Pharmacy Enterprise Customization System (PECS) User Guide



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Date	Revised Pages	Patch Number	Description of Change
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	123, 141, 169		Removed unnecessary link
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	63		Added quotation marks to "Display in Query" for clarity.
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	68		Changed "an" to "a"
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05/30/2014	All	PREC*3.0*1	Reviewed and fixed typos from search and replace Marella Colyvas
05/27/2014	i-vi; all	PREC*3.0*1	Changed format of Revision History pages; changed FDB-DIF to FDB MedKnowledge Framework Marella Colyvas
05/08/2014	All	PREC*3.0*1	Made additional changes per CPS Marella Colyvas
05/07/2014	All	PREC*3.0*1	Made changes per CPS: graphics caption formatting, added links, created new heading for cross-reference purposes (Drug Pair Customization; changed "Records You Can Modify" to Modifying Records.") Marella Colyvas
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06/26/2012	Title Page	PREC*2.2*1	Updated title page to reflect the update month Marella Colyvas
06/13/2012	All	PREC*2.2*1	Updated to address Sonia T, Joanne C comments. B Holihan
06/12/2012	All	PREC*2.2*1	Updated to address Radu C comments of 06/11/12 B Holihan
05/31/2012	101-108	PREC*2.2*1	Entered nearly all of Joanne's comments re: FDB Comparison Reports. Marella Colyvas
05/23/2012	All	PREC*2.2*1	Updated TOC; changed some heading levels; replaced screen shots for Requestor & Approver home pages; adjusted pagination and section breaks Marella Colyvas
05/09/2012	61-62	PREC*2.2*1	Updated Quick Drug Pair selection. B Holihan
05/08/2012	84-85	PREC*2.2*1	Added screen capture to Null Drug Pair section; Reduced size of Custom Update samples Marella Colyvas
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05/04/2012	84-85	PREC*2.2*1	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	39	PREC*2.2*1	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	2, 62	PREC*2.2*1	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
4/27/2012	61-62; 75	PREC*2.2*1	Added PBM feedback to Release Manager write-up; added short write-up on Quick Drug Pair Selection Marella Colyvas
4/12/2012	39; 75	PREC*2.2*1	More changes to Drug Pair Notification; added Release Manager write-up Marella Colyvas
4/11/2012	39	PREC*2.2*1	More changes to Drug Pair Notification Marella Colyvas

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4/9/2012	39	PREC*2.2*1	Renamed the Title of the Drug Pair Notification Section (was "Working with Drug Pairs") Marella Colyvas
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3/23/2012	39	PREC*2.2*1	Drafted Drug Pair Notification Marella Colyvas
3/15/2012	50-53	PREC*2.2*1	Cleaned up Record Locking; made edits from Sonia on Creating Multiple Custom DDIs to One FDB Record and Prevention of Duplicate DP on Single Record
			Marella Colyvas
3/13/2012	51	PREC*2.2*1	Added information on Creating Multiple Custom DDIs to One FDB Record and Prevention of Duplicate DP on Single Record Marella Colyvas
03/12/2012	63; All	PREC*2.2*1	Added data on Forward/Reverse Monographs and Multiple DDIs to one FDB; included Lynn Teague's changes Marella Colyvas
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02/16/2012	44	PREC*2.2*1	Made a few additions to Record Locking Marella Colyvas
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1/26/2012	All	PREC*2.2*1	Created text for Not Editing Single Drug Pair window; added some screen shots; still have to add Sonia's changes. Marella Colyvas
1/23/2012	All	PREC*2.2*1	Beginning of changes for PECS 2.2. Added new Read-Only screens for each concept; eliminated edit mode screen shots for now; Marella Colyvas
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10/7/11	All	PREC*2.2*1	Reviewed and provided feedback / comments Hussain Kedwaii
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Date	Revised Pages	Patch Number	Description of Change
10/12/2010 CR 3391	All	N/A (First Release)	Updated elements found in Enterprise Infrastructure Engineering (EIE) review for Operational Readiness Testing (ORT) Marella Colyvas
4/14/2010	All	N/A (First Release)	Baseline Russell Chachula and Marella Colyvas

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(This page included for two-sided copying.)

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1 Introduction

The Pharmacy Enterprise Customization System (PECS) is a Graphical User Interface (GUI) application that currently allows the VA's Pharmacy Benefits Management (PBM) pharmacists and Automated Data Processing Application Coordinators (ADPACs) to customize the contents of the following five business concepts:

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

1.1 Purpose

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.

1.2 Overview

When a VA provider orders a drug for a patient (either through CPRS or VistA), the Medication Order Check Healthcare Application (MOCHA) performs order checks on that drug, and alerts the provider if the drug they are ordering has any of the following anomalies:

- Causes an interaction with other drugs the patient is taking
- Is in the same Therapeutic Class as other drugs the patient is taking
- Is prescribed in a dose that is incompatible with patient factors such as age, weight and Body Surface Area

The drug information used as a basis for these order checks comes from a Commercial Off the Shelf (COTS) product provided by First Databank (FDB) called the Drug Information Framework (FDB-DIF).

Sometimes, the information provided by FDB is not optimal for the VA Providers or the Veteran community they serve. The primary purpose of the Pharmacy Enterprise Customization System (PECS) is to give Pharmacy Benefits Management (PBM) the ability to customize the drug information provided by FDB so the order checks and resulting alerts are based on drug information tailored specifically for the VA.

The major users of PECS are Pharmacy Benefits Management (PBM) personnel and the Automated Data Processing Application Coordinators (ADPACs) who will research and request the customization of FDB data. Once approved by the National Drug File (NDF) committee members, the changes made will affect all of the VA sites throughout the country to where the data is sent and used in the enhanced order check. The order check is used by VA physicians and pharmacists to see if any serious drug conflicts occur with the patients' existing medication. It will also check for duplication of therapy of other prescribed drugs also taken by the VA patient.

The advantages to the VA for using PECS are as follows:

- 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.

1.3 Project References

This User Guide relies on the following documents, which can be found here:

http://vaww.oed.portal.va.gov/projects/pre/PRE_IPT_Rev/PRE_IPT_Rev_PECS/Lists/PECS% 20v50% 20 Review/AllItems.aspx

Note: Due to policy constraints, active links cannot be included in this document. Please copy and paste the URLs into your browser.

- PECS Requirements Specification Document (RSD)
- Pharmacy Reengineering (PRE) Configuration Management Plan (CMP)
- PECS Database Design Document
- PEPS Style Guide
- PECS Project Architecture Document
- PECS Interface Control Document
- PECS Product Operational Manual (POM)

1.3.1 Project Contacts

Note: Due to policy constraints, this document cannot support live links. Please copy and paste the links into your browser.

Project contacts for PD PRE PECS project are as follows:

- OIT PD Program Manager
- OIT PD Project Manager PECS
- Business Sponsor/Stakeholder
- Business Subject Matter Expert (SME)/Lead Clinical Analyst

The current names of those serving these roles can be found in the organization chart for PD PRE: Be sure to look at the tab for PECS:

http://vaww.oed.portal.va.gov/projects/pre/OverArching%20Documents/PRE_Organization_Chart_all%20tabs.pdf

These people can be contacted through the Global Address List (GAL).

1.3.2 Coordination

Any coordination activities that must occur will take place between the PBM group and their ADPACs. If something has to be escalated, the ADPACs will have specific procedures for each site.

1.3.3 Help Desk

Each site needs to use the help desk escalation that they normally use. Since each site is different, the only instructions for users are to go their ADPACs and to report issues.

See the Contact Us tab in the PECS Application for guidance.

1.4 Acronyms and Abbreviations

Here is a table of Acronyms and Abbreviations used in this document.

Term	Definition	
ADPAC	Automated Data Processing Application Coordinator	
AITC	Austin Information Technology Center	
API	Application Program Interface	
COTS	Commercial Off-the-Shelf	
DATUP	Application that implements the FDB-DIF update business logic using the FDB Updater APIs to process the update file	
FDB	First Databank	
FDB-DIF	First Databank Drug Information Framework database	
FTP	File Transfer Protocol	
GUI	Graphical User Interface	
J2EE	Java 2 Enterprise Edition	
KAAJEE	Kernel Authentication and Authorization for J2EE	
NDF	National Drug File	
PBM	Pharmacy Benefits Management	
PECS	Pharmacy Enterprise Customization System	
PEPS	Pharmacy Enterprise Product System	
PRE	Pharmacy Reengineering	
RSD	Requirements Specification Document	
URL	Uniform Resource Locator	
VA	Department of Veterans Affairs	

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2 System Summary

The Pharmacy Enterprise Customization System (PECS) was born out of the need to support enhanced order checks. A decision was made to replace the home-grown order checking process, implemented in M, with a COTS product. However, the VA desired to be able to customize the drug information (such as drug interaction severity, monographs etc.) existing in FDB. PECS will satisfy this need, while adhering to stringent requirements intended to ensure patient safety.

The PECS application has been designed to allow for the following functionality:

- Allow for customization of FDB data used in the enhanced order checking by National Drug File (NDF) Managers
- Provide access to GUI customization application by facility users to request custom changes
- Provide role based system accessibility
- Provide a report to list all customizations created to date compared against corresponding FDB standard reference data
- Provide a process to allow drug interaction information in VistA to be transferred to the custom tables
- Provide a process via FTP to update from a national database to all local/regional instances of FDB standard and custom tables

As a GUI, PECS has been developed to allow for easy customization of FDB standard reference tables such as Duplicate Therapy, Dose Range, Drug-Drug Interaction, and Drug-Drug Interaction Professional Monograph, which are used in the enhanced order checking by the MOCHA system.

In more detail, PECS does the following:

- Allows users to customize the FDB standard reference tables used in the enhanced order checking
 that will be used by the Pharmacy Benefits Management (PBM) group, the Automated Data
 Processing Application Coordinators (ADPACs), and National Drug File (NDF) managers or
 designees to enter and update the custom table values.
- Allows users to do the following customizations:
 - o A custom drug-drug interaction, and any important attributes for that interaction.
 - o Drug pairs associated with a custom drug-drug interaction.
 - A custom Professional Monograph for a drug-drug interaction, including any important attributes.
 - o A custom duplication allowance value for a duplicate therapy class.
 - o Custom values for attributes associated with a custom dose range check table.
- Provides a Searching capability for a user to see Drug-Drug Interaction, Duplicate Therapy, or Professional Monograph information separately or together, for chosen drugs.
- Provides the following reports:
 - o History of custom changes for each of the five concepts.
 - Exportable FDB or Custom Data Individual query data can be exported from the five FDB-DIF or Custom tables. The available format is Excel.
 - o FDB Comparison Reports to compare incoming updated FDB data against VA customized data to help determine if the VA customized data needs to be modified.
- Provides a process via File Transfer Protocol (FTP) to transfer Custom data from a National server to all local/regional instances servers.
- Leverages the existing FDB data loader utility at each site that is used to update the FDB-DIF databases.

Custom table content distribution involves using an automated utility, Data Update (DATUP). The distribution method supports the following data content scenarios:

Only FDB standard reference table data

- FDB standard reference table data and Custom table data
- Only Custom table data

Custom table content distribution supports both periodic and as-needed releases.

2.1 System Configuration

PECS is installed in two environments: Pre-Production, and Production environment at the Austin Information Technology Center (AITC), Austin, TX. The new PECS build, database changes (updates), security patches, etc., are first applied to PECS Pre-Production and then on successful deployment promoted to PECS Production.

2.1.1 Deployment Design – PECS

<u>Figure 1: Logical Deployment Design for the PRE PECS Application</u> shows the overview of the logical deployment design for the PRE PECS Application.

Application Server

The WebLogic Application Server 10.3 will host PRE PECS and its business services.

Data Base Server

The Database Server- Oracle 11g will have Red Hat Linux Enterprise version RHEL5 as it OS. It will host the Custom Table Staging database and FDB-DIF database.

Failover Server

There will be a Failover server. It will host both the BEA WebLogic Application Server and Oracle Database Server to provide redundancy.

Legacy Interface

There will be an existing VistA server which will host legacy KAAJEE and VistALink interface.

PRE PECS National

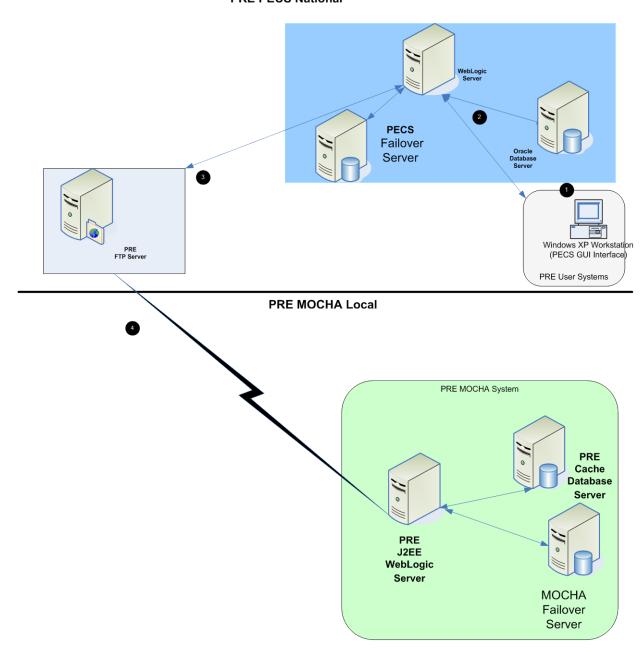


Figure 1: Logical Deployment Design for the PRE PECS Application

2.1.2 Hardware/Software Components

The Hardware/Software components and deployment architecture of the Pre-Production and Production environments are the same. The PECS Application and database are kept in synchronization for both.

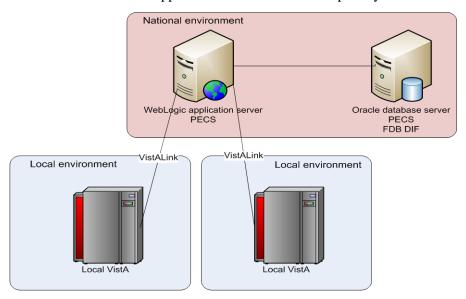


Figure 2: PECS High Level Deployment Design

2.1.3 Production Environment

The figure below shows the Production environment that will be supported, and the local networks to which they will be attached for Local VAMCs, where PECS users are located.

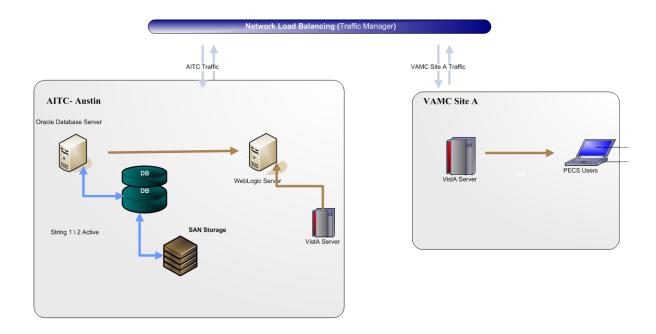


Figure 3: Production Environment for PECS

2.2 Data Flows

See the following two sections that talk about data flows.

2.2.1 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.

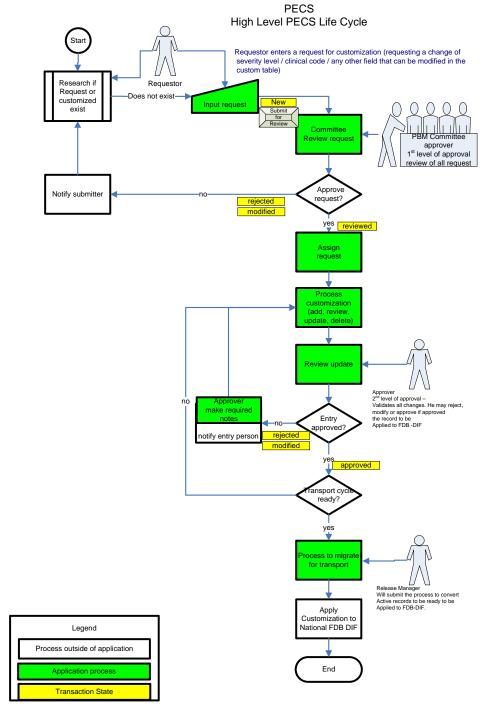


Figure 4: PECS Customization Life Cycle

<u>Figure 4</u> 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.

2.2.2 Transaction Flow

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

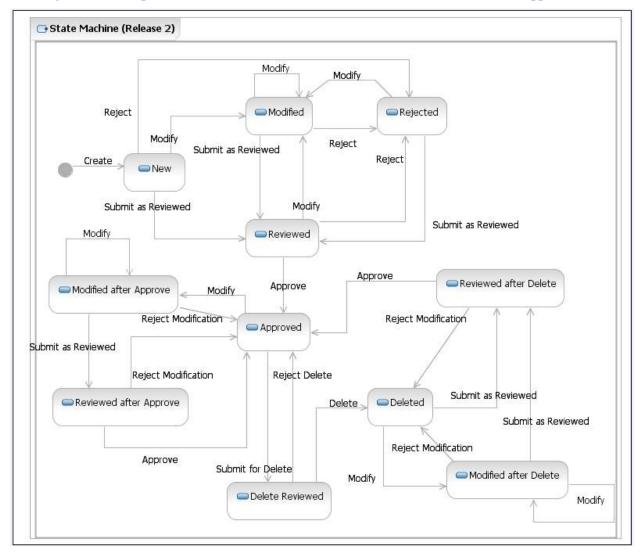


Figure 5: Action Statuses

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</u> <u>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.

2.3 User Access Levels

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.

2.3.1 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

2.3.2 Role Descriptions for Identify Management

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

<u>Requestor:</u> 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, add or delete users to/from the approver role, and initiate the process to remove drug pairs that contain a null routed generic drug.

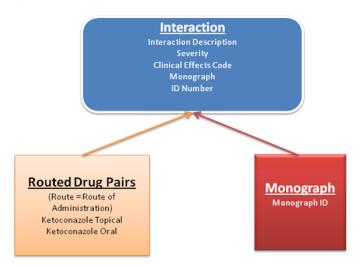
3 Customization Information

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

3.1 Drug-Drug Interaction and Professional Monograph

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 6: 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.

Displaying the Reverse FDB Drug-Drug Interaction ID

The Reverse FDB Drug-Drug Interaction (DDI) ID is displayed in the VA custom DDI and DP Detail pages, in the results of DDI and Drug Pair queries and on the FDB Custom DDI Report. The Reverse FDB DDI Interaction ID is defined as the reverse of the FDB DDI ID and is obtained by executing this equation:

32,000 – (minus) FDB Monograph ID.

For example:

- If FDB monograph ID is 2246, the reverse FDB DDI ID is 29745 (32,000 2246 = 29745)
- If FDB monograph ID is 29754, the reverse FDB DDI ID is 2246 (32,000 29754 = 2246)
- If FDB monograph ID is 0, the reverse FDB Interaction ID is 0 (i.e., DDI was created from scratch using the Open Blank Form option)

Displaying the reverse FDB DDI Interaction ID in the DDI and DP detail pages, query results, and reports enables you to find information about reverse DDIs easily.

3.2 Duplicate Therapy

The Duplicate Therapy concept allows you to specify the maximum number (0, 1, 2, 3, or 4) 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.

3.3 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.

3.4 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.

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4 Getting Started

This section provides information that is essential for a user to get started with the system. It is not comprehensive enough for all details, nor does it cover the different nuances that are displayed on application pages for different user roles.

4.1 Login

Below is information on login instructions and an explanation of how users are authenticated to the PECS Application.

4.1.1 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 <u>12</u>.

4.1.2 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:

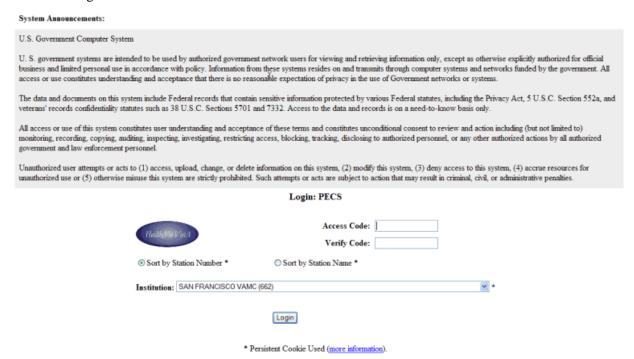


Figure 7: KAAJEE Login Screen

4.2 Changing User ID and Password

All users are assigned VistA access and verify codes,. which are their assigned/designated "User IDs" and passwords for authentication in PECS.

Password changes, account activation/inactivation, etc., must be performed through VistA. Contact your ADPAC for instructions.

4.3 Application Organization

Instead of seeing a main menu upon logging in successfully, PECS users are presented with a window that displays tab groups which house the functions of the PECS application. This window is customized to the role the user has. The tabs are unique to that user's role; the tabs that display will be different for each role.



Figure 8: PECS Tab Groups Displayed

All available tabs; note that not all tabs are seen by any one user role.

- Home
- Advanced Query / Customization

- Easy Search
- Drug Pair Lookup
- Reports
- Help
- Contact Us
- Custom Updates
- Administration

4.3.1 Welcome and Update Information

The Welcome and Update Information section displays the current user's account name and the dates of the last FDB-DIF Update and the last Custom Update.

Welcome THREE_CUSTOM

Last update to First DataBank DIF database occurred on: 07-06-2012 version: 3.3 Last customization update file creation occurred on: 07-18-2012

Figure 9: Welcome User Text

To Those Using Screen-Reading Assistive Technology

The window that displays the PECS tab groups also contains a link at the top, "Go to Main Content." This link is for screen readers to jump directly to the main content of the selected tab and not read each and every tab every time a tab is selected.



Figure 10: PECS Tab Groups with "Go to Main Content" Link

4.3.2 Help and "Contact Us" Information

All home pages have tabs for accessing the online help file and a Contact Us page.

The Help tab launches the PECS Online Help System and displays the "front page" of the Help System. To get context-sensitive help, click the Page Help link on the page you need help with.

The Contact Us page contains a list of PECS Project Contacts should you need additional information about the PECS product. The content of the Contact Us page is decided by users with the Administrator role. Click the link associated with the name to send that person (or group) an email.

Note: Clicking the link opens your mail application and a new email message to the person specified in the properties of the link. This may produce a warning message. This is normal.

4.3.3 Home Page

The Home Page is the first page that the user sees after logging into the application, and is accessed by the Home Tab. The purpose of the Home page is to provide the users with summary counts of the number of active customization records that they can access. It also provides information about when the last

update to the First Databank DIF database tables occurred and also when the last customization update file was created.

The Home page is organized into panels (created as HTML tables) containing specific information. Only panels that are appropriate to the role of the current user are displayed. The common tabs for all users are Home, Help, and Contact Us.

Users with the Requestor role are shown only the My Request History panel. Users with the Approver role are shown nearly all available panels. The counts in the panels are organized by the action (Review/Approve/Delete) the user can perform on the customization records for each concept type (Professional Monograph, Dose Range, Drug-Drug Interaction and Duplicate Therapy). 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 as they move through the approval process.

