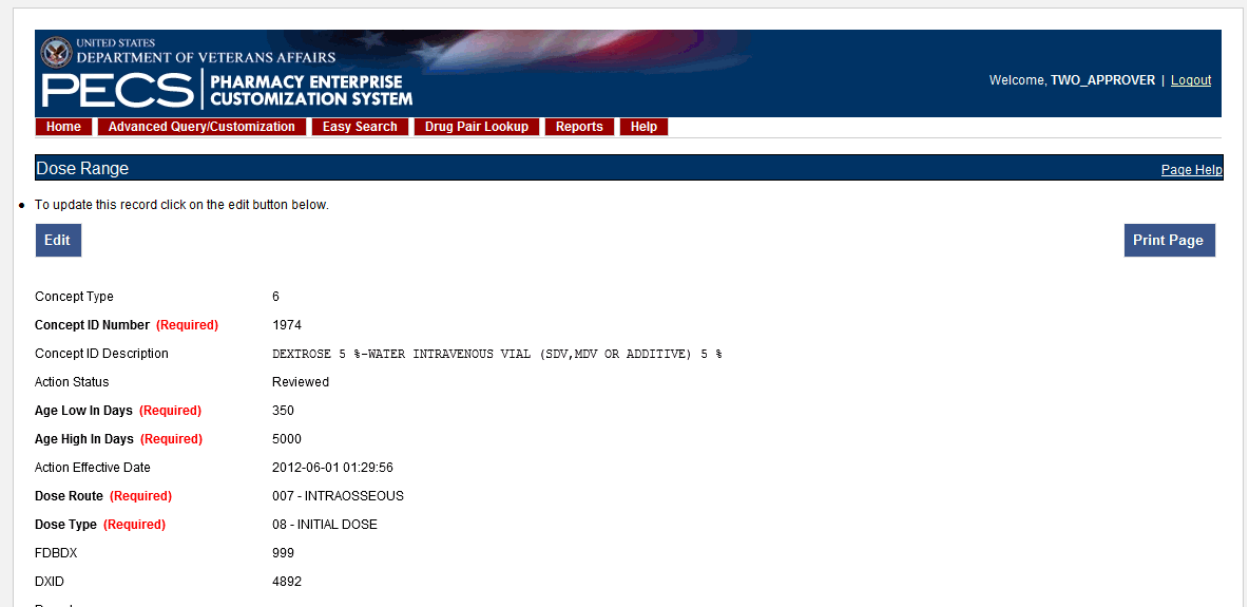


Figure 20: Dose Range Panel - Read-Only

Professional Monograph

During customization, you can edit the professional monograph that is displayed. Below is an example in read-only mode. Click the Edit button to modify.

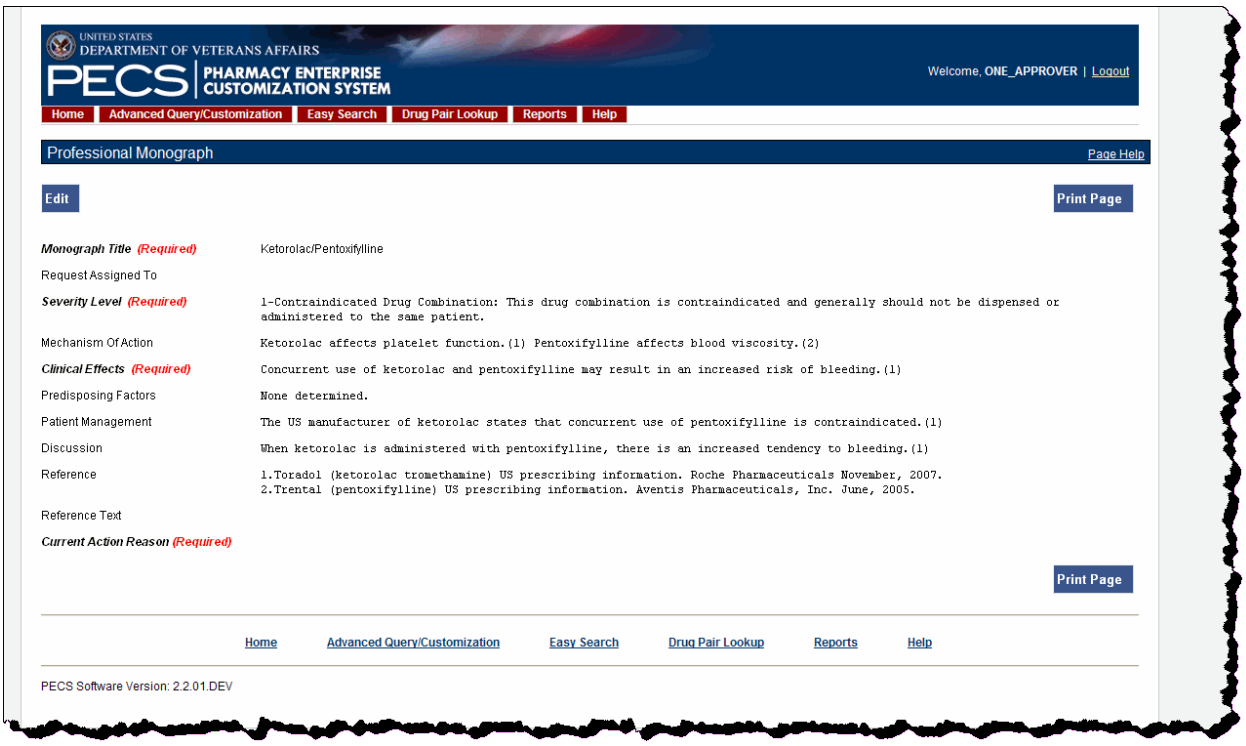


Figure 21: Professional Monograph Panel - Read Only

Duplicate Therapy

You may also edit the Duplicate Therapy panel if you have the authority and click the Edit button.

Figure 22: Duplicate Therapy Panel - Read-Only

Drug-Drug Interaction

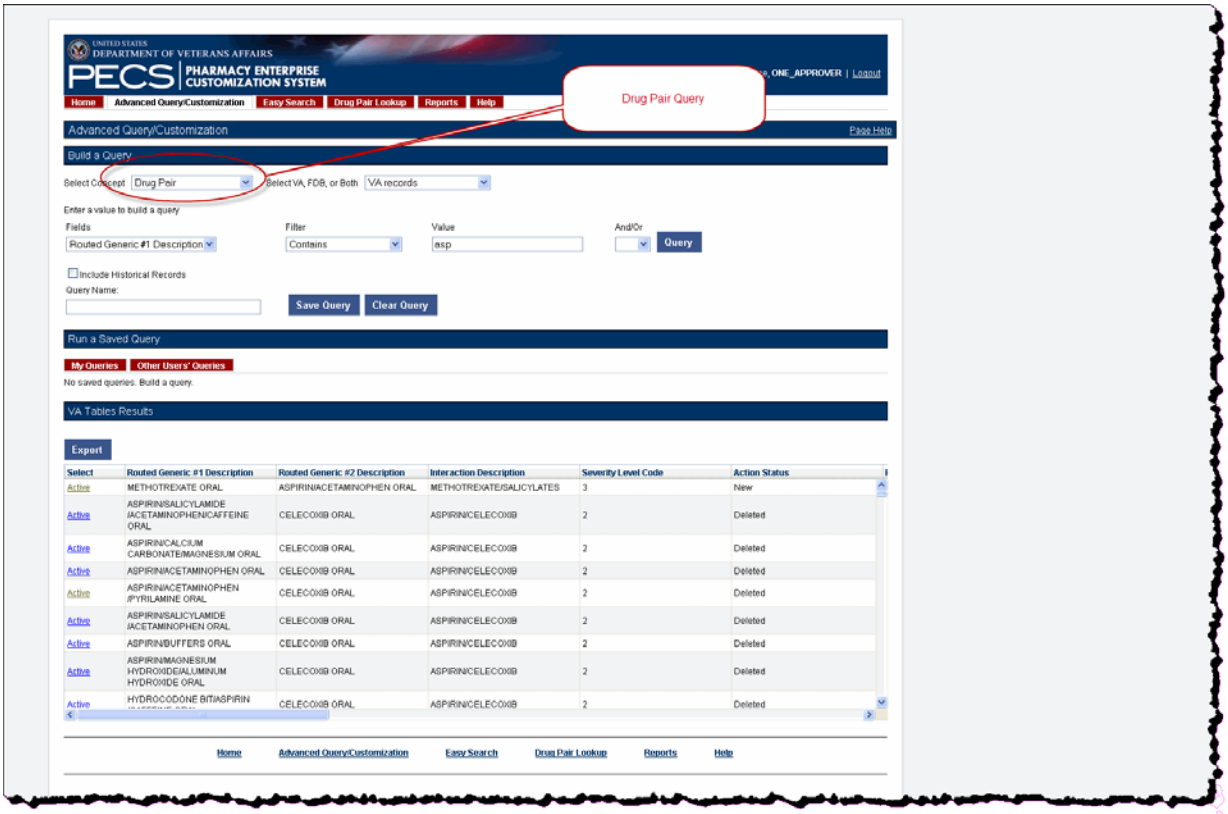
The Drug-Drug Interaction Panel can be edited only if you have the proper authority and after you click the Edit button.

Figure 23: Drug-Drug Interaction Panel - Read Only

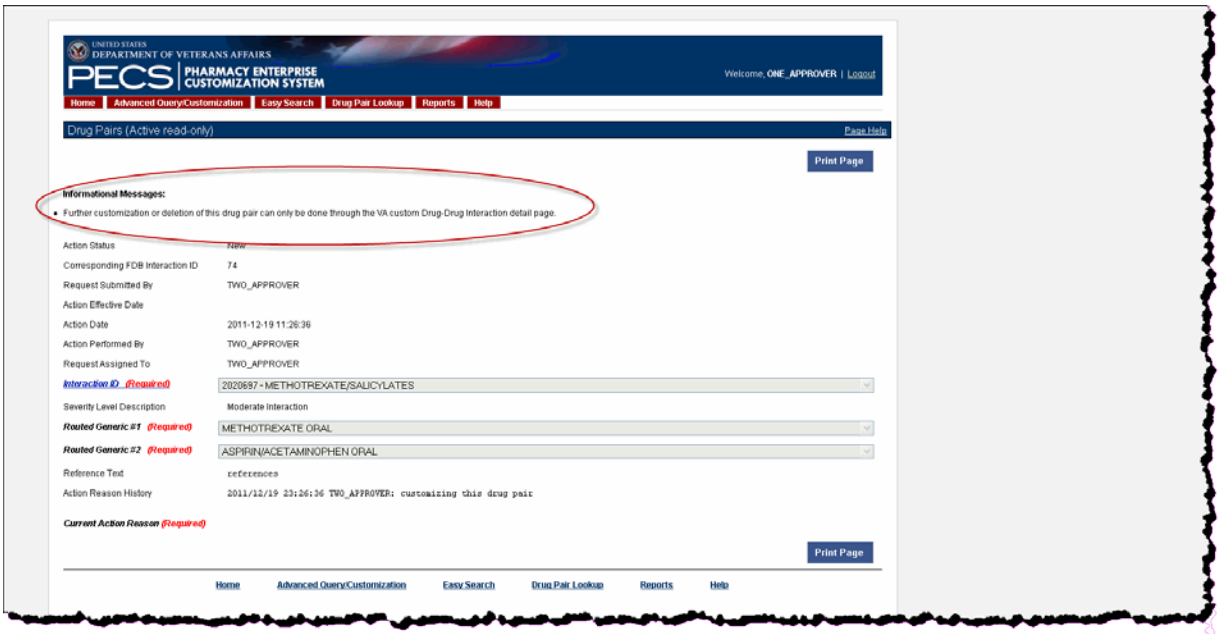
Single Drug Pair Page Modification Not Allowed

You cannot modify or customize a drug pair if you display a single drug pair from a query on the Drug Pair concept, as shown below:

1. Pick the Drug Pair concept, as shown below, and select one of the drug pairs displayed.



2. The page that displays is the single drug pair, and an information message is displayed: “Further customization or deletion of this drug pair can be done only through the VA custom Drug-Drug Interaction detail page.”



3. The easiest way to get to the custom Drug-Drug Interaction detail page is to use the Easy Search tab. See the section “Easy Search Query Page.”

Notification of Drug Pairs Needing Action for an Approved Drug-Drug Interaction

The drug pairs that are associated with a Drug-Drug Interaction (DDI) need to go through the approval/state change process themselves (be approved, rejected, modified, or deleted), separately from the DDI. If the drug pairs are acted upon at the same time as the DDI is acted upon, there is no problem in an approver knowing that the drug pair needs to be acted upon. However, drug pairs may be added or have their status changed even after a DDI has been acted upon. The way an approver will know if they need to act on a drug pair associated with an already-approved DDI is by the row on each of the home page tables that displays "Approved Drug-Drug Interaction with Pending Drug Pairs."

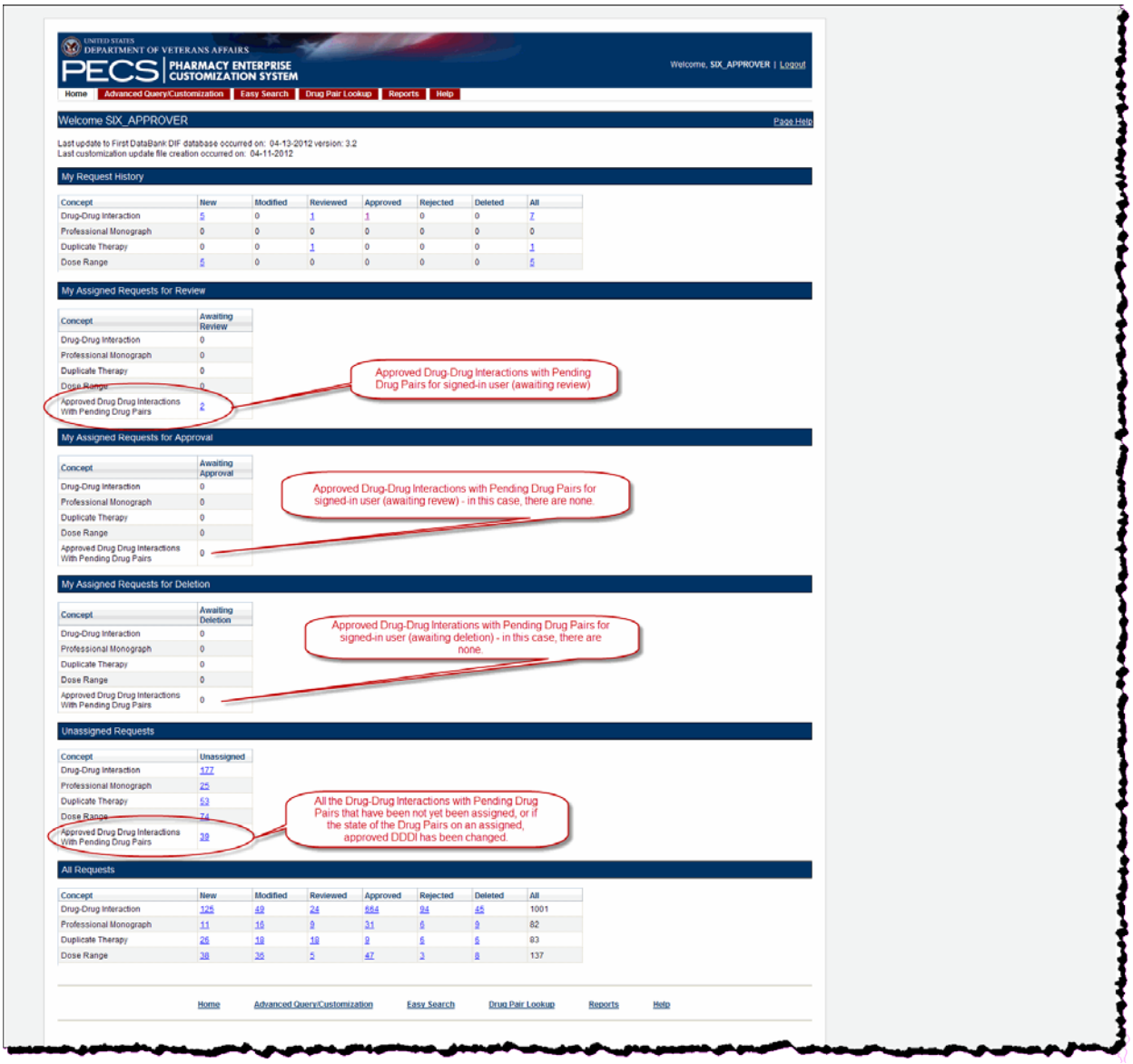


Figure 24: Home Page with Approved DDIs with Pending Drug Pairs

On the screen above in the application, if you select the link “My Assigned Drug Pairs Associated with Approved Drug-Drug Interactions” for one of the states listed that has actual counts (not zero), you are taken to the Advanced Query/Customization page, shown below, that displays the results for all approved Drug-Drug Interactions with associated Drug Pairs assigned to you in that state.

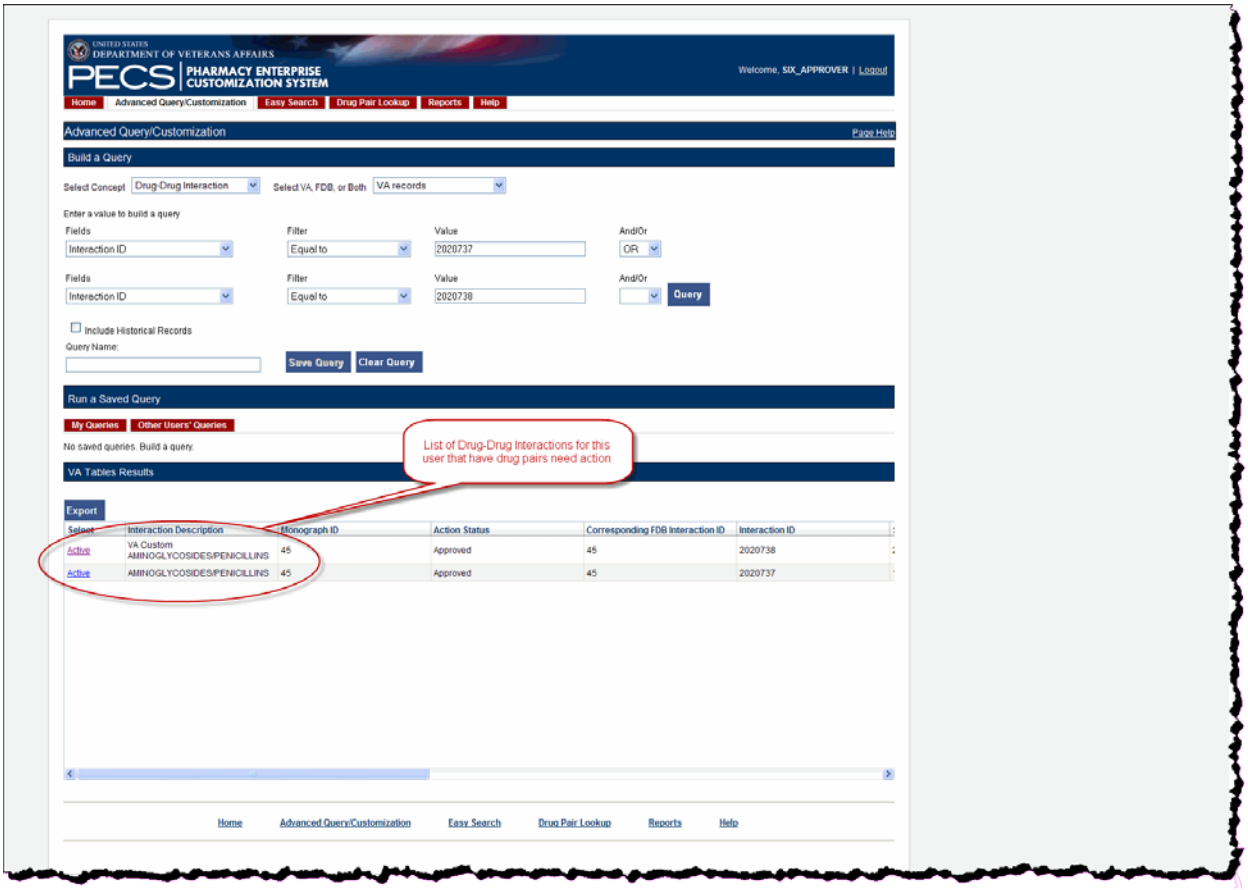


Figure 25: My Assigned DDIs with Pending Drug Pairs List

Here is the Interaction window shown after the link is clicked from the Advanced Query Page (previous screen shot). On the Interaction window you can act on the drug pairs -- to do so, click the Drug Pairs button:

