Pharmacy Enterprise Customization System (PECS) User Guide



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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.

<u>Approver</u>: 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.

<u>Release Manager</u>: 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.

<u>Administrator</u>: Can run queries and view detail records. In addition, Administrators can modify field settings for each concept type and add or delete users to/from the approver role.

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.

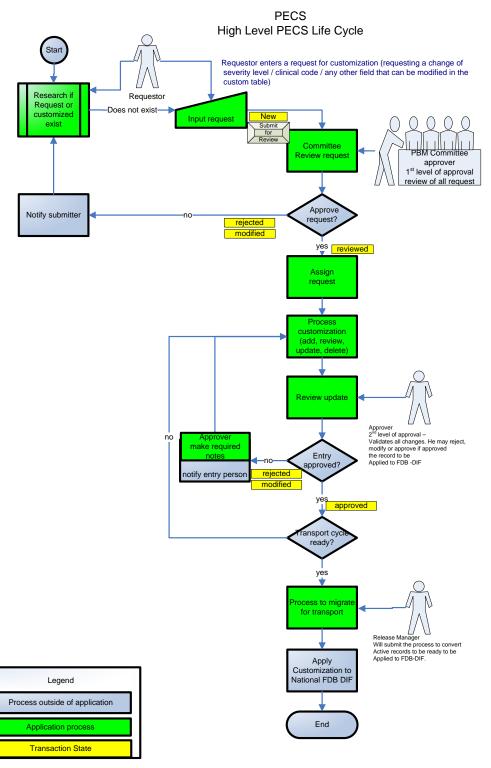


Figure 1: PECS Customization Life Cycle

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.

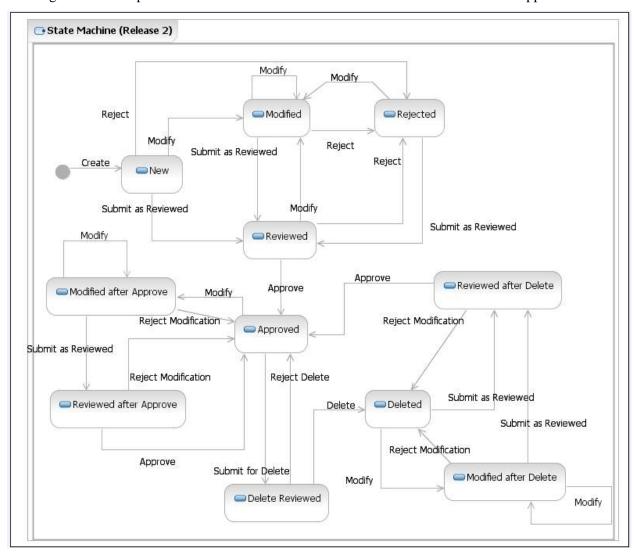


Figure 2: Action Statuses

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.

<u>New</u> - 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).

<u>Modified</u> - 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.

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

<u>Modified After Delete</u> - (*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.

<u>Reviewed</u> - 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.

<u>Reviewed After Approve</u> - (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.

<u>Reviewed After Delete</u> (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.

<u>Rejected</u> - 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.

<u>Approved</u> – 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.

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

<u>Deleted</u> – 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.

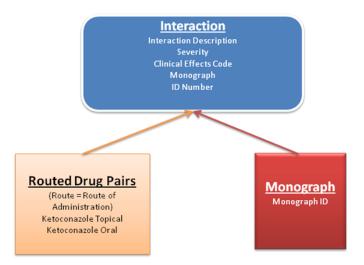
Customization Information

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

Drug-Drug Interaction

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

Drug-Drug Interaction Relationship



Drug interaction now between routed generics within an interaction description that is also associated with a monograph.