Clicking on the link to the number of records under each panel (if more than '0') will redirect the user 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.

Users with the role of Release Manager or Administrator each have a Home page that differs from the other and from the Requestor or Approver role.

The bottom of all home pages (and every page) contains navigation links providing access to various areas of the system. These links are identical to the navigation tabs at the top of every page.

Using Home Page Tables with Screen-Reading Assistive Technology

The panels that a user sees on the home page are really HTML tables. They can pose challenges for users of screen-reading assistive technology. PECS has keyboard shortcuts to help users of screen-reading assistive technology navigate the home page tables.

- 1. On the Home Page, press Alt + Y to move from one table to another.
- 2. Press T to enter the table.
- 3. Use Arrow keys to move around the table.
- 4. Press Alt + Y to exit the table.

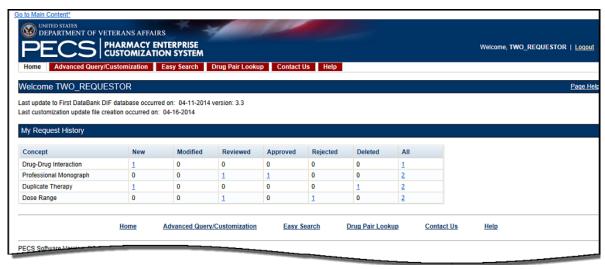


Figure 11: Requestor Home Page

4.4 How System Idle Time is Handled

If the PECS system is idle for 28 minutes, a warning message is displayed, informing the user that their session will end in two minutes:

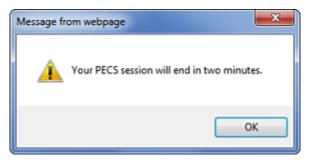


Figure 12: Session End Warning Message

If you click OK within the two minutes, you are returned to the window you were working with. You must do something active on that page within the same two minutes, such as edit, query, or click another tab. If you do not do so, your session ends and the next action you take returns you to the login screen:

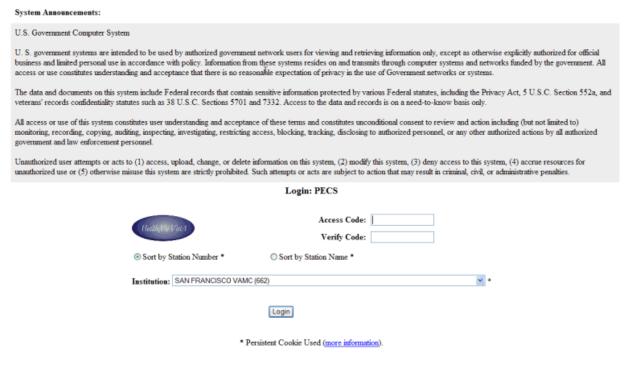


Figure 13: KAJEE Login Screen

If you click OK beyond the two minutes, you are again returned to the screen you were working on, but if you click anything, you are returned to the login screen.

4.5 How To Turn Off Compatibility Setting in Internet Explorer 9

The PECS application has been developed to display the various panels as cleanly as possible. If, however, an Internet Explorer 9 setting of Compatibility View has been set, it will result in a difficult-to-read table:



Figure 14: Panel with Compatibility View ON

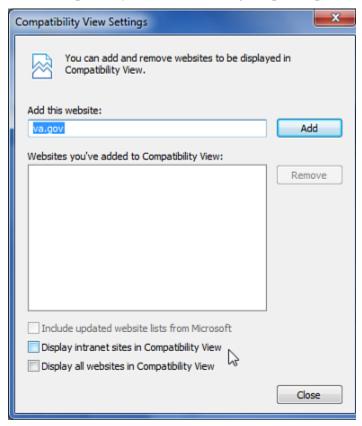
If, however, you use the default and/or turn off the Compatibility Mode, the panels appear very cleanly, like this:



Figure 15: Panel with Compatibility View OFF

To turn off the IE Compatibility Mode:

- 1. In IE 9, Select Tools.
- 2. Select Compatibility Mode View settings. A panel opens:



3. Make sure the checkbox for "Display intranet sites in Compatibility View" is NOT checked. This results in better displays for the panels.

(This page included for two-sided copying.)

5 Common Task: Searching For Records

One task that is common to all PECS roles is that of searching, or querying, for specific records, whether they are records from the COTS FDB-DIF database or from VA customizations. The way to do this is to use the functionality found under the Advanced Query/Customization tab.

5.1 Accessing the Advanced Query/Customization Page

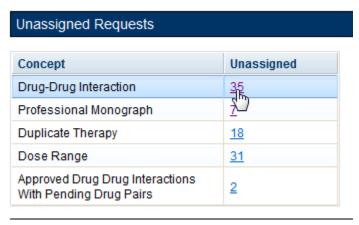
The Query Builder Panel on the Advanced Query/Customization page allows you to retrieve a specified set of records the VA Custom Tables, the FDB standard tables or both in order to perform research, make customizations, make customization changes, or export data. You can use it to create a new query,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

The Advanced Query / Customization page is accessed in one of two ways:

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



2. 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.



5.2 Build a Query Panel

To build a query panel, you start with a window that looks like the following:

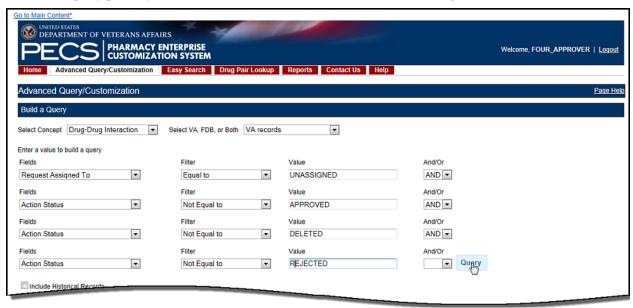


Figure 16: Advanced Query/Customization Build Query Page

After selecting values for those two fields, additional fields display, through which you can create your Query.

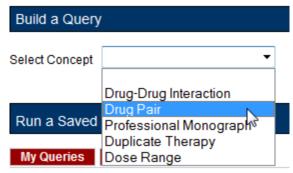
Field Name	Definition
Fields	A drop-down list of the fields available to be queried against for the Concept selected. Different concepts will have different fields eligible for query.
Filter	A drop-down list of the filters that can be used in the Query. See Query Filters.
Value	A blank field into which the user inserts the particular value they are searching for/by
And/Or	If the user is creating a query searching for one set of criteria AND an additional set of criteria, the user will utilize the 'And' option. After selecting 'And' an additional row of 'Field', 'Filter' and 'Value' will be displayed to be filled out. If the user is creating a query searching for one set of criteria OR another set of criteria, the user will utilize the 'Or' option. See And/Or Usage Example for additional information.
Query button	The user clicks this to run the written query.
Add Default DRC Query button Dose Range Only.	Adds two standard criteria (Concept Type = '6' and AGEHIGHINDAYS >= '6570) to the query.
'Include Historical records' checkbox	The user checks/selects this box to include records in the Query results that are considered historical versions of active records. No action can be taken on them, they can only be viewed.
'Clear Query' button	The user clicks this if they want to totally remove the Query they have written above.
'Save Query' button	The user clicks this if they want to save the Query they have written above.
'Query Name'	The user enters a name for the Query they have written above, and want to save.

5.3 Create a Query

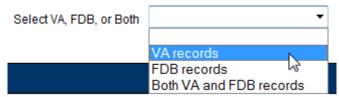
Note: This Feature is available to users with the Requestor and Approver roles.

To create a query:

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

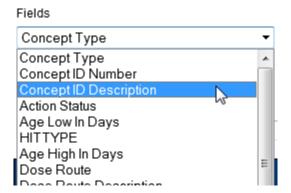


2. Select the data you want to view – VA, FDB, or Both.



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.

Enter a value to build a query



4. Select the Filter you want to impose on the Field. See Query Filters for additional information.

Filter

Greater than

Contains
Equal to
Less than or Equal to
Greater than or Equal to
Begins with
Ends with
Greater than
Less than
Not Equal to

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.



- a. AND indicates the results must match the new criteria and all the AND-connected criteria above it
- b. OR indicates that the results must match either the new criteria or the AND-connected criteria above it. See And/Or Usage Example 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.

Export			
Select	Concept Type	Concept ID Number	Concept ID D
<u>Active</u>	6	15532	BCG LIVE IN' (SDV,MDV OF
<u>Active</u>	6	22222222	
Historical	6	476	NITROGLYCI TABLET,SUB
Historical	6	1234	POTASSIUM BICARBONA' CITRATE/CIT

5.3.1 Query Filters

The Advanced Query/Customization query function provides Filters that allow you to control what data is returned by the query. The filters are.

Filter Name	Filter Function
Contains	The contents of the Value field appears somewhere in the database row of the Field being queried. Used primarily for fields containing text data. Contains is the default Filter option.
Equal To	The contents of the Value field exactly matches the contents of the database row of the Field being queried.
Less than or Equal to	The contents of the Value field is less than or equal to the contents database row of the Field being queried.
Greater than or Equal to	The contents of the Value field is greater than or equal to the contents database row of the Field being queried.
Begins with	The contents of the database row of the Field being queried starts with the contents of the Value field.
Ends with	The contents of the database row of the Field being queried ends with the contents of the Value field.
Greater than	The contents of the Value field is greater than the contents database row of the Field being queried.
Less than	The contents of the Value field is less than the contents database row of the Field being queried.
Not equal to	The contents of the Value field does not exactly match the contents of the database row of the Field being queried.

5.3.2 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	

5.3.3 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

5.3.4 Add Default DRC Query

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 pre-defined search that enters a default Dose Range query (DRC = Dose Range Concept). 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:

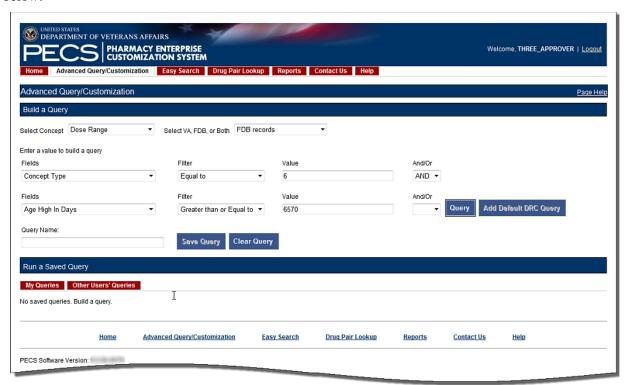


Figure 17: Default Dose Range Query Window, with Default Dose Range Query

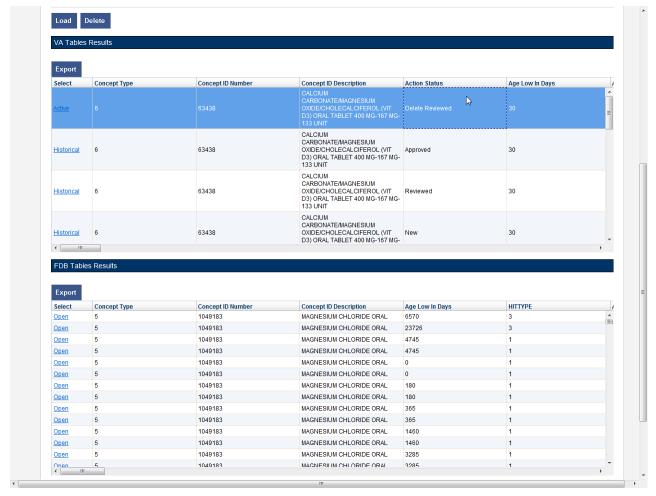


Figure 18: Results from Building a Dose Range Query with Default DRC Query

5.4 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.

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:

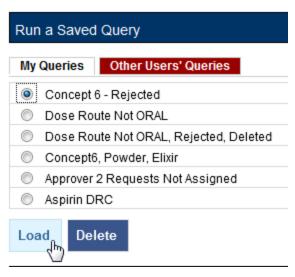
- 1. Create a query in the Build A Query panel. See Build A Query for additional information.
- 2. Enter a name for the query in the Query Name field. The name must contain at least five characters and cannot be longer than 64 characters..
- 3. Click Save Query.

5.5 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' 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.

5.6 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.

5.7 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.

5.8 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.

Action Performed By	Action Date	← Reference Text
SIX_APPROVER	2012-05-10 13:39:25	Sort Direction
SIX_APPROVER	2012-05-10 13:30:32	Indicator
TWO_APPROVER	2012-05-10 13:12:57	
TWO_APPROVER	2012-05-10 13:09:47	
SIX_APPROVER	2012-05-10 10:38:44	
SIX_APPROVER	2012-05-10 10:35:22	
FOUR_APPROVER	2012-05-09 17:35:26	
TWO_APPROVER	2012-05-03 16:00:44	

Figure 19: How to Sort a List of Queries

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

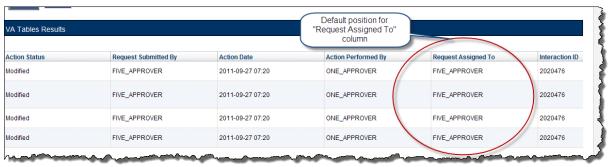


Figure 20: Default Position of "Request Assigned To"



Figure 21: Re-positioned "Request Assigned To" Column

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 resorted 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

5.9 Export Query Results

You can export query results for both VA and FDB records to an Excel spreadsheet.

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:
 - a) Open
 - b) Save
 - c) Cancel
- 3. Click Open to display the exported data in the spreadsheet; click Save to save a copy of the report to your system, or Cancel to abandon the export operation.

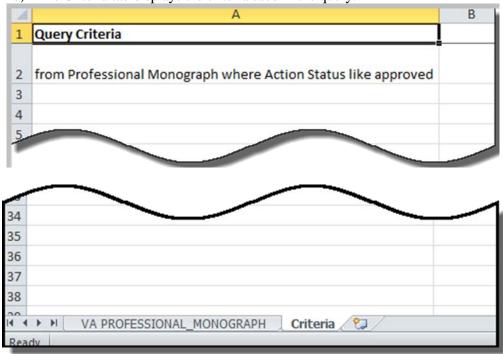


1. The spreadsheet contains two tabs:

a) The [Name of Concept] tab (either VA or FDB) displays the results of the query.

A	В	C	D	E	F
1 Record Type	Action Status	Monograph Title	Corresponding FDB Monograph ID	Monograph ID	Action Date
2 Active	Approved	VA Customized: Avoid concurrent use when possible (Significant) (AVD2)xx	0	150043	2013-12-11 20:20:1
3 Active	Approved	VA Customized: Avoid concurrent use when possible (Critical) (AVD1)xx	0	150026	2013-12-11 20:16:2
4 Active	Approved	Levodopa/MAOIsxxx	144	150444	2013-12-11 20:13:3
5 Active	Approved	VA Customized: Contraindicated (Critical) (CIS1)xxx	0	150029	2013-12-11 18:21:4
6 Active	Approved	VA Customized: Additive Side Effects (Significant) (ADD2)	0	150021	2013-12-11 18:19:4
7 Active	Approved	VA Customized: Additive Side Effects (Critical) (ADD1)xxx	0	150000	2013-12-11 18:17:4
8 Active	Approved	VA Custom Create from Blank	0	150429	2013-11-29 17:48:3
9 Active	Approved	Anticoagulants/Quininexxx	140	150425	2013-11-26 16:38:0
10 Active	Approved	VA custom: Valproic Acid/Carbamazepine	246	150405	2013-11-26 15:18:0
11 Active	Approved	Alfentanil; Fentanyl; Oxycodone/Selected CYP3A4 Inhibitors VA Custom	1500	150424	2013-11-25 16:04:2
12 Active	Approved	Mefloquine; Quinidine; Quinine/Rifamycins	139	150423	2013-11-22 13:50:5
13 Active	Approved	va custoum: Sirolimus/Posaconazole	1884	150416	2013-11-21 15:13:3
14 Active	Approved	Hydantoins/Rifamycins xxx	138	150407	2013-11-18 11:15:4
15 Active	Approved	Diazoxide/Hydantoins xxx	137	150404	2013-11-15 17:36:2
16 Active	Approved	VA CUSTOM - Ace Inhibitors; ARBs/Potassium Preparations	136	150388	2013-11-08 15:38:5
17 Active	Approved	VA CUSTOM - Ace Inhibitors; ARBs/Potassium Sparing Diuretics	135	150386	2013-11-07 08:40:5
18 Active	Approved	va custom: Haloperidol/Lithium	245	150384	2013-11-04 16:05:1
19 Active	Approved	ACE Inhibitors; ARBs/NSAIDs xxx	134	150377	2013-10-31 14:57:1
20 Active	Approved	Metoprolol/Lumefantrine	1202	150371	2013-10-25 15:08:4
21 Active	Approved	VA CUSTOM - Selected Beta-blockers/Selected Calcium Channel Blockers	132	150370	2013-10-24 13:11:5
22 Active	Approved	VA_CUSTOM_Anticoagulants/Cholestyramine; Colesevelam	10	150368	2013-10-22 16:36:4
23 Active	Approved	VA CUSTOM Barbiturates/Corticosteroids (mono deleted 02/02/2012)	131	150346	2013-10-18 14:46:4
24 Active	Approved	monograpy A	0	150345	2013-10-16 16:39:2
25 Active	Approved	VA Custom Selected Narcotics/MAOIs	130	150344	2013-10-16 09:32:0
26 Active	Approved	Amiodarone; Dronedarone/Digitalis Glycosides	129	150325	2013-10-10 10:58:0
27 Active	Approved	Lidocaine/Beta-Blockers UNIQUE	122	150324	2013-10-08 13:18:3
28 Active	Approved	Cimetidine/Procainamide	22	150309	2013-10-04 00:18:2
29 Active	Approved	Propoxyphene/Carbamazepinexxx	118	150304	2013-09-30 19:11:2
30 Active	Approved	VA CUSTOM Valproic Acid/Barbiturates xxx	116	150293	2013-09-24 19:51:1
31 Active	Approved	Alfentanil; Fentanyl; Oxycodone/Selected CYP3A4 Inhibitors	0	150290	2013-09-23 15:42:5
32 Active	Approved	VA custom: Sibutramine/Serotoninergic Agents	342	150289	2013-09-23 14:18:3
33 Active	Approved	Selected Anticoagulants/Sulfinpyrazonexxxx	114	150287	2013-09-20 12:58:3

b) The Criteria tab displays the criteria used in the query.



Export Query Line Limit

If you make a query that returns more than 10,000 records, be aware that there is a 10,000 line limit on the export to the spreadsheet. If your query returned more than 10,000 records and you submitted the records for export anyway, the 2^{nd} tab in the report gives you a message like the following:

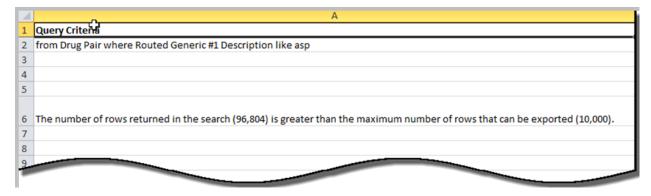


Figure 22: Export Query Line Limit Message



Figure 23: Bottom of Report, Criteria Tab Detail

5.10 Query Errors

Running a query will sometimes return an error message.



Figure 24: Generic Query Error

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.

6 Home Page by Role

6.1 Requestor

This window displays an example of what a user with the Requestor role may see on the home page. Note that the history is only the Requestor's request history; requestors don't have review or approval authority so don't see requests ready for review or approval.

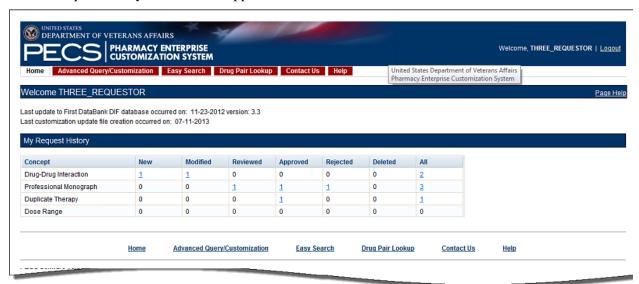


Figure 25: Requestor's Home Page

In addition to the Home tab, users with the Requestor role see the following tabs on their Home page:

- Advanced Query/Customization; see page 25.
- Easy Search; see page <u>71</u>.
- Drug Pair Lookup; see page 85.
- Contact Us; see page 94
- Help Tab; see page <u>96</u>.

The following information is displayed on the Requestor Home tab:

• My Request History; see page 37.

6.1.1 My Request History: Requestor

My Request History displays active customization records created by the logged in user (Requestor and Approver roles only). The results will be broken down into numbers of active records, created by the logged in user by the following Action Statuses: New, Modified, Reviewed, Approved, Rejected, Deleted and All.

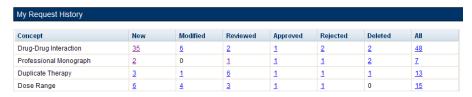


Figure 26: My Request History

The following table defines the columns found on the My Request History window.

Column Name	Column Definition
New	The count is the number of active records in the "New" status created by the logged in user.
Modified	The count is the number of active records in the ""Modified" status created by the logged in user.
Reviewed	The count is the number of active records in the "Reviewed" and "Delete Reviewed" status created by the logged in user.
Approved	The count is the number of active records in the "Approved" status created by the logged in user.
Rejected	The count is the number of active records in the "Rejected" status created by the logged in user.
Deleted	The count is the number of active records in the "Deleted" status created by the logged in user.
All	The count is the number of all active records in any status, created by the logged in user.

Clicking the links within the summary table open pre-defined queries to provide details of the requests. For example, clicking the New - Professional Monograph link will display a query with the appropriate criteria and the query results: Concept = Professional Monograph, Request Submitted By = <current user>, Action Status = New.



Figure 27: Home Tab Summary | Pre-Defined Query

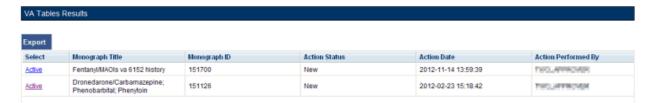


Figure 28: Query Results

6.2 Approver

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

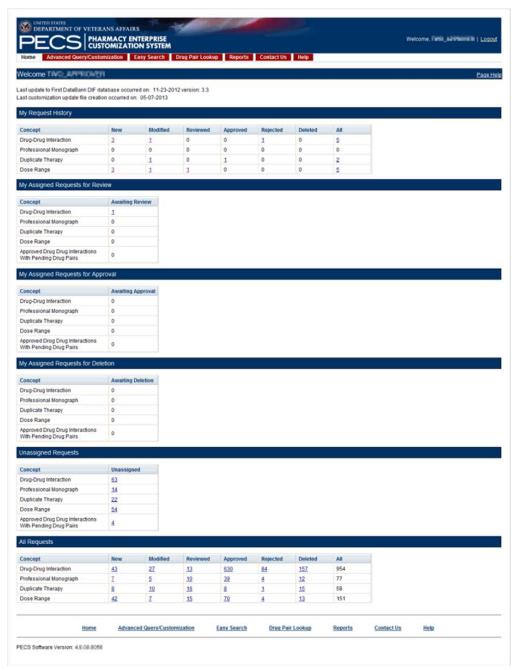


Figure 29: Approver's Home Page

In addition to the Home tab, users with the Approver role see the following tabs on their Home page:

- Advanced Query/Customization; see page <u>25</u>.
- Easy Search; see page 71.
- Drug Pair Lookup; see page 85.
- Reports; see page <u>91</u>

- Contact Us; see page <u>94</u>
- Help Tab; see page 96.