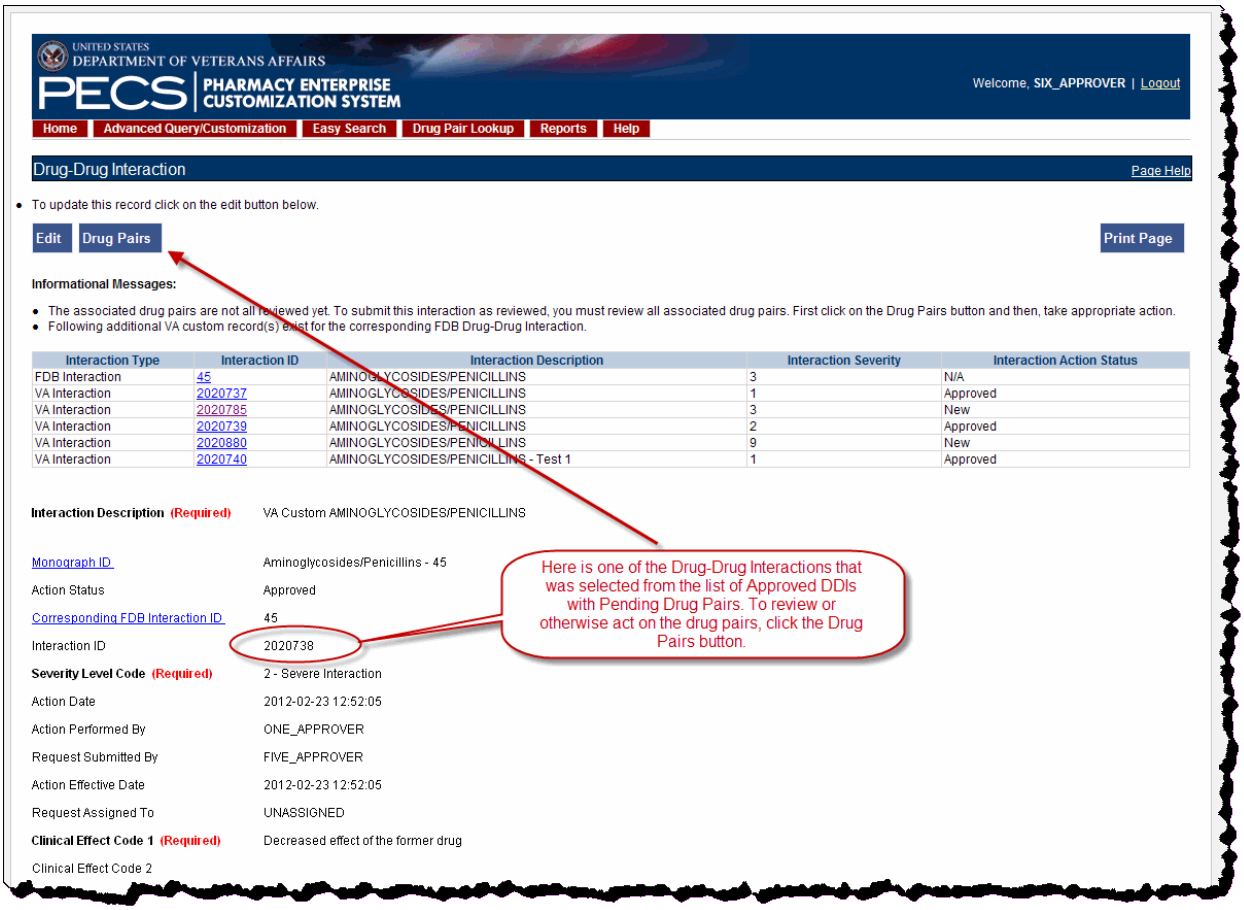


Figure 26: Drug-Drug Interaction Window

After you click the Drug Pairs button, you see a window similar to the one below. After you click the Edit button, you can act on the drug pairs.

Figure 27: List of Drug Pairs You Can Act On

When you add new drug pairs, they are by default assigned to the same User ID as the associated DDI, but an Approver can reassign the drug pairs.

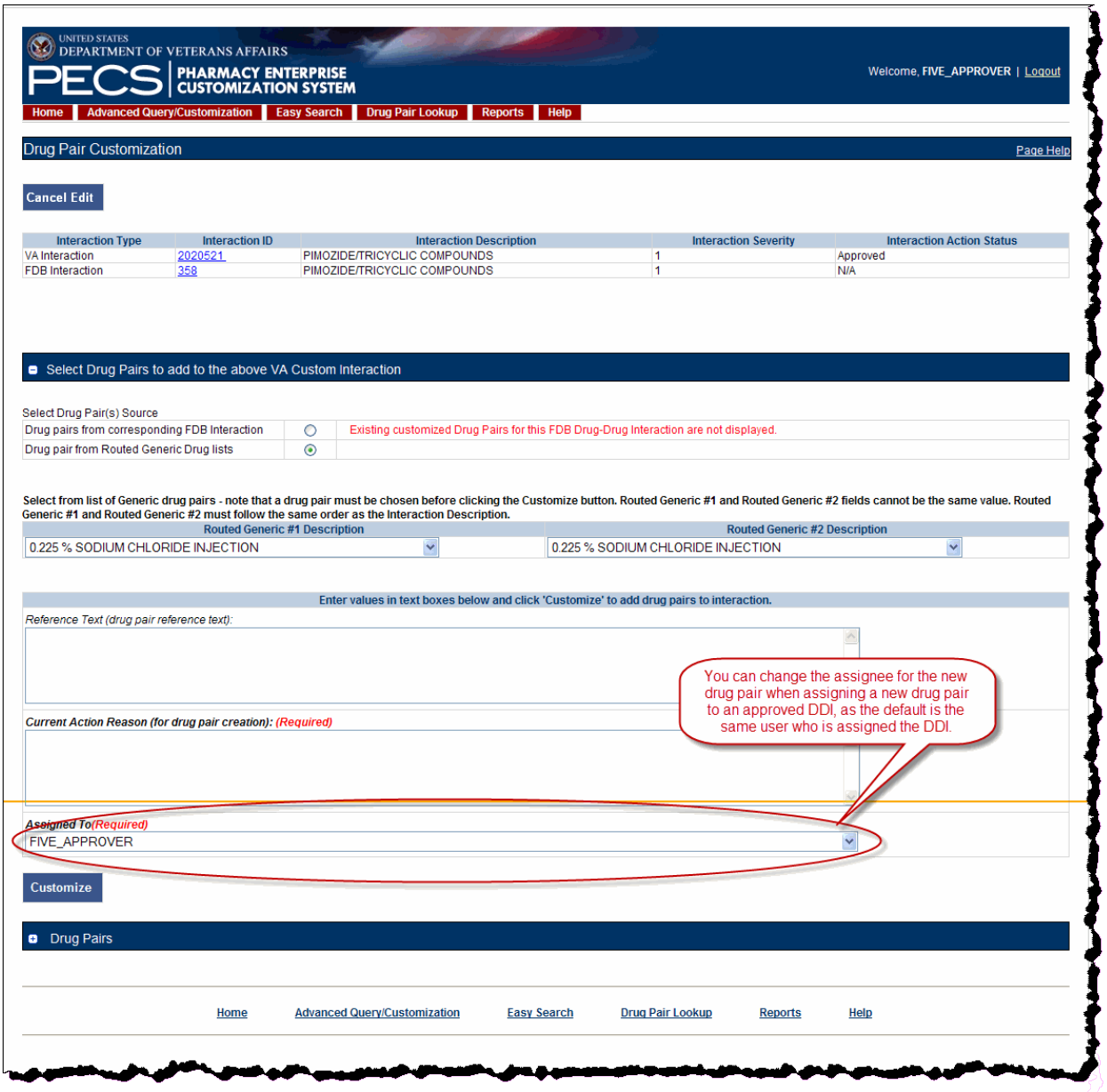


Figure 28: Assigned To Drop-Down When Adding a Drug Pair

When you are working with the Drug Pair customization window and handling the pending drug pairs, you can use the drop-down to assign the Drug Pairs to a different user. The default is the Approver who is assigned to the DDI, but you can change that.

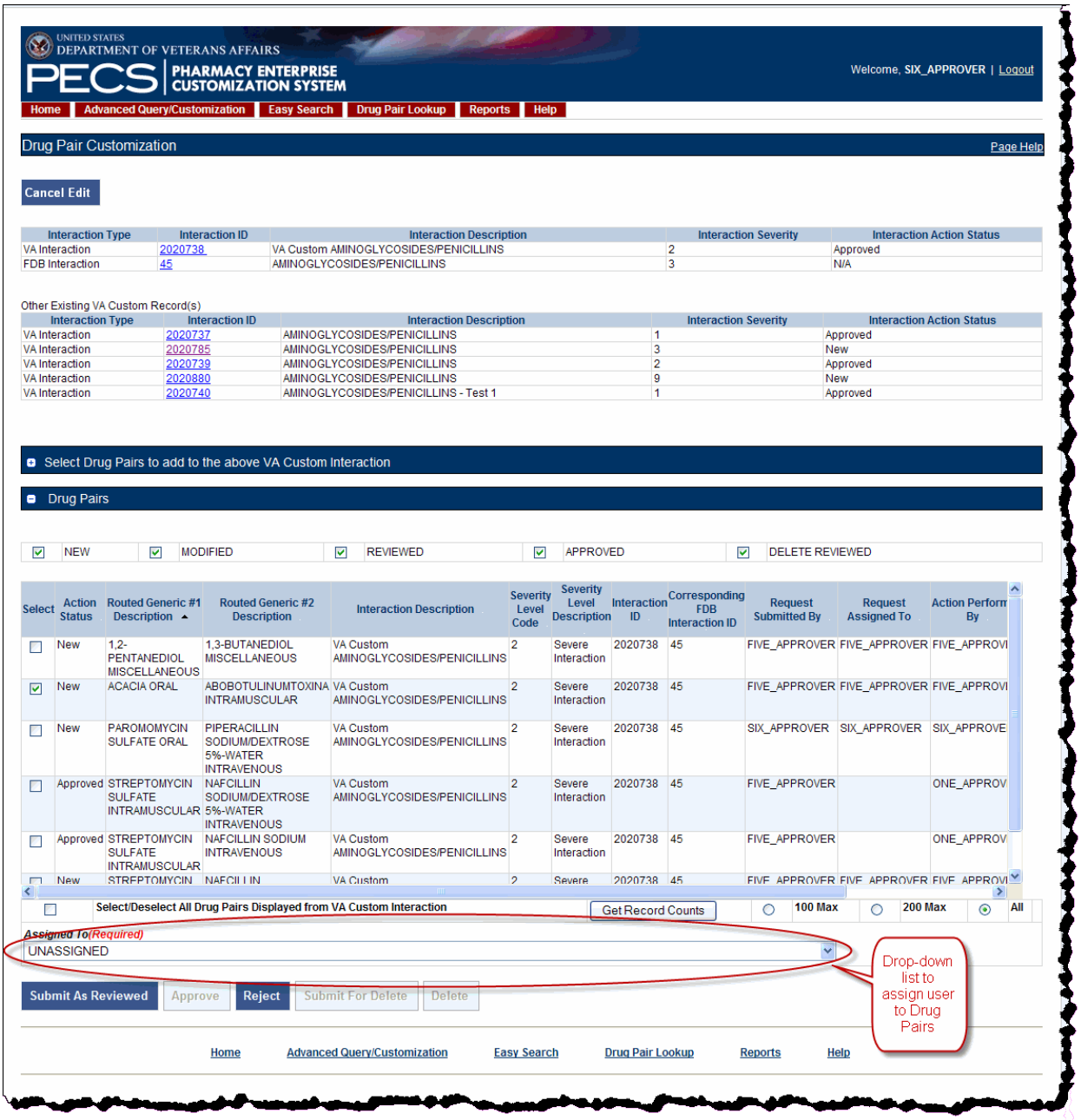


Figure 29: Assigned To Drop Down When Editing Drug Pairs

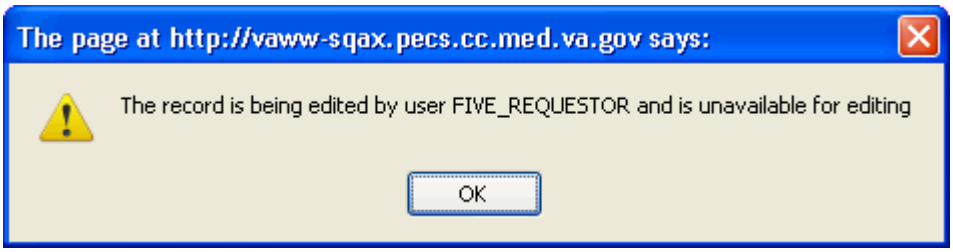
Note: If you change the state of the drug pairs to Submit as Reviewed or Submit for Delete, the drug pairs are automatically reassigned to the "Unassigned" category.

Also note: If you wish to put a Drug-Drug Interaction (DDI) into the Delete_Reviewed state, the Drug Pairs associated with the DDI must be in either a "Delete Reviewed," "Rejected" or "Deleted" state.

Record Locking Feature

All five concepts available in PECS, Drug-Drug Interaction, Drug Pairs, Professional Monograph, Dose Range, and Duplicate Therapy all have a record locking feature, which means that only a single user can edit a PECS record. Multiple users can no longer simultaneously edit a record. This feature eliminates the possibility that users can overwrite each others' changes and/or omit changes made by another.

For instance, if a user is editing a Drug-Drug Interaction and another user tries to edit the same record, here is the message that is displayed:



Here is the scenario:

1. User 1 logs in (e.g., Approver 1).
2. User 1 opens an active (not historical) record (in this sample, a Drug-Drug Interaction, but could be any concept) from either their own list or from building a query:

3. User 1 determines they need to make a change to this record. They click the Edit button and the following window displays:

4. At the same time User 2 (e.g., Approver 3) signs into the same record:

5. User 2 clicks Edit, and the following message displays:

6. User 1 makes changes and clicks the Modify button. The record is returned in read-only mode with the changes:
7. User 2 waits a few minutes and clicks the Edit button again. They receive this message:

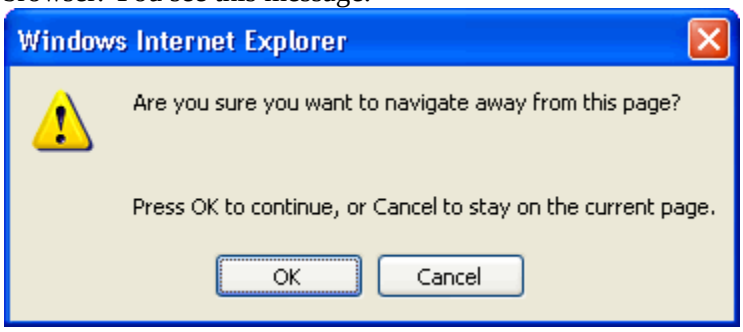
User 2 and all users will now be able to access the latest changes that have been made to a customization.

The Record Locking feature has safeguards that prevent a user from keeping a record locked too long; also, if the user leaves the record for any reason without completing the modification, the user is warned that they will lose their changes if they continue to navigate away from the record.

If the user does choose to leave the record without completing and saving their changes, the record is unlocked so others may work on it. If the user does not respond to the warning message, the

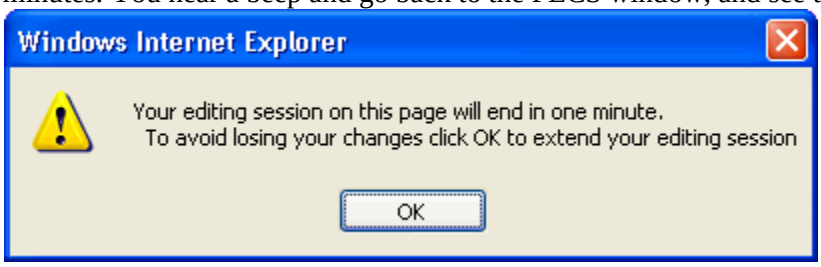
Here is another scenario:

1. You sign on and run a query for the concept for a customized record you want to modify.
2. You find the record and click the Modify button. The record opens in Edit mode and is locked for other users.
3. You begin to edit the record and for whatever reason, decide to do any one of the following: click any link on the page (except the help link), click any of the top navigation buttons, or close the browser. You see this message:



What this message means is that if you click OK, you will be taken to whatever link you clicked, your changes will be lost, and the record will be unlocked so others may edit it. If you click Cancel, you remain on the record you were editing, in Edit mode and the record remains locked for other users.

4. You continue to edit the record, but end up having to answer several instant messages for 19 minutes. You hear a beep and go back to the PECS window, and see this message:



5. You click OK and continue to edit the record, but are called away. You are called away for 30 minutes. When you return, you see the same message as in Step 4, but this time if you click OK, you are returned to the read-only record, and any changes you made will have been lost.

   Note: The same is true if you do not respond to the message that is displayed in Step 3 within 19 minutes. The editing expiration message shown in Step 4 displays, and if you do not click OK within one minute, the record is unlocked. When you return, you must click OK and you are returned to the read-only record.

Creating Multiple VA Custom Drug-Drug Interactions to One FDB Record

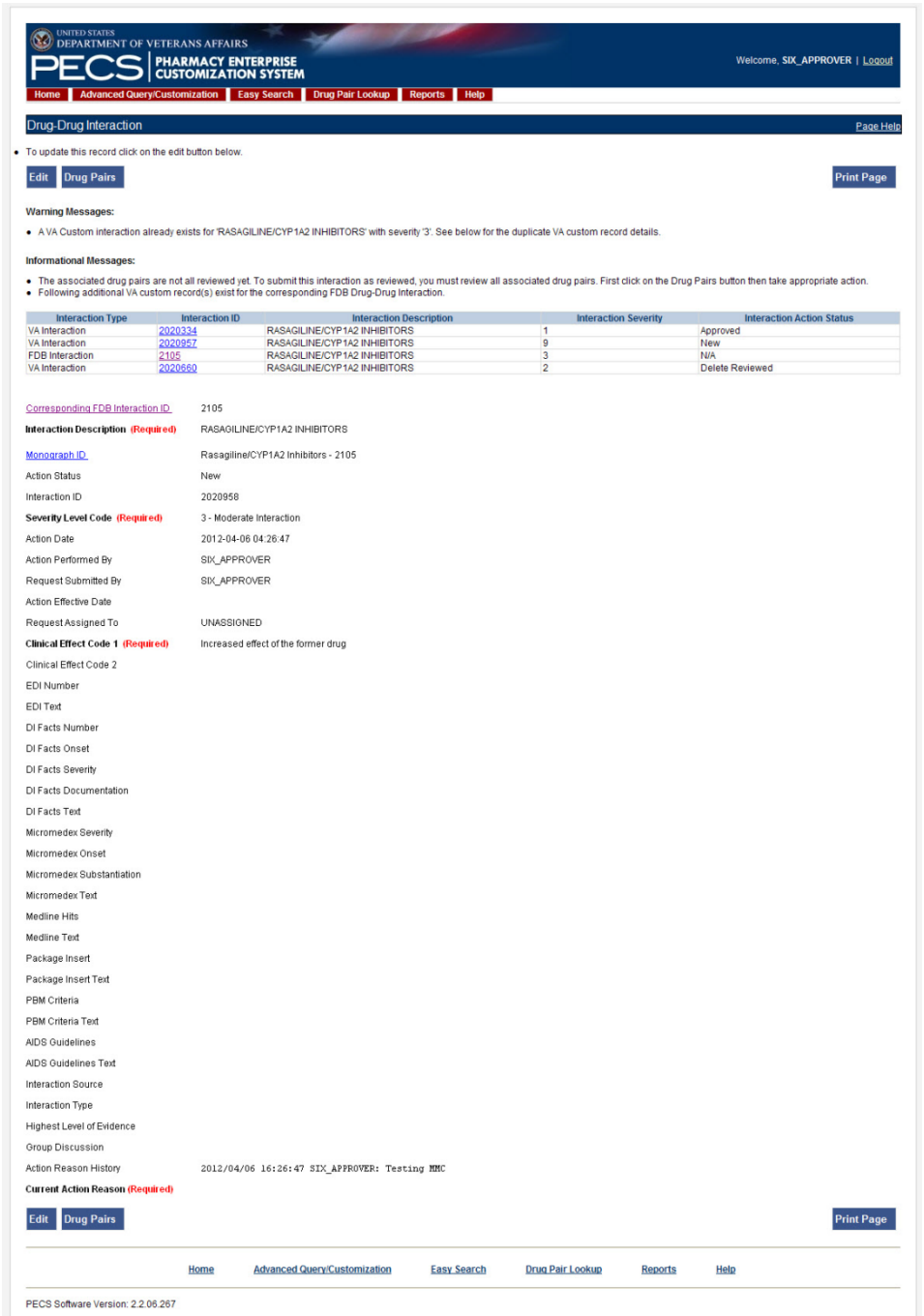
You can create multiple VA Custom Drug-Drug Interactions (DDIs) from one corresponding FDB Record. If you open an FDB DDI record on the Advanced Query/Customization page, the DDI Detail page will open. If there are any VA custom records for this FDB DDI, you'll see a message stating that "The following VA custom record(s) already exist for this FDB Drug-Drug Interaction," and a table and a link to any interactions displays. See below:

From here, you can create another custom record if you wish. Checks exist in the system so that the same user cannot make duplicate DDIs *or* another user cannot come in and make the same DDI that another user just made.