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.
- **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

Accessing the PECS Application

The PECS application is located at

https://vapreapp1.aac.va.gov:8443/ct/public/welcome.html

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 <u>Identity Management</u> 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:

System Announcements:				
U.S. Government Computer System				
U. S. government systems are intended to be used by authorized government network users for viewing and retrieving information only, except as otherwise explicitly authorized for official business and limited personal use in accordance with policy. Information from these systems resides on and transmits through computer systems and networks funded by the government. All access or use constitutes understanding and acceptance that there is no reasonable expectation of privacy in the use of Government networks or systems.				
The data and documents on this system include Federal records that contain sensitive information protected by various Federal statutes, including the Privacy Act, 5 U.S.C. Section 552a, and veterans' records confidentiality statutes such as 38 U.S.C. Sections 5701 and 7332. Access to the data and records is on a need-to-know basis only.				
All access or use of this system constitutes user understanding and acceptance of these terms and constitutes unconditional consent to review and action including (but not limited to) monitoring, recording, copying, auditing, inspecting, investigating, restricting access, blocking, tracking, disclosing to authorized personnel, or any other authorized actions by all authorized government and law enforcement personnel.				
<u>♥</u>				
Login: KAAJEE Sample				
Access Code: Verify Code:				
Institution: SAN FRANCISCO VAMC (662) ★				
Login				
* Persistent Cookie Used (more information).				

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 (Professional Monograph, Dose Range, Drug-Drug Interaction, and Duplicate Therapy). The "Unassigned Requests" panel contain 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:

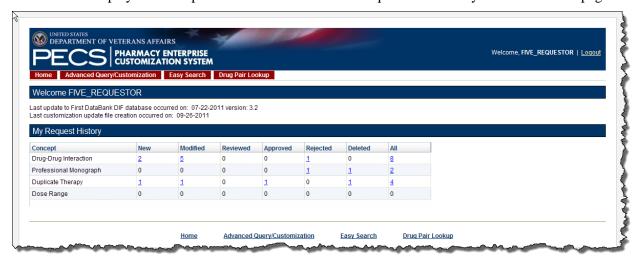


Figure 6: Home Page for Requestor

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.