6.2.1 My Request History: Approver

My Request History displays active customization records created by the logged in user (Requestor and Approver roles only). The results will be broken down into numbers of active records, created by the logged in user by the following Action Statuses: New, Modified, Reviewed, Approved, Rejected, Deleted and All.



Figure 30: My Request History

The following table defines the columns found on the My Request History window.

Column Name	Column Description
New	The count is the number of active records in the "New" status created by the logged in user.
Modified	The count is the number of active records in the ""Modified" status created by the logged in user.
Reviewed	The count is the number of active records in the "Reviewed" and "Delete Reviewed" status created by the logged in user.
Approved	The count is the number of active records in the "Approved" status created by the logged in user.
Rejected	The count is the number of active records in the "Rejected" status created by the logged in user.
Deleted	The count is the number of active records in the "Deleted" status created by the logged in user.
All	The count is the number of all active records in any status, created by the logged in user.

Clicking the links within the summary table open pre-defined queries to provide details of the requests. For example, clicking the New - Professional Monograph link will display a query with the appropriate criteria and the query results: Concept = Professional Monograph, Request Submitted By = <current user>, Action Status = New.



Figure 31: Home Tab Summary | Pre-Defined Query

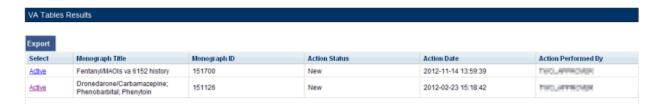


Figure 32: Query Results

6.2.2 My Assigned Requests for Review: Approver

My Assigned Requests for Review are active customization records assigned to the logged in user to be reviewed. The Awaiting review count is the number of records that are in the "New" or "Modified" status, that have been assigned to the logged in user. This section will only be displayed for users in the Approver role.



Figure 33: My Assigned Request for Review Example

6.2.3 My Assigned Requests for Approval: Approver

My Assigned Requests for Approval are active customization records assigned to the logged in user to be approved. These records have been "reviewed" by another "Approver" in the system. This section will only be displayed for users in the Approver role.



Figure 34: Approver's List of Requests for Approval

6.2.4 My Assigned Requests for Deletion: Approver

My Assigned Requests for Deletion are active customization records assigned to the logged in user to be deleted. The records have been "delete reviewed" by another "Approver" in the system. This section will only be displayed for users in the Approver role.

My Assigned Requests for Deletion		
Comment	Aidin - Daladian	
Concept	Awaiting Deletion	
Drug-Drug Interaction	0	
Professional Monograph	1	
Duplicate Therapy	1	
Dose Range	1	
Approved Drug Drug Interactions With Pending Drug Pairs	0	

Figure 35: Approver's List of Requests for Deletion

6.2.5 Unassigned Requests: Approver

Active customization records in the approval process that have not yet been assigned to any user. These records may be in the Action Status of New, Modified, or Reviewed. This section will only be displayed for users in the Approver role.

6.2.6 All Requests: Approver

All active customization records currently in the system by status. The result detail will display the active records associated with the selected custom table summary. The categories are:

Column Name	Column Description
New	The count is the number of active records in the "New" status.
Modified	The count is the number of active records in the "Modified" status.
Reviewed	The count is the number of active records in the "Reviewed" and "Delete Reviewed" status.
Approved	The count is the number of active records in the "Approved" status.
Rejected	The count is the number of active records in the "Rejected" status.
Deleted	The count is the number of active records in the "Deleted" status.
All	The count is the number of all active records, by status. This is NOT a link, just informational

6.3 Release Manager

This screen shot displays the home page for a user with the Release Manager role. The Custom Updates tab is the main task tab for the Release Manager, but that role can also search for information in the Advanced Query/Customization tab, as well as use the Contact Us and Help tabs.

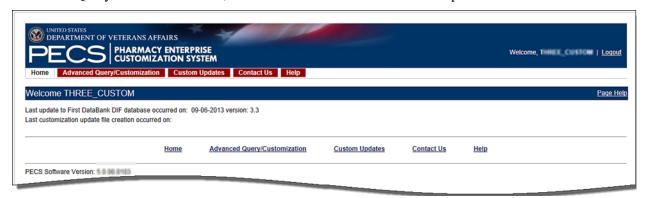


Figure 36: Release Manager's Home Page

In addition to the Home tab, users with the Release Manager role see the following tabs on their Home page:

- Advanced Query/Customization; see page <u>25</u>.
- Custom Updates; see page <u>95</u>.
- Contact Us; see page 94
- Help Tab; see page <u>96</u>.

6.4 Administrator

The following screen shot displays the home tab seen by a user with the Administrator role. The Administration tab is the main task tab for the Administrator, but that role can also search for information in the Advanced Query/Customization tab, as well as use the Contact Us and Help tabs.



Figure 37: Administrator's Home Page

In addition to the Home tab, users with the Administrator role see the following tabs on their Home page:

- Advanced Query/Customization; see page <u>25</u>.
- Administration; see page 95.

- Reports; see page <u>161</u>.
- Contact Us; see page 157.
- Help; see page <u>96</u>.

6.5 More Information

For more information on all the roles, see <u>User Roles and Tasks</u>, starting on page $\underline{45}$. For information on the functions, see the section <u>PECS by Tab</u> on page $\underline{69}$.

7 User Roles and Tasks

The following sections explain the four roles of those who use the PECS Application and discuss the various tasks that are available for them based upon that role.

7.1 Requestor

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

A requestor commonly performs the following tasks:

- Search for records (COTS or customized) see the section <u>Using Home Page Tables with Screen-Reading Assistive Technology</u> starting on page 20.
 - Create a customization request– see <u>Create a Customization Request (Generic)</u> on page <u>45</u>.
 - Create a custom record from an FDB Drug-Drug Interaction see <u>Creating a Custom Record</u> <u>from an FDB Drug-Drug Interaction</u> on page <u>46</u>.
 - Query Drug Pairs in PECS by drug name, interaction ID, or severity level see <u>Customizing Drug Pairs from the Selection List</u> on page <u>129</u>.

Here is an example of a Requestor's Home Page:

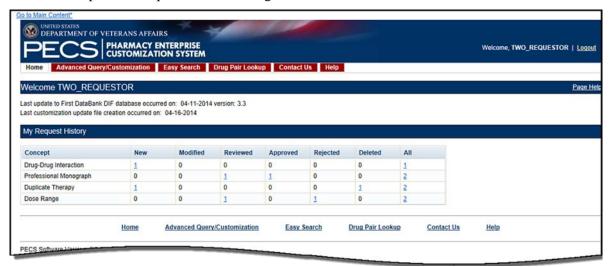


Figure 38: Requestor's Home Page, Partial

7.1.1 Additional Role-Based Tasks

In addition to the Home tab, users with the Requestor role see the following tabs on their Home page:

- Advanced Query/Customization see section <u>5.1</u>, starting on page <u>25</u>.
- Easy Search see page 71
- Drug Pair Lookup see page 85.
- Contact Us see page <u>94</u>.
- Help see page 96.

7.1.2 Create a Customization Request (Generic)

A Requestor can create a customization request on any of the five concepts – Duplicate Therapy, Drug-Drug Interaction, Drug Pairs, Dose Range, and Professional Monograph.

Process

The process for creating the customizations differs with the concept itself. See the following:

- Creating a custom Drug-Drug Interaction has two areas for information on customization
 - o Drug-Drug Interaction Detail
 - o Creating a Custom Record from an FDB Drug-Drug Interaction
- Drug-Pair Customization
- Creating a custom Dose Range record
- Creating a custom Duplicate Therapy record
- Creating a custom Professional Monograph
- Creating New Records

Customization Workflow

A customization's workflow can be complex; however, a simplified version follows:

A Requestor creates a customization. The same requestor can make changes to the request after it is created, if new information is received..

An Approver signs on and the customization displays in their list of customizations to review. The Approver can either Submit the customization for Review if all is well, or Reject the customization. If Rejected, the Requestor must be notified. The Requestor may make changes to the customization and again it will display on the Approver's list as needing review (this time in Modified Status). If the Approver makes changes first, the Approver must notify the Requestor, and the record falls into the list of records needing review.

The Approver can then Submit the record for Review, the first stage in the Approval process. The record can go through various statuses here: it can have items changed/updated, can be reviewed again, or be deleted.

The second level of the approval process is that another Approver validates all changes. This approver may reject, modify, or approve the record. If it is approved, the record will be applied to the FDB-DIF database via DATUP.

Happy path: Create, Submit for Review, Approve. Record is now complete. In between the record can be modified and reviewed again, rejected for further work, or deleted.

Note: Most changes require that a record go through the approval process again; however, certain changes to a record do not change its status (e.g., DDI non-required field).

7.1.3 Creating a Custom Record from an FDB Drug-Drug Interaction

- 1. Click the Advanced Query/Customization tab.
- 2. From the Concept list, select Drug-Drug Interaction.
- 3. From the Select VA, FDB, or Both list, select FDB.
- 4. Use the query to find the defined FDB interaction you want to customize.
- 5. Select the Open link next to the FDB Drug Interaction that you want to create a custom record for.
- Click the Edit button
- 7. Modify the record as appropriate. At minimum, you are required to provide a Current Action Reason.

- 8. Click the Customize button to submit the customization request. Click Cancel Edit to abandon request and return to the original record.
- 9. Once the customization request is established, you can add Drug Pairs. See <u>Drug-Drug Interaction Detail</u> on page <u>116</u> and <u>Drug Pair Customization</u> on page <u>124</u>.

7.2 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. They can delete another approver's request after it has been approved and placed in the Submit for Delete state.

A user with the Approver role commonly performs the following tasks:

- Create a Customization Request see page <u>49</u>
- Approve a Customization Request see page <u>50</u>
- Review, Reject, or Modify a Customization Request see page <u>51</u>
- Delete a Customization Request see page <u>52</u>

Here is an example of an Approver's Home Page.

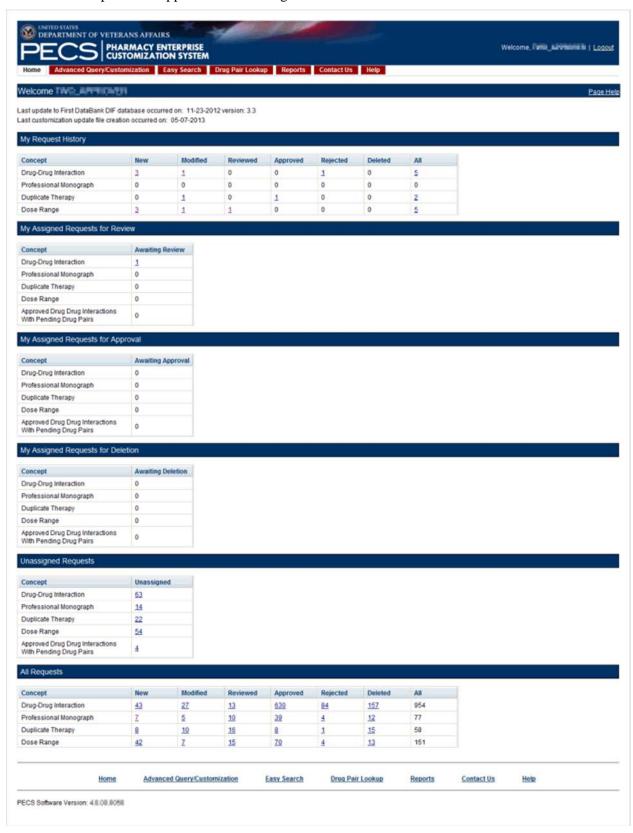


Figure 39: Approver's Home Page

7.2.1 Create a Customization Request (Generic)

An Approver can create a customization request on any of the five concepts – Duplicate Therapy, Drug-Drug Interaction, Drug Pairs, Dose Range, and Professional Monograph.

Process

The process for creating the customizations differs with the concept itself. See the following:

- Creating a custom Drug-Drug Interaction -- two areas for customization information:
 - o Drug-Drug Interaction Detail
 - o Creating a Custom Record from an FDB Drug-Drug Interaction
- Drug-Pair Customization
- Creating a custom Dose Range record
- Creating a custom Duplicate Therapy record
- Creating a custom Professional Monograph
- Creating New Records

Customization Workflow

A customization's workflow can be complex; however, a simplified version follows:

A Requestor creates a customization. The same requestor can make changes to the request after it is created, if new information is received..

An Approver signs on and the customization displays in their list of customizations to review. The Approver can either Submit the customization for Review if all is well, or Reject the customization. If Rejected, the Requestor must be notified. The Requestor may make changes to the customization and again it will display on the Approver's list as needing review (this time in Modified Status). If the Approver makes changes first, the Approver must notify the Requestor, and the record falls into the list of records needing review.

The Approver can then Submit the record for Review, the first stage in the Approval process. The record can go through various states here: it can have items changed/updated, can be reviewed again, or be deleted.

The second level of the approval process is that another Approver validates all changes. This approver may reject, modify, or approve the record. If it is approved, the record will be applied to the FDB-DIF database via DATUP.

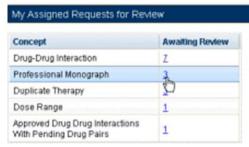
Happy path: Create, Submit for Review, Approve. Record is now complete. In between the record can be modified and reviewed again, rejected for further work, or deleted.

Note: Most changes require that a record go through the approval process again; however, certain changes to a record do not change its status (e.g., DDI non-required field).

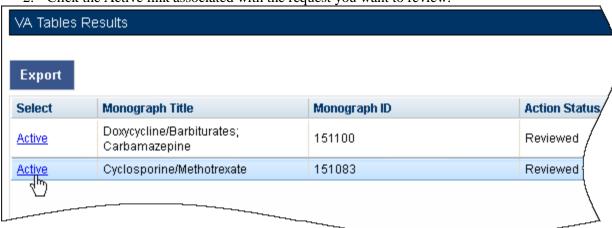
7.2.2 Approve a Customization Request

To approve a customization request:

1. From the PECS Home page, select a Concept for customization request to review from the My Assigned Requests for Approval area by clicking the link in the Awaiting Review column.



2. Click the Active link associated with the request you want to review.



3. Click Edit.

Professional Monograph

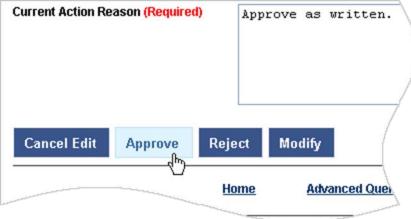
To update this record click on the edit button below.



Monograph Title (Required)

Disopyram

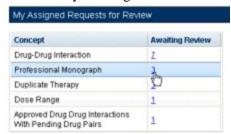
4. Review the content. If you are satisfied with the content of the customization request, make a note in the Current Action Reason field and click Approve.



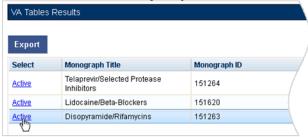
7.2.3 Review, Reject, or Modify a Customization Request

To review, reject, or modify a customization request that has been assigned to you:

1. From the PECS Home page, select a Concept for customization request to review from the My Assigned Requests for Review area by clicking the link in the Awaiting Review column.



2. Click the Active link associated with the request you want to review.



3. Click Edit.



4. Review the content and make revisions as necessary. Describe the changes you made in the Current Action Reason field or indicate that no changes are necessary.



- 5. If you made changes to the customization request, click Modify. You can also do one of the following:
 - a. To allow the customization request to move to the Approval phase without changes, click Submit As Reviewed.
 - b. To reject the customization request, click Reject.
 - c. To put the record in the Delete Reviewed state, click Submit for Deletion.
 - d. To abandon the current review, click Cancel Edit.



Note: Customization requests can be modified after they have been Reviewed.

7.2.4 Delete a Customization Request

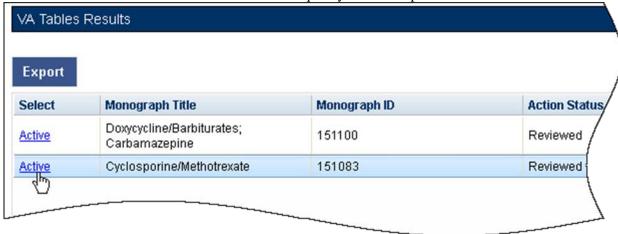
Note: To delete a customization request, the following must be true: 1) the record must be in the Approved State; 2) a different approver from the approver who approved the record is the one who can delete it.

There are two steps to deleting a customization request:

- 1. The approver who initially approves the requests can submit it for deletion (the record is then in the Delete Reviewed state.)
- 2. A different approver then can actually delete the request. If, during the Submit for Delete process, this second approver was assigned the record, it will show up in their "My Assigned Requests for Deletion" area of their home page.

To delete a customization request (first approver):

- 1. From the PECS Home page, determine which Concept group you are going to review under the Awaiting Review column from the My Assigned Requests for Review area by clicking the number link associated with that concept.
- 2. Click the Active link associated with the request you want to put in the Delete Reviewed state.



3. Click Edit.



To update this record click on the edit button below.



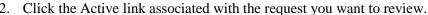
Monograph Title (Required)

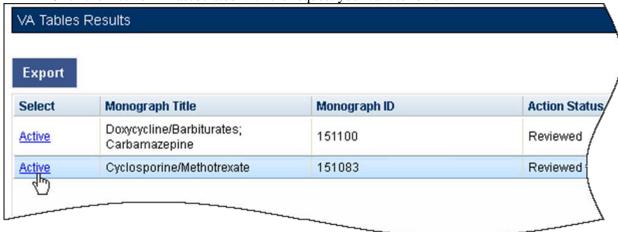
Disopyram

- 4. To submit a customization request for deletion, verify the record is in the Approved State. You would run a query for Approved records before selecting one.
- 5. Enter a Current Action Reason and click Submit For Delete. At this point, the record is in Delete Reviewed state.

To delete a customization request (second approver):

1. From the PECS Home page, select a Concept from the My Assigned Requests for Deletion area by clicking the link in the Awaiting Deletion column.





3. Click Edit.



4. Enter the Current Action Reason and click Delete. Now the record is in Deleted state.

7.2.5 Additional Role-Based Tasks

In addition to the Home tab, users with the Approver role see the following tabs on their Home page:

- Advanced Query/Customization – see section 5.1, starting on page 25.
- Easy Search see section 8.3, starting on page 71
- Drug Pair Lookup see section 8.4, starting on page 85
- Reports see section 8.5, starting on page 91
- Contact Us see section 8.6, starting on page 94
- Help see section 8.9, starting on page 96

7.2.6 Creating a Custom Record from an FDB Drug-Drug Interaction

To create a custom record from an FDB Drug-Drug Interaction:

- 1. Click the Advanced Query/Customization tab.
- 2. From the Concept list, select Drug-Drug Interaction.
- 3. From the Select VA, FDB, or Both list, select FDB.

- 4. Use the query to find the defined FDB interaction you want to customize.
- 5. Select the Open link next to the FDB Drug Interaction that you want to create a custom record for.
- 6. Click the Edit button
- 7. Modify the record as appropriate. At minimum, you are required to provide a Current Action Reason.
- 8. Click the Customize button to submit the customization request. Click Cancel Edit to abandon request and return to the original record.
- Once the customization request is established, you can add Drug Pairs. See <u>Drug Pair</u>
 <u>Customization</u>. The Drug-Drug Interaction cannot be completely approved until drug pairs are added and approved.

7.3 Release Manager

The Release Manager has one main role and they can do a few other tasks.

7.3.1 Release Manager's Main Role

The Release Manager's main role is to handle custom updates. A custom update is a zip file containing files for each Order Check in the FDB update file format. Update files are created by clicking the "Create New Update" button.

Note: Due to a DATUP limitation, only one set of custom updates can be created per calendar day.

To create Custom Updates, the Release Manager starts with this tab:

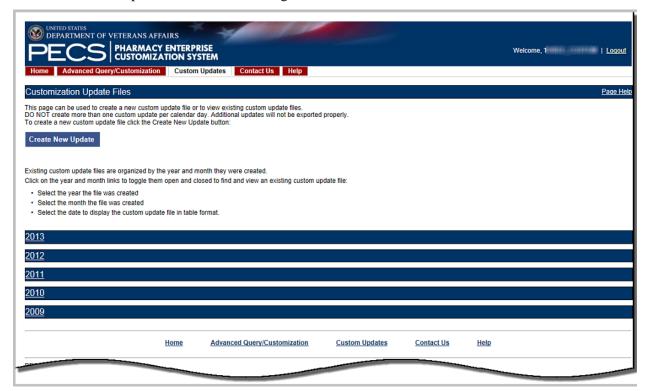


Figure 40: Release Manager's Custom Updates Tab

Custom updates can be run at any time, but as previously noted, 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).

The existing Custom Updates are compartmentalized by Year and Month. Click the Year to display the custom updates for that year, then click a month to display the custom updates performed during that month. The custom updates for more than one month can be displayed simultaneously. Clicking a month a second time will collapse (hide) the display of that month's custom updates.

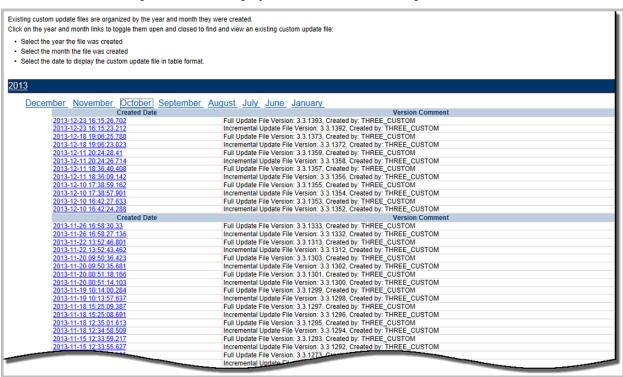


Figure 41: Display of Existing Custom Updates by Month

7.3.2 Additional Release Manager Tasks

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.

These are common, unique tasks performed by a Release Manager.

- Request new Custom Updates on page <u>57</u>.
- View Specific Custom Updates -see Update Files Explained on page 57.

For information on the Release Manager's home page, see Release Manager on page 43.

The Release Manager has the following tabs:

• Advanced Query/Customization— – see section 5.1, starting on page 25.

Note that the Release Manager cannot create new customizations; they can only view those that currently exist.