Create Multiple DDIs per One FDB Record

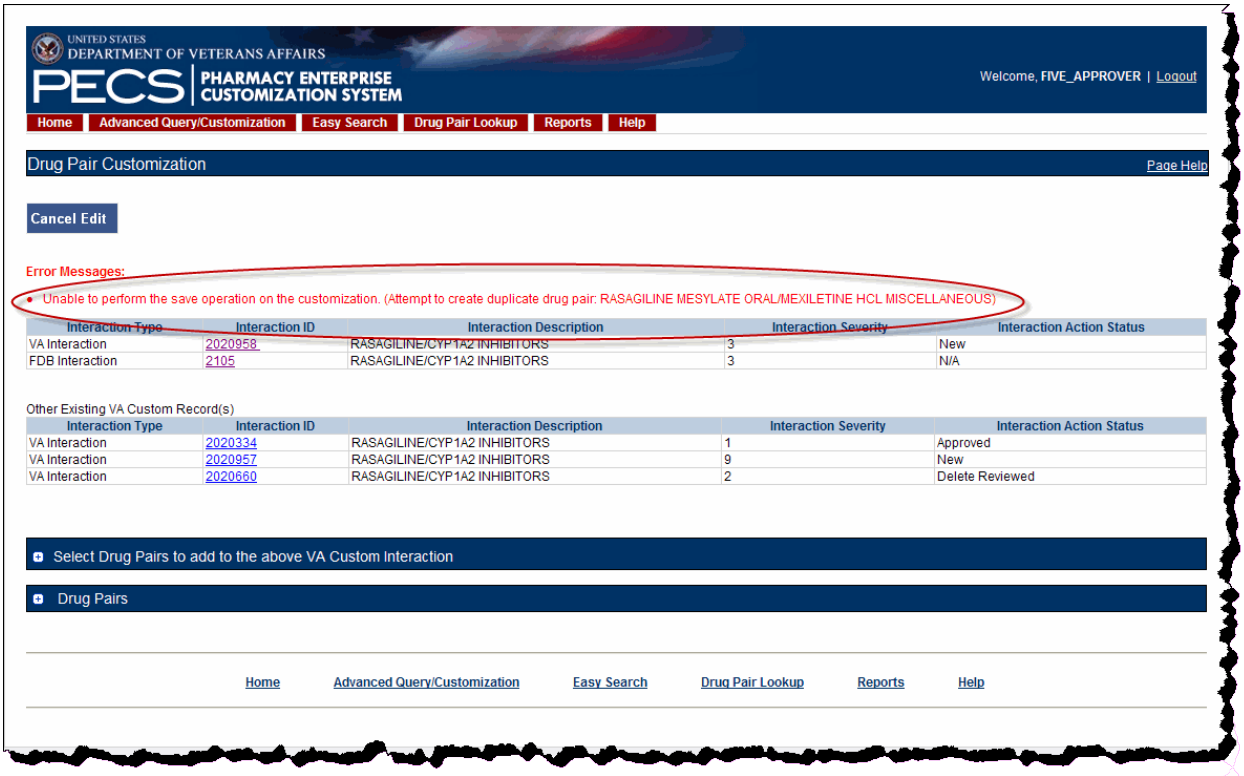
1. Log on and go to the Advanced Query/Customization tab.
2. Choose Drug-Drug Interaction for the Concept.
3. Select FDB Records.
4. Build the query as follows: Fields=Interaction ID; Filter=Contains; Value= for user guide purposes, let's say 2105.
5. Click Query.
6. Open Interaction ID 2105 from the list that displays.
7. Click Edit.
8. Create the custom record by changing something.

9. Your new record is created. The record ID is displayed on the Interaction ID field. If you have any duplicates or other discrepancies, you will see a warning message (such as an identical interaction severity, as shown below):

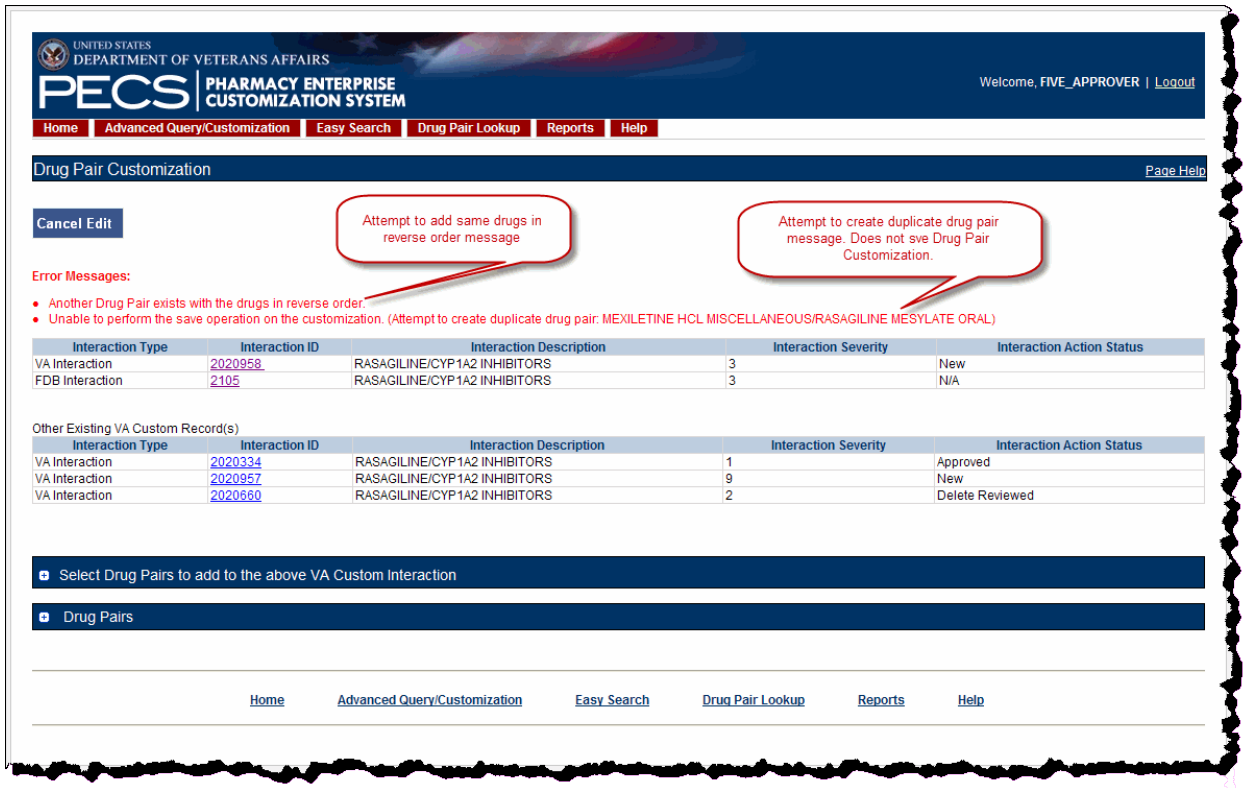


Prevention of Two Users Adding Identical Drug Pairs to the Same DDI

1. After you have created a new DDI or added new drug pairs to an existing DDI, a second user can come in and attempt to add the same drug pairs. If so, they see a message similar to the one circled below:



2. The second user will also receive an error if they attempt to customize drugs that exist for an interaction in reverse order. Note the error messages.



Quick Selection of Drug Pairs from the Selection List

When adding FDB Drug Pairs to an interaction on the Batch Customization page, you may select single drug pairs, groups of consecutive drug pairs, or a combination of both.

To select single drug pairs, simply click on the corresponding checkboxes of the drug pairs you want to select.

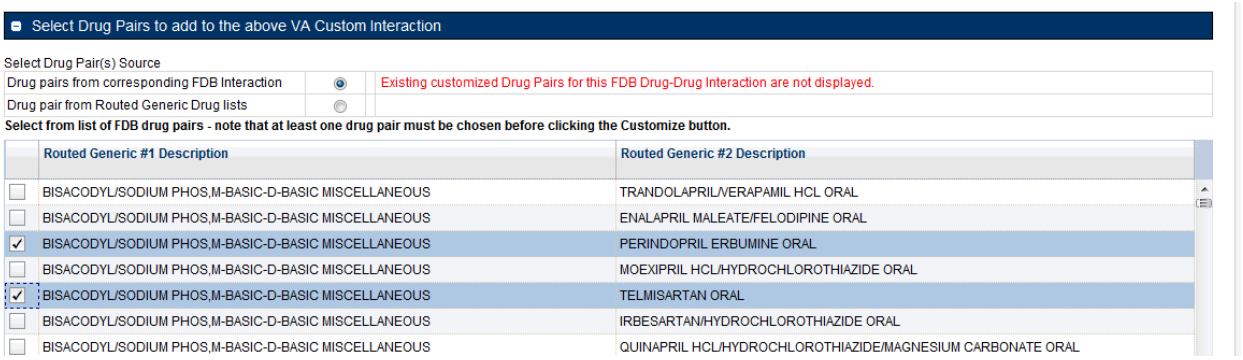


Figure 30: Select Single Drug Pairs

To select groups of consecutive drug pairs, click on the first checkbox in the group and then shift/click on the last checkbox in the group. All drug pairs between the first and last checkboxes will be selected. If you wish to add another group to your selection, simply click on the first checkbox in the second group and shift/click on the last checkbox in the group. You will now have two groups of drug pairs selected. To add other non-consecutive drug pairs, click on the corresponding checkbox.

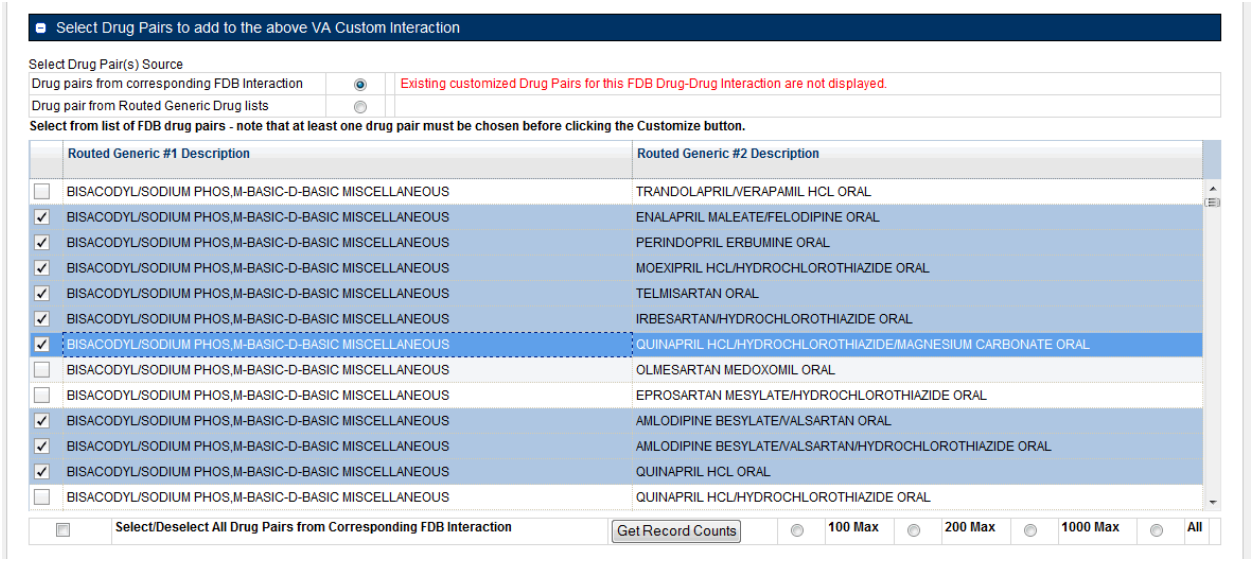


Figure 31: Range of Drug Pairs Selected with Shift Key

Forward and Reverse Professional Monograph

A single VA Custom Drug-Drug Interaction could be associated with a separate custom Professional Monograph for the forward and reverse interactions. An interaction described as Drug A and Drug B would have a different Custom Monograph from an interaction described as Drug B and Drug A. These different monographs may be necessary because there could be a different Clinical Effect Code between forward and reverse interactions (DrugA+DrugB: Clinical Effect Code = Adverse effects of the former drug; DrugB+DrugA: Clinical Effect Code = Adverse effects of the latter drug).

The following VA Custom Professional Monograph pairs will be associated with each other. This means that when a Monograph is assigned to a VA Custom Drug-Drug Interaction, the corresponding Monograph will be automatically assigned to the reverse Drug-Drug Interaction (DDI1 = DrugA + DrugB; DDI2 = DrugB+DrugA).

Monograph ID and Title	Paired Monograph ID and Title
150022 VA Customized: Adverse Effects of Former Drug (Critical) (ARF1)	150024 VA Customized: Adverse Effects of Latter Drug (Critical) (ARL1)
150023 VA Customized: Adverse Effects of the Former Drug (Significant) (ARF2)	150025 VA Customized: Adverse Effects of the Latter Drug (Significant) (ARL2)
150030 VA Customized: Decreased Effects (Critical) (DEF1)	150032 VA Customized: Decreased Effects (Critical) (DEL1)
150031 VA Customized: Decreased Effects (Significant) (DEF2)	150033 VA Customized: Decreased Effects (Significant) (DEL2)
150034 VA Customized: Increased Effects (Critical) (INF1)	150036 VA Customized: Increased Effects (Critical) (INL1)
150035 VA Customized: Increased Effects (Significant) (INF2)	150037 VA Customized: Increased Effects (Significant) (INL2)
150040 VA Customized: Mixed Effects of Former Drug (Critical) (MXF1)	150103 VA Customized: Mixed Effects of Latter Drug (Critical) (MXL1)
150041 VA Customized: Mixed Effects of the Former Drug (Significant) (MXF2)	150104 VA Customized: Mixed Effects of the LatterDrug (Significant) (MXL2)

When viewing a Drug-Drug Interaction, the PECS user interface will display only the Professional Monograph associated with the Forward interaction. The associated Reverse Professional Monograph will be visible only in the custom updates file created by the Release Manager. A sample is on the next page.

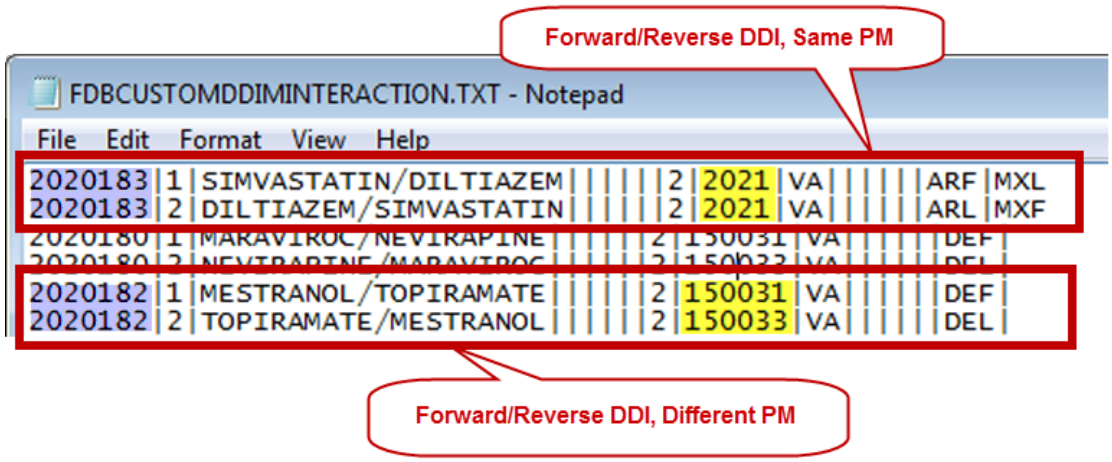


Figure 32: Forward/Reverse DDIs with Professional Monographs, Custom Update File Created by Release Manager

Easy Search Query Page

This page allows you to easily query for any Drug-Drug Interactions (and associated Professional Monographs) that may exist within PECS for at least two and up to 10 drugs. This page also allows you to search for Duplicate Therapy information for any drug you select. The example shown is for Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy.

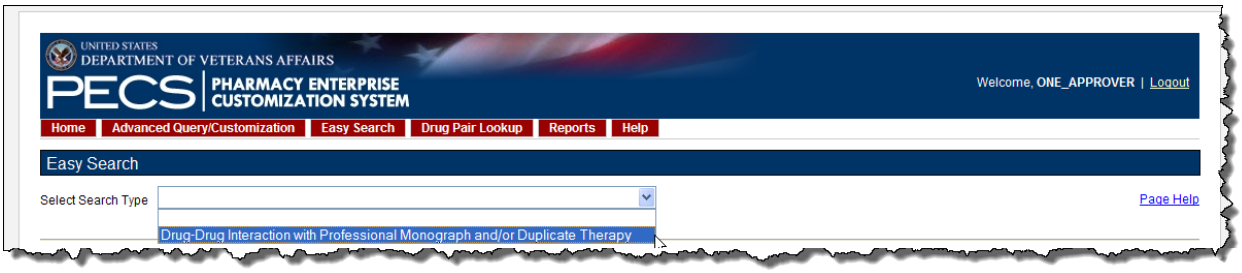


Figure 33: Initial Easy Search Window

To begin an Easy Search:

1. From the "Select Search Type" drop-down list, select Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy.' After you select these values, you see the "Select Information Type", "Search and Select Drugs", "Search Results" and "Drugs to Check" panels:

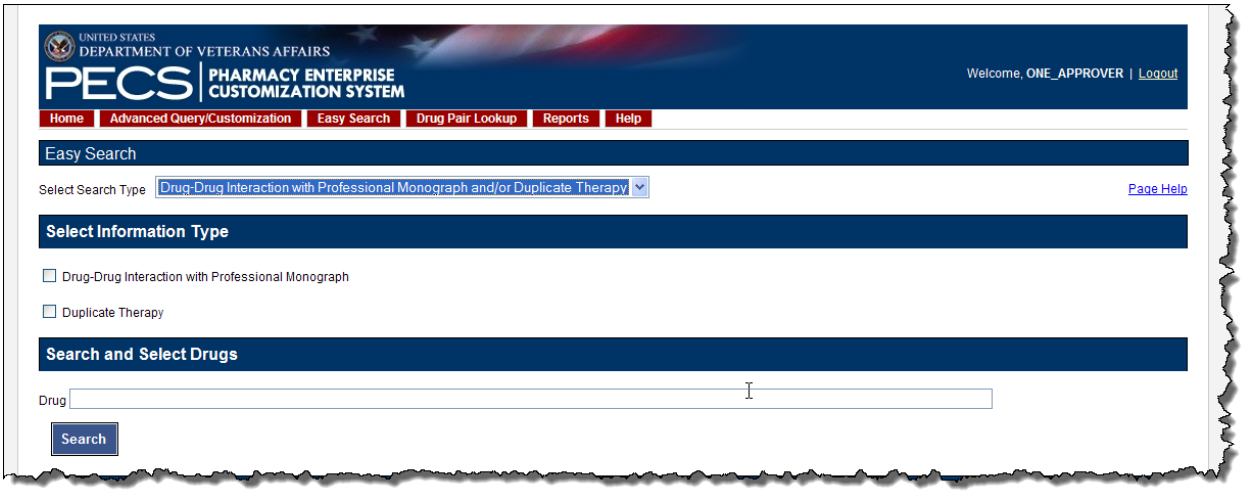
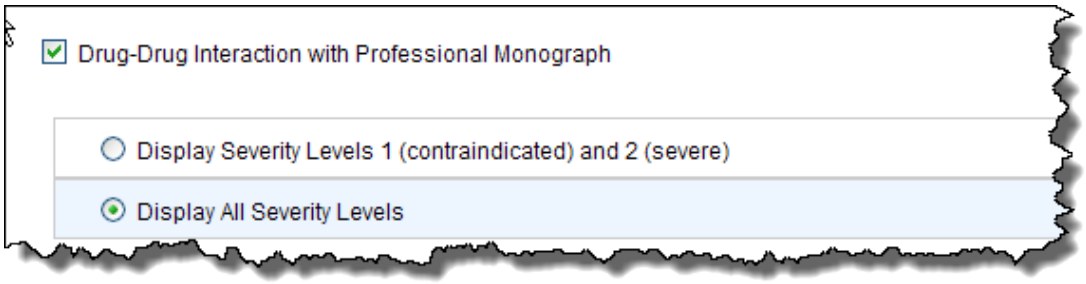


Figure 34: Select Drug-Drug Interaction with Professional Monograph and Duplicate Therapy

2. Select either the ‘Drug-Drug Interaction with Professional Monograph’ checkbox, or the ‘Duplicate Therapy’ checkbox, or both.
    - If you have selected the ‘Drug-Drug Interaction with Professional Monograph’ checkbox, you must select one of the options provided, Display Severity Levels 1 (contraindicated) and 2 (severe)’ or ‘Display All Severity Levels’.