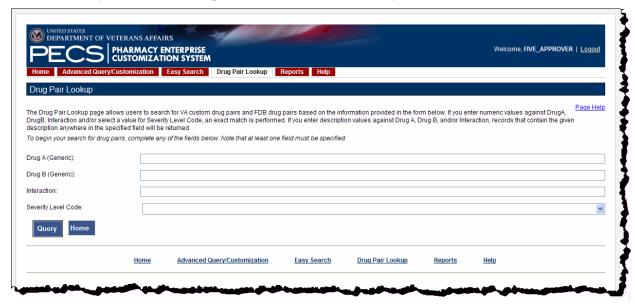


Figure 7: Drug-Drug Pair Query Window



Figure 8: Sample Data

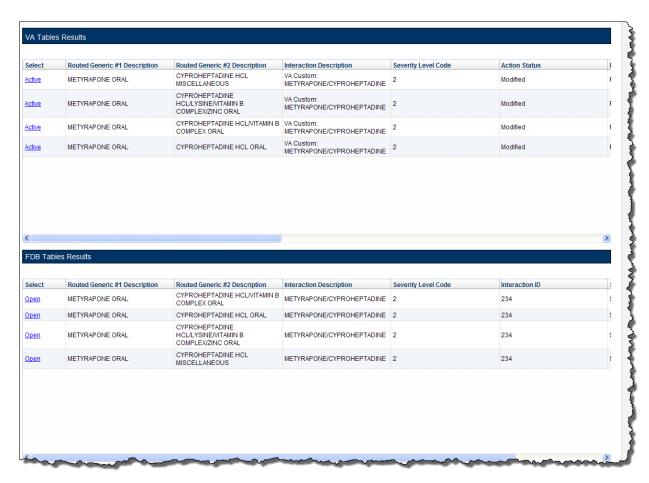


Figure 9: Drug Pair Query Result

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

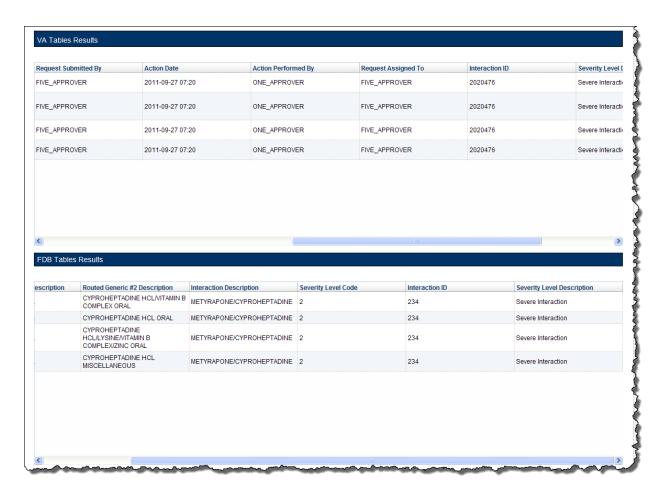


Figure 10: VA & FDB Tables, continued

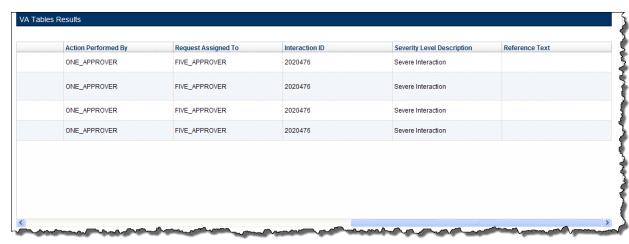


Figure 11: VA Table, continued

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

If you have the proper authority, you can access the Customization Page by clicking the Advanced Query/Customization tab. This tab is a starting point from which to research or customize the First DataBank records.

Query

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.

You can enter this page in one of two ways.

- 1. Select an entry from the home page
- 2. Select the Advanced Query/Customization tab and then select a concept type from the list.

You may create a new query search or select one created from the "Other User's Queries" tab, if you have the authority.

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.

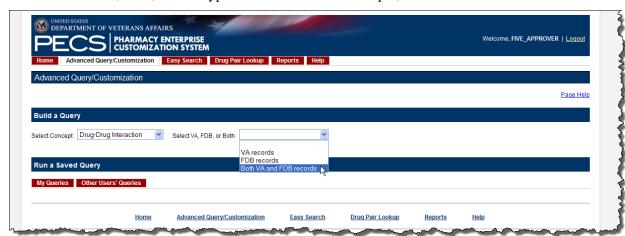
To create a customization or begin a query:

1. Select the concept for which you want to run the query. Choose from the drop-down box to begin. In our example, we choose Drug-Drug Interaction:

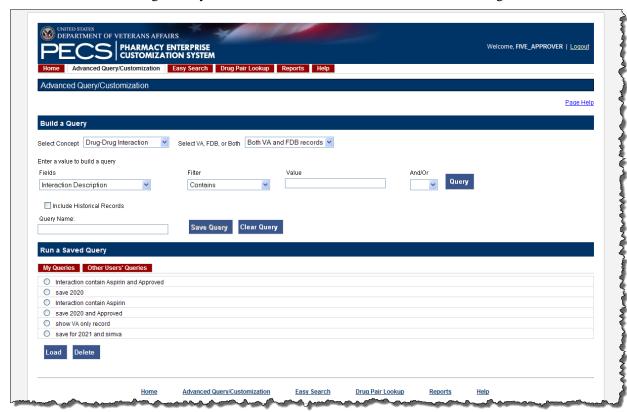


Figure 14: Advanced Query/Customization Page

2. Select VA, FDB, or both types of records. In this example, we select Both.



3. The screen changes and you can now enter the filter criteria in the following four fields:



- Columns field ("Fields"): A drop down list of available record fields you may select.
- Constraint field ("Filter"): A drop down list of available constraint conditions.
- Value field ("Value"): The value which is to be retrieved by the Query.
- Historical Record checkbox ("Include Historic Records"): This checkbox allows you the option to include or not include the Historical versions of the records that meet the query criteria. The default is that the field is left unchecked and the query will not include historic records.
- 4. After you have selected or entered items in the Query Builder fields, click the And/Or drop-down to select more criteria if desired to build the Query statement. If you want only one set of criteria,