Custom Updates

– see page <u>57</u>

- Contact Us– see section 8.6, starting on page <u>94</u>
- Help– see section 8.9, starting on page 96

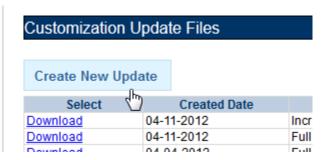
7.3.3 How to Perform Custom Updates

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

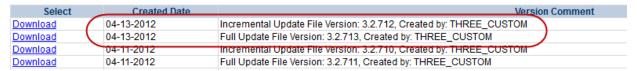
- 1. Log in to PECS as a Release Manager.
- 2. Click the Custom Updates tab:



3. Click Create New Update:



4. After processing, the two new update files will appear in the list.



- 5. Verify today's date in Created Date column. The dates in the Created Date column should match the current date.
- 6. If an error message is received, report it to PECS Administrator.

7.3.4 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

For example, the 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.

Incremental Update File

The Incremental Update File contains just the updates delivered by FDB. The custom zip file contains a proddefinition.xml, FDBPRODCONTROL.DAT and several data files that have an extension of UPD. Here is a picture of the zip file:

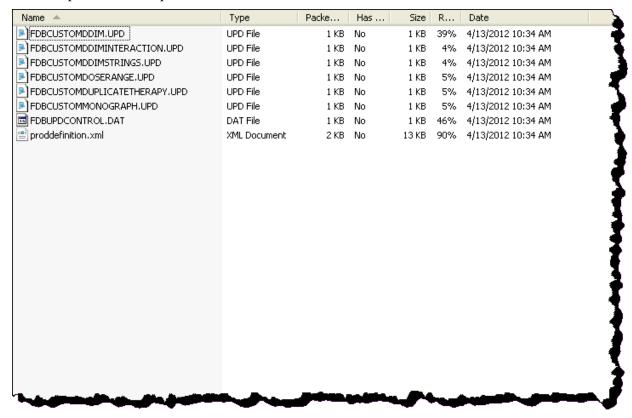


Figure 42: Custom Update Zip File

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|uicategory4|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|2
D|1052533|1050027|2020134|1
```

Figure 43: Custom Update Text File

Full Update File

The Full Update File contains the complete FDB distribution. The files are:

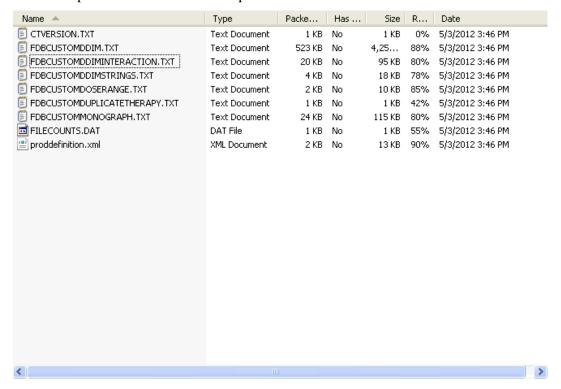


Figure 44: Full Update File

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



Figure 45: Custom Drug-Drug Interaction Full Update File

7.4 Administrator

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

The Administrator can

- Go to the Administration tab see the Home Page for the Administrator.
- Go to the Customize Settings tab see Customize Settings
- Run Reports see Reports
- Perform Null Drug Pair Removal see Null Drug Pair Removal Process
- Edit the Contact Us page see <u>Contact Us</u>

These are unique tasks performed by an Administrator.

- Customize Settings
- Update <u>Approver User Settings</u>
- Null Drug Pair Removal Process
- Edit the Contact Us display

7.4.1 Customize Settings

The Settings page allows users in the Administrator role to customize application settings and add and remove Approver-role users. Settings are available to Administrator users only.

Customize Settings enables the Administrator to change table/field settings by concept type. The user selects which concept to update.

Approver User Settings Enables the Administrator to add and/or delete users to/from the Approver role within the PECS system.

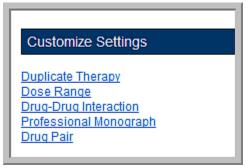
Access Settings Functions

To access the Settings functions:

- 1. Log in as an Administrator.
- 2. Click the Administration tab.



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



Customize Settings Table Description

There are currently five Settings Pages, one for each concept: Drug Pair, Drug-Drug Interaction, Dose Range, Duplicate Therapy and Professional Monograph.

Column Heading Name	Column Heading Description
Name	All the table fields associated with the particular table that was selected in the settings tab. The field names cannot be changed, they are the actual name of the field for the table.
Display Name	User defined name that can be changed by the system administrator. This name is what is displayed in the query selection, the data entry field and reports for the selected table.
Display in Query	This true or false radio button option specifies if the field will be displayed in the Advance Query/Customization results tables. Certain column rows will only have the 'true' radio button. Those fields are required and not allowed to be turned off.
Display in Details	This true or false radio button option specifies if the field will be displayed on the Detail page of the selected concept.
Include in Reports	This true or false radio button option specifies if the field will be displayed in any applicable reports.
Display Order	A numeric value designating the order the field will be displayed in.

The Customize Settings function allows you as Administrator to change the label name for the Field (Display Name), and 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.

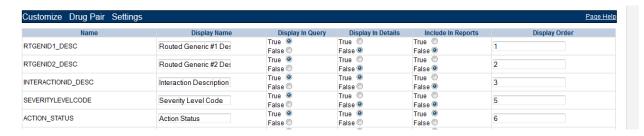


Figure 46: Customize Settings Example (Drug Pairs)

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.

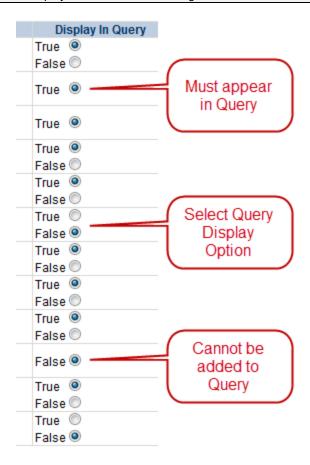
Note: Cancel is immediate; you will not be warned that you are about to lose your changes.

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.



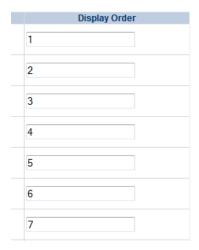
- 3. Repeat the process as necessary.
- 4. Click Save to save your changes; click Cancel to abandon the changes and return to the Settings page.

Note: Cancel is immediate; you will not be warned that you are about to lose your changes.

7.4.2 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.



7.4.3 Approver User Settings

The Approver User Settings allow you to delete or add 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.



7.4.4 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:

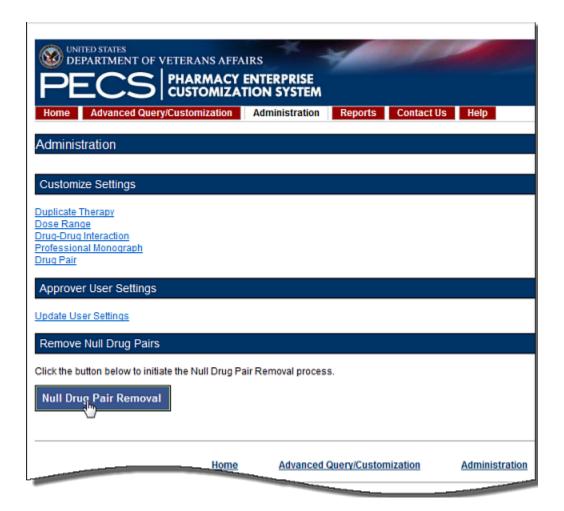


Figure 47: Null Drug Pair Removal Button on Administration Tab

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

Administration

Informational Messages:

Null Drug Pair Removal processing has completed.

Figure 48: 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.

7.4.5 Reports

The Administrator and Approver roles can run reports. For more information about how Reports are used, see the Reports section.

7.4.6 Contact Us

Administrator users can edit the content of the Contact Us page. See detailed information in Contact Us on page 157.

To edit the Contact Us page, see the detailed information in Editing Contact Us on page 157.

To add a Contact Link, see the detailed information in Add a Contact Link on page 158.

To edit a Contact Link, see the detailed information in Edit a Contact Link on page 159.

(This page included for two-sided copying.)

8 PECS by Tab

This section describes the PECS functions that are grouped by tabs found on the main application window. Although the groups are not necessarily how the user approaches the system, the functionality is presented through the tabs.

8.1 Home

The PECS Home tab is the first page you see after you have successfully completed Login. The appearance of the home tab is Role-specific; what appears on the page is different depending on the Role associated with your login credentials. See the <u>Home Page section in Getting Started</u> on page <u>19</u>, and the Home Page by Role starting on page <u>37</u>.



Figure 49: Requestor Home Page

8.2 Advanced Query/Customization

Searching for records is the one common task for all roles in PECS. It is done from the Advanced Query/Customization tab through the Query Builder Panel, which is displayed on all users' home pages.

The Query Builder Panel on the Advanced Query/Customization page allows you to retrieve a specified set of records from the VA Custom Tables, the FDB standard tables, or both in order to perform research, make customizations, 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.

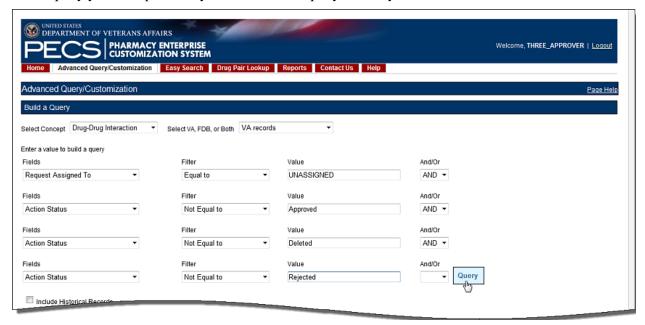


Figure 50: Advanced Query/Customization Window with Sample Data

For detailed information on how to use this page, see the <u>Using Home Page Tables with Screen-Reading Assistive Technology</u> section on page <u>20</u>.

8.3 Easy Search

Easy Search provides a simple way to display commonly-requested PECS information. Easy Search differs from other methods for finding information in that the results are display-only; the records displayed as a result of an Easy Search query cannot be modified. However, in some cases, a link is provided to an editable version of the resulting records.

The Easy Search tab is displayed on the Home pages of the Approver and Requestor roles only.

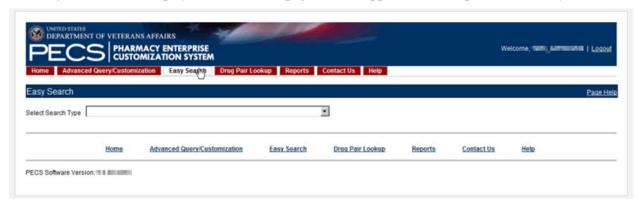


Figure 51: Initial Easy Search Window

The Easy Search queries are handled slightly differently depending on which type of search you want to perform. There are three types of Easy Search Query:

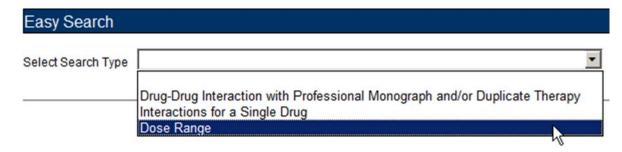
- Dose Range
- Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy
- Interactions for a Single Drug

8.3.1 Easy Search Dose Range Query

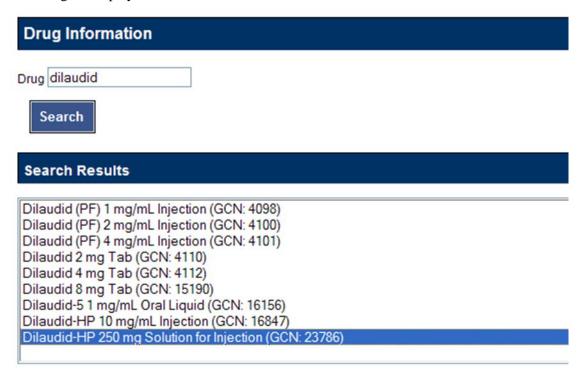
The Dose Range query allows you to easily query the appropriate dosage information based on the patient and dose particulars entered for a selected drug. The results of this query allow the user to ensure the amount being prescribed is an acceptable amount. An Easy Search Dose Range query allows you to find the acceptable dose range for a drug quickly and easily, and presents the results in an easy to understand format.

To perform an Easy Search Dose Range query:

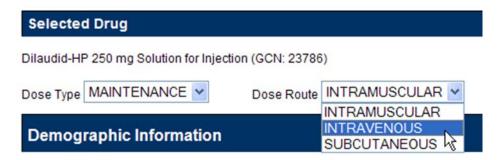
1. From the Select Search Type drop-down list on the Easy Search page, select 'Dose Range.'



- 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 is, both routed generic drugs and dispensable drugs that contain the partial string/whole drug name entered.
- 4. Select the appropriate drug from the Search Results list. Note that if the drug does not have a defined dose route and/or a defined dose unit, the query cannot be performed and an error message is displayed.



5. In the Selected Drug section, select the Dose Type and Dose Route. The available selections will be limited to those appropriate for the selected drug; in some cases, the default values may be the only options available.



- 6. The Demographic Information section will automatically be populated with standard values. If more appropriate patient information is available, the default values can be replaced. Factors included are:
 - Age (years)
 - Weight (kg or lbs.)
 - Height (cm or in)



In the Dosing Information section, enter information about the proposed dose. Factors include:

- Single Dose
- Dose Unit
- Dose Rate Unit
- Frequency



Dose Range Query Results

The Dose Range Results section displays (if available) the appropriate dose range for the selected drug.

Easy Search Results

Drug Checked: Dilaudid 8 mg tablet (GCN: 15190)

Dosing Information Submitted

Single Dose Amount: 1

Dose Unit: EACH

Dose Rate Unit: DAY

Frequency: 1

Dose Range Results

Dose Range - FDB

Max Single Dose: 16 milligram

Max Single Dose Message:

Max Single Dose Status: Passed

High Daily Dose: 16 milligram per day

High Daily Dose Message:

Daily Dose Status: Passed

Frequency Message:

Frequency Status: Passed

Dose Type Description: SINGLE DOSE

Dose Route Description: ORAL

Max Daily Dose Message:

Frequency Low: 1.0 Frequency High: 1.0

Figure 52: Results for a Dose Range Easy Search

Drug Information

The Easy Search Results section displays the information you entered in the query.

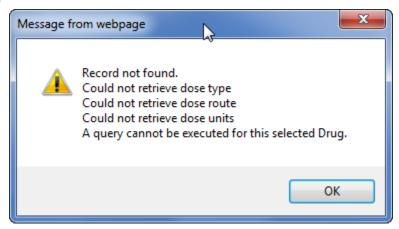
- Drug Checked
- Drug Information Submitted
 - o Single Dose Amount
 - o Dose Unit
 - o Dose Rate Unit
 - o Frequency

Dose Range Information

The Dose Range Results section displays (if available) the appropriate dose range for the selected drug.

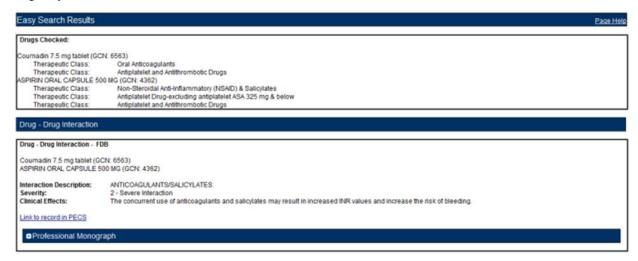
- Max Single Dose
- Max Single Dose Message
- Max Single Dose Status
- High Daily Dose
- High Daily Dose Message
- Daily Dose Status
- Frequency Message
- Frequency Status
- Dose Type Description
- Dose Route Description
- Max Daily Dose Message
- Frequency Low
- Frequency High

Note: When PECS can't retrieve the selected dose type, dose unit, and dose route for a drug, it displays a message in a popup:



8.3.2 Easy Search Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy Query

The Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy query allows the user to easily search for any Drug-Drug Interaction (and associated Professional Monographs) and/or Duplicate Therapy records that may exist within PECS for at least two and up to ten drugs that are selected by the user. This page also allows the user to search for Duplicate Therapy information for any drug they select.



To perform a Drug-Drug Interaction Easy Search Query

1. From the Select Search Type drop-down list, select 'Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy.' After selecting this value, the system will then display the 'Select Information Type', 'Search and Select Drugs', 'Search Results' and 'Drugs to Check' panels.



- 2. Choose the appropriate options from the Select Information Type panel:
 - Select Drug-Drug Interaction with Professional Monograph to find Drug-Drug Interactions with the associated Professional Monograph. If you select the Drug-Drug Interaction with Professional Monograph checkbox, the system will display two options: Display Severity Levels 1 (contraindicated) and 2 (severe) and Display All Severity Levels. You must select one of these options.
 - Select Duplicate Therapy checkbox to display Duplicate Therapy records (if any) for the selected drugs.



3. Enter a partial string or whole drug name into the Drug field and click Search. The system returns all drugs, that is, both routed generic drugs and dispensable drugs that contain the partial string/whole drug name entered.



4. Select a drug from the Search Results window and click Add to Drugs to Check. The selected drug will appear in the Drugs to Check box.

thalidomide 200 mg Cap (GCN: 51879) Natural Fiber Laxative (aspartame) Oral Powder (GCN: 16668)

- 5. If necessary, repeat the Search/Select process to add more drugs to the check. For Drug-Drug Interaction queries, you must select at least two drugs. For Duplicate Therapy, you can select multiple drugs to find duplicate therapies; you can also select a single drug to display the associated Therapeutic Class.
- 6. When all drugs have been added, click Submit. The query results will appear on a results page.

Results

The Drug-Drug Interaction with Professional Monograph and/or Duplicate Therapy query will produce the following results based on the selections made in the query.

Drugs Checked

- All Drugs that were selected by the User are listed first on the page after 'Drugs Checked'.
- After each drug name, the Therapeutic Class(es) that drug belongs to are listed for reference.

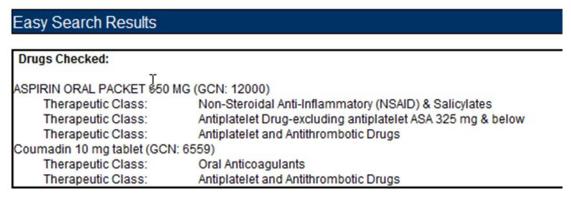


Figure 53: Easy Search Results for DDI with PM, Drugs Checked

Drug-Drug Interaction

The Easy Search query Drug-Drug Interaction with Professional Monograph information will display any Drug-Drug Interactions that apply to any combination of the drugs searched. Click the hyperlink on the screen that reads "<u>Link to record in PECS</u>" to display the record in the standard PECS application where it can undertake additional processing.



Figure 54: DDIs Shown Applicable to Drugs Checked

Professional Monograph

Any associated Professional Monographs to those Drug-Drug Interactions will be listed after the Drug-Drug Interaction information. Click the + symbol to expand the Professional Monograph (collapsed by default). If there is no Professional Monograph associated to the Drug-Drug Interaction returned by the Easy Search query, this option will not expand.

flonograph Title:	Anticoagulants/Salicylates
Severity Level:	2-Severe Interaction: Action is required to reduce the risk of severe adverse interaction.
fechanism Of Action:	Multiple processes are involved: 1) Salicytate doses greater than 3 gm daily decrease plasma prothrombin levels. 2) Salicytates may also displace anticoagulants from plasma protein binding sites. 3) Salicytates impair platelet function, resulting in prolonged bleeding time. 4) Salicytates may cause gastrointestinal bleeding due to irritation.
Clinical Effects:	The concurrent use of anticoagulants and salicylates may result in increased INR values and increase the risk of bleeding.
redisposing Factors:	None determined.
Patient Management:	Avoid concomitant administration of these drugs. If salicylate use is necessary, monitor proffbrombin time, bleeding time, or INR values closely. When possible, the administration of a non-aspirin salicylate would be preferable.
Necussion:	This interaction has been reported between aspirin and warfarin and between aspirin and dicumarol. Diffunisal, sodium salicylate, and topical methyl salicylate have been shown to interact with anticoagulants as well. Based on the proposed mechanisms, other salicylates would be expected to interact with anticoagulants as well. The time or highest risk for a coumarin-type drug interaction is when the precipitant drug is initiated, altered, or discontinued.
References:	 Quick AJ, Clesceri L. Influence of acetylsalicylic acid and salicylamide on the coagulation of blood. J Pharmacol Exp Ther 1960;128:95-8.
	 Watson RM, Pierson RN Jr. Effect of anticoagulant therapy upon aspirin-induced gastrointestinal bleeding. Circulation 1961 Sep;24:613-6.
	3.Barrow MV, Quick DT, Cunningham RW. Salicylate hypoprothrombinemia in rheumatoid arthritis with liver disease. Report of two cases. Arch Intern Med 1967 Nov;120 (5) 620-4.
	 Weiss HJ, Aledort LM, Kochwa S. The effect of salicylates on the hemostatic properties of platelets in man. J Clin Invest 1968 Sep; 47(9):2169-80. Udall JA, Drug interference with warfarin therapy. Clin Med 1970 Aug; 77:20-5.
	 Fausa O. Salicytate-induced hypoprothrombinemia. A report of four cases. Acta Med Scand 1970 Nov; 188(5):403-8.
	7.Zucker MB, Peterson J. Effect of acetylsalicytic acid, other nonsteroidal anti-inflammatory agents, and dipyridamole on human blood platelets. J Lab Clin Med 1970 Jul;76 (1):66-75.
	8.0 TReilly RA, Sahud MA, Aggeler PM. Impact of aspirin and chlorthalidone on the pharmacodynamics of oral anticoagulant drugs in man. Ann N Y Acad Sci 1971 Jul 6;179:173-86.