3. Enter a partial string or whole drug name into the “Search and Select Drugs” field. Note that you can enter multiple partial strings, and the system returns drugs that match on both strings -- the order of the strings and case are ignored.
4. Click the “Search” button. The system returns all drugs that contain the partial string/whole drug name entered.

Figure 35: Severity Levels 1 and 2 Selected, and Drug Name to Search

5. Within the Search Results box, you can select up to ten drugs to run the Easy Search query for. You can click one drug at a time to select it for inclusion (highlighted). Alternately, you can click one drug, hold down the ‘shift’ key, and click as many drugs above or below you want to select, or you can click one drug, hold down the ‘Ctrl’ key to select additional drugs.
6. After you have selected all desired drugs, click the “Add to Drugs to Check” button. The selected drugs are moved down to the “Drugs to Check” panel.

7. You may perform additional searches to select more drugs, but only ten drugs can be submitted for a query. If you select more than ten, only the first ten drugs are added to the "Drugs to Check" panel and you receive an error message. Note that you can remove a drug from the "Drugs to Check" listing by highlighting it and clicking the 'Remove from Drugs to Check' button. To remove all drugs at once from the "Drugs to Check" listing, click the 'Remove All Drugs to Check".
8. When the drugs in the "Drugs to Check" are finalized, click the "Submit" button to run the query.

Here is a sample return:

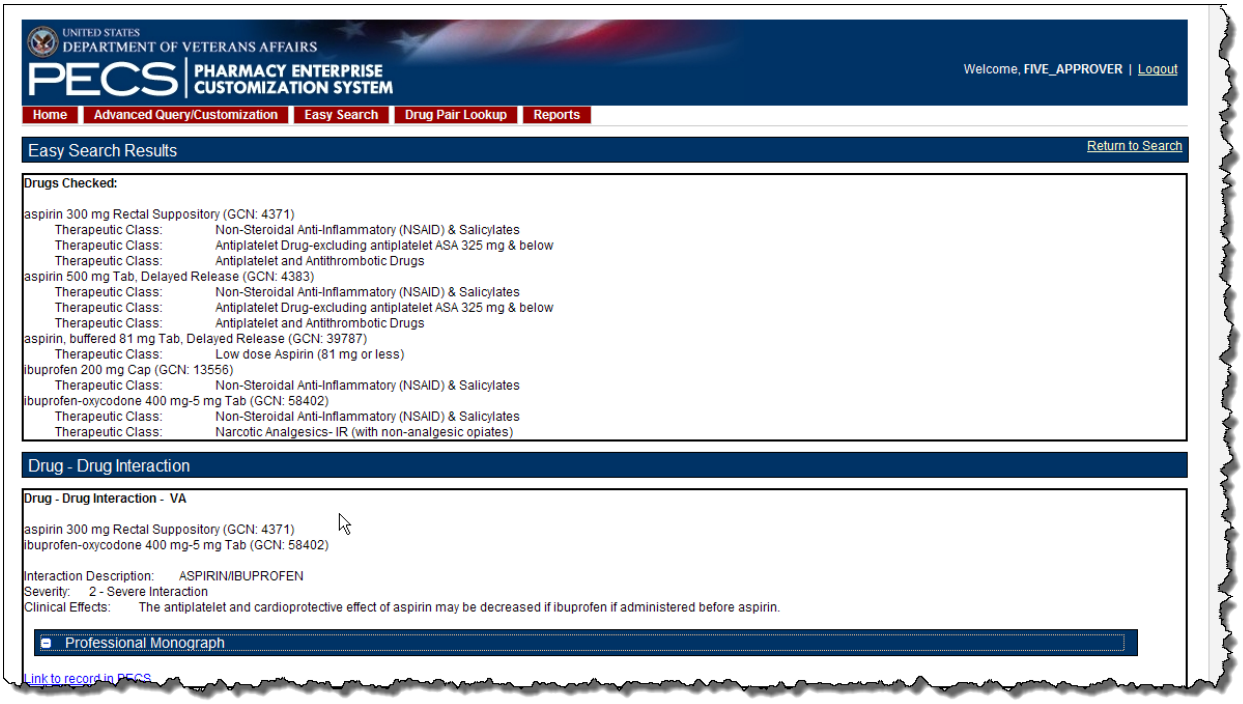


Figure 36: Partial Easy Search Results - Drug-Drug Interaction

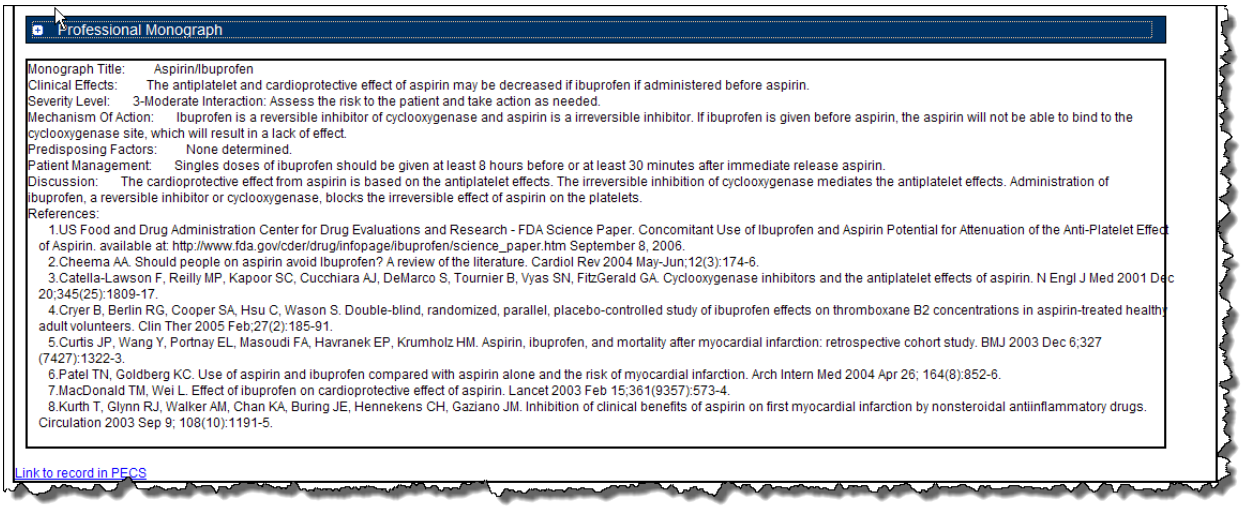


Figure 37: Partial Easy Search Results: Professional Monograph

Professional Monograph initially displays as collapsed; you can expand it by clicking the plus sign. Note that some drugs do NOT have a professional monograph to display (this is rare).

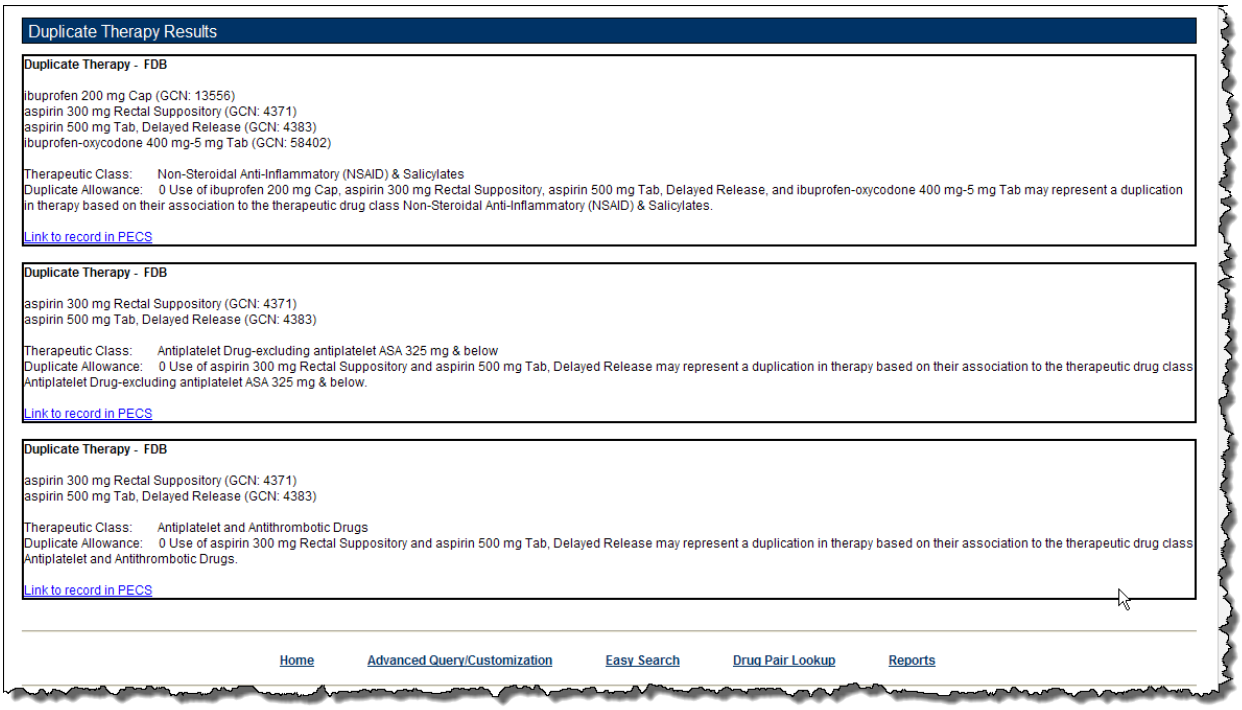


Figure 38: Partial Easy Search Results - Duplicate Therapy

9. Duplicate Therapy results only display those results that fall outside the value established by the duplicate allowance indicator. In Figure 27, the duplicate allowance indicator for each therapeutic class is 0, indicating that no duplicate drugs in each therapeutic class are allowed. Note that if the duplicate allowance indicator for a therapeutic class had been set to 1, the Duplicate Therapy results for that therapeutic class would no longer display, since they would be within the acceptable duplicate allowance.

Potential Discrepancy Between Easy Search Results and PECS Records

The custom detail pages in PECS (e.g., Figure 20: Dose Range Panel, Figure 21: Professional Monograph Panel, and Figure 22: Duplicate Therapy Panel) show the custom record as it exists in PECS. These detail pages are accessed through either the Advanced Query/Customization tab, or by clicking the "Link to record in PECS" link found on the Easy Search Results screens.

When you use Easy Search to look up Drug-Drug Interactions or Duplicate Therapy, in the background you are searching a different database table than the one used to store the actual PECS record. The Easy Search results page shows only data from custom records in an Approved state that have been exported in a custom update and processed by an external process named DATUP. If a custom record hasn't gone through these steps, you will see the FDB record and there will be a discrepancy.

Also, if a previously approved/exported custom record is updated, Easy Search will not show the updated data in the results page until the record is approved, exported, and processed by DATUP. Instead, Easy Search will show the custom record results that were last uploaded to DATUP.

Here is an example. Do the following:

1. Click the Easy Search tab from the home page.
2. Select Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy from the drop-down.
3. Select the Drug-Drug Interaction with Professional Monograph check box.
4. Select the Display All Severity Levels radio button.
5. Enter “fluti” in the search box,
6. From the list of drugs, select fluticasone furoate 27.5 mcg/Actuation Nasal Spray, Susp (GCN: 62658) to be included in the search.
7. Enter “lopinavir” in the search box.
8. From the list of drugs, select lopinavir-ritonavir 133.3 mg-33.3 mg Cap (GCN: 46600) to be included in the search.
9. Click Submit.

Here is a sample of the Easy Search screen you see:

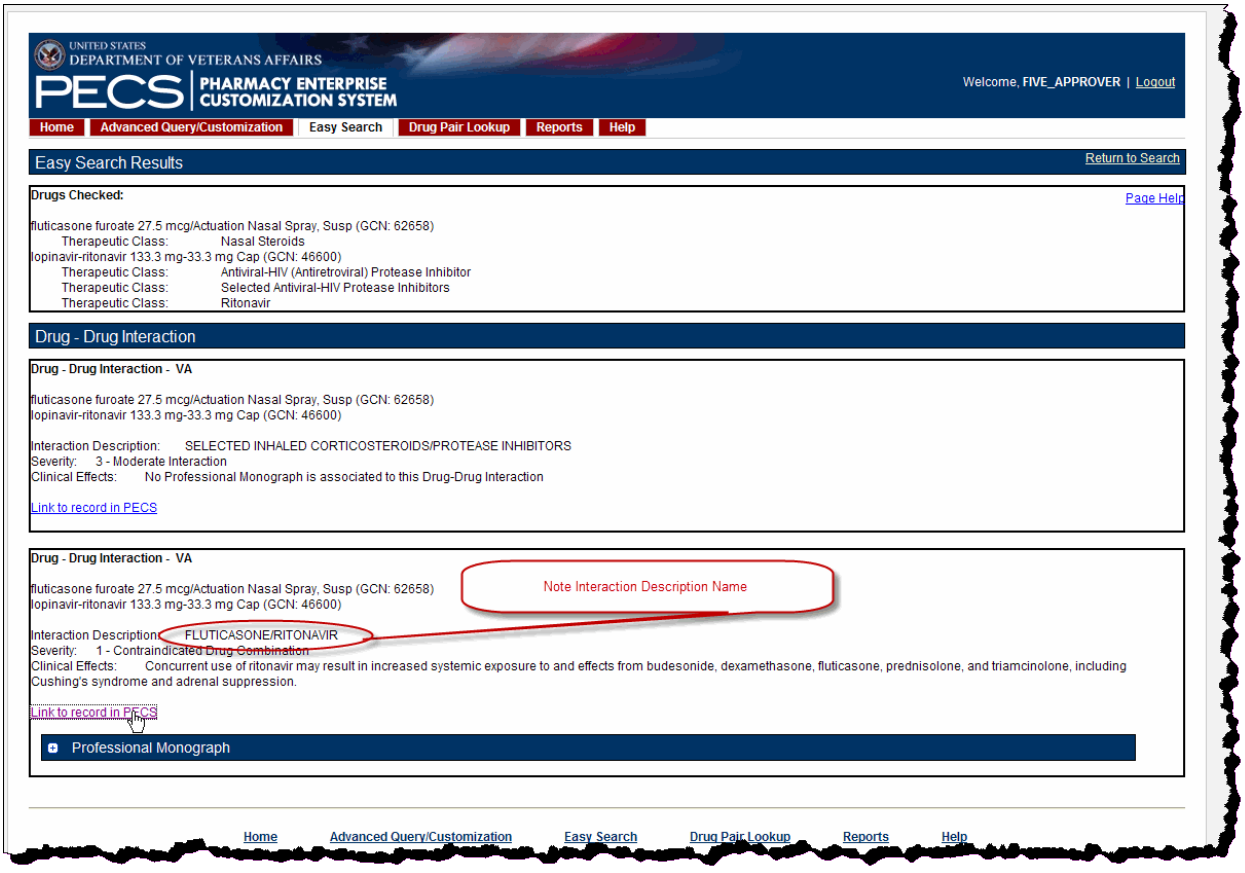


Figure 39: Easy Search DDI Record

Note the second Interaction Description Name, as is shown above (FLUTICASONE/RITONAVIR) Now, click the “Link to record in PECS” link as is shown above. The next picture displays the name discrepancy.

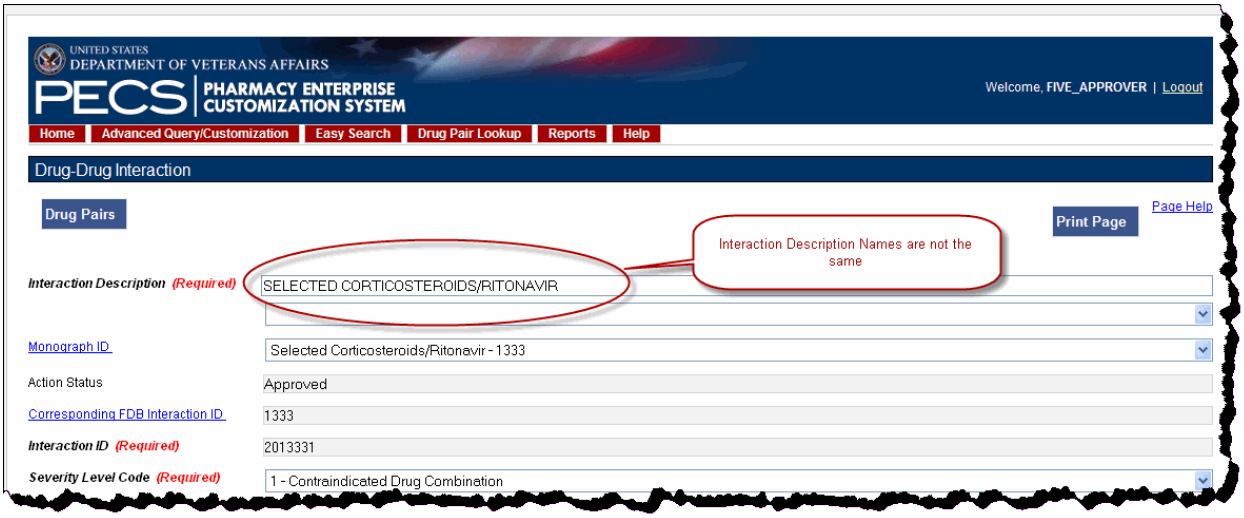


Figure 40: Referenced PECS Record with Name Discrepancy

This potential discrepancy applies to Drug-Drug Interaction, Professional Monograph, Duplicate Therapy, and Dose Range concepts.

Easy Search Dose Range

This page allows you to easily query the appropriate dosage information based on the patient and dose particulars entered for a selected drug. The results of this query allows you to ensure the amount being prescribed is an acceptable amount.

To begin a Dose Range Easy Search:

1. From the “Select Search Type” drop-down list, select ‘Dose Range.’
2. Enter a partial string or whole drug name into the “Drug” field. Note that you can enter multiple partial strings, and the system returns drugs that match on both strings -- the order of the strings and case are ignored.
3. Click the “Search” button. The system returns all drugs that contain the partial string/whole drug name entered.
4. Within the Search Results box, you can select a single drug to run the Easy Search query for by clicking the drug to select it for inclusion (highlighted). Note that if the drug does not have a defined dose route and/or a defined dose unit, the query will not be able to be performed. (Query on aspartame and select aspartame Powder (GCN: 48696) for an example)
5. After you have selected the desired drug, the Selected Drug box is populated with drug information for the selected drug and Dose Type and Dose Route drop downs are populated.
6. Patient demographic information defaults, and if the Add Default BSA checkbox remains checked, the body surface area value displays. Note that as the fields are updated to match the patient specifics, the body surface area is automatically recalculated.
7. The Single Dose and Frequency fields in the Dosing Information default to 1. The Dose Unit dropdown only contains values associated with the selected drug. Note that a blank option exists in the Does Rate Unit dropdown because this field is not required for oral doses.
8. When the fields in the Demographic Information and Dosing Information, are finalized, click the “Submit” button to run the query.

User Roles

Requestor

The Requestor's role is to create customization requests, modify their own requests, and run, save, and export queries.

Approver

The Approver's role is to create, review, approve, modify, delete or reject customization requests. They also run, save, and export queries, and run reports. An approver can review but cannot approve their own requests.