- check the "Include Historic Records" checkbox if desired, then click the Query button to execute the Query.
- 5. To build a complex Query (one which contains several "Fields" and their corresponding desired criteria) after you have selected or entered values in the Query Builder, select "And" or "Or" from the And/Or drop-down to start building the Query statement as desired. Fill out the Query Builder set of fields again and continue to select "And" or "Or" from the And/Or drop-down to add as many conditions as desired. When you are ready to execute the Query, check the "Include Historic Records checkbox" if desired, and finally, click the "Query" button.

Here is an example of a complex query:

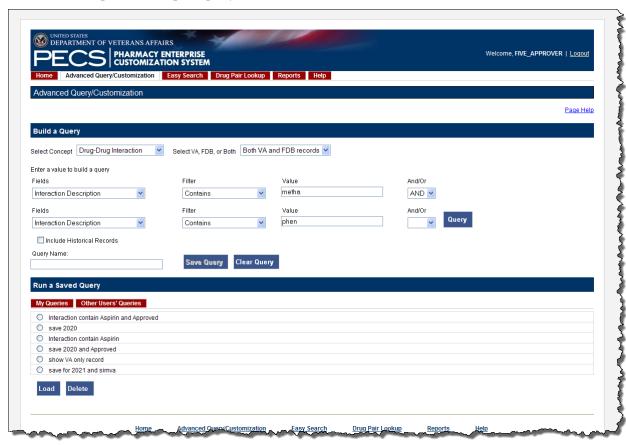


Figure 15: Initial Window for a Complex Query

Results on next page:

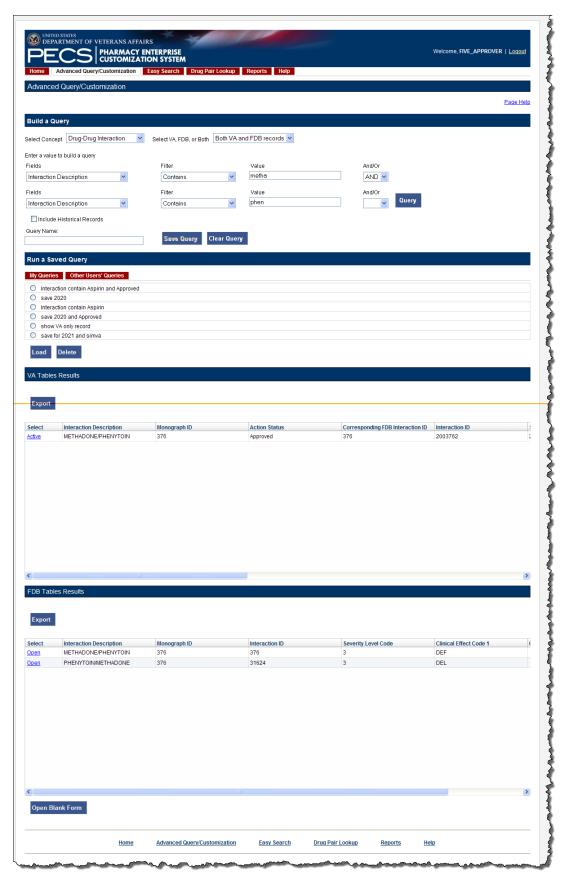


Figure 12: Query Panel with Complex Query Results

The Query Results panel provides data results in a table format.