	9.Dale J, Myhre E, Loew D. Bleeding during acetylsalicytic acid and anticoagulant therapy in patients with reduced platelet reactivity after acrtic valve replacement. Am Hear J 1980 Jun 99(6):746-52.
	10. Donaldson DR, Sreeharan N, Crow MJ, Rajah SM. Assessment of the interaction of warfarin with aspirin and dipyridamole. Thromb Haemost 1982 Feb 26;47(1):77. 11. Chesebro JH, Fuster V, Ehvback LR, McGoon DC, Pluth JR, Puga FJ, Wallace RB, Danielson GK, Orszulak TA, Pleihler JM, Schaff HV. Trial of combined warfarin plus dipyridamole or aspirin therapy in prosthetic heart valve replacement. danger of aspirin compared with dipyridamole. Am J Cardiol 1983 May 15,51(9):1537-41. 12. Chow WH, Cheung KL, Ling HM, See T. Potentiation of warfarin anticoagulation by topical methylsalicytate ointment. J R Soc Med 1989 Aug;82(8):501-2.
	13.Meade TW, Roderick PJ, Brennan PJ, Wilkes HC, Kelleher CC. Extra-cranial bleeding and other symptoms due to low dose aspirin and low intensity oral anticoagulation. Thromb Haemost 1992 Jul 6;68(1):1-6.
	14 Dentali F, Douketis JD, Lim W, Crowther M. Combined aspirin-oral anticoagulant therapy compared with oral anticoagulant therapy alone among patients at risk for cardiovascular disease: a meta-analysis of randomized trials. Arch Intern Med 2007 Jan 22:167(2):117-24.

Figure 55: The Professional Monograph Associated with the DDI/PM Easy Search

Duplicate Therapy

Duplicate Therapy results the Duplicate Therapy for the drugs selected in the Drugs to Check box. The record contains the Therapeutic Drug Class that the two drugs belong to and Duplicate Allowance numerical value (0,1, 2, 3, or 4) followed by a short message stating these two drugs may represent a duplication in therapy. To view the Duplicate Therapy record in PECS, click the Link to record in PECS.

Duplicate Therapy Results

Duplicate Therapy - FDB

ASPIRIN ORAL PACKET 650 MG (GCN: 12000)
Coumadin 10 mg tablet (GCN: 6559)

Therapeutic Class:
Duplicate Allowance:

Antiplatelet and Antithrombotic Drugs
0 Use of ASPIRIN ORAL PACKET 650 MG and Coumadin 10 mg tablet may represent a duplication in therapy based on their association to the therapeutic drug class

Link to record in PECS

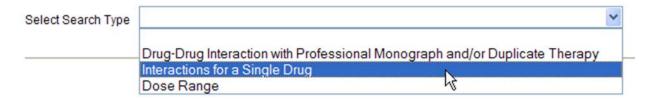
Figure 56: Duplicate Therapy Easy Search Results

8.3.3 Easy Search Interactions for a Single Drug Query

Interactions for a Single Drug allows you to generate a report for all the drug pairs that would be returned in VistA for the selected drug. The report displays FDB and Approved VA custom drug pairs with the specified severity level. FDB drug pairs will display only if there is not a corresponding Approved VA customized drug pair.

To perform a Drug Interactions Report Query:

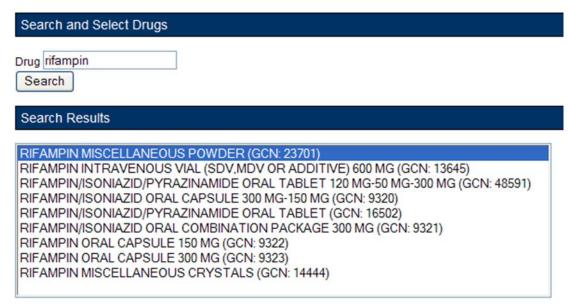
1. Select "Interactions for a Single Drug" from the Select Search Type drop-down list.



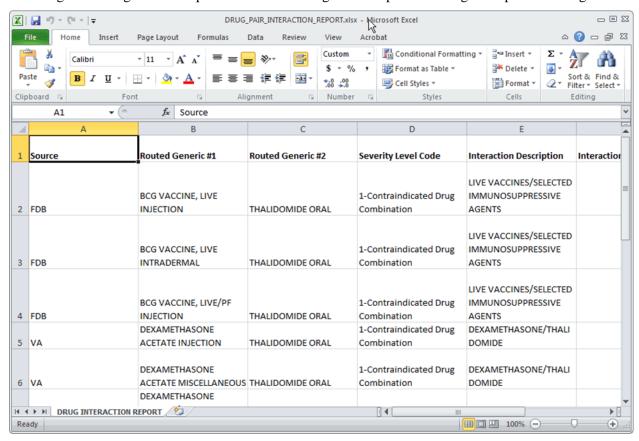
2. From the Select Information Type panel, choose the desired Severity Level with the appropriate radio button - Severity Level 1 (contraindicated), Severity Level 2 (severe), or Severity Levels 1 (contraindicated) and 2 (severe).



3. Enter a partial string or whole drug name into the Drug field and click Search. Items that match the search string are displayed in the Search Results box. The drug list displays the drug name, dose, route of delivery, and the drug's GCN sequence number. Note that if both a dispensable generic drug and dispensable drug are found that have the same GCN sequence number, only the dispensable drug are displayed on the list. Select an entry from the list.



4. Click the Generate Report button. The report generates in Excel. It contains the FDB and VA custom drug pairs whose severity level matches the selected severity level and contain a routed generic drug that corresponds to the selected generic dispensable drug or dispensable drug.



Interactions for a Single Drug Report Details

Field	Description
Source	Source of the record; either VA or FDB
Routed Generic #1	A generic drug name, e.g. "Rifampin Oral"
Routed Generic #2	A generic drug name, e.g. "Rifampin Oral"
Severity Level Code	The severity of the interaction.
Interaction Description	A brief description of the interaction.
Interaction ID	A numerical identifier assigned to the interaction.
Corresponding FDB Interaction ID	VA records only: the interaction as described by First DataBank. If there is no corresponding interaction, this field will contain '0'.
Action Date	The date and time of the most recent update to the record.

8.3.4 Potential Easy Search Result and PECS Record Discrepancy

The custom detail pages in PECS 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, Easy Search uses 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 has not gone through this process, 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.

Below are examples of discrepancies. Remember that these discrepancies cannot be duplicated and redisplayed after a custom update has been approved and run through DATUP, so do not try to recreate them. They are for informational purposes only, and even show an older screen capture of PECS (no Contact Us tab).

Example #1, from Easy Search:

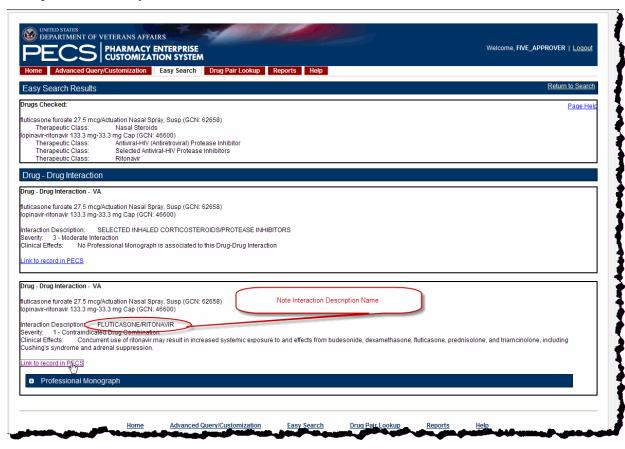


Figure 57: Easy Search DDI Record

Example #2, shown by clicking the "Link to record in PECS" link as is shown above. This discrepancy means the custom record has not been approved and/or not processed through DATUP. This potential discrepancy applies to Drug-Drug Interaction, Professional Monograph, Duplicate Therapy, and Dose Range concepts.

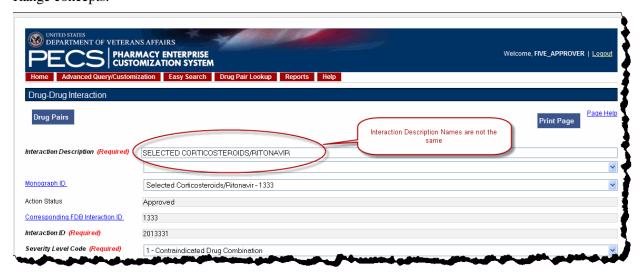


Figure 58: Referenced PECS Record with Name Discrepancy

8.4 Drug Pair Lookup

The Drug Pair Lookup page provides the ability to perform a quick query search on the most common elements: Drug A, Drug B, Interaction, and Severity Code.

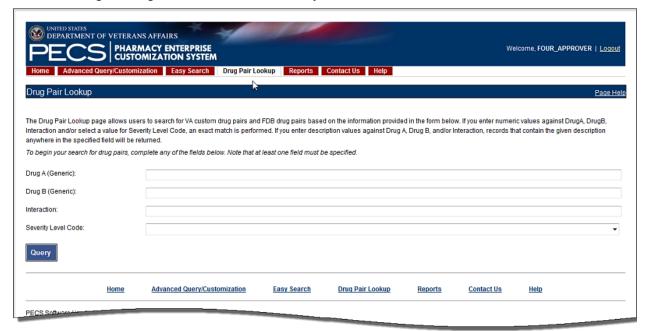


Figure 59: Drug-Drug Pair Lookup Window

You can perform a simple query to find a record from the FDB-DIF and VA Custom tables. Enter query criteria in any or all of the four entry fields (Drug A, Drug B, Interaction, or Severity Level Code). The results are displayed under the VA Table Results and FDB Table Results panels. These consist of active

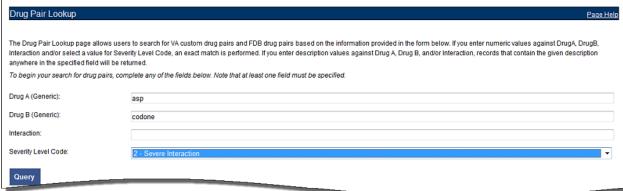
customized Drug Pair records from the VA custom database that are available for modification, as well as their related Drug Pair records from the FDB database from which they were customized.

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 number and description associated with the drug pair. This can be entered in conjunction with the Drug A and Drug B entries or can be used on its own. Enter either *all* of the Interaction ID, or all or part of the interaction description.
- Severity Level Code A drop-down list of available severity codes that are allowed for an interaction. This can be used on its own, but is most useful to limit the results produced by the other criteria.

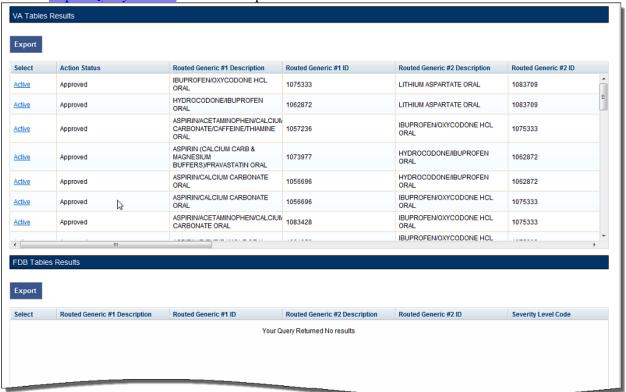
To perform a Drug Pair Lookup query:

1. Enter as much information as possible into the query form. The more detail that is added to the query, the more relevant the results.



2. Click the Query button.

3. Drug Pairs matching the query criteria (both VA and FDB) will be displayed. If the results are unsatisfactory, you can adjust the query criteria and click the Query button again. You can also Export Query Results to an Excel spreadsheet.



4. Click the adjacent link in the Select Column to view the drug pair record. VA records will display and Active link; FDB records display an Open link.

Select	Action Status	Routed Generic #1 Description	Routed Generic #1 ID
<u>Active</u>	Approved	IBUPROFEN/OXYCODONE HCL ORAL	1075333
Active	Approved	HYDROCODONE/IBUPROFEN ORAL	1062872
Active	Approved	ASPIRIN/ACETAMINOPHEN/CALCIUN CARBONATE/CAFFEINE/THIAMINE ORAL	1057236

5. To further customize the record, click the Interaction ID link to display the Drug-Drug Interaction (and the associated Drug Pairs).

Severity Level Description	Severe Interaction
Interaction ID (Required)	2001192 - NSAIDS/LITHIUM
Corresponding FDB Interaction ID	119
Reverse FDB DDI ID	31881
Action Date	2010-05-05 10:50:47

Export Query Results

You can export the results of a Drug Pair Lookup query to an Excel spreadsheet.

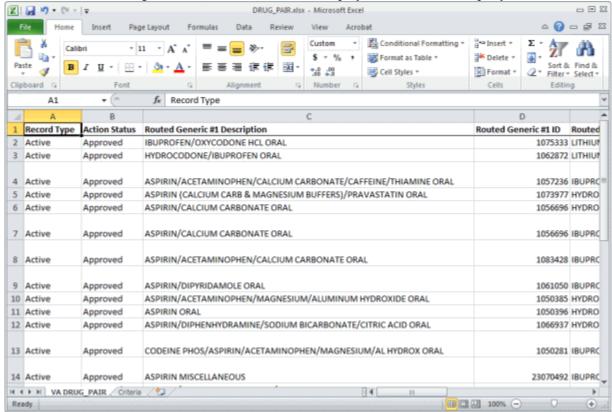
- 1. Perform a Drug Pair Lookup Query.
- 2. Click the Export button associated with the Results list. The Export option is available for both VA and FDB results.



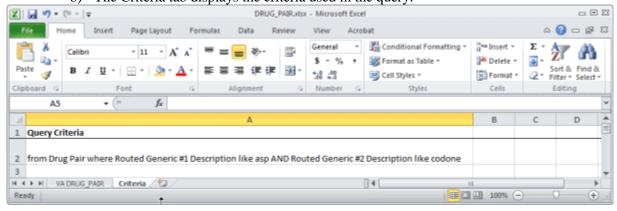
3. Click Open to display the History Report; click Save to save a copy of the report to your system.

4. The spreadsheet contains two tabs:

a) The Drug Pair tab (either VA or FDB) displays the results of the query.

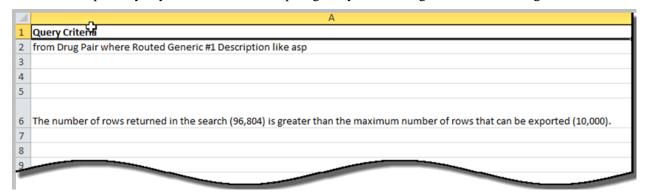


b) The Criteria tab displays the criteria used in the query.



Export Query Line Limit

If you make a query that returns more than 10,000 records, be aware that there is a 10,000 line limit on the export to the spreadsheet. If your query returned more than 10,000 records and you submitted the records for export anyway, the 2^{nd} tab in the report gives you a message like the following:



For more information, see

- Drug Pair Detail
- Drug-Drug Interaction Detail

8.5 Reports

The Reports tab displays a list of available reports in PECS.

Note: The Reports tab is not visible to users with the Requestor or Release Manager roles.

Note to Assistive Technology Users: Please refer the documentation included with your screen reader for commands related to reading column and row headers.

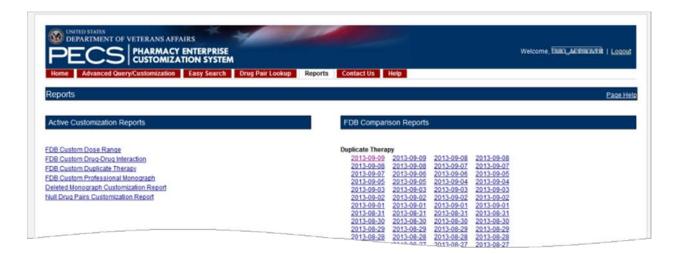


Figure 60: List of Reports

There are two types of Reports:

- Active Customization Reports
- FDB Comparison Reports

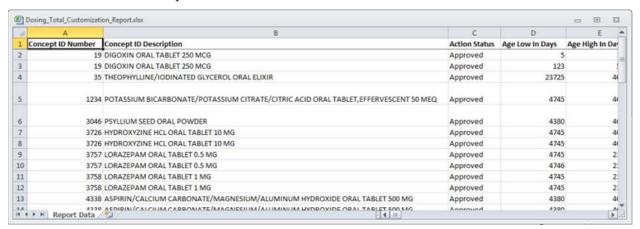
Reports are generated in the form of Excel spreadsheets. To run a Report, click the associated link.

8.5.1 Active Customization Reports

There are currently sixe Active Customization Reports:

- FDB Custom Dose Range Report
- FDB Custom Drug-Drug Interaction Report
- FDB Custom Duplicate Therapy Report
- FDB Custom Professional Monograph Report
- Deleted Monograph Customization Report
- Null Drug Pairs Customization Report

The first four reports display concept records in an Approved status along with their corresponding FDB record data. Here is an example:



The last two reports look for problems – the Deleted Monograph Customization Report displays Drug-Drug Interactions (DDIs) with an associated Professional Monograph (PM) that has been deleted (e.g. the FDB update deleted an FDB PM, and that FDB PM is associated to a custom DDI), and the Null Drug Pairs Customization Report displays custom DDIs that have an associated Drug Pair in which one or both routed generics is null because an FDB update deleted the routed generic(s).

See the details in Active Customization Reports for additional information.

8.5.2 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, Dose Range, 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.

Changed data is marked with an asterisk (*) and colored red. The reports are organized by type and the date of the FDB Incremental Update.

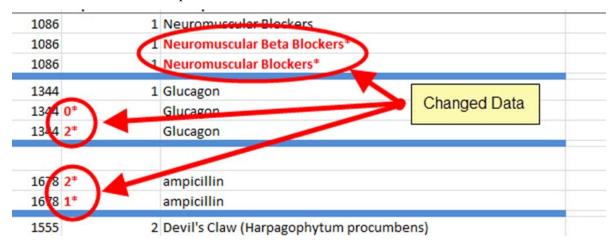


Figure 61: Examples of Changed Data

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

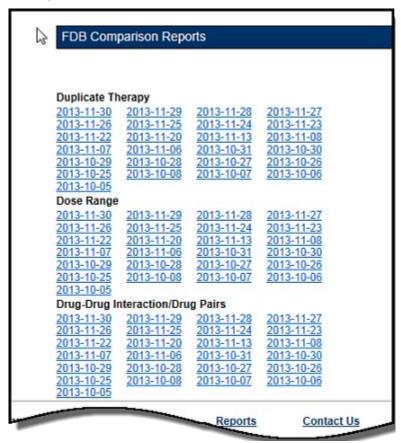


Figure 62: Examples of Incremental Updates Under Report Headings

8.5.3 Reports Explained

See the main <u>FDB Comparison Reports</u> section for all information on reports, such as what they display and how they are used, as well as how to run them.

8.6 Contact Us

The Contact Us page contains a list of PECS Project Contacts should you need additional information about the PECS product. The content of the Contact Us page is decided by users with the Administrator role. Click the link associated with the name to send that person (or group) an email.

Note: Clicking the link opens your mail application and a new email message to the person specified in the properties of the link. This may produce a warning message. This is normal.

Contact Us

For general questions or comments about PECS, please contact <u>PECS Product Manager</u> - (000) 000-0000 Contact the <u>PECS Workgroup</u>

Key Members:

<u>Clinical Pharmacist</u> - (999) 888-7777 <u>Pharmacist Specialist</u> - (666) 555-4444 <u>PBM Lead</u> - (333) 222-1111

Figure 63: Example of Contact Us Data

Note that the above example is only an example – it can be changed to display just about anything. For information on how an Administrator edits the Contact Us page, see <u>Contact Us</u>.

8.7 Custom Updates

The Custom Updates tab is seen and used by a Release Manager to generate a zip file containing files for each Order Check in the FDB update file format. Both updates files are created by clicking the "Create New Update" button.

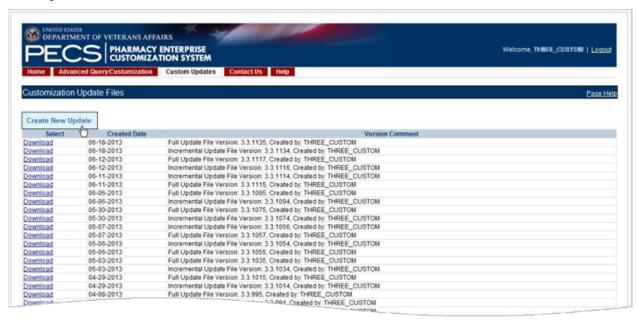


Figure 64: Custom Updates Tab for Release Manager

For information on how to run custom updates and an explanation of Update Files, see <u>How to Perform</u> Custom Updates and Update Files Explained under the Release Manager role.

8.8 Administration

The Administration tab is used by PECS users with Administrator privileges to perform specialized tasks such as modifying certain aspects of the PECS environment, adding or deleting Approver users, and removing Null Drug Pairs. The Administration tab is visible only to users with Administrator role privileges.



Figure 65: Administrator's Home Page

See Administrator in the Home Page By Role section for more information.

8.9 Help

The Help tab launches the PECS Online Help System and displays the "front page" of the Help System. To get context-sensitive help, click the Page Help link on the page you need help with.

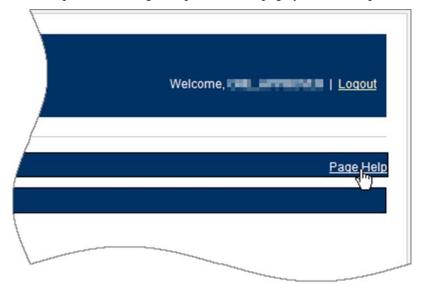


Figure 66: Link to Help in PECS Application

9 Detail Pages

One of the main screens that users encounter is the detail page of any of the four concepts.

9.1 Detail Page Overview

Detail Pages display the details of the record appropriate to the concept being viewed for both FDB and VA records. The sections below are taken from a Drug-Drug Interaction records, but the detail page behaviors are consistent among the different Concepts.

FDB Records

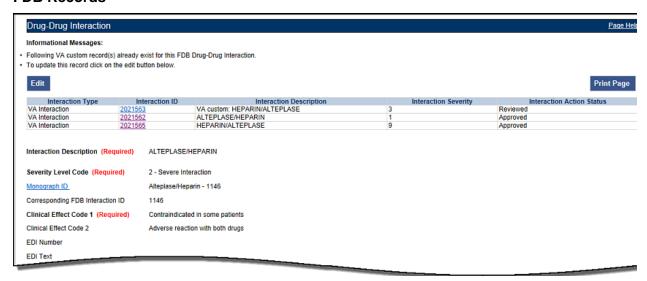


Figure 67: FDB DDI Record

With FDB records, you can:

- Review record details see <u>Reviewing Record Details</u>
- View VA-customized versions of this same record see View Associated Record Links

VA Records

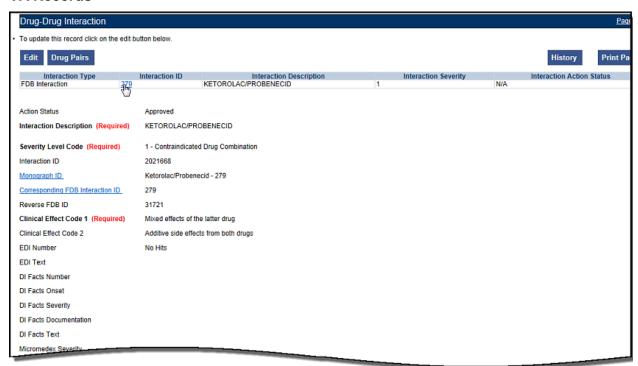


Figure 68: VA Custom DDI

With VA records, you can:

- Review record details see Reviewing Record Details
- Edit a Record
- Print a Record
- Add Pre-Customization Comments (see page <u>103</u>).
- View Associated Record Links and any additional VA-customized versions of the same record
- View a History Report
- View Field History (<u>Field-Level History Table</u>)
- View Export Date

9.2 Using Detail Pages

Detail pages provide information about the PECS records. The information on the page is slightly different for each concept, but the basic functions are the same.



Figure 69: Example of a Detail Page

9.2.1 Reviewing Record Details

From the Home Page, Approvers can review record details that they are assigned.

9.2.2 Modifying Record Details

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

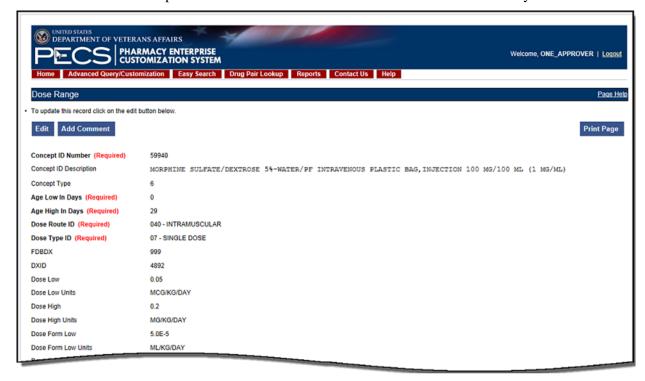


Figure 70: Dose Range Record - Read-Only

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.

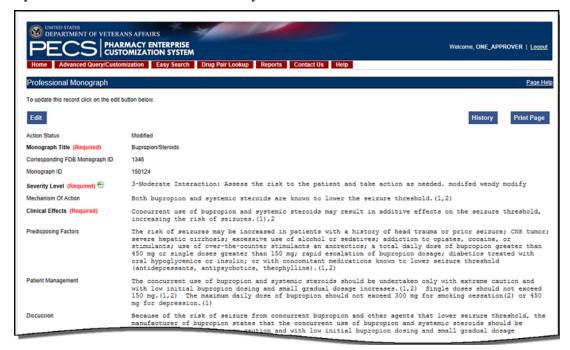


Figure 71: Professional Monograph Record- Read Only

Duplicate Therapy

Click the Edit button to modify the record.

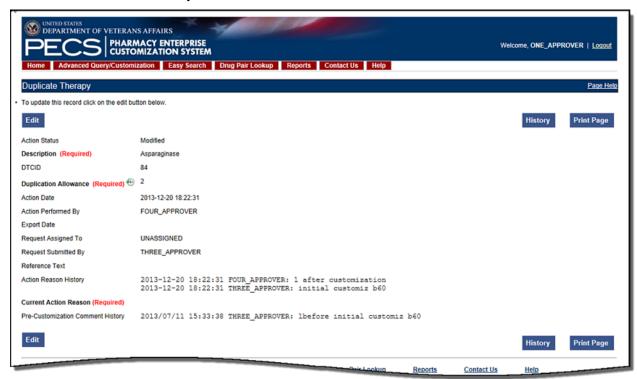


Figure 72: Duplicate Therapy Record - Read-Only

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.

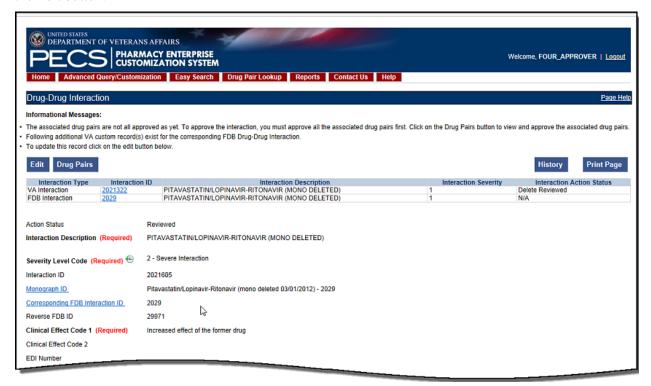


Figure 73: Drug-Drug Interaction Detail - Read-Only

9.2.3 Informational and Warning Messages

Some records have informational and warning messages associated with them. These messages provide information about the record itself and not necessarily the contents of the record.

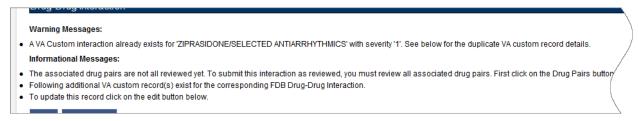


Figure 74: Informational and Warning Messages

9.2.4 Edit a Record

Click the Edit button to make changes to the record. If the current record is an FDB record, editing will result in a new customization.



9.2.5 Print a Record

The Print Page button calls the browser Print function, allowing you to print the page to any printer you have connected to your system.



9.2.6 Add Pre-Customization Comments

Approver users can add comments to FDB records that do not have customized VA versions. The comments are visible on the FDB record and contain the text of the comment as well as the date and time it was entered and the PECS User ID of the person who entered it. Once entered, these comments cannot be edited or deleted.

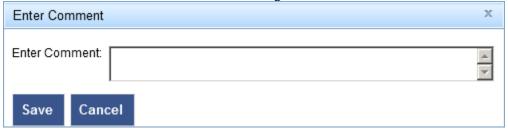
If the FDB record is customized, the pre-customization comments will become part of the customized record. Once customized, you cannot add additional comments to an FDB record.

To add a pre-customization comment:

1. Click the Add Comment button:



2. Enter the comment in the Enter Comments dialog box:



3. Click Save to save your changes; click Cancel to abandon the enter comments and return to the record. The comments appear in the Pre-Customization Comment History of the record.

Pre-Customization Comment History