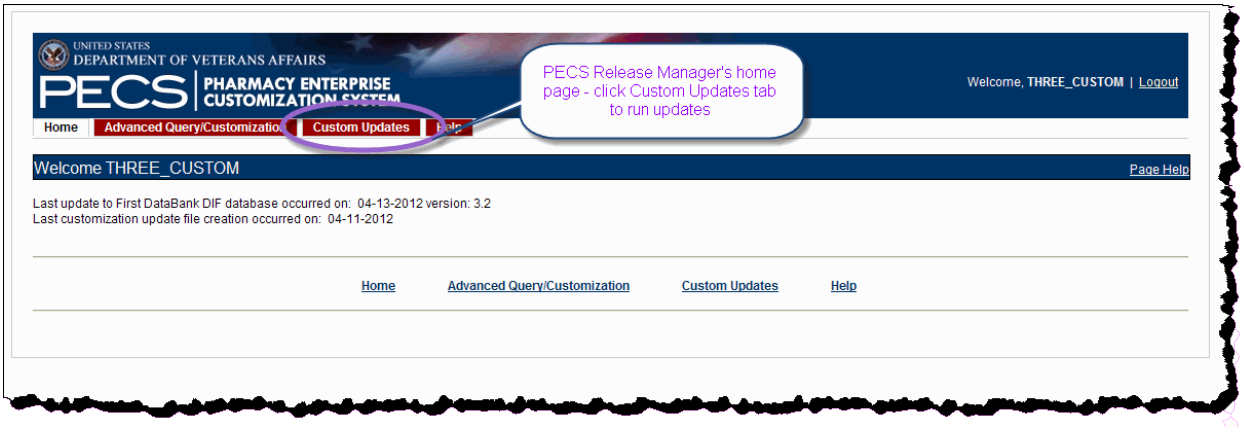
Release Manager Role

The Release Manager's role is to handle custom updates. Custom updates can be run at any time, but not more than once per day. The custom update will contain any custom records that have been APPROVED or DELETED since the previous custom update and can be for any of the five main PECS concepts (Dose Range, Drug Pairs, Drug-Drug Interaction, Duplicate Therapy, and Professional Monograph).

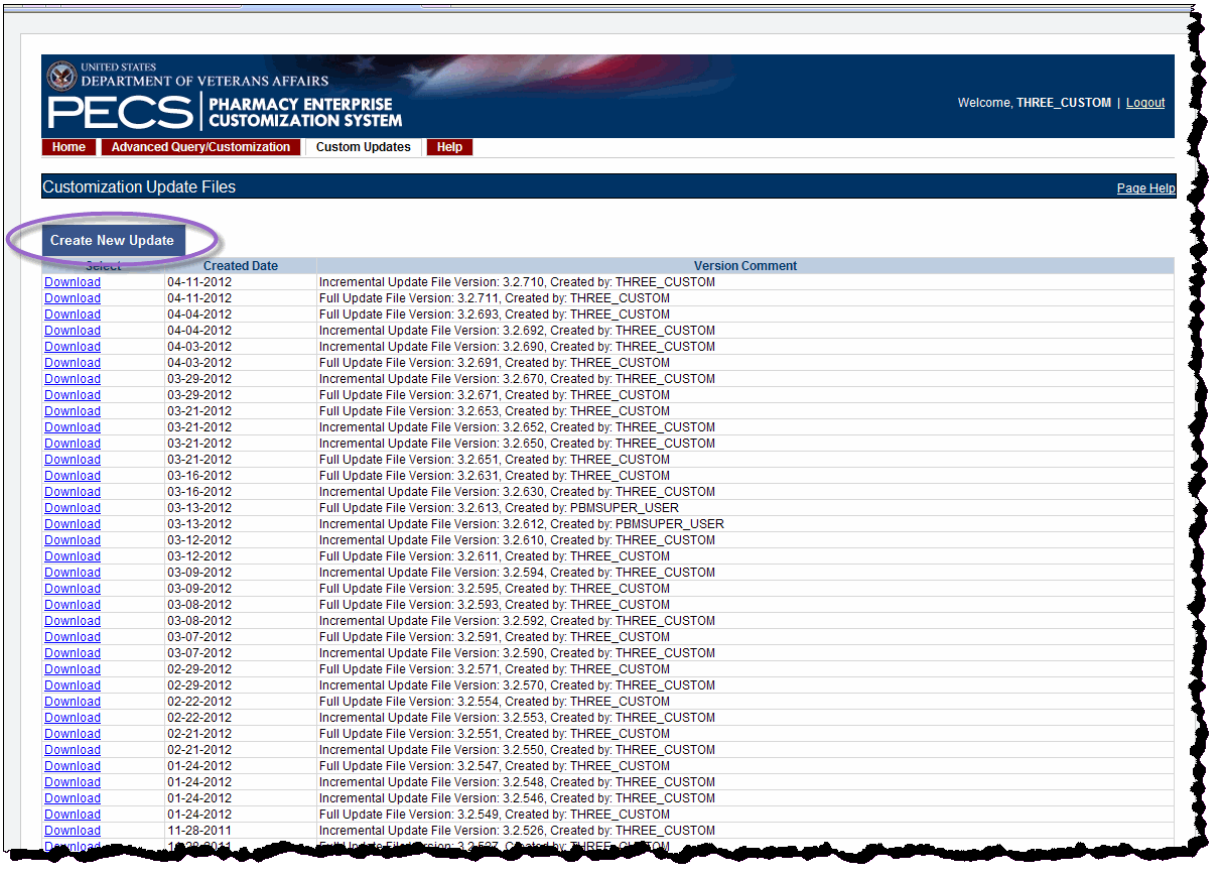
Release Managers can search for and view records but they are not allowed to create or approve customizations. They run custom updates at the instruction of the PECS Administrator and/or the National Drug File (NDF) Support Group. They will send an Outlook email to the PECS Administrators after the update has been created.

Here are the steps a Release Manager takes to run a custom update:

1. Log in to PECS.
2. Click the Custom Update tab:



3. Click Create New Update button:



4. Verify today's date in Created Date column.
5. If an error message is received, report it to PECS Administrator.

Update Files Explained

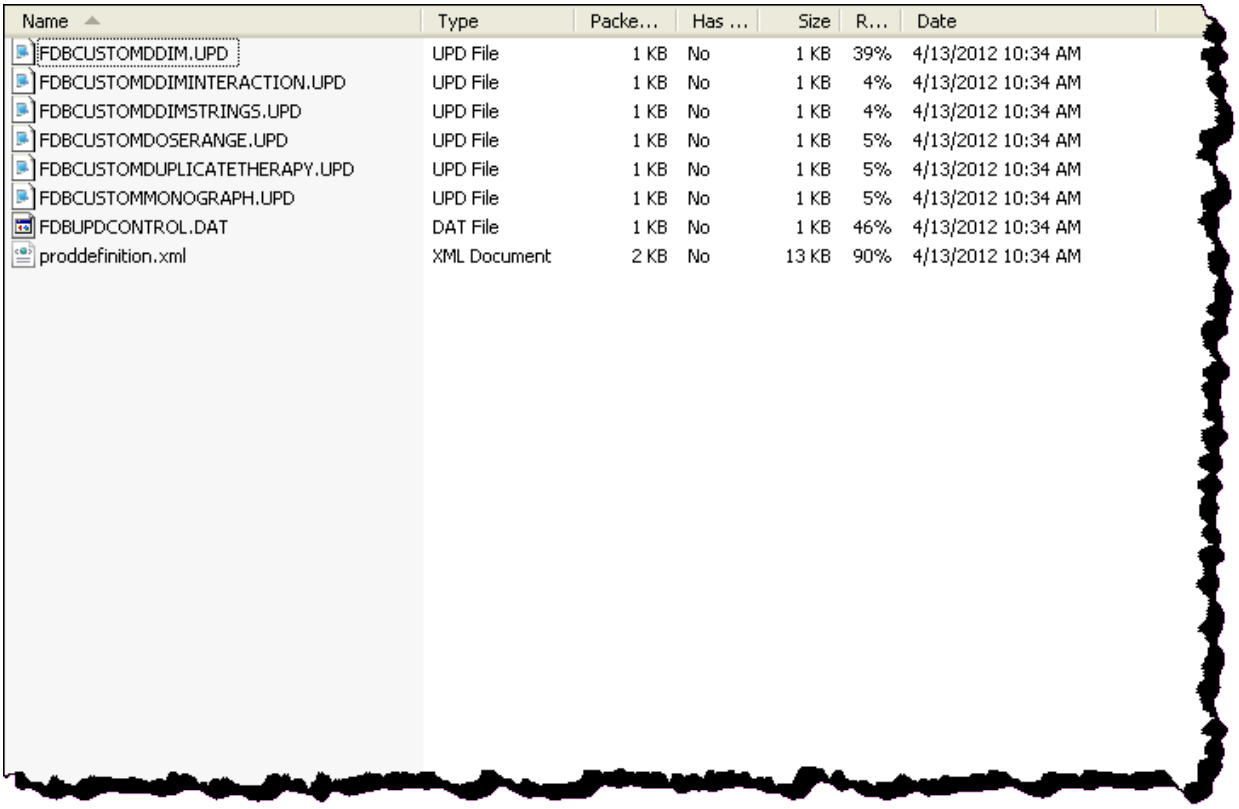
The custom update files that are run include both a full update and an incremental update. It is rare that a Release Manager will ever have to view these files, but if they do, here is an explanation.

A Custom Update file will always follow the same file naming standard. This standard is:

CstmUpdFile_{*FDB Version}*.{*PECS Generated Version Number*}_{*Date/Time Stamp*}.zip

So a file with the name CstmUpdFile_3.2.751_20120503154622.zip has an FDB Version number of "3.2," a PECS Generated Version Number of "751," and was created on May 3, 2012 at 15:46:22 (military time). The contents of the zip file will determine if this is an Incremental or a Full update.

The custom zip file contains a proddefinition.xml, FDBPRODCONTROL.DAT and several data files that have an extension of UPD. Here is a picture:



Name	Type	Packe...	Has ...	Size	R...	Date
FDBCUSTOMDDIM.UPD	UPD File	1 KB	No	1 KB	39%	4/13/2012 10:34 AM
FDBCUSTOMDDIMINTERACTION.UPD	UPD File	1 KB	No	1 KB	4%	4/13/2012 10:34 AM
FDBCUSTOMDDIMSTRINGS.UPD	UPD File	1 KB	No	1 KB	4%	4/13/2012 10:34 AM
FDBCUSTOMDOSERANGE.UPD	UPD File	1 KB	No	1 KB	5%	4/13/2012 10:34 AM
FDBCUSTOMDUPLICATETHERAPY.UPD	UPD File	1 KB	No	1 KB	5%	4/13/2012 10:34 AM
FDBCUSTOMMONOGRAPH.UPD	UPD File	1 KB	No	1 KB	5%	4/13/2012 10:34 AM
FDBUPDCONTROL.DAT	DAT File	1 KB	No	1 KB	46%	4/13/2012 10:34 AM
proddefinition.xml	XML Document	2 KB	No	13 KB	90%	4/13/2012 10:34 AM

Figure 41: Custom Update Zip File

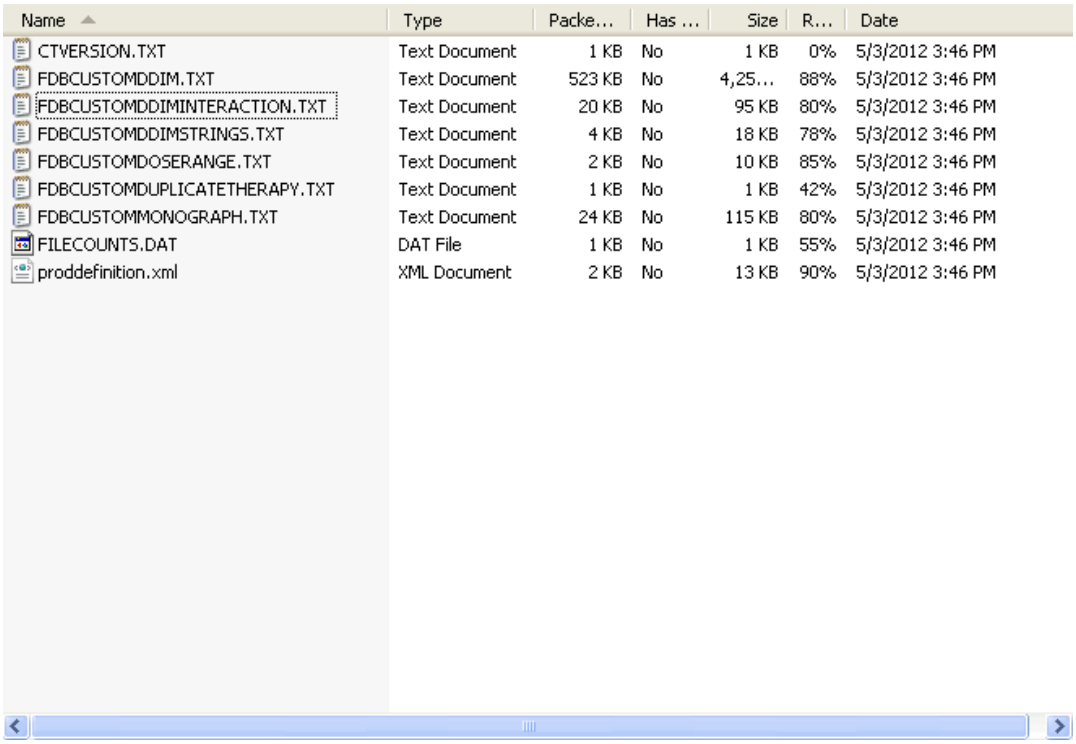
The proddefinition.xml file is a file from FDB that defines the table structures for the FDB tables in an XML format. The FDBUPDCONTROL.DAT file contains control information used by the FDB Data Updater software when determining if this Incremental update should be applied to a database. The UPD files contain data updates for a particular FDB table in the database.

Here is a sample: Note that the “D”, “C”, and “A” in the left column mean Delete, Change, and Add, respectively.

```
H|fdb_custom_ddim|26|4|40|3.2|W|20120416|USA
F|10|1|rtgenid1|2|rtgenid2|3|interactionid|4|seqno|5|uicategory1|6|uicategory2|7|uicategory3|8|uicateg
ory4|9|uicategory5|10|uicategory6
P|4|1|2|3|4
D|1052533|1050026|2020134|1
D|1050026|1052533|2020134|2
D|10489717|1050028|2020134|1
D|1050028|10489717|2020134|2
D|1052533|1050027|2020134|1
D|1050027|1052533|2020134|2
```

Figure 42: Custom Update Text File

The full update contains text files.



Name	Type	Packe...	Has ...	Size	R...	Date
CTVERSION.TXT	Text Document	1 KB	No	1 KB	0%	5/3/2012 3:46 PM
FDBCUSTOMDDIM.TXT	Text Document	523 KB	No	4,25...	88%	5/3/2012 3:46 PM
FDBCUSTOMDDIMINTERACTION.TXT	Text Document	20 KB	No	95 KB	80%	5/3/2012 3:46 PM
FDBCUSTOMDDIMSTRINGS.TXT	Text Document	4 KB	No	18 KB	78%	5/3/2012 3:46 PM
FDBCUSTOMDOSERANGE.TXT	Text Document	2 KB	No	10 KB	85%	5/3/2012 3:46 PM
FDBCUSTOMDUPLICATETHERAPY.TXT	Text Document	1 KB	No	1 KB	42%	5/3/2012 3:46 PM
FDBCUSTOMMONOGRAPH.TXT	Text Document	24 KB	No	115 KB	80%	5/3/2012 3:46 PM
FILECOUNTS.DAT	DAT File	1 KB	No	1 KB	55%	5/3/2012 3:46 PM
proddefinition.xml	XML Document	2 KB	No	13 KB	90%	5/3/2012 3:46 PM

Figure 43: Full Update File

Here is a sample of the full update of Drug-Drug Interactions:

```
1048627|1050000|2004892|1|VA|||||
1050000|1048627|2004892|2|VA|||||
1048627|1050001|2004892|1|VA|||||
1050001|1048627|2004892|2|VA|||||
1048627|1050014|2004892|1|VA|||||
1050014|1048627|2004892|2|VA|||||
1048627|1050015|2004892|1|VA|||||
1050015|1048627|2004892|2|VA|||||
1048627|1052651|2004892|1|VA|||||
1052651|1048627|2004892|2|VA|||||
1048627|23070090|2004892|1|VA|||||
23070090|1048627|2004892|2|VA|||||
```

Figure 44: Custom Drug-Drug Interaction Full Update File

Administrator Role

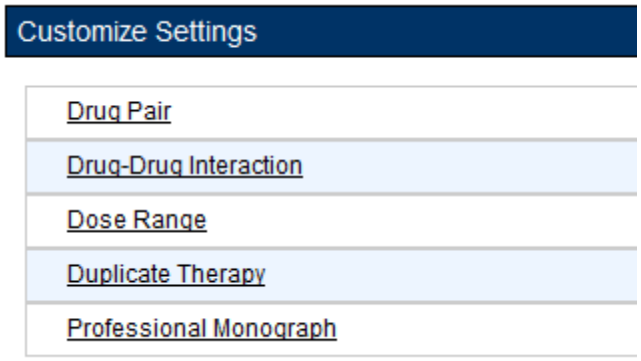
A PECS Administrator specific maintenance tasks grouped on the Administration tab that are not available to the other User Roles in the application.

The Administrator can

- Advanced Query/Customization
- Customize Settings
- Run Reports
- Initiate the process to remove drug pairs containing a null routed generic drug

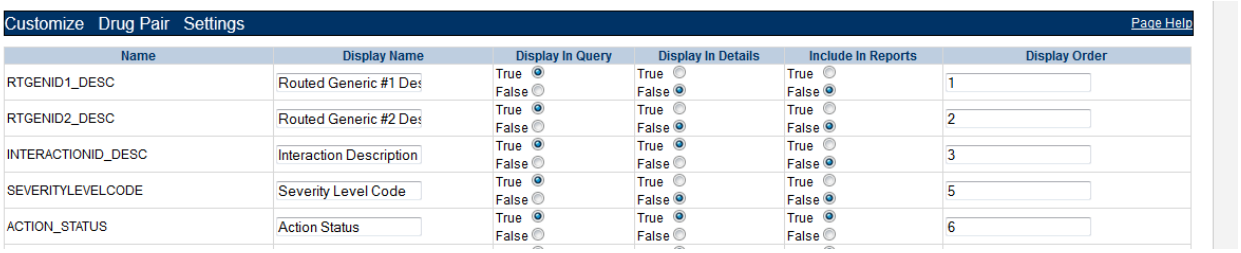
Customize Settings

Use Customize Setting to change the way data appears in various ways related to a specific concept.



Customize Settings allows you to change the label name for the Field (Display Name), whether the field should appear in Queries, Detail Pages, and Reports. It also allows you to change the order the individual fields are displayed on their respective pages.

Warning: Changes made on the Settings page will affect all PECS users. Please proceed cautiously.



Change Field Display Name

To change how the name of a field is displayed on the page, modify the contents of the Display Name field.

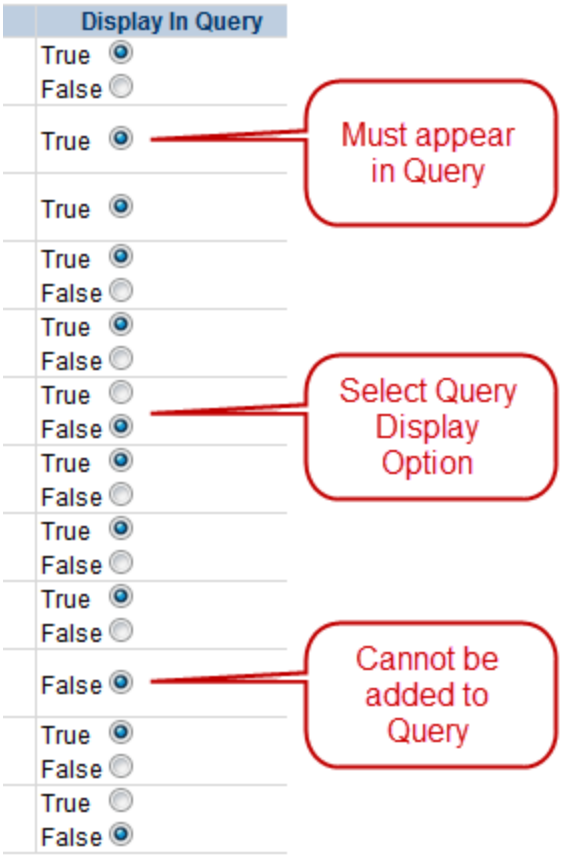
1. In the Customize <Concept> List, find the name of the database field you want to change.
2. Modify the contents of the field in the Display Name column.
3. Repeat the process as necessary.

4. Click Save to save your changes; click Cancel to abandon the changes and return to the Settings page. NOTE: Cancel is immediate; you will not be warned that you are about to lose your changes.