The column headers, such as "Interaction Description," "Monograph ID," etc., allow you to sort in either a descending or ascending order by clicking the column heading name. An arrow direction in the column heading is displayed to show the order in which the data has been sorted.

When Historical Records *are not* selected to be included in the Query results, only the Active versions of each record are returned. Clicking the "Active" or "Open" link under the "Select" column opens the record to the data customization page, where you may make changes if desired.

Use the Export button to export the data in the Excel spreadsheet format.

When Historical Records *are* selected to be included in the Query results, both the Active *and* the Historical versions of each record are returned. Clicking on the "Active" link under the "Select" column opens the record to the data customization page, where you may make changes if desired. Clicking on the "Historical" link under the "Select" column opens the record and displays its details in read-only mode. No changes can be made to historical versions of records.

Only one record can be opened at a time.

Saving A Query

If you want to save a query that you have built, you may do so after you've displayed the desired results. Give the query a name, and press the Save Query button.

This list that displays under the Saved Queries area defaults to queries you have saved. You may also view and run other users' queries by clicking the "Other Users' Queries" tab, but you cannot modify them.

You can update a query you've saved if you give it the same name after you change the criteria.

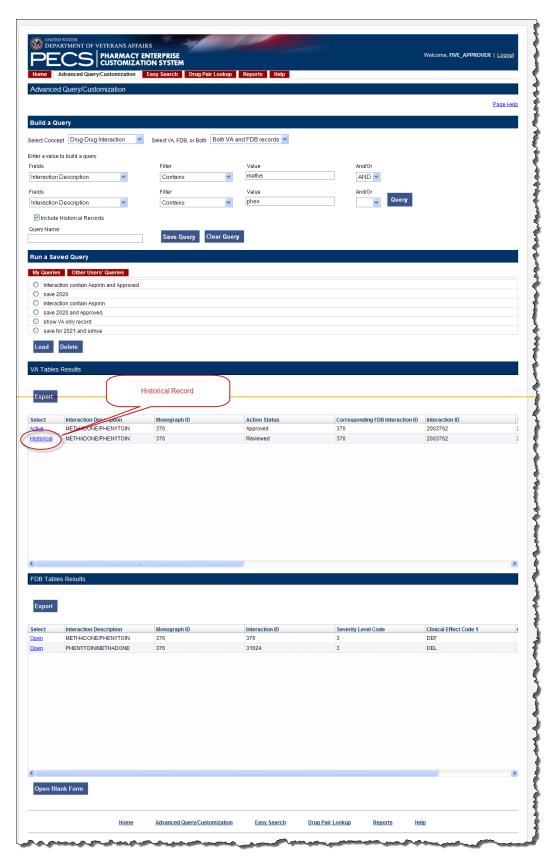


Figure 16: Query Results Showing Historical Records and Active Records

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:

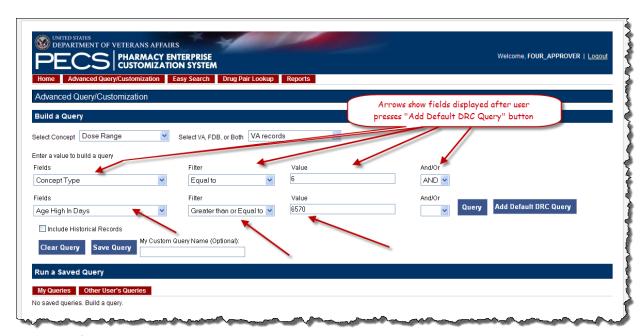


Figure 17: Default Dose Range Query Window



Figure 18: 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 that you can modify:

Note that shaded fields on the detail pages for each concept cannot be modified.

Dose Range



Figure 19: Dose Range Panel

Professional Monograph

During customization, you can edit the professional monograph that is displayed. Below is an example.