2013/06/10 09:47:13 This interaction has been reviewed the NDF Support Group. After thorough review of drug interaction references, PBM documents and the medical literature it was determined that the interaction does not have sufficient evidence to be customized to a different level at this time.

9.2.7 View Associated Record Links

If an FDB record has been customized, links to the VA-customized records are provided.



Figure 75: VA Custom Record ID Links

VA records provide links to the original FDB record as well as any additional customizations created from the original FDB record.



Figure 76: VA Custom and FDB Record Links

9.2.8 History Report

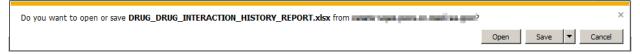
Click the History button to produce a History Report detailing all the changes made to the current record. The History Report is presented as a Microsoft Excel spreadsheet.

To display a History Report:

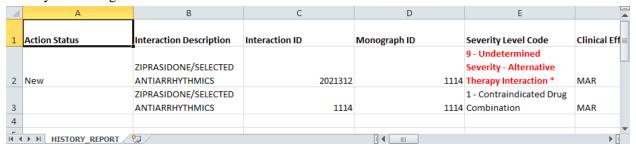
1. From the Detail page, click the History button.



2. Click Open to display the History Report; click Save to save a copy of the report to your system:



3. If you chose to Open the report, it will be displayed. If you chose Save, the report can be opened at any time using Excel.



9.2.9 Field-Level History Table

You can review a list of changes to an individual field by hovering over the History Table icon next to a field that has been changed. Field-level history is retained only while the record is in its current state. The field-level history is reset when the state changes to Approved or Deleted (Modified or Reviewed doesn't cause a reset). Field-level history is only displayed for Required Fields with the exception of Current Action Reason; field-level history is not retained for Current Action Reason, but it can be viewed on the History Report along with changes to non-required fields.



Figure 77: At-a-Glance History Icon

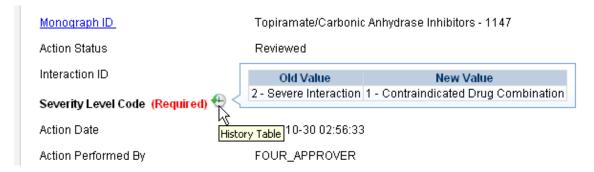


Figure 78: On-Screen History Table from Icon

9.2.10 Export Date

The Export Date field on the Detail Page for an approved or deleted record lists the date when the Release Manager executed the Custom Update command and the record was exported to the incremental update file. If a custom record is not approved or deleted, the Export Date field will be null.

Since records that roll back to the Approved Action Status are included in incremental updates, an updated export date will be in the Export Date field for the rollback record. However, in a deleted rollback record, the Export Date will not change because this type of record is not included in incremental updates.

The example shows the changes to the Export Date for a record that was customized after the Export Date functionality was implemented. The Export Date says null until the record is Approved and exported to the incremental file (Record Version #4). When the record gets into the Modified state, the Export Date value becomes null and a date does not appear until the record is Deleted and Exported to the incremental file (Record Version #9). When the record rolls back to the Deleted state, the Export Date value does not change because deleted rollback records are not included in incremental updates (Record Version #11). When the record gets back into the approved state, the Export Date stays null because it was not exported to the incremental update file (Record Version #14). However, when the record rolls back to the Approved state and is exported to the incremental update file, an Export Date value appears (Record Version #16).

Record Version	Action Date	Status	Export Date
1	2/5/2013	New	
2	2/10/2013	Modified	

Record Version	Action Date	Status	Export Date
3	2/11/2013	Review	
4	2/15/2013	Approved	
5	2/16/2013	Modified	
6	3/2/2013	Review	3/1/2013 (exported on 3/1)
7	3/2/2013	Approved	
8	3/2/2013	Delete Review	
9	3/2/2013	Delete	
10	3/5/2013	Modified	
11	3/5/2013	Delete	3/3/2013 (exported on 3/3)
12	3/7/2013	Modified	
13	3/7/2013	Review	3/3/2013 (rollback-not exported)
14	3/7/2013	Approved (record not exported)	
15	3/7/2013	Modified (rejected on 3/7)	
16	3/7/2013	Approved	3/8/2013 (exported on 3/8)

The Export Date functionality was implemented in PECS 5.0. If a record was customized before the Export Date functionality was implemented, the Export Date for the most recently approved or deleted record is set to that record's Action Date. For custom records in all other statuses, the Export Date value is null. In the example below, Export Date functionality was implemented on March 9, 2013. The record has been approved and deleted several times. The most recent approved record has an Action Date of 3/7/2013, so the Export Date for this record will be set to 3/7/2013.

Record Version	Action Date	Status	Export Date
1	2/5/2013	New	
2	2/10/2013	Modified	
3	2/11/2013	Review	
4	2/15/2013	Approved	
5	2/16/2013	Modified	
6	3/2/2013	Review	
7	3/2/2013	Approved	
8	3/2/2013	Delete Review	
9	3/2/2013	Delete	
10	3/5/2013	Modified	
11	3/5/2013	Review	
12	3/5/2013	Approved	
13	3/6/2013	Modified (Rejected on 3/7)	
14	3/7/2013	Approved	3/7/2013

Anyone who has access to the detail page can see the Export Date field. PECS allows an administrator to change Export Date field settings, such as the Display Name, on the Customize Settings page.

The Export Date is displayed on the History Report for each concept.

9.3 Drug Pair Detail

The Drug Pair detail page allows the user to view the details of an FDB Drug Pair or a VA Customized Drug Pair. In either case, this page is read only and the Drug Pair cannot be customized or modified from this page. Customization or modification of Drug Pairs is done through the VA Custom Drug-Drug Interaction detail page. See Drug Pair Customization for information on customizing drug pairs.

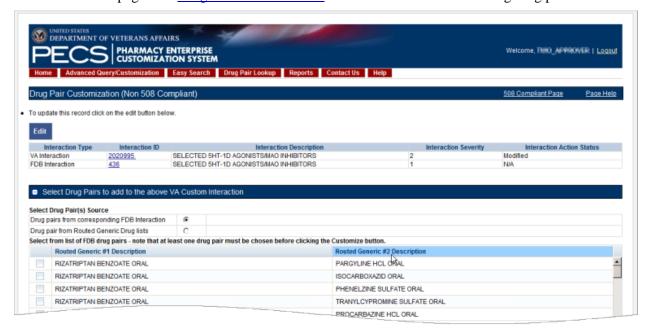


Figure 79: Drug Pair Customization Window (Non-508 Compliant)

The following sections describe what can and cannot be done and what can be viewed on a drug pair detail page.

9.3.1 Field Descriptions for FDB and VA Custom Drug Pair Detail Page

Field Name	Field Description	
Action Status	Applicable to VA record only. It is the status of this customization within the VA Approval Workflow.	
Routed Generic #1 (required)	The ID of the first drug in this Drug Pair.	
Routed Generic #1 Description	Applicable to FDB record only. The description of the first drug in this Drug Pair.	
Routed Generic #2 (required)	The ID of the second drug in this Drug Pair.	
Routed Generic #2 Description	Applicable to FDB record only. The description of the second drug in this Drug Pair	
Severity Level Code	Applicable to FDB record only. The severity level code for this Drug-Drug Interaction.	
Severity Level Description	The description of the severity level code for this Drug-Drug Interaction.	

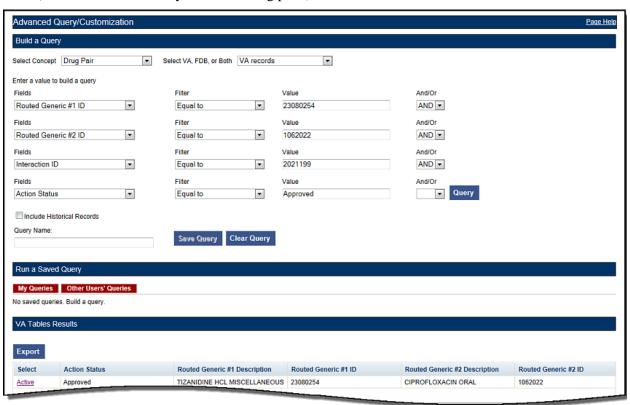
Field Name	Field Description
Interaction ID (required)	The FDB or VA Custom Drug-Drug Interaction ID that the drug pair is associated with.
Interaction Description	Applicable to FDB record only. The description of the Interaction ID that the drug pair is associated with.
Corresponding FDB Interaction ID	Applicable to VA records only. It is the Interaction ID of the FDB record from which the VA Drug interaction customization was created.
Reverse FDB ID	Applicable to VA records only. It is the Reverse FDB Drug-Drug Interaction ID, or the Reverse Interaction ID of the DDI FDB record from which the DDI custom record was created. For more information about the Reverse FDB DDI ID, see "Displaying the Reverse FDB DDI Interaction ID" on page 14.
Action Performed By	Applicable to VA records only. The name of the user who performed the action.
Request Assigned To	Applicable to VA records only. A drop down list to select an assigned user.
Request Submitted by	Applicable to VA records only. The name of the user that submitted this VA request.
Reference Text	Applicable to VA records only. Field for the user to enter any reference text needed to support customization of the drug pair.
Action Reason History	Applicable to VA records only. All historical 'current action reason' comments for this record, in one viewable field.
Current Action Reason	Applicable to VA records only. Free form text that can be used to specify the reason for taking the specific action of creating new, modifying, assigning, rejecting, reviewing, approving, or deleting the customization.
Export Date	Applicable to VA records only. Date that the approved or deleted drug pair record was exported to the incremental update file
Action Date	Applicable to VA records only. The date of the last action taken on the record.

9.3.2 Accessing the Single Drug Pair Detail Page

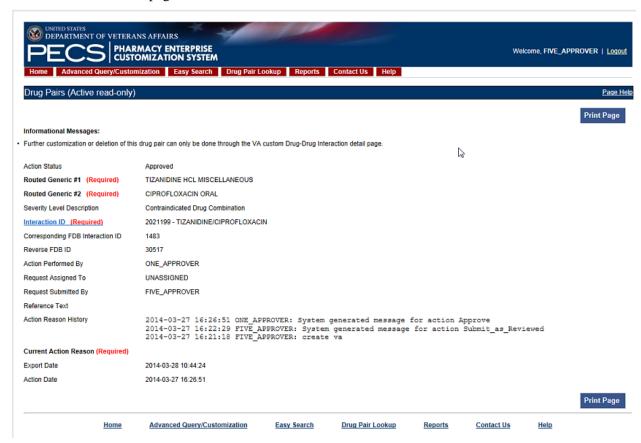
Note that you cannot modify or customize a drug pair if you display a single drug pair from a query on the Drug Pair concept. You can access it and get information about the Drug Pairs and their associated DDIs, however.

To access the single drug pair detail page through the Advanced Query/Customization tab:

1. Pick a Drug Pair concept, as the example below shows, and select one of the drug pairs displayed (in this case there is only one set of drug pairs).



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 Drug Pairs Detail Page is read-only. As it says in the Informational Messages, the only way to customize a drug pair is through the VA Custom DDI Detail Page. The easiest way to get to the DDI detail page is to click the Interaction ID link.

9.3.3 FDB Drug Pair Detail Page

When a user opens an FDB Drug Pair that is not customized, but the associated FDB Drug-Drug Interaction is customized, they will be presented with the following page:

Note: The informational message will contain all VA Custom Drug-Drug Interactions associated with the FDB Drug-Drug Interaction.

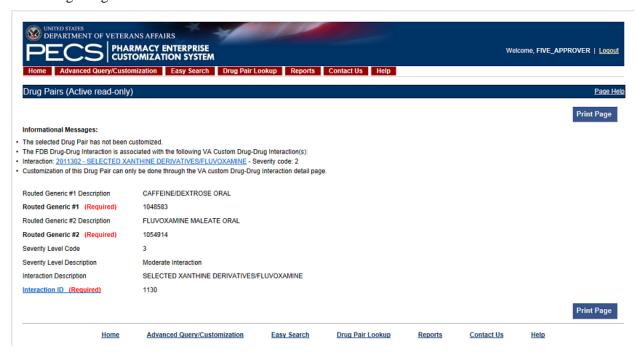


Figure 80: Informational Messages About Uncustomized Drug Pair

The easiest way to customize the drug pairs is to click the VA Customized Drug-Drug Interaction link in the informational message.

FDB Drug Pair Not Customized

When a user opens an FDB Drug Pair that is not customized, and the associated Interaction is also not customized, they will be presented with the following page.

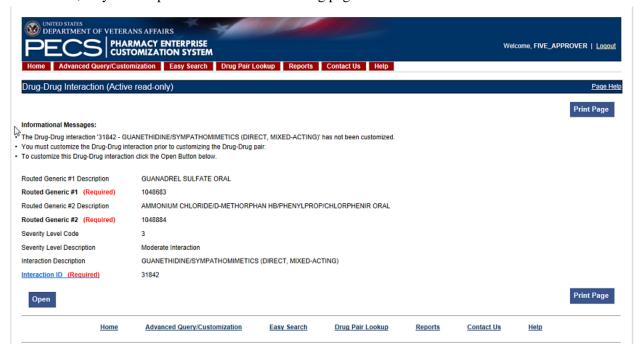


Figure 81: FDB Drug-Drug Interaction without Customized Drug Pairs

The easiest way to get to the Interaction to customize it is to click the Interaction ID link.

FDB Drug Pair Customized Once

When a user opens an FDB Drug pair that has been customized once, they will be presented with the customized drug pair and a link to the associated VA Drug-Drug Interaction ID.

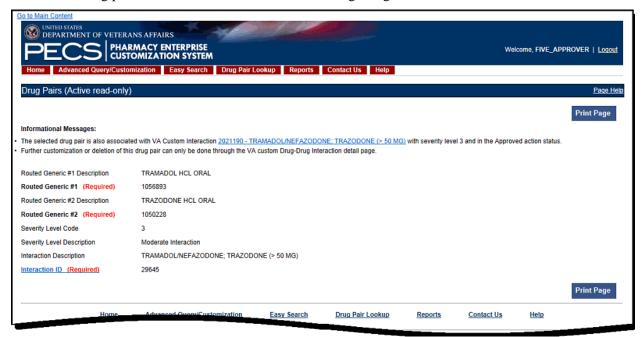
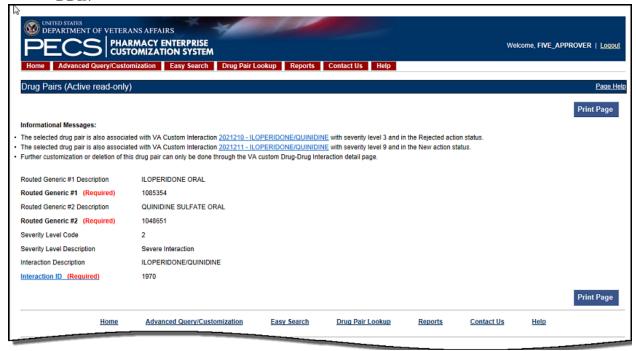


Figure 82: Drug Pair Detail Page (Read Only)

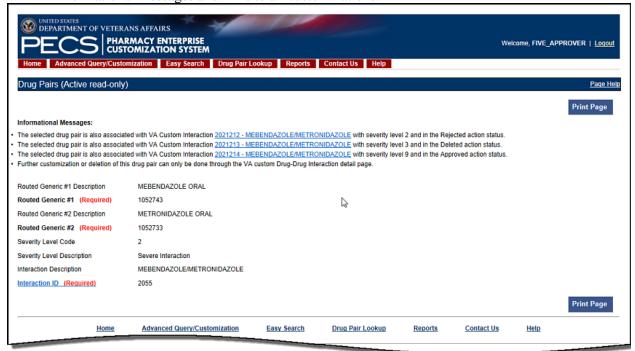
FDB Drug Pair Customized More Than Once

An FDB Drug Pair can be customized more than once. For example; a Drug Pair can be customized for a VA Drug-Drug Interaction and subsequently rejected or deleted. It can then be customized a second time for a different VA DDI. In this case, when the user opens the FDB Drug Pair record, they will not only get information about the FDB drug pair and its associated FDB DDI, they will see two messages about the drug pair and the custom VA DDIs it is associated with. One message says that the drug pair is rejected and another message says that it is in the New Action Status. Two examples follow:

The following example shows what will display if the user opens an FDB Drug Pair that was
customized for and subsequently rejected from DDI 2021210, and then customized a second time
for DDI 2021211. Note the informational messages and the links to the FDB and custom VA
DDIs:



2. The following example shows what will display if the user opens an FDB Drug Pair that was customized and subsequently rejected from DDI 2021212, customized a second time and subsequently deleted from DDI 2021213, and customized for DDI 2021214. Note the informational messages and links to all customizations:



9.3.4 VA Customized Drug Pair Detail Page

When the user opens a VA Customized drug pair, they will be presented with the customized Drug Pair as follows:

The Drug Pair Detail window when accessed from <u>Drug Pair Lookup</u>.

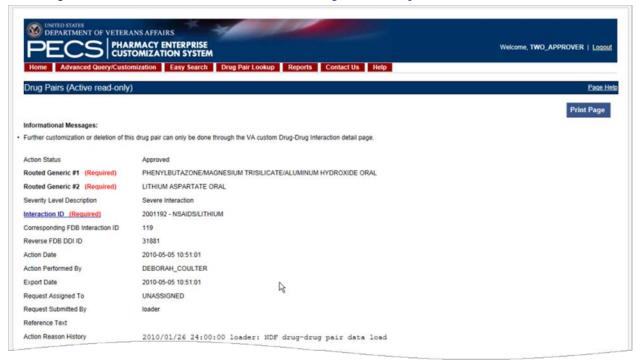


Figure 83: VA Customized Drug Pair

9.4 Drug-Drug Interaction Detail

The Drug-Drug Interaction Detail page allows users to view the details of an FDB Drug-Drug Interaction and create a VA Customization, if desired. If you are viewing an FDB Drug-Drug Interaction you will see the Customize button at the bottom of the record. Any values changed (and then the Customize button clicked) will result in a VA Customization of this FDB Drug-Drug Interaction.

Requestors and Approvers can create a VA Customization request. To create a customization request:

- 1. Click the Edit button
- 2. Modify the record as desired
- 3. Click the Customize button

This page also allows you to view and/or modify the details of a VA Customized Drug-Drug Interaction. If you are viewing a VA Customized Drug-Drug Interaction, you will NOT see the Customize button (if the record can be modified from its current state and you have permissions to do so, you will see the Modify or other VA Approval Workflow buttons.) Also on this page, you will find the Drug Pairs button. Clicking this button will take you to the Drug Pair customization page to create or delete custom drug pairs to associate with the custom Drug-Drug Interaction. On Approved VA custom records, the Submit for Delete button will not appear until all associated drug pairs are in Delete Reviewed, Deleted or Rejected action status.

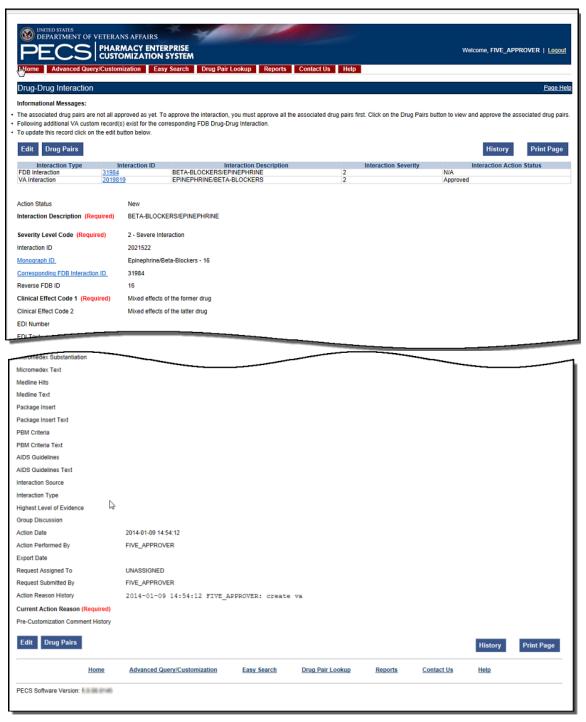


Figure 84: Detail Page of VA Customized DDI, Top and Bottom

9.4.1 Creating Multiple VA Custom DDIs 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:

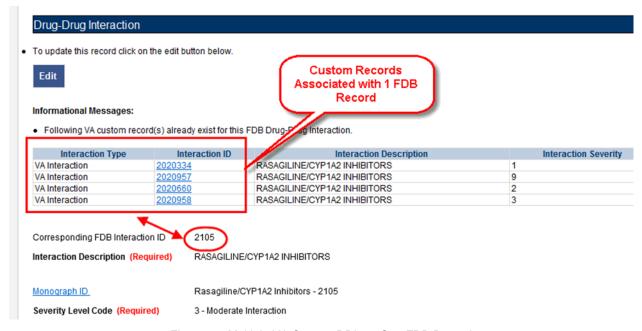


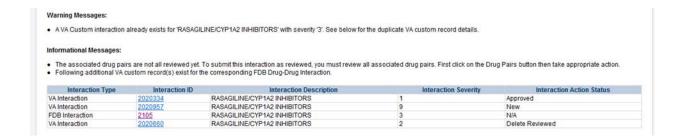
Figure 85: Multiple VA Custom DDIs to One FDB Record

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.

9.4.2 Create Multiple DDIs per One FDB Record

To 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.
- 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):



9.4.3 Cannot Add Identical Drug Pairs to Same DDI

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. One cannot add a drug pair that currently exists for the selected DDI:



Figure 86: Error for Duplicate Drug Pairs for One DDI

You will also receive an error if you attempt to customize a drug pair for a DDI in Reverse Order:



Figure 87: Error for Duplicate Drug Pairs in Reverse Order for One DDI

9.4.4 Reverse Drug-Drug Interactions

Multiple Drug-Drug Interaction records may exist for the same drugs listed in reverse order. For example, FDB Interaction ID 1234 is Drug A/Drug B and FDB Interaction ID 30766 is Drug B/Drug A. Information about reverse DDIs is displayed in the table at the top of the detail page. The screen shot below displays FDB record 1637, which has a DDI customization and a reverse DDI customization.

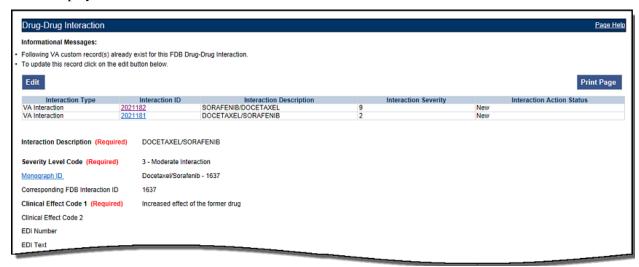


Figure 88: FDB DDI with a Customization and a Reverse Customization

If you click the link associated with the reverse DDI, you will see its detail page (next screen shot):

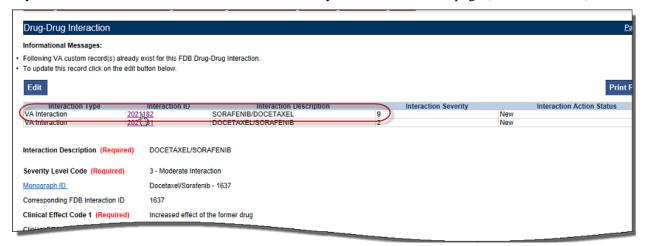


Figure 89: Choosing the Reverse VA DDI Customization

The detail page of the Reverse VA Customization is displayed:

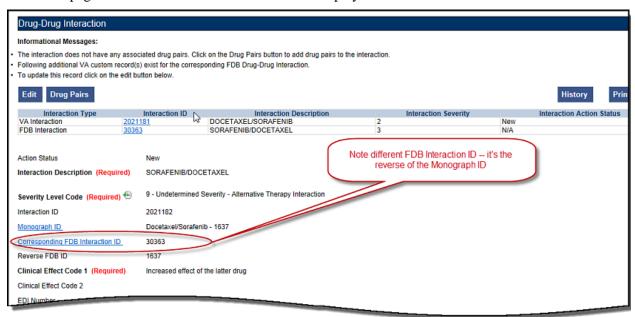


Figure 90: Reverse FDB Interaction ID

Displaying the Reverse FDB DDI Interaction ID

The Reverse FDB DDI Interaction ID is displayed in the VA custom DDI and DP Detail pages, in the results of DDI and Drug Pair queries and on the FDB Custom DDI Report. The Reverse FDB DDI Interaction ID is defined as the reverse of the FDB DDI ID and is obtained by executing this equation: 32,000 - (minus) FDB Monograph ID.

For example:

- If FDB monograph ID is 2246, the reverse FDB DDI ID is 29745 (32,000 2246 = 29745)
- If FDB monograph ID is 29754, the reverse FDB DDI ID is 2246 (32,000 29754 = 2246)
- If FDB monograph ID is 0, the reverse FDB Interaction ID is 0 (i.e., DDI was created from scratch using the Open Blank Form option)

Displaying the reverse FDB DDI Interaction ID in the DDI and DP detail pages, query results, and reports enables you to find information about reverse DDIs easily.

9.4.5 Working with Drug Pairs within the DDI

Note that you can work with a drug pair only by starting from the Drug-Drug interaction page, and clicking the Drug Pairs button.

See the following links for additional information.

• Drug Pair Customization

9.4.6 Review a Drug-Drug Interaction

An Approver may be assigned to review a drug-drug interaction.

If a Drug-Drug Interaction is New, or Modified, you will be able to perform a "Submit as Reviewed" action (i.e., click the Submit as Reviewed button on the DDI window) if:

• At least one of the associated drug pair has been Approved or Reviewed

AND

• No associated drug pairs are in the New or Modified state

To review a Drug-Drug Interaction:

- 1. From the Drug-Drug Interaction record, click Edit.
- 2. If Submit as Reviewed is not an available option, the record does not meet the criteria for review and approval. Click Cancel Edit, then click Drug Pairs. See Review A Drug Pair for information on reviewing drug pairs.
- 3. Enter text in the Current Action Reason field.
- 4. Using the Assigned To list, select the person to Approve the drug-drug interaction. If you are not sure who this should be, select Unassigned.
- 5. Once the required fields are populated and the Drug Pairs associated with the drug-drug interaction record meet the required criteria, you have the following options:
 - a) Click Submit as Reviewed to indicate that you have reviewed and agree that the drugdrug interaction is valid and should be approved.
 - b) Click Reject to indicate that you do not agree that the drug-drug interaction is valid

- c) Click Modify to add additional information or edit the existing information on the drugdrug interaction record
- d) Click Cancel Edit to abandon the current editing session and leave the record unchanged

9.4.7 Fields

Table Heading Name	Table Heading Description
Monograph ID	The Professional Monograph ID associated with the drug interaction pair.
Action Status	Applicable to VA record only. The point this customization is at, within the VA Approval Workflow.
Corresponding FDB Interaction ID	The system ID of the FDB record from which the VA customization was created.
Interaction ID	The system ID of this VA customization.
Reverse FDB ID	The FDB ID associated with a customized reverse interaction ID.
Severity Level Code	The level of severity for this Drug-Drug Interaction.
Action Date	Applicable to VA record only. The date of the last action taken on the record.
Action Performed By	Applicable to VA record only. The name of the user that performed the last action.
Request Submitted By	Applicable to VA record only. The name of the user that submitted this VA request.
Action Effective Date	Applicable to VA record only. The date of the last action taken on the record.
Request Assigned To	Applicable to VA record only. A drop down list to assign an approver.
Clinical Effect Code 1	Clinical effect code.
Clinical Effect Code 2	Clinical effect code
EDI Number	The severity level from the Evaluations of Drug Interactions (EDI) system.
EDI Text	The interaction text found in EDI.
DI Facts Number	Severity number of interaction found in DI Facts.
DI Facts Onset	The onset of the interaction as found in DI facts.
DI Facts Severity	The severity level of the interaction found in DI facts.
DI Facts Documentation	Documentation of the interaction found in the DI Facts.
DI Facts Text	The text of the interaction from DI facts.
Micromedex Severity	The severity found in Micromedex.
Micromedex Onset	The onset of the interaction as found in Micromedex.
Micromedex Substantiation	Level of documentation of the interaction found in the Micromedex.
Micromedex Text	The interaction text found in Micromedex.
Medline Hits	A dropdown list to select whether or not this reference was checked.
Medline Text	Brief description of literature results.
Package Insert	A dropdown list to select whether or not this reference was checked.
Package Insert Text	The interaction text found in the package insert.
PBM Criteria	A dropdown list to select whether or not this reference was checked.
PBM Criteria Text	Text information found in PBM criteria.
AIDS Guidelines	A dropdown list to select whether or not this reference was checked.
AIDS Guidelines Text	Text information from the AIDS guidelines.
Interaction Source	A drop-down list to select source.

Table Heading Name	Table Heading Description
Interaction Type	A drop-down list to select type.
Highest Level of Evidence	A drop-down list to select the source of the evidence to support the described drug-drug interaction.
Group Discussion	General comment from meeting.
Action Reason History	Applicable to VA record only. All historical current action reason comments for this record, in one viewable field.
Current Action Reason (optional)	Applicable to VA record only. Free form text that can be used to specify the reason for taking the specific action of creating new, modifying, assigning, rejecting, reviewing, approving, or deleting the customization.
Export Date	For Approved or Deleted records. Indicates the date of the last Custom Update. See Export Date for additional information.
Pre-Customization Comment	Approvers can add comments to uncustomized FDB records in this field and click the add comment button to save the comment
Pre-Customization Comment History	Displays all comments that have been added to this record prior to customization

9.5 Drug Pair Customization (Non 508-Compliant) Detail

The Drug Pair Customization (Non 508 Compliant) page allows users to create or delete drug pairs associated with the VA Customized Drug-Drug interaction as well as perform mass VA Workflow updates to all associated Drug Pairs. To reach this page, the user must click the 'Drug Pairs' button on a VA customized Drug-Drug interaction detail page.

The table on the page displays information related to the drug pair.

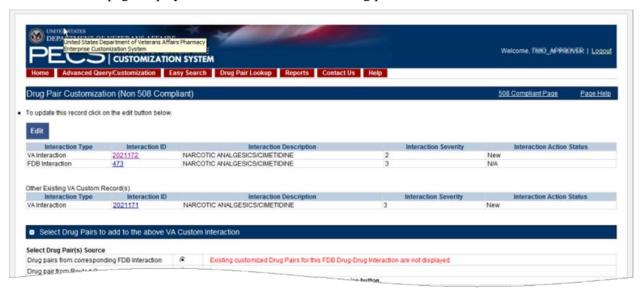


Figure 91: Drug Pair Customization Window

Field Name	Field Description
Interaction Type	The type of interaction displayed, either VA or FDB.
Interaction ID	The numerical reference number assigned to the interaction by the agency referenced in the Interaction Type field.
Interaction Description	The name of the drug associated with the interaction.

Field Name	Field Description
Interaction Severity	A numerical indicator of the severity of the interaction.
Interaction Action Status	The status of the interaction in the VA Approval Workflow. The Action Status for FDB Records will always be 'N/A,' as it does not go through the VA Approval Workflow

There are two methods to add drug pairs to a drug-drug interaction customization: from existing FDB Drug Pairs (see page 129) and from Routed Generics (see page 131).

Fields

Shaded fields cannot be modified in PECS.

Field Name	Field Description
Reference Text	Field for the user to enter any drug pair reference text needed to support the addition of this/these drug pair(s).
Current Action Reason	Applicable to VA record only. Free form text that can be used to specify the reason for taking the specific action of creating new, modifying, assigning, rejecting, reviewing, approving, or deleting the customization.

Buttons

Button Name	Button Description
Customize	Creates the Drug Pair record and associates it to the VA Customized Drug-Drug Interaction.
Cancel Edit	Disregards chosen Drug Pair and any text entered into fields and collapses this panel.

9.5.1 Drug Pairs Panel

The Drug Pairs panel contains all the VA Customized Drug Pairs already associated to the VA Customized Drug-Drug Interaction (noted at the top of the page). The panel contains

- Interaction Description VA Customized Drug-Drug Interaction Description
- Routed Generic #1 Description First drug in the drug pair
- Routed Generic #2 Description Second drug in the drug pair
- Action Status current status of the Drug Pair
- Request Submitted By User ID of the PECS user who made the initial customization request
- Action Date The date of the most recent action
- Action Performed By User ID of the PECS user who performed the most recent action
- Request Assigned To User ID of the PECS user who is responsible for reviewing the drug pair information
- Interaction ID The numerical identifier for the Drug-Drug Interaction
- Severity Level Description A text description of the interaction severity
- Reference Text Contents of the Reference Text field
- Severity Level Code A numerical identifier for the severity of the Drug-Drug Interaction

The checkboxes at the top allow the user to what is displayed in the interaction table by Action Status (Historical records are not displayed). The drug pairs must be in the same state before an action can be performed on them.



Figure 92: Drug Pair List Filters

The 'Get Record Counts' button will display the count of all VA customized drug pairs. This helps the user to determine how many drug pairs to select to perform an action against at one time. It is recommended that quantities be limited to 200 drug pairs at a time to prevent negative impacts to system performance.

For more information, see the following:

- Customizing Drug Pairs from the Selection List
- <u>Drug-Drug Interaction Detail</u>

9.5.2 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/status 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 modified 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 the home page tables that displays the row "Approved Drug-Drug Interaction with Pending Drug Pairs."

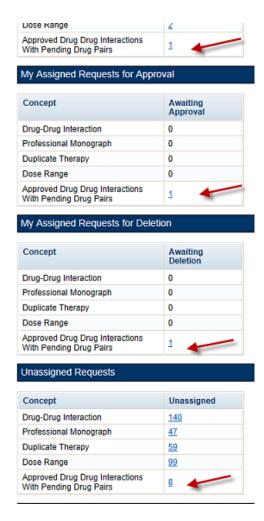


Figure 93: Approved DDIs with Pending Drug Pairs on Home Page

From the screen above, 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 that displays the results for all Drug-Drug Interactions with associated Drug Pairs assigned to you in that state. Here you can act on the drug pairs.



Figure 94: 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:

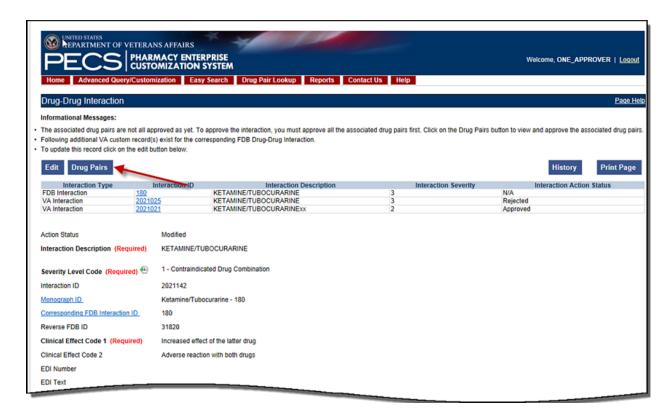


Figure 95: DDIs with Needed Drug Pairs – Add with Drug Pairs Button

After you click the Drug Pairs button, you can go through the process described in <u>Customizing Drug</u> <u>Pairs from the Selection List</u> (after you click the Edit button).

The paragraphs below describe in detail the process for assigning the request to other Approvers for action.

When you are working with the Drug Pair customization window, there is a drop-down where you can assign the request to a user ID. The default is the Approver who is assigned to the DDI, but you can change that.

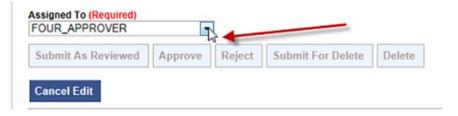


Figure 96: Assigned To: Drop-Down

If you change the status of the drug pairs to Submit as Reviewed or Submit for Delete, the drug pairs are automatically reassigned to the "Unassigned" User ID if the user who is assigned to the DDI is the same user who is making the status change. The reassignment happens because the person who submits can't also do the approval or delete the drug pairs.

Notes:

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

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

A routed generic Drug Pair that was deleted and then customized in the reverse order will be listed with those in the New Action Status and displayed in reverse order in the Drug Pairs table on the Drug Pairs Customization page.

9.5.3 Customizing Drug Pairs from the Selection List

PECS allows you to create multiple drug pairs for an interaction at one time. This same multi-select method allows you batch process drug pairs for other operations such as Review, Reject, and Delete. The process differs slightly between drug pairs created from a corresponding FDB interaction or using routed generic drugs.

Adding Drug Pairs from Corresponding FDB Interaction

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.

Note: The following instructions are written for the screen that is non-compliant for Section 508. See Section 508 Compliant Drug Pair Customization Detail for instructions on how to use the compliant screen.

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

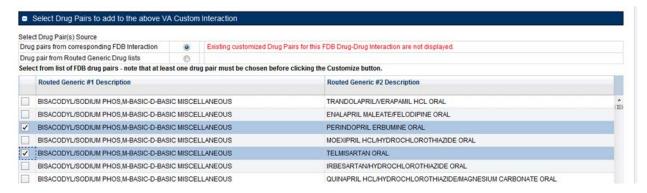


Figure 97: Drug Pair Selection List

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.

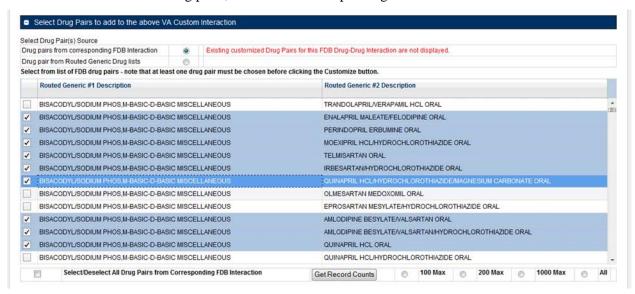
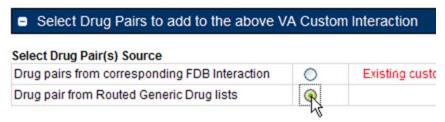


Figure 98: Large Group of Selected Drug Pair for Batch Update

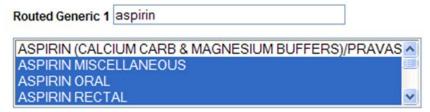
Drug Pairs from Routed Generic Drugs

To select multiple drug pairs from Routed Generic drugs:

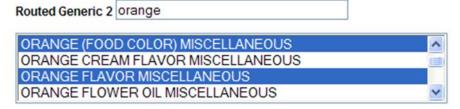
1. On the Drug Pair Customization window, select Drug pair from Routed Generic Drug lists from the Select Drug Pair(s) Source list.



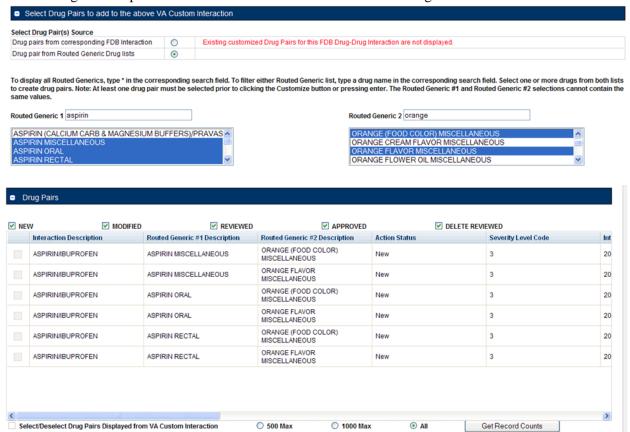
- 2. Click Edit.
- 3. Enter all or part of a routed generic drug name in the Routed Generic 1 field. To display all routed generic drugs, enter *. The list will populate automatically, but the process may take some time based on server load and the specificity of the search term.
- 4. Enter all or part of a routed generic drug name in the Routed Generic 2 field. To display all routed generic drugs, enter *. The list will populate automatically, but the process may take some time based on server load and the specificity of the search term.
- 5. To select a range of routed generic drugs from the results list, click the first item in the range, then Shift + click (click while holding down the shift key) the last item in the range. You can use the scroll bar on the results list if the last item in the range is not immediately visible.



6. To select non-contiguous items in the results list, click to select the first item, then Ctrl + click (click while holding down the Ctrl key) any additional items. You can use the scroll bar on the results list if the last item in the range is not immediately visible. This technique can also be used to de-select items within a previously selected range of items.



7. Click the Customize button. After processing, the new drug pairs will appear in the Drug Pairs list. In this example, six new drug pairs were created: each of the three selected Routed Generic 1 drugs is now paired with the two selected Routed Generic 2 drugs.



Batch Update Drug Pairs

You can use the quick selection processes describe above to change the actions status of multiple drug pairs at the same time. The Action buttons available are dependent upon the action status of the selected drug pairs. Only mutually appropriate actions will be available.

9.5.4 Review a Drug Pair

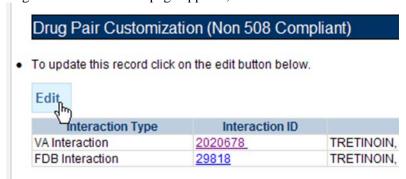
An Approver may be assigned to review drug pairs associated with a drug-drug interaction. Your options are to either Submit as Reviewed, indicating that the Drug Pair associated with the drug-drug interaction is appropriate, or Reject the Drug Pair as inappropriately associated with the Drug-Drug interaction.

To review a drug pair associated with an interaction customization:

1. From the Drug-Drug Interaction record, click Drug Pairs.



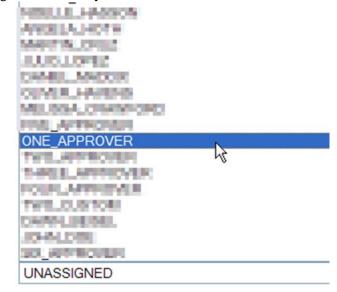
2. When the Drug Pair Customization page appears, click Edit.



3. In the Drug Pairs panel, select one or more drug pairs currently associated with the drug-drug interaction. For information on selecting multiple items within a list, see <u>Customizing Drug Pairs</u> from the Selection List.



4. Using the Assigned To list, select the person to Approve the drug pair association with the selected drug-drug interaction. If you are not sure who this should be, select Unassigned.



5. Click Submit as Reviewed to indicate that you have reviewed and agree that the drug pair is correctly associated with the selected drug-drug interaction; Click Reject to indicate that you do not agree that the drug pair is correctly associated with the selected drug-drug interaction-- this will remove the drug pair from the record; Click Cancel Edit to abandon the current editing session and leave the record unchanged.



Note: Drug Pair records can be modified after they have been Reviewed.

9.6 Section 508 Compliant Drug Pair Customization Detail

Note: These are the instructions for the Section 508 compliant version of the Drug Pair Customization page. See Drug Pair Customization for information about the standard Drug Pair Customization page.

The Drug Pair Customization Page allows users to create or delete drug pairs to associated with the VA Customized Drug-Drug interaction as well as perform mass VA Approval Workflow updates to all associated Drug Pairs.

The table on the page displays information related to the drug pair.

Field Name	Field Description
Interaction Type	The type of interaction displayed, either VA or FDB.
Interaction ID	The numerical reference number assigned to the interaction by the agency referenced in the Interaction Type field.
Interaction Description	The name of the drug associated with the interaction.
Interaction Severity	A numerical indicator of the severity of the interaction.
Interaction Action Status	The status of the interaction in the VA Approval Workflow. The Action Status for FDB Records will always be 'N/A,' as it does not go through the VA Approval Workflow

9.6.1 Accessing the Section 508-Compliant Drug Pair Customization Page

To reach the Section 508-Compliant version of the Drug Pair Customization page:

- 1. Click the 'Drug Pairs' button on a VA customized Drug-Drug interaction detail page.
- 2. Click the 508-Compliant Page link in the Drug Pair Customization banner.



Figure 99: Link to Access 508-Compliant Drug Pair Selection Page

9.6.2 Select Drug Pairs to Add to the Above VA Custom Interaction Panel

These are instructions on how to select drug pairs on the Section 508 Compliant Drug Pair Customization page.

Add Routed Generic to VA Custom Interaction

If the interaction is customized from a blank form there are no FDB drug pairs to choose from. The user will choose drug pairs from Routed Generic drug lists. The user will select the first drug "Routed Generic #1 Description" and then select the second drug "Routed Generic #2 Description" for the Drug Pair they are associating to this VA customized Drug-Drug Interaction. Note that a drug pair must be chosen before clicking the "Customize button". "Routed Generic #1" and "Routed Generic #2" fields cannot contain the same chosen value. "Routed Generic #1" and "Routed Generic #2" must follow the same order as the Interaction Description. The user must be careful to select all routed generics that contain the desired drug as an ingredient. Combination products may not fall alphabetically close to single ingredient products. The Routed Generic drug lists can also be used to add drug pairs to a drug-drug interaction customized from an FDB record if the drug pairs to be added do not exist in the FDB database.

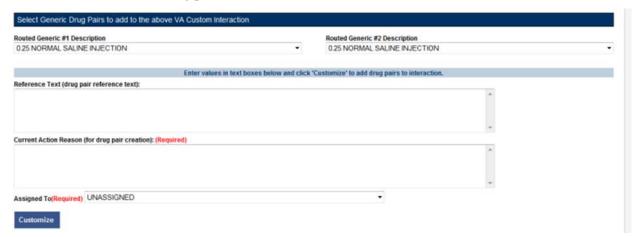


Figure 100: Routed Generic Drug List on 508-Compliant Page

To add a Routed Generic drug pair:

- 1. Click the Edit button.
- 2. In the "Select Generic Drug Pairs to add to the above VA Custom Interaction" panel, select the first drug from the Routed Generic #1 Description list.

- 3. Select the second drug from the Routed Generic #2 Description list.