Add/Remove Field from Query Options

To add (or remove) a field from Query options

1. In the Customize <Concept> List, find the name of the database field you want to change.
2. In the Display in Query column, select True to display the field in Query options, select False to prevent the field from displaying in Query options. NOTE: Display in Query options are not available for all fields; some fields are explicitly required to be displayed in the Query options while others are forbidden from being displayed. In these cases, the required display option (True or False) will be the only options displayed and cannot be changed.



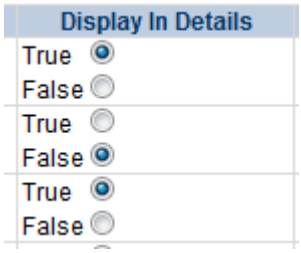
3. Repeat the process as necessary.
4. Click Save to save your changes; click Cancel to abandon the changes and return to the Settings page. NOTE: Cancel is immediate; you will not be warned that you are about to lose your changes.

Add/Remove Field from Detail Pages

To add (or remove) a field from Detail pages

1. In the Customize <Concept> List, find the name of the database field you want to change.

2. In the Display in Detail column, select True to display the field on the concept Detail page, select False to prevent the field from displaying on the concept Detail page.

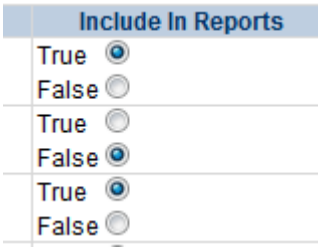


3. Repeat the process as necessary.
4. Click Save to save your changes; click Cancel to abandon the changes and return to the Settings page. NOTE: Cancel is immediate; you will not be warned that you are about to lose your changes.

Add/Remove Field from Reports

To add (or remove) a field from Reports

1. In the Customize <Concept> List, find the name of the database field you want to change.
2. In the Include in Reports column, select True to display the field on concept-related reports, select False to prevent the field from displaying on the concept-related reports.

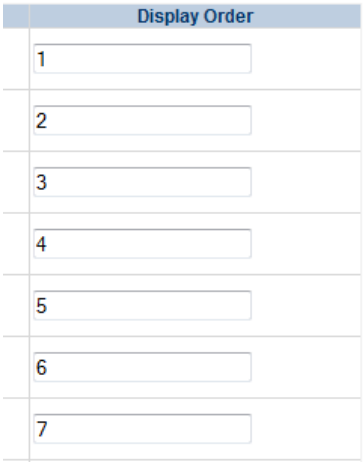


3. Repeat the process as necessary.
4. Click Save to save your changes; click Cancel to abandon the changes and return to the Settings page. NOTE: Cancel is immediate; you will not be warned that you are about to lose your changes.

Change Field Display Order

To change the order that the fields appear in Detail pages and drop-down lists, change the adjacent number in the Display Order field. Note that changing the Display Order is an entirely manual process; each field must be changed individually and the order is not validated in any way. Multiple fields can have the same display order.

When all changes are complete, click Save; click Cancel to abandon the changes and return to the Settings page.



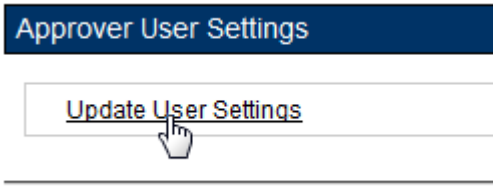
Approver User Settings

The Approver User Settings allow you to add or delete a user with the Approver role.

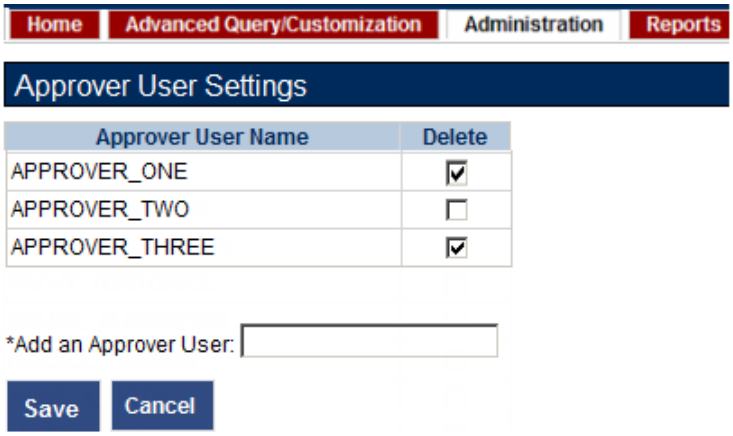
Delete an Approver

To Delete an Approver User

1. From the Settings tab, click Update User Settings.

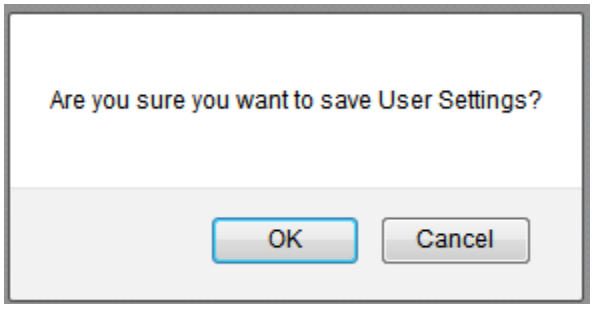


2. Select one or more users from the Approver User Name list.



3. Click Save.

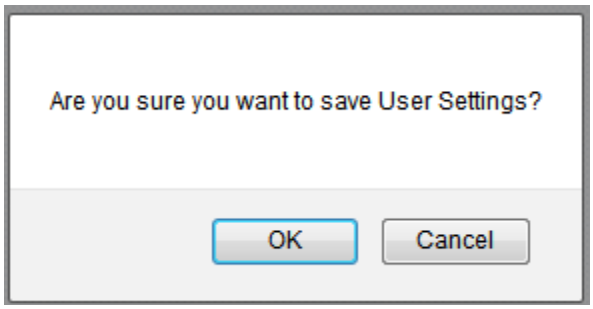
4. Click OK to delete the user(s); click Cancel to abandon the delete user operation and return to the Settings page.



Add an Approver

To add a user with the Approver role

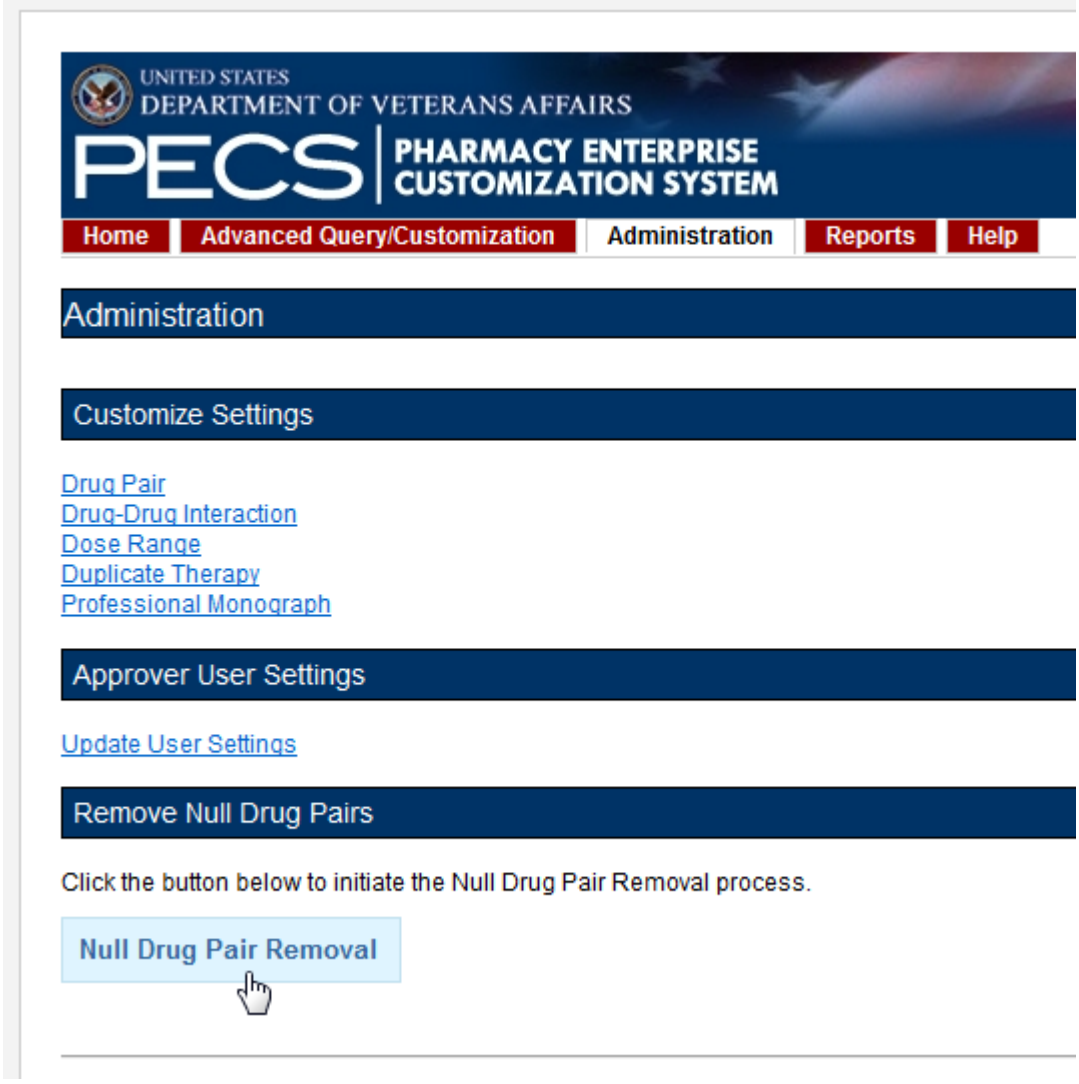
1. From the Settings tab, click Update User Settings.
2. In the Add an Approver User field, type in the name of the person you want to add.
3. The name must be in ALL CAPS and include both the first and last name (in that order) separated by an underscore . Examples: FIRSTNAME_LASTNAME, ERIC_SHINSEKI, JOHN_DOE.
4. Click Save.
5. Click OK to add the approver user; click Cancel to abandon the add user operation.



Null Drug Pair Removal Process

The purpose of the Null Drug Pair Removal process is to change the status of any VA Drug Pair that contains a null Routed Generic to “Deleted”, and to remove the null drug pairs from their associated VA Drug-Drug Interactions. VA Drug Pairs end up with null Routed Generics because one or both of the Routed Generics that make up the Drug Pair has been deleted by FDB. PECS applies the FDB Routed Generic deletes as part of the weekly FDB-DIF update, so it is recommended that the Null Drug Pair Removal process be run weekly, after the FDB-DIF update completes.

The Administrator may initiate this process at any time by clicking the “Null Drug Pair Removal” button on the following window:



When the process is complete, a message will appear at the top of the page to indicate that the process has completed.

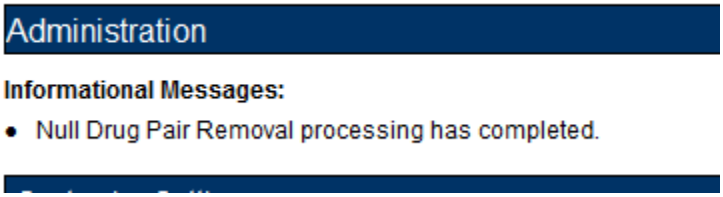


Figure 45: Null Drug Pair Removal Process Complete

Note: The Null Drug Pairs Customization Report can be used to identify *approved* VA Drug-Drug Interactions that contain null Drug Pairs. However, the Null Drug Pair Removal Process removes null drug pairs from *any* VA Drug-Drug Interaction, regardless of status. All VA Custom drug pairs that contain a null routed generic drug are updated as follows: the action status of the drug pair is changed to "Deleted" and the current action reason is "FDB Deleted," with the value of the FDB issue date when the custom drug pair was deleted. The FDB issue date is the date associated with the FDB update file that includes the deletion.

Sample Modification Scenarios

The following scenarios are examples of the types of modifications a typical user may perform. It is not a step-by-step guide in instructing users how to perform actual modifications. Sample steps are given, but these could differ based on the customizations being modified.

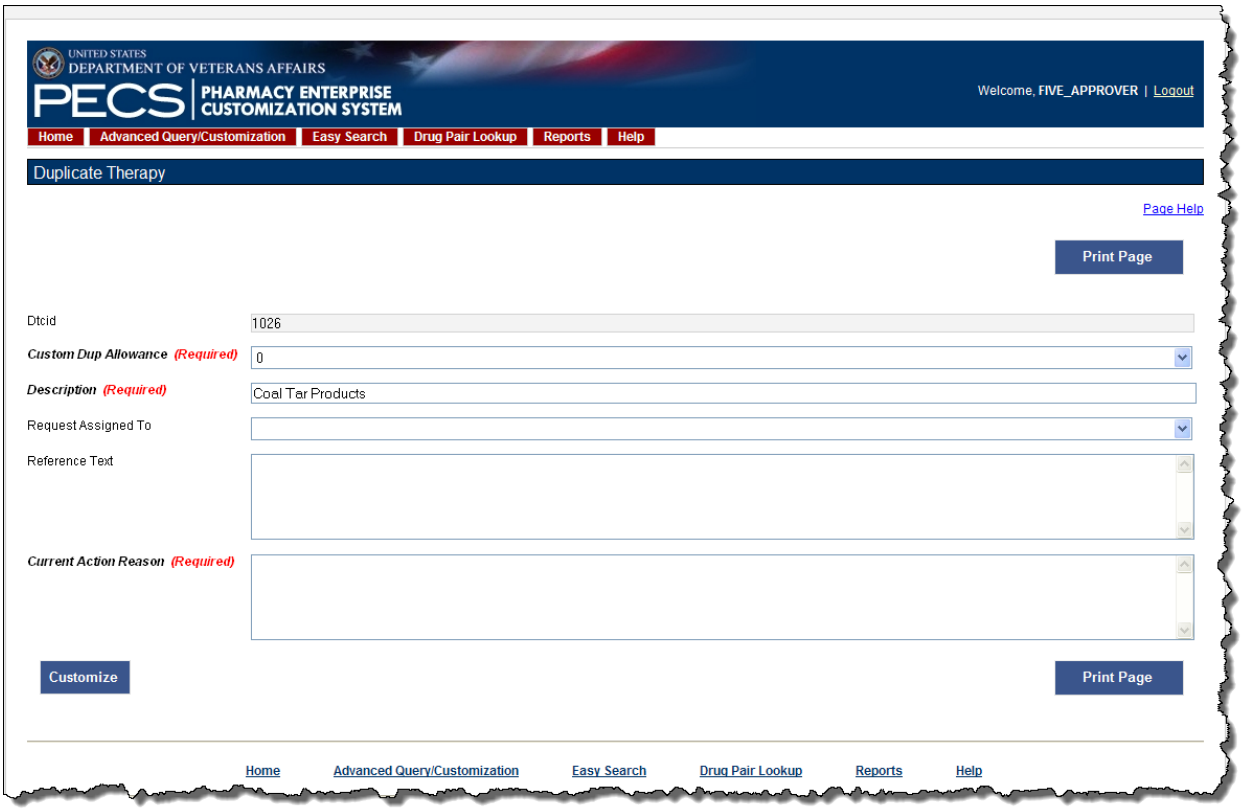
Duplicate Therapy Modification

Process Steps

Edit duplicate therapy allowance:

1. From the Home Page, click the Advanced Query/Customization tab.
2. Select “Duplicate Therapy” from the *Select a Concept* drop-down and select ‘FDB’ from the *Select VA, FDB, or Both* drop-down.
3. Build the query as follows: Fields=Description; Constraints=contains; Value=Tar.
4. Click the Query button.
5. Look at the query results at the bottom of the page.
6. Click the Open link for the desired class of drug.

7. You see the following:



8. Click the drop down arrow on Custom Dup Allowance (required).
9. Enter a Description (required).
10. Enter the Current Action Reason (required).
11. Add any reference text you think is needed (optional).
12. Click the Customize button.

Duplicate Therapy Approval

Sample Case: After the duplication allowance has been edited for the above situation, you need to submit the request for approval. Assign this request to FOUR_APPROVER.

Process Steps

1. From the Home page, look at My Request History.
2. Click the link to the NEW Duplicate Therapy requests.
3. Look at the query results at the bottom of the page.
4. Click the link for the desired class of drug (Topical Pine Tar).
5. Review the information.
6. Select the next business reviewer's name in Request Assigned To (optional) field.
7. Indicate the action reason in Current Action Reason (optional) field.
8. Click the Submit As Reviewed button.

Drug Interaction Research

Sample Case: The chief of urology has been told by the Pfizer sales rep that the VA has no drug-drug interaction between sildenafil and tamsulosin. The chief insists that a significant (severity level 2) interaction be added to the system.

Process Steps for Severity Check, Case 1

1. Check severity of an existing drug-drug interaction.
2. From the Home page, click the Drug Pair Lookup tab.
3. Fill in known information (Drug A: Sildenafil; Drug B: Tamsulosin).
4. Click the Query button.
5. Review the VA custom records and FDB record.
6. Note existing VA custom interaction between sildenafil and tamsulosin with severity level 2 and FDB interaction with severity level 3.
7. No action needed.

Drug Interaction Severity Change

Sample Case: The FDA recently issued a black box warning stating that cyclosporine and tolterodine should never be used together due to risk of renal toxicity. This interaction is considered severity level 3 (moderate) by First Data Bank. Based on the issuance of this black box warning, the NDF support group is recommending the severity level be changed to 1 (critical). Create custom drug-drug pairs for this new VA custom drug-drug interaction.

Process Steps for Editing Case 1

Edit the severity of an existing FDB drug interaction

1. From Home page, choose the Advanced Query/Customization tab.
2. Select "Drug-Drug Interaction" from the *Select a Concept* drop-down and select 'FDB' from the *Select VA, FDB, or Both* drop-down.
3. Build the Query: Column=Interaction Description; Constraints=contains; Value=cyclosporine.
4. Click the And button.
5. Build Query: Column=Interaction Description; Constraints=contains; Value=tolterodine.
6. Click the And button.
7. Click the Query button.
8. Look at the query results at the bottom of the page.
9. Click the Open link for desired Interaction Description.
10. Click the drop down arrow on Severity Level Code (required).
11. Select the new desired severity level code (1).
12. Indicate the action reason in the free text Current Action Reason (optional) field.
13. Click the Customize button.
14. Click Drug Pairs button.
15. Click plus sign on Select Drug Pairs to add to the above VA Custom interaction bar.
16. Click the radio button for "Drug Pairs from Corresponding FDB Interaction."
17. Select desired drug pairs to add to the custom interaction
18. Indicate the action reason in the free text Current Action Reason (optional) field.
19. Click the Customize button.

To Submit as Reviewed:

1. From the home page, look at My Assigned Requests for Review.
2. Click Drug-Drug Interaction.
3. Look at the query results at the bottom of the page.
4. Click the link for the desired interaction description (tolterodine/cyclosporine).
5. Click the Modify button.
6. Review the information.
7. Indicate the Action Reason in the free text Current Action Reason (optional) field.
8. Click the Submit For Review button.
9. Choose the Customization tab.
10. Click 'VA' under 'Drug-Drug Interaction.'
11. Build the Query: Column=Interaction Description; Constraints=contains; Value=tolterodine.

12. Click the And button.
13. Build the Query: Column=Interaction Description; Constraints=contains; Value=cyclosporine.
14. Click the And button.
15. Click the Query button.
16. Look at the query results at the bottom of the page.
17. Select the link for the desired Interaction Description.
18. Click the Modify button.
19. Indicate the Action Reason in the free text Current Action Reason (optional) field.
20. Click the Drug Pairs button at the bottom of the page.
21. Click the plus sign before 'Select Drug Pairs to add to the above VA Custom Interaction.'
22. Click the radio button for 'Select/Deselect all drug pairs from corresponding FDB interaction.'
23. Indicate the Action Reason in the free text Current Action Reason (optional) field.
24. Click the Submit for review button.

Drug Interaction Severity Change

Sample Case: Over the past six months, several local VA facilities have reported adverse reactions (ADRs) involving the use of digoxin and metoclopramide resulting in digoxin toxicity requiring hospital admissions for management. This interaction is classified as severity level 3 (moderate) by FDB and therefore does not create an alert in the physician order entry process. The NDF support group has approved the change of the severity level from 3 to 2 (severe) to provide for order alerts and has assigned you to perform this task. Create custom drug-drug pairs for this new VA custom drug-drug interaction. Then submit the new interaction and drug pairs as reviewed.