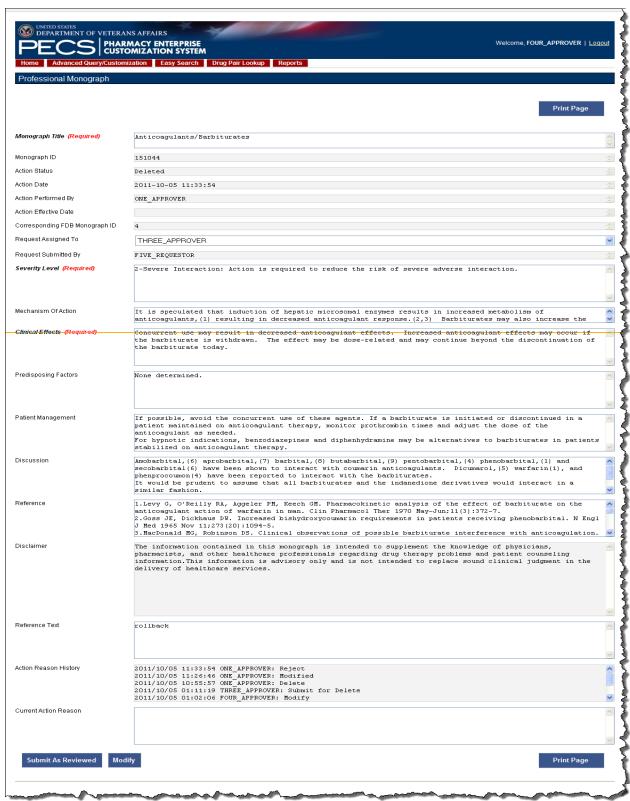


Figure 20: Professional Monograph Panel

Duplicate Therapy

You may also edit the Duplicate Therapy panel, again if you have the authority.

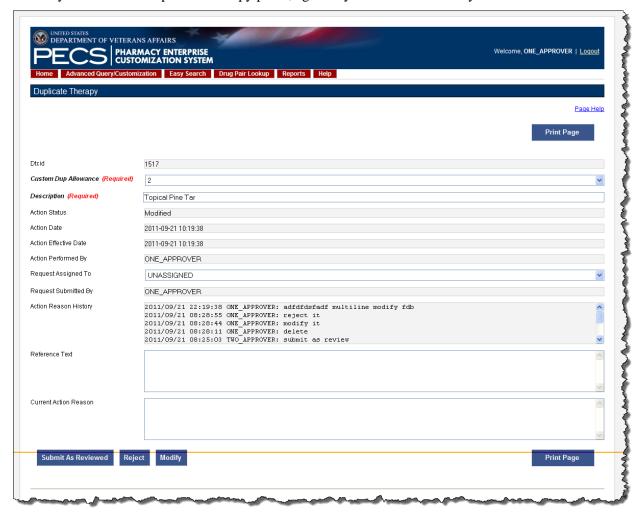


Figure 21: Duplicate Therapy Panel

Drug-Drug Interaction



Figure 22: Drug-Drug Interaction Panel

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 23: 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:

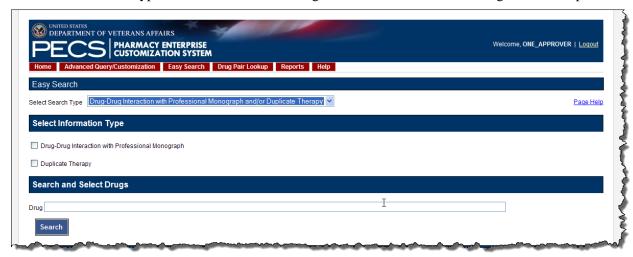
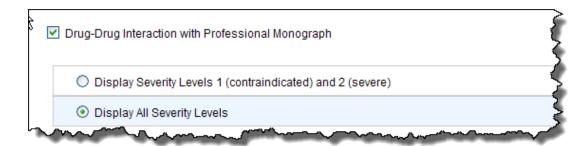


Figure 24: Select Drug-Drug Interaction with Professional Monograph and Duplicate Thearpy

- 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.

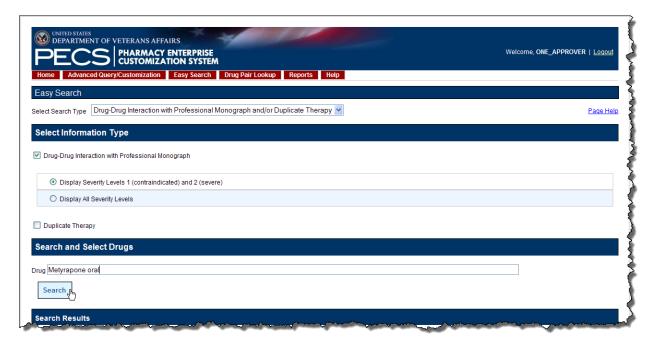


Figure 25: Severity Levels 1 and 2 Selected, and Drug Name to Search

- 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 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:

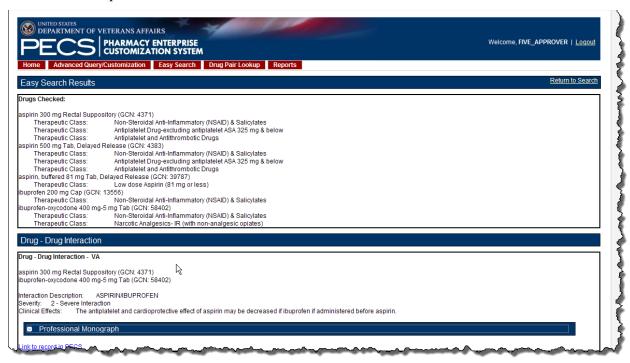


Figure 26: Partial Easy Search Results - Drug-Drug Interaction

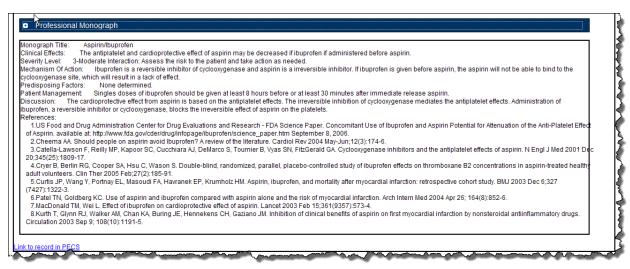


Figure 27: Partial Easy Search Results: Professional Monograph

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 28: 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 19: Dose Range Panel, Figure 20: Professional Monograph Panel, and Figure 21: 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 that is 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:

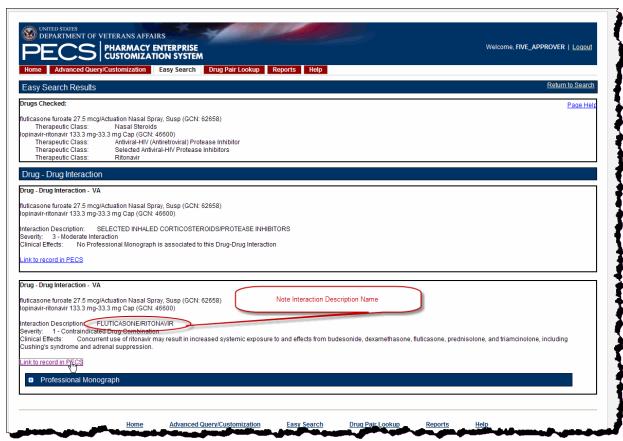


Figure 29: Easy Search DDI Record

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 30: Referenced PECS Record with Name Discrepancy