Process Steps for Editing Case 2

Edit the severity of an existing FDB drug interaction

1. From the Home page, choose the Advanced Query/Customization tab.
2. Select "Drug-Drug Interaction" from the *Select a Concept* drop-down and select 'FDB' from the *Select VA, FDB, or Both* drop-down.
3. Build the Query: Column=Interaction Description; Constraints=contains; Value=digoxin.
4. Click the And button.
5. Build the Query: Column=Interaction Description; Constraints=contains; Value=metoclopramide.
6. Click the And button.
7. Click the Query button.
8. Look at the query results at the bottom of the page.
9. Click the Active link for the desired Interaction Description.
10. Click the drop down arrow on Severity Level Code (required).
11. Select the desired new severity level code (2).

12. Indicate the action reason in the free text Current Action Reason (optional) field.
13. Click the Customize button.
14. Click Drug Pairs button.
15. Click the plus sign on Select Drug Pairs to add to the above VA Custom interaction bar.
16. Click the radio button for 'drug pairs from corresponding FDB interaction.'
17. Click the checkbox for 'Select/Deselect all drug Pairs from corresponding FDB interaction.'
18. Indicate the action reason in the free text Current Action Reason (optional) box
19. Click the Customize button.
20. From the Home page, look at My Request History.
21. Click the NEW Drug-Drug Interactions link.
22. Look at the query results at the bottom of the page.
23. Click on the Active link for the desired interaction description (digoxin/metoclopramide).
24. Click Drug Pairs button (Drug pairs should be submitted as reviewed prior to submitting the interaction for review)
25. Click the plus sign on Drug Pairs Bar
26. Click the checkbox for 'Select/Deselect All Drug Pairs Displayed from VA Custom Interaction'
27. Click the Submit as Reviewed button.
28. Click on the VA Interaction ID at top of page to navigate to Drug Interaction Detail page
29. Click the Submit as Reviewed button.

Remove Drug Pair from Interaction

Sample Case: You have been asked to remove the drug pair SUMATRIPTAN NASAL/TRANYLCYPROMINE SULFATE ORAL from the existing VA custom drug-drug interaction SELECTED 5HT-1D AGONISTS/MAO INHIBITORS.

Process Steps

Remove or add a drug pair from an existing VA custom drug-drug interaction.

1. Choose the Advanced Query/Customization tab.
2. Select "Drug-Drug Interaction" from the *Select a Concept* drop-down and select 'VA' from the *Select VA, FDB, or Both* drop-down.
3. Build the Query: Column=Interaction Description; Constraints=contains; Value=SELECTED 5HT.
4. Click the And button.
5. Click the Query button.
6. Look at the query results at the bottom of the page.
7. Select the Active link for the desired Interaction Description.

8. Click the Drug Pairs button at the bottom of page.
9. Click the plus sign on ‘Drug Pairs’ bar.
10. Click on the checkbox associated with Sumatriptan Nasal and Tranylcypromine Sulfate Oral.
11. Click the Submit for Delete button.
12. Alert another Approver that the drug pair needs to be deleted.

Create Professional Monograph

Sample Case: Create a new VA custom monograph using the current FDB interaction monograph created for cyclosporine and tolterodine as the guide. Modify the FDB monograph severity level from level 3 to level 1 – contraindication.

Process Steps

1. Choose the Advanced Query/Customization tab.
2. Select “Professional Monograph” from the *Select a Concept* drop-down and select ‘FDB’ from the *Select VA, FDB, or Both* drop-down.
3. Build the Query: Column=Monograph Title; Constraints=contains; Value=cyclosporine.
4. Select “And” from the drop-down.
5. Build the Query: Column=Monograph Title; Constraints=contains; Value=tolterodine.
6. Click the Query button.
7. Look at the results at the bottom of the page.

8. Click the link for the desired monograph title in the FDB table results. The Monograph is displayed, as shown.

9. Change the Severity level to 1 – Critical.
10. Indicate the action reason in the free text Current Action Reason (optional) field.
11. Click the Customize button.

Reports

The Reports page displays a list of available reports in PECS. PECS Reports are essentially exported Excel spreadsheets that can be manipulated and formatted as the user sees fit.

Note, the Reports page is not visible to Requestor role users.

To run a report, click the link associated with it. You will be provided the option of opening the file directly or saving it to copy of the file to a location on your workstation (or accessible network location).

Customization Reports

FDB Custom Dose Range Report

The FDB Custom Dose Range Report contains active VA custom Dose Range records in an Approved status along with their corresponding FDB record data. The default file name is Dosing_Total_Customization_Report.xlsx.

FDB Custom Drug-Drug Interaction Report

The FDB Custom Drug-Drug Interaction Report contains active VA custom Drug-Drug interaction records in an Approved status along with their corresponding FDB record data.

To Run the FDB Custom Drug-Drug Interaction Report

3. Click the Reports tab on the PECS Application Window.
4. Select the FDB Custom Drug-Drug Interaction Report radio button and click the Export button.
5. Select Open to view the exported file in Excel; select Save to save a copy of the file to a location on your workstation (or accessible network location). The file name is Ddiminteraction_Total_Customization_Report.xlsx.
6. If you selected Open, the report will automatically appear in the Excel application.

FDB Custom Duplicate Therapy Report

The FDB Custom Duplicate Therapy Report contains active VA custom Duplicate Therapy records in an Approved status along with their corresponding FDB record data.

To Run the FDB Custom Duplicate Therapy Report

1. Click the Reports tab on the PECS Application Window.
2. Select the FDB Custom Duplicate Therapy Report radio button and click the Export button.
3. Select Open to view the exported file in Excel; select Save to save a copy of the file to a location on your workstation (or accessible network location). By default, the file name is Dtcat_Total_Customization_Report.xlsx.
4. If you selected Open, the report will automatically appear in the Excel application.

FDB Custom Professional Monograph Report

The FDB Custom Professional Monograph Report contains active VA custom Professional Monograph records in an Approved status along with their corresponding FDB record data.

To run the FDB Custom Professional Monograph Report

1. Click the Reports tab on the PECS Application Window.
2. Select the FDB Custom Professional Monograph Report radio button and click the Export button.
3. Select Open to view the exported file in Excel; select Save to save a copy of the file to a location on your workstation (or accessible network location). By default, the file name is Monograph_Total_Customization_Report.xlsx.
4. If you selected Open, the report will automatically appear in the Excel application.

Deleted Monograph Customization Report

The Deleted Monograph Customization Report contains active VA custom Drug-Drug interaction records in an Approved status that are associated with a deleted FDB Professional Monograph.

To Run the Deleted Monograph Customization Report

1. Click the Reports tab on the PECS Application Window.
2. Click the Deleted Monograph Customization Report link.
3. Select Open to view the exported file in Excel; select Save to save a copy of the file to a location on your workstation (or accessible network location). By default, the file name is Deleted_Monograph_Report.xlsx.
4. If you selected Open, the report will automatically appear in the Excel application.

Null Drug Pairs Customization Report

The Null Drug Pairs Customization Report contains approved VA custom Drug-Drug Interactions that contain Drug Pairs with null Routed Generic #1 or Routed Generic #2 fields. If this report contains any entries, it is recommended that a user in the Administrator role initiate the Null Drug pair Removal Process.

To Run the Null Drug Pairs Customization Report

1. Click the Reports tab on the PECS Application Window.
2. Click the Null Drug Pairs Customization Report link.
3. Select Open to view the exported file in Excel; select Save to save a copy of the file to a location on your workstation (or accessible network location). By default, the file name is Deleted_Monograph_Report.xlsx.
4. If you selected Open, the report will automatically appear in the Excel application.

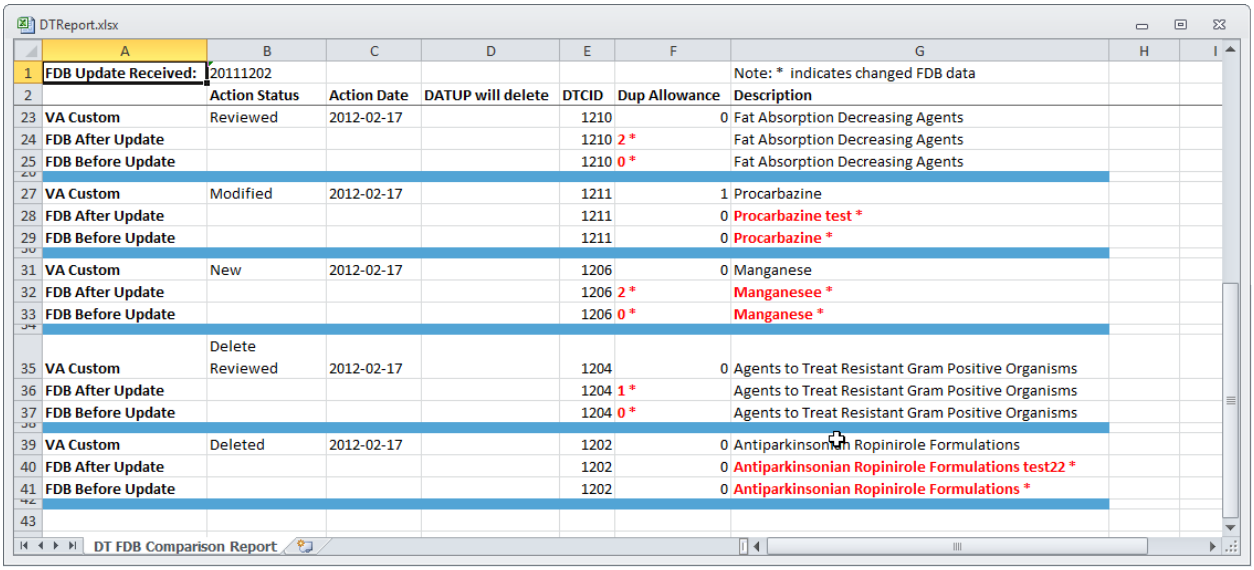
FDB Comparison Reports

The FDB Comparison Reports display the changes to existing data included in the Incremental FDB updates. They inform an approver or administrator of the latest FDB changes for the Duplicate Therapy, Drug-Drug Interaction, and Drug Pair concepts and provide data that helps them decide whether to change a custom record. The FDB Comparison Reports help an approver or administrator keep PECS customizations in sync with FDB changes.

FDB Comparison Reports display:

- Customized records in all action statuses that have differences between the PECS FDB data and the data in the Incremental FDB Update file.
- Un-customized records that have differences between the PECS FDB data and the data in the Incremental FDB Update file.
- Indications that an FDB record is scheduled to be deleted by DATUP.
- Lists of the drug pairs that will be added or deleted by DATUP.
- A "no data found" message if the Incremental FDB Update file has no changes to the FDB data.

Structure of the FDB Comparison Report



DTReport.xlsx

	A	B	C	D	E	F	G
1	**FDB Update Received:**	20111202					Note: * indicates changed FDB data
2		**Action Status**	**Action Date**	**DATUP will delete**	**DTCID**	**Dup Allowance**	**Description**
23	**VA Custom**	Reviewed	2012-02-17		1210	0	Fat Absorption Decreasing Agents
24	**FDB After Update**				1210	2 *	Fat Absorption Decreasing Agents
25	**FDB Before Update**				1210	0 *	Fat Absorption Decreasing Agents
27	**VA Custom**	Modified	2012-02-17		1211	1	Procarbazine
28	**FDB After Update**				1211	0	**Procarbazine test ***
29	**FDB Before Update**				1211	0	**Procarbazine ***
31	**VA Custom**	New	2012-02-17		1206	0	Manganese
32	**FDB After Update**				1206	2 *	**Manganesee ***
33	**FDB Before Update**				1206	0 *	**Manganese ***
		Delete					
35	**VA Custom**	Reviewed	2012-02-17		1204	0	Agents to Treat Resistant Gram Positive Organisms
36	**FDB After Update**				1204	1 *	Agents to Treat Resistant Gram Positive Organisms
37	**FDB Before Update**				1204	0 *	Agents to Treat Resistant Gram Positive Organisms
39	**VA Custom**	Deleted	2012-02-17		1202	0	Antiparkinsonian Ropinirole Formulations
40	**FDB After Update**				1202	0	**Antiparkinsonian Ropinirole Formulations test22 ***
41	**FDB Before Update**				1202	0	**Antiparkinsonian Ropinirole Formulations ***
43							

DT FDB Comparison Report

Figure 46: Sample FDB Comparison Report - Duplicate Therapy

Each FDB Comparison Report lists the "FDB Update Received" date, which is the date listed in the Incremental FDB Update file.

Each report lists comparison sets of VA and FDB data. Each comparison set consists of at least three rows separated by a blue line. The three rows are:

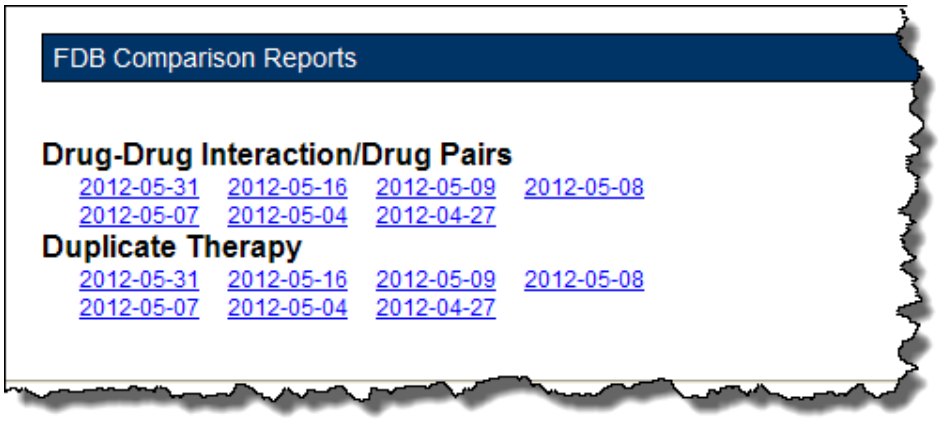
VA Custom	Data in the Custom VA record. If the corresponding FDB record has not been customized, a "Not customized" message will be in the Action Status column and the rest of the row will be blank.
FDB After Update	Data in the Incremental FDB Update File. This data will be in the PECS database shortly after the incremental FDB update is done via DATUP.
FDB Before Update	Data in the PECS FDB record. This data will be replaced by the 'FDB After Update' data. If the **FDB After Update** and **FDB Before Update** data of the same type are different, they are marked with an asterisk (*) and colored red. Records that do not have any differences between the **FDB Before Update** and **FDB After Update** data of the same type are not listed in the report.

Each FDB Comparison Report has the following columns:

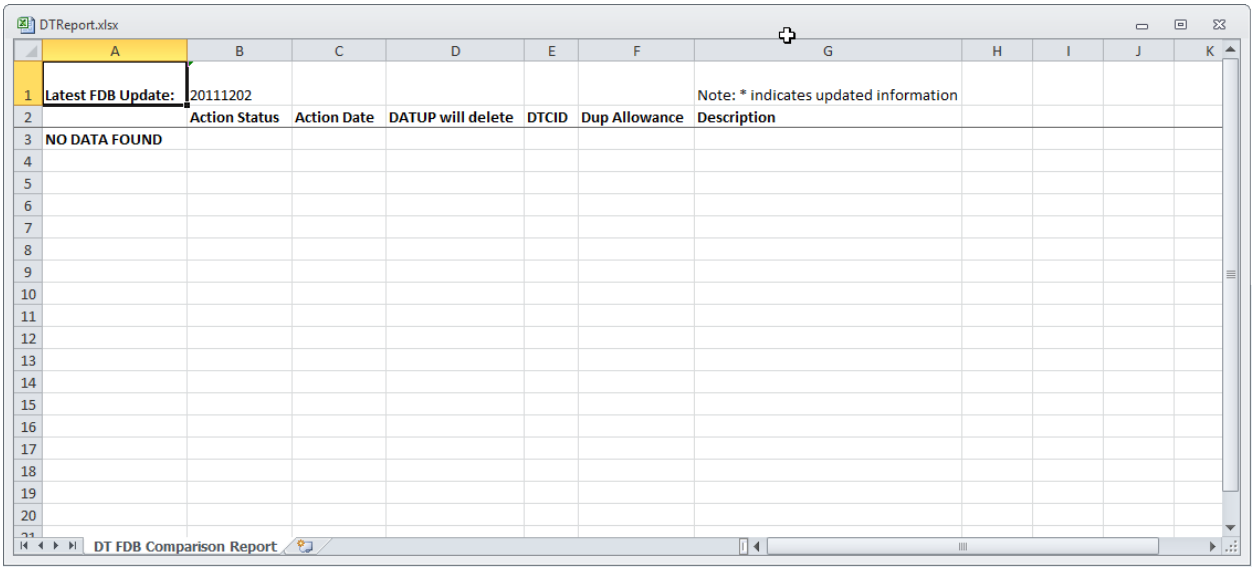
Action Status	The state of the associated VA record based on the most recent action performed. PECS compares FDB data with VA customizations in any Action Status, including Rejected or Deleted.
Action Date	The date the current action (Action Status) was taken.
DATUP will delete	YES in this column Indicates the associated FDB record will be deleted by DATUP. If the column is blank, the associated FDB record will not be deleted by DATUP. If the FDB record will be deleted by DATUP, only the FDB Interaction ID and DATUP will delete columns will be filled out in the FDB After Update row. All the other columns will be blank.

The reports are organized by type and the date of the FDB Incremental Update. Links to the reports are kept for eight weeks on the Reports page.

To run an FDB Comparison report, click the appropriate FDB Incremental Update date under the appropriate Report Heading.



If there are no differences between the FDB After Update and FDB Before Update data of the same type in any of the records, a "No Data Found" message is printed on the FDB Comparison Report.

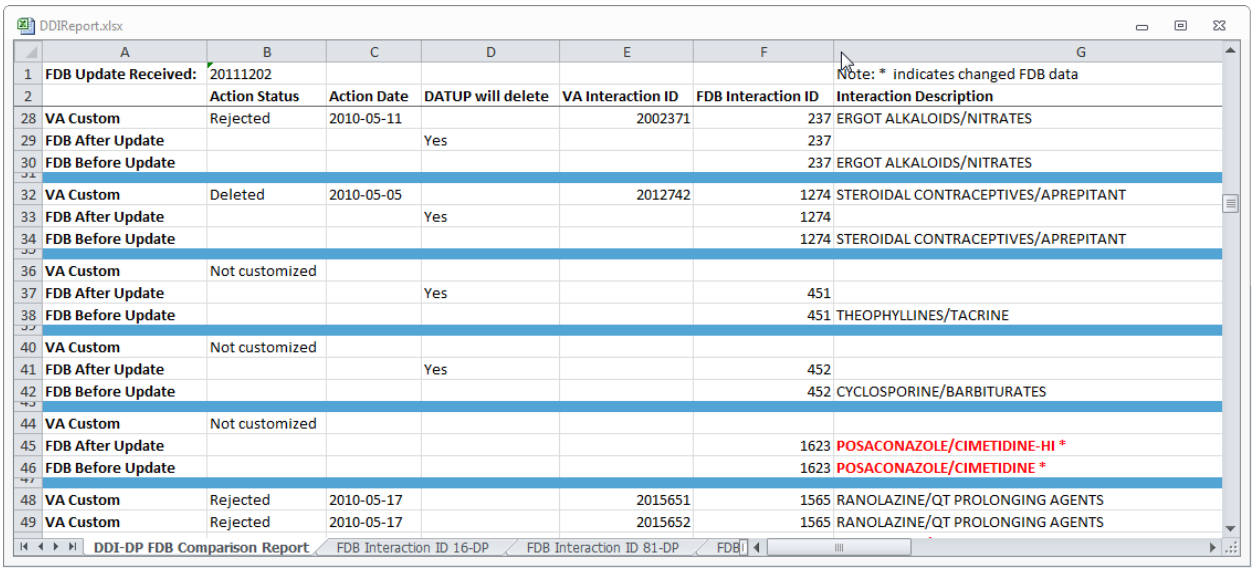


DTReport.xlsx

	A	B	C	D	E	F	G	H	I	J	K
1	**Latest FDB Update:**	20111202					Note: * indicates updated information				
2		**Action Status**	**Action Date**	**DATUP will delete**	**DTCID**	**Dup Allowance**	**Description**				
3	**NO DATA FOUND**										

DT FDB Comparison Report

Drug-Drug Interaction/Drug Pair Report



DDIReport.xlsx

	A	B	C	D	E	F	G
1	**FDB Update Received:**	20111202					Note: * indicates changed FDB data
2		**Action Status**	**Action Date**	**DATUP will delete**	**VA Interaction ID**	**FDB Interaction ID**	**Interaction Description**
28	**VA Custom**	Rejected	2010-05-11		2002371	237	ERGOT ALKALOIDS/NITRATES
29	**FDB After Update**			Yes		237	
30	**FDB Before Update**					237	ERGOT ALKALOIDS/NITRATES
32	**VA Custom**	Deleted	2010-05-05		2012742	1274	STEROIDAL CONTRACEPTIVES/APREPITANT
33	**FDB After Update**			Yes		1274	
34	**FDB Before Update**					1274	STEROIDAL CONTRACEPTIVES/APREPITANT
36	**VA Custom**	Not customized					
37	**FDB After Update**			Yes		451	
38	**FDB Before Update**					451	THEOPHYLLINES/TACRINE
40	**VA Custom**	Not customized					
41	**FDB After Update**			Yes		452	
42	**FDB Before Update**					452	CYCLOSPORINE/BARBITURATES
44	**VA Custom**	Not customized					
45	**FDB After Update**					1623	**POSACONAZOLE/CIMETIDINE-HI ***
46	**FDB Before Update**					1623	**POSACONAZOLE/CIMETIDINE ***
48	**VA Custom**	Rejected	2010-05-17		2015651	1565	RANOLAZINE/QT PROLONGING AGENTS
49	**VA Custom**	Rejected	2010-05-17		2015652	1565	RANOLAZINE/QT PROLONGING AGENTS

DDI-DP FDB Comparison Report | FDB Interaction ID 16-DP | FDB Interaction ID 81-DP | FDB

The FDB Comparison Drug-Drug Interaction/Drug Pairs Report displays the changes to existing Drug-Drug Interactions included in the Incremental FDB updates. All Action Statuses are compared and are included in the report. The following data points are compared between the FDB update and the VA Drug-Drug Interaction records:

- Corresponding FDB Interaction ID
- Interaction Description
- Monograph ID
- Severity Level Code
- Clinical Effect 1
- Clinical Effect 2

- Deleted Drug Pairs
- Added Drug Pairs

The DDI-DP FDB Comparison Report contains two types of spreadsheets:

- The DDI-DP FDB Comparison Report – gives information about the FDB comparisons and the associated VA custom records.
- FDB Interaction ID-DP – gives information about the added or deleted drug pairs for a specific FDB record. Each FDB update record that has added or deleted drug pairs has its own FDB Interaction ID-DP spreadsheet.