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

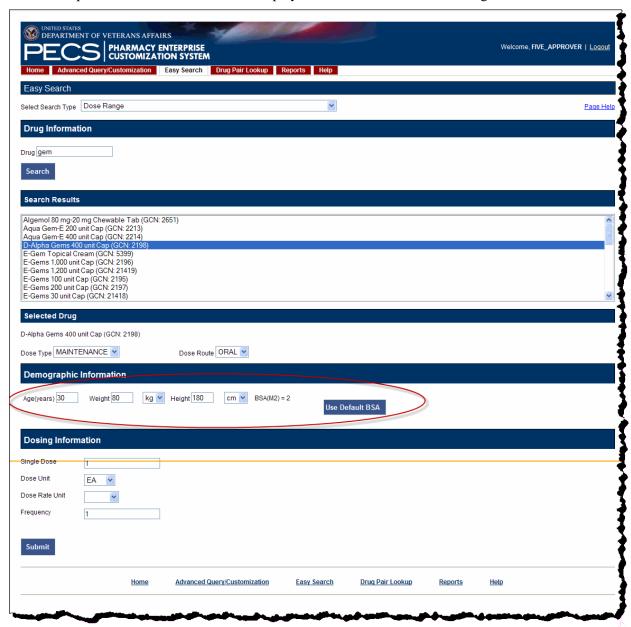
Easy Search Dose Range

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 allow the user 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 for which to run the Easy Search query by clicking the drug to select it and it becomes 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. (Try to 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 the Dose Type and Dose Route dropdowns are populated.

6. The default patient demographic information displays, which is the default Body Surface Area (BSA) data and BSA display. You can update the fields to match the patient specifics, and the BSA is automatically recalculated. If you click the Use Default BSA button after you have entered unique data, the default BSA data displays and the BSA is recalculated again.



- 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.

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.

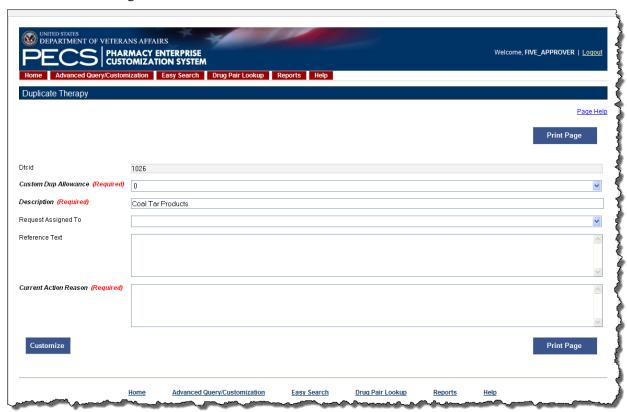
Duplicate Therapy Modification

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.

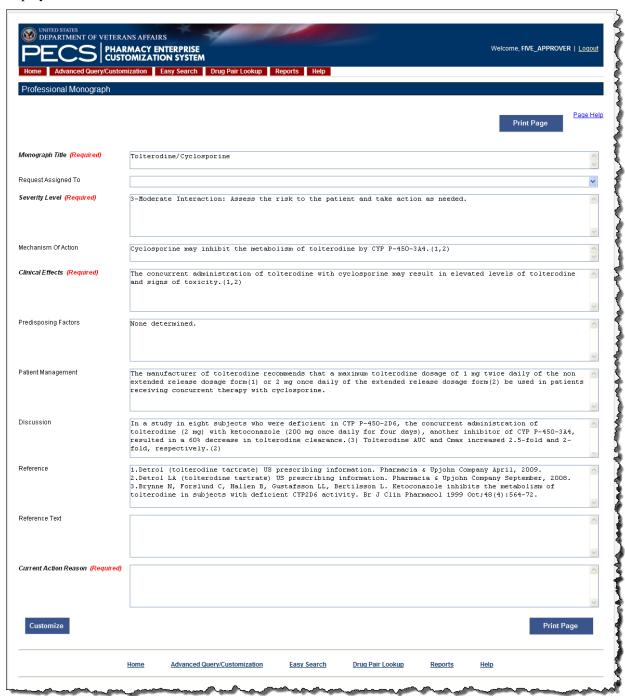
Create Professional Monograph

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.

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