The following DDI-specific fields are included in the DDI-FDB Comparison Report spreadsheet:

VA Interaction ID	A VA-assigned numerical identifier for the interaction.
FDB Interaction ID	An FDB-assigned numerical identifier for the interaction.
Interaction Description	A text description of the interaction.
Monograph ID	A numerical identifier for the Professional Monograph associated with the interaction.
Severity Level	A coded severity indicator. See Severity Level Codes for additional information.
Clinical Effect 1	A three letter code describing the clinical effect. See Clinical Effect Codes for additional information.
Clinical Effect 2	A three letter code describing the clinical effect. See Clinical Effect Codes.
Drug Pairs	If a DDI has drug pairs scheduled to be added or deleted by DATUP, there will be a message, "See FDB Interaction ID <FDB Interaction ID number>-DP." If a DDI record in the incremental FDB update file does not have added or drug pairs, this column will remain blank.

Here are screen shots of a DDI Comparison Report with the “See FDB Interaction ID <> DP” message and the tab that relates to it. Notice the highlighted row:

A	B	C	D	E	F	G
FDB Update Received:	20111202					Note: * indicates changed FDB data
	Action Status	Action Date	DATUP will delete	VA Interaction ID	FDB Interaction ID	Interaction Description
VA Custom	Modified	2012-03-09		2020866	1581	DROSPIRENONE/ACE INHIBITORS; ARBS
FDB After Update					1581	DROSPIRENONE/ACE INHIBITORS; ARBS
FDB Before Update					1581	DROSPIRENONE/ACE INHIBITORS; ARBS
VA Custom	New	2012-03-09		2020864	30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)
VA Custom	New	2012-03-09		2020865	30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)
FDB After Update					30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)
FDB Before Update					30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)
VA Custom	New	2012-03-14		2020881	112	ANTIDIABETICS, ORAL/SALICYLATES
VA Custom	Modified	2012-03-15		2020882	112	ANTIDIABETICS, ORAL/SALICYLATES
FDB After Update					112	ANTIDIABETICS, ORAL/SALICYLATES-Test *
FDB Before Update					112	ANTIDIABETICS, ORAL/SALICYLATES *
VA Custom	Reviewed	2012-03-01		2020857	31809	QUINOLONES/THEOPHYLLINES
FDB After Update					31809	QUINOLONES/THEOPHYLLINES
FDB Before Update					31809	QUINOLONES/THEOPHYLLINES
VA Custom	Deleted	2012-01-23		2020502	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS
VA Custom	Rejected	2010-05-06		2002582	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS
VA Custom	Approved	2010-05-06		2002581	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS
FDB After Update					258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS
FDB Before Update					258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS
VA Custom	Delete Reviewed	2012-02-24		2020828	30120	CIPROFLOXACIN/AGOMELATINE
FDB After Update					30120	CIPROFLOXACIN/AGOMELATINE-FUN *
FDB Before Update					30120	CIPROFLOXACIN/AGOMELATINE *

DDI-DP FDB Comparison Report | FDB Interaction ID 81-DP | FDB Interaction ID 112-DP | FDB Interaction ID 1565-DP

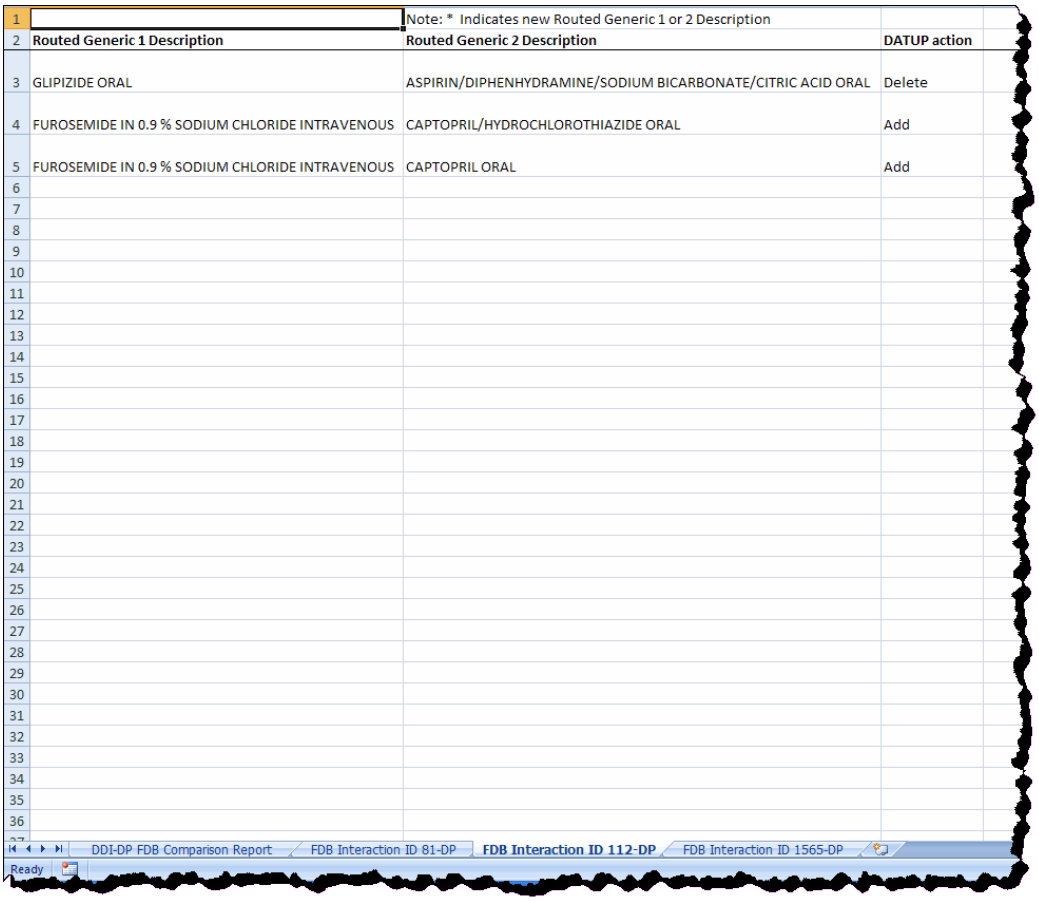
Figure 47: First Half of FDB Comparison Report for DDI

H	I	J	K	L
Monograph ID	Severity Level	Clinical Effect 1	Clinical Effect 2	Drug Pairs
Drospirenone/Ace Inhibitors; ARBs - 1581		3 Decreased effect of the former drug		
Cyclosporine/Calcium Channel Blockers - 258 *		3 Additive side effects from both drugs		
Drospirenone/Ace Inhibitors; ARBs - 1581 *		3 Additive side effects from both drugs		
Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) - 1214		3 Increased effect of the latter drug		
Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) - 1214		2 Increased effect of the latter drug		
Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) - 1214		3 Adverse reaction of the former drug *		
Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) - 1214		3 Increased effect of the latter drug *		
Antidiabetics, Oral/Salicylates - 112		3 Increased effect of the former drug		
Antidiabetics, Oral/Salicylates - 112		2 Increased effect of the former drug		
Antidiabetics, Oral/Salicylates - 112	1 *	Increased effect of the former drug		See FDB Interaction ID 112-DP
Antidiabetics, Oral/Salicylates - 112	3 *	Increased effect of the former drug		
Theophyllines/Quinolones - 191		1 Increased effect of the latter drug	Adverse reaction of the former drug	
Theophyllines/Quinolones - 191		2 Increased effect of the latter drug	Adverse reaction of the former drug *	
Theophyllines/Quinolones - 191		2 Increased effect of the latter drug	*	
Cyclosporine/Calcium Channel Blockers - 258		3 Labeling conflicts between countries or products		
Cyclosporine/Calcium Channel Blockers - 258		2 Increased effect of the former drug		
Cyclosporine/Calcium Channel Blockers - 258		1 Increased effect of the former drug		
Cyclosporine/Calcium Channel Blockers - 258	1 *	Adverse reaction of the former drug *	Additive side effects from both drugs *	
Cyclosporine/Calcium Channel Blockers - 258	3 *	Increased effect of the former drug *	*	
VA Customized: Decreased Effects (Significant) (DEL2) - 150033 (custom)		1 Increased effect of the latter drug		
Ranolazine/QT Prolonging Agents - 1565 *	2 *	Increased effect of the latter drug	Additive side effects from both drugs *	
Agomelatine/Ciprofloxacin - 1880 *	1 *	Increased effect of the latter drug	*	

DDI-DP FDB Comparison Report | FDB Interaction ID 81-DP | FDB Interaction ID 112-DP | FDB Interaction ID 1565-DP

Figure 48: Second Half of FDB Comparison Report for DDI

If the latest FDB update contains added or deleted drug pairs, these will be displayed on separate tabs titled "FDB Interaction ID <FDB Interaction ID number>-DP". Here are the contents of the FDB Interaction ID tab, i.e., the drug pairs that have been updated by FDB:

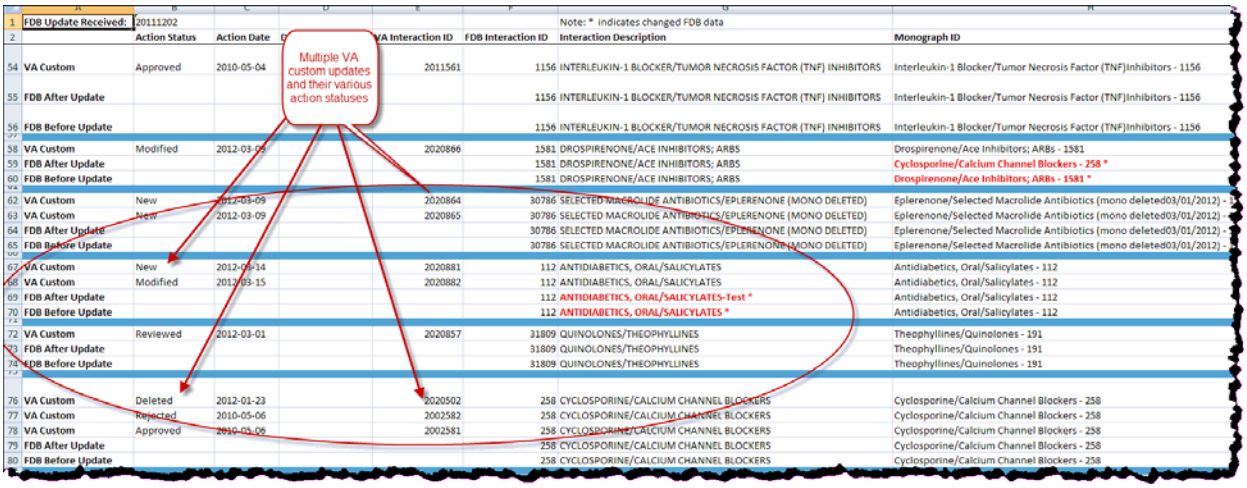


		Note: * Indicates new Routed Generic 1 or 2 Description	
2	**Routed Generic 1 Description**	**Routed Generic 2 Description**	**DATUP action**
3	GLIPIZIDE ORAL	ASPIRIN/DIPHENHYDRAMINE/SODIUM BICARBONATE/CITRIC ACID ORAL	Delete
4	FUROSEMIDE IN 0.9 % SODIUM CHLORIDE INTRAVENOUS	CAPTOPRIL/HYDROCHLOROTHIAZIDE ORAL	Add
5	FUROSEMIDE IN 0.9 % SODIUM CHLORIDE INTRAVENOUS	CAPTOPRIL ORAL	Add

DDI-DP FDB Comparison Report | FDB Interaction ID 81-DP | **FDB Interaction ID 112-DP** | FDB Interaction ID 1565-DP

Ready

If an FDB record has been customized multiple times, all of the customizations will be listed in the report, as shown below:



	FDB Update Received:	20111202					Note: * indicates changed FDB data	
2		**Action Status**	**Action Date**		**VA Interaction ID**	**FDB Interaction ID**	**Interaction Description**	**Monograph ID**
54	**VA Custom**	Approved	2010-05-04		2011561	1156	INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS	Interleukin-1 Blocker/Tumor Necrosis Factor (TNF)Inhibitors - 1156
55	**FDB After Update**					1156	INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS	Interleukin-1 Blocker/Tumor Necrosis Factor (TNF)Inhibitors - 1156
56	**FDB Before Update**					1156	INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS	Interleukin-1 Blocker/Tumor Necrosis Factor (TNF)Inhibitors - 1156
58	**VA Custom**	Modified	2012-03-09		2020866	1581	DROSPIRENONE/ACE INHIBITORS; ARBS	Drospirenone/Ace Inhibitors; ARBs - 1581
59	**FDB After Update**					1581	DROSPIRENONE/ACE INHIBITORS; ARBS	**Cyclosporine/Calcium Channel Blockers - 258 ***
60	**FDB Before Update**					1581	DROSPIRENONE/ACE INHIBITORS; ARBS	**Drospirenone/Ace Inhibitors; ARBs - 1581 ***
62	**VA Custom**	New	2012-03-09		2020864	30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)	Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) -
63	**VA Custom**	New	2012-03-09		2020865	30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)	Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) -
64	**FDB After Update**					30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)	Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) -
65	**FDB Before Update**					30786	SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED)	Eplerenone/Selected Macrolide Antibiotics (mono deleted03/01/2012) -
67	**VA Custom**	New	2012-03-14		2020881	112	ANTIDIABETICS, ORAL/SALICYLATES	Antidiabetics, Oral/Salicylates - 112
68	**VA Custom**	Modified	2012-03-15		2020882	112	ANTIDIABETICS, ORAL/SALICYLATES	Antidiabetics, Oral/Salicylates - 112
69	**FDB After Update**					112	**ANTIDIABETICS, ORAL/SALICYLATES-Test ***	Antidiabetics, Oral/Salicylates - 112
70	**FDB Before Update**					112	**ANTIDIABETICS, ORAL/SALICYLATES ***	Antidiabetics, Oral/Salicylates - 112
72	**VA Custom**	Reviewed	2012-03-01		2020857	31809	QUINOLONES/THEOPHYLLINES	Theophyllines/Quinolones - 191
73	**FDB After Update**					31809	QUINOLONES/THEOPHYLLINES	Theophyllines/Quinolones - 191
74	**FDB Before Update**					31809	QUINOLONES/THEOPHYLLINES	Theophyllines/Quinolones - 191
76	**VA Custom**	Deleted	2012-01-23		2020502	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS	Cyclosporine/Calcium Channel Blockers - 258
77	**VA Custom**	Rejected	2010-05-06		2002582	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS	Cyclosporine/Calcium Channel Blockers - 258
78	**VA Custom**	Approved	2010-05-06		2002581	258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS	Cyclosporine/Calcium Channel Blockers - 258
79	**FDB After Update**					258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS	Cyclosporine/Calcium Channel Blockers - 258
80	**FDB Before Update**					258	CYCLOSPORINE/CALCIUM CHANNEL BLOCKERS	Cyclosporine/Calcium Channel Blockers - 258

The following fields are included in the FDB Interaction ID-DP spreadsheet:

Routed Generic 1 Description	The Routed Generic Description of Drug 1 in the Drug Pair
Routed Generic 2 Description	The Routed Generic Description of Drug 2 in the Drug Pair
DATUP action	The action that DATUP will perform. DATUP will either add the drug pair to the PECS database or delete it from PECS.

Note: A DDI record that is not listed on the DDI-DT FDB Comparison Report spreadsheet can still have added or deleted drug pairs listed in the latest incremental FDB update file. In that case, the drug pair information is just listed on an FDB Interaction ID-DP spreadsheet.

Duplicate Therapy Report

	A	B	C	D	E	F	G
1	FDB Update Received:	20120525					Note: * indicates changed FDB data
2		Action Status	Action Date	DATUP will delete	DTCID	Dup Allowance	Description
3	VA Custom	Approved	2012-05-07		1338	1	Antidiarrheal Formulations with Gut Flora Microorganisms
4	FDB After Update			Yes	1338		
5	FDB Before Update				1338	0	Antidiarrheal Formulations with Gut Flora Microorganisms
7	VA Custom	Approved	2012-04-16		376	1	Stimulant Laxatives
8	FDB After Update			Yes	376		
9	FDB Before Update				376	0	Stimulant Laxatives
11	VA Custom	Reviewed	2012-02-23		375	0	Steroids - Mouth
12	FDB After Update			Yes	375		
13	FDB Before Update				375	0	Steroids - Mouth
15	VA Custom	Modified	2012-02-23		378	1	Sulfonamides
16	FDB After Update			Yes	378		
17	FDB Before Update				378	0	Sulfonamides
19	VA Custom	Reviewed	2012-04-13		1132	0	Thrombin Inhibitors (Non-Heparinoid)
20	FDB After Update			Yes	1132		
21	FDB Before Update				1132	0	Thrombin Inhibitors (Non-Heparinoid)
23	VA Custom	Modified	2012-02-23		1213	1	Dantrolene
24	FDB After Update			Yes	1213		
25	FDB Before Update				1213	0	Dantrolene
27	VA Custom	Modified	2012-04-09		1456	1	Orotic Acid
28	FDB After Update			Yes	1456		
29	FDB Before Update				1456	0	Orotic Acid
31	VA Custom	Reviewed	2012-02-23		1310	1	Lymphocyte Immune Globulin
32	FDB After Update			Yes	1310		
33	FDB Before Update				1310	0	Lymphocyte Immune Globulin
35	VA Custom	Modified	2012-02-23		1319	2	Typhoid Vaccine
36	FDB After Update			Yes	1319		
37	FDB Before Update				1319	0	Typhoid Vaccine
39	VA Custom	Not customized					
40	FDB After Update			Yes	1564		
41	FDB Before Update				1564	0	Malic Acid
43	VA Custom	New	2012-02-21		1131	0	Nasal Antihistamines
44	FDB After Update			Yes	1131		
45	FDB Before Update				1131	0	Nasal Antihistamines

DT FDB Comparison Report

Ready

Figure 49: FDB Comparison Report - Duplicate Therapy

The Duplicate Therapy FDB Comparison Report displays the differences between the PECS FDB data and the data in the Incremental FDB Update file for the Duplicate Therapy (DT) concept. This report displays the following DT-specific data:

DTCID	Duplicate Therapy Control ID. A numerical identifier for the DT FDB and VA records.
Dup Allowance	Duplicate Allowance. The number of drugs performing the same function before a warning is issued.
Description	A description (name) of the drug that is the basis of the DT record.

Dose Range Report

Not implemented in this release.

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