- 4. Add any available reference text to the Reference Text field. This is not required.
- 5. Add a reason for your current action in the Action Reason field. This is required.
- 6. Select a PECS user to review your action in the Action Reason field.
- 7. Click the Customize button.

Add FDB Drug Pairs to VA Custom Interaction

If the interaction is customized from an FDB record, you can select any or all of the corresponding FDB drug pairs. Each FDB drug pair consists of Routed Generic #1 and Routed Generic #2. Select the checkbox adjacent to the drug pair or pairs to select it to add to the custom interaction.

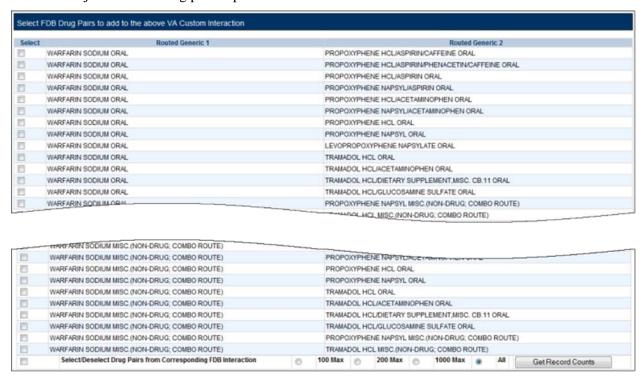


Figure 101: Corresponding FDB Drug Pairs, 508-Compliant Page

To add a FDB drug pair:

- 1. Click the Edit button.
- 2. In the "Select FDB Drug Pairs to add to the above VA Custom Interaction" panel, select the check box adjacent to the drug pair you want to add to the customization. You can select more than one drug pair. To select all the drug pairs, select the 'Select/Deselect All Drug Pairs Displayed from Corresponding FDB Interaction' check box; to limit the number selected, select one of the number-specific radio buttons.
- 3. Add any available reference text to the Reference Text field. This is not required.
- 4. Add a reason for your current action in the Action Reason field. This is required.
- 5. Select a PECS user to review your action in the Action Reason field.
- 6. Click the Customize button.

Drug Pairs Panel

The Drug Pairs panel contains all the VA Customized Drug Pairs already associated to the VA Customized Drug-Drug Interaction (noted at the top of the page). The panel contains:

- Interaction Description VA Customized Drug-Drug Interaction Description
- Routed Generic #1 Description First drug in the drug pair
- Routed Generic #2 Description Second drug in the drug pair
- Action Status current status of the Drug Pair
- Request Submitted By User ID of the PECS user who made the initial customization request
- Action Date The date of the most recent action
- Action Performed By User ID of the PECS user who performed the most recent action
- Request Assigned To User ID of the PECS user who is responsible for reviewing the drug pair information
- Interaction ID The numerical identifier for the Drug-Drug Interaction
- Severity Level Description A text description of the interaction severity
- Reference Text Contents of the Reference Text field
- Severity Level Code A numerical identifier for the severity of the Drug-Drug Interaction

The checkboxes at the top allow the user to what is displayed in the interaction table by Action Status (Historical records are not displayed). The drug pairs must be in the same state before an action can be performed on them.



Figure 102: Drug Pair List Filters

The 'Get Record Counts' button will display the count of all VA customized drug pairs. This helps the user to determine how many drug pairs to select to perform an action against at one time. It is recommended that quantities be limited to 200 drug pairs at a time to prevent negative impacts to system performance.

To perform a batch update on the drug pairs:

- 1. Use the Action Status checkbox filters to make sure all drug pairs selected are in the same Action Statuses
- 2. Select the amount that will be updated in this one action
- 3. Select all or the individual drug pairs
- 4. Select the allowed Approval Workflow action to be performed (Submit as Reviewed, Approve, Reject, etc.)

Repeat this process for all of the drug pairs until the entire set of drug pairs is in the desired point in the Approval Workflow.

9.7 Professional Monograph Detail

The Professional Monograph Detail Page allows the user to view the details of an FDB Professional Monograph and create a VA Customization, if desired. If you are viewing an FDB Professional Monograph you will see the "Customize" button at the bottom of the record. If you change any values and then click the "Customize" button, the result is a VA Customization of this FDB Professional Monograph.

This page also allows the user to view and/or modify the details of a VA Customized Professional Monograph. If you are viewing a VA Customized Professional Monograph, you will NOT see the

"Customize" button (if the record can be modified from its current state and you have permissions to do so, you will see the "Modify" or other VA Approval Workflow buttons.) FDB monographs are not generally customized, however some Professional Monographs have been created from blank documents at the national level for drug interactions that do not appear in the FDB database

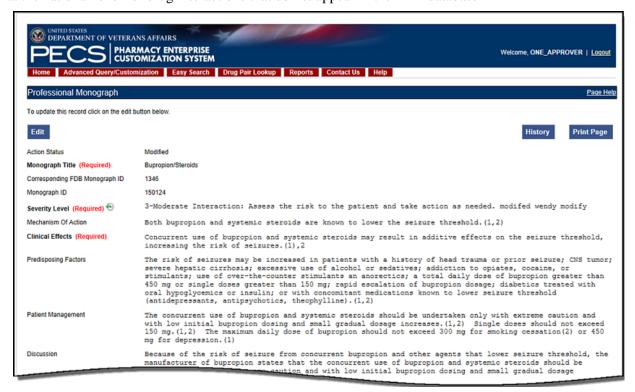


Figure 103: Professional Monograph Detail, Top

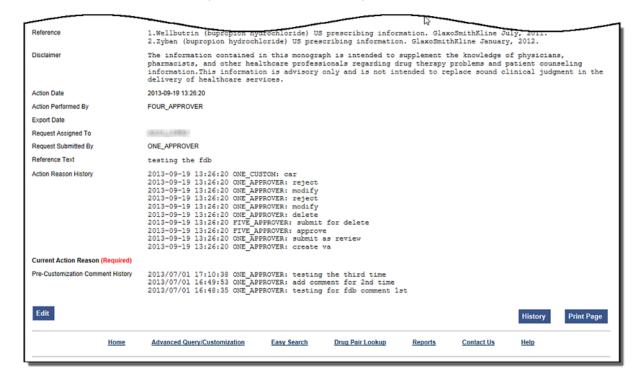


Figure 104: Professional Monograph Detail, Bottom

9.7.1 Fields

Fields that cannot be modified are shaded within PECS.

Field Name	Field Description	
Monograph Title	The title Monograph is usually the two drugs that have the interaction.	
Monograph ID	The VA-assigned numerical identifier for the Monograph.	
Action Status	Applicable to VA record only. The point this customization is at, within the VA Approval Workflow.	
Action Date	Applicable to VA record only. The date of the last action taken on the record.	
Action Performed by	Applicable to VA record only. The name of the user that performed the last action.	
Action Effective Date	Applicable to VA record only. The date of the last action taken on the record.	
Corresponding FDB Monograph ID	The First Databank (FDB)-assigned numerical identifier for the Monograph.	
Request Assigned To	Applicable to VA record only. Approver the request is assigned to.	
Request Submitted By	Applicable to VA record only. The name of the user that submitted this VA request.	
Severity Level	The severity level associated with the interaction.	
Mechanism Of Action	The specific biochemical interaction through which a drug interaction occurs. For instance, pharmacokinetic drug interactions may include: o Inhibition of absorption o Enzyme inhibition increasing the risk of toxicity o Enzyme inhibitors resulting in reduced drug effect	
	 Enzyme induction resulting in reduced effect Enzyme induction resulting in toxic metabolites Altered renal elimination Pharmacodynamic drug interactions include: Additive effects Antagonistic pharmacodynamic effects 	
Clinical Effects (required)	The Clinical effects associated with the interaction.	
Predisposing Factors (optional)	The factors or conditions that render an individual vulnerable to a drug interaction?	
Patient Management (optional)	Describe the management options available to the provider, for example: Discontinuation of the medication Increased monitoring Laboratory tests Scheduling the medication at different times	
Discussion	Usually case reports or discussion.	
Reference	Cited reference information.	
Disclaimer	Textual reminder that the information provided is not intended to replace the user's clinical judgment.	
Reference Text	Applicable to VA record only. Field for the user to enter any reference text needed to support customization of the Professional Monograph.	
Action Reason History	Applicable to VA record only. All historical current action reason comments for this record, in one viewable field.	
Current Action Reason	Free form text that can be used to specify the reason for taking the specific action of creating new, modifying, assigning, rejecting, reviewing, approving, or deleting the customization.	
Export Date	For Approved or Deleted records. Indicates the date of the last Custom Update. See Export Date for additional information.	

9.7.2 Buttons

Print Page -- Allows the user to print the page being viewed.

History -- Allows the user to open the history of changes report.

9.7.3 More Information

See also:

• <u>Using Detail Pages</u>

9.7.4 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).

Here is a list of the monograph IDs and titles, and the paired Monograph ID and title.

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 Latter Drug (Significant) (MXL2)

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

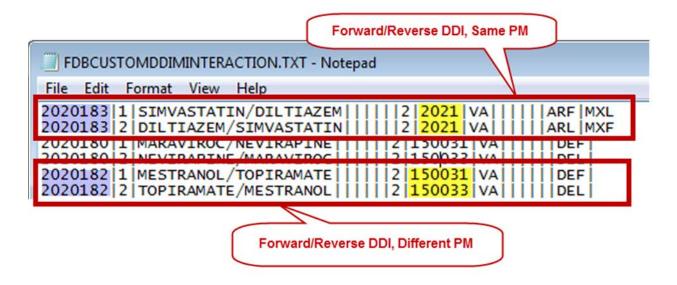


Figure 105: Forward/Reverse DDIs with Professional Monographs, Custom Update File Created by Release Manager

9.8 Duplicate Therapy Detail

This page allows you to view the details of an FDB Duplicate Therapy and create a VA Customization, if desired. If you are viewing an FDB Duplicate Therapy you will see the 'Customize' button at the bottom of the record. Any values changed (and then the 'Customize' button clicked) will result in a VA Customization of this FDB Duplicate Therapy.

This page also allows you to view and/or modify the details of a VA Customized Duplicate Therapy. If you are viewing a VA Customized Duplicate Therapy, you will NOT see the 'Customize' button (if the record can be modified from its current state and you have permissions to do so, you will see the 'Modify' or other VA Approval Workflow buttons.)

If you are viewing an FDB record that has an associated VA Custom Record, the FDB record's Detail page will display the original FDB source record with an informational message at the top of the window that explains that an associated VA Custom Record already exists. The informational message will contain a link on the DTCID (Duplicate Therapy Custom ID) field that links you to the associated VA Custom Record. If the Duplicate Therapy FDB record has already been customized, you will see the FDB Detail page in Read-only mode, and you will not be able to customize it again (the Edit button will not display).

9.8.1 Fields

Field Name	Field Description
DTCID	Duplicate therapy ID assigned by First Databank (FDB).
Custom Dup Allowance	The number of drugs a patient can be prescribed, within a Therapeutic Drug Class, before an alert is generated. 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.
Description	The name of this Therapeutic Drug Class.
Action Status	Applicable to VA record only. The point this customization is at, within the VA

Field Name	Field Description
	Approval Workflow.
Action Date	Applicable to VA record only. The date of the last action taken on the record.
Export Date	For Approved or Deleted records. Indicates the date of the last Custom Update. See Export Date for additional information.
Action Effective Date	Applicable to VA record only. The date of the last action taken on the record.
Action Performed By	Applicable to VA record only. The name of the user that performed the last action.
Request Assigned To	Applicable to VA record only. A drop down list to assign an approver.
Request Submitted By	Applicable to VA record only. The name of the user that submitted this VA request.
Action Reason History	Applicable to VA record only. All historical current action reason comments for this record, in one viewable field.
Reference text	Field for the user to enter any reference text needed to support customization of the Duplicate Allowance.
Current Action Reason	Applicable to VA record only. Free form text that can be used to specify the reason for taking the specific action of creating new, modifying, assigning, rejecting, reviewing, approving, or deleting the customization.

9.8.2 Buttons

Print Page -- Allows the user to print the page being viewed.

History -- Allows the user to open the history of changes report

9.8.3 More Information

See also:

• Using Detail Pages

9.9 Dose Range Detail

The Dose Range Detail Page allows you to view the details of an FDB Dose Range and create a VA Customization, if desired.

9.9.1 FDB Records

If you are viewing an FDB Dose Range record you will see the 'Edit' and 'Add Comment' buttons at the top and bottom of the record. If you have permission and can edit the record, any values changed will result in a VA Customization of this FDB Dose Range.

Note that a Dose Range record can be associated to different drug Concept Types (a type associated in the FDB drug database that PECS uses). They are, in order of Concept Type, as follows:

- 1 -- Drug Name
- 2 -- Routed Drug
- 3 -- Dispensable Drug
- 4 -- Generic Drug Name
- 5 -- Generic Routed Drug
- 6 -- Generic Dispensable Drug

- 7 -- Routed Dosage Form Drug
- 8 -- Generic Routed Dosage Form Drug
- 100 -- Packaged Drug
- 101 -- Manufactured Drug
- 102 -- Reference Only Item
- 103 -- Compound
- 104 -- Ingredient
- 105 -- Regional Packaged Drug
- 106 -- Total Parenteral Nutrition Solution

The important thing about these Concept Types is that PECS can handle Dose Range customizations ONLY on Concept Type 6, Generic Dispensable Drug. You can search and display Dose Ranges for the other Concept Types, but you cannot customize them.

If you are viewing an FDB Record that has been customized, you will see a link to the customized record as well as information on the customized record's status.



Figure 106: FDB Record with Link to VA Custom Record

9.9.2 VA Custom Records

The Dose Range Detail Page also allows you to view and/or modify the details of a VA Customized Dose Range. If you are viewing a VA Customized Dose Range, you will NOT see the 'Edit' button. If the record can be modified from its current state and you have permission to do so, you will see the 'Modify' or other VA Approval Workflow buttons.

The only way you can tell if you are viewing a VA custom Dose Range record is to look for specific VA Custom fields. Examples are:

- Action Status
- Action Date
- Request Submitted By

You will also see a link to the Corresponding FDB record for this customization.



Figure 107: VA Custom Record with Link to Corresponding FDB Record

10 History of Changes

PECS provides two ways to view the changes made to a customized record: At-a-Glance and a History of Changes report.

10.1 At-a-Glance

Whenever changes occur to any of the Customization requests (Duplicate Therapy, Professional Monograph, Dose Range, or Drug-Drug Interaction), it can be important to know what those changes are at a glance. You can see these changes in the read-only detail page of each of the concepts (the editable detail page of each concept cannot support the icons and mouse-over tables due to limitations with a screen-reader). The Drug-Drug Interaction detail page is shown below, but the view is virtually identical in all the concepts with, of course, the relevant fields for that particular concept identified. See the list of relevant fields in the Customization concepts Drug-Drug Interaction Detail, Professional Monograph, Duplicate Therapy Detail, and Dose Range.

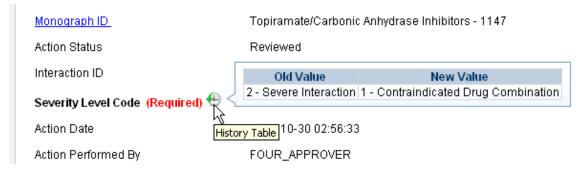


Figure 108: History of Changes At-a-Glance

The History of Changes is displayed in two ways: on-screen, via an on-screen table that is displayed interactively above an icon that displays over the name of the required field that has been changed (see screen shot above), and via the History of Changes Report. On the on-screen table, for all concepts, only required fields are reported upon.

The on-screen table that displays the History of Changes shows a quick snapshot of the record's history. It shows the changes that occurred during a record's life between important baselines - FDB/New. Approved, and Deleted. However, the on-screen view displays only the changes that occurred during a milestone, e.g., from New to Approved, or from Approved to Deleted. To view ALL the historical changes a record has incurred on the reportable fields, the user needs to access the History of Changes Report.

10.2 History Report

In the History of Changes Report, changes to most editable fields will appear in the report as red text with an asterisk (*). Note that although Current Action Reason is a required field, changes to this field will not be reported on in either the History Report or the At-A-Glance history display.

The image below is a partial image of the FDB Comparison Report for Drug-Drug Interaction. All changes are shown in red.

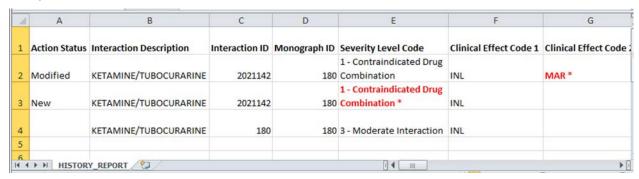


Figure 109: History of Changes Report

11 Record Locking Feature

Records from all five concept types (Drug-Drug Interaction, Drug Pairs, Professional Monograph, Dose Range, Duplicate Therapy) can be edited only by a single user at a time. If more than one user attempts to edit the same record at the same time, the user who entered the record first will have precedence and the subsequent users will receive a message that the record is in-use and cannot be edited at the current time.



Figure 110: Record in Use

If you have opened a record that has been modified by another user while you are looking at it, PECS will warn you that the data is stale. Click OK to load the modified record.



Figure 111: Record Recently Modified

To prevent the record from being locked for too long a time, the lock will be automatically removed if no edits are done in two consecutive minutes. Click OK to continue editing the record.



Figure 112: Editing Time-Out Warning

If you navigate away from an un-saved record, a warning dialog box will appear. Click Cancel to continue editing the page; click OK to return to the read-only display.



Figure 113: Re-navigation Causing Loss of Changes Warning

12 Create New Records

You can create a new record using the Open Blank Form button. This method can be used to create new Drug-Drug Interaction, Professional Monograph, and Dose Range records.

Open Blank Form

To create a new record:

- 1. Perform an Advanced Query/Customization Query for the record type (Concept) on both VA and FDB Records you want to create.
- 2. Complete the form with as much information as possible. Fields marked as Required must be completed before the record can be saved. Some record types (concepts) have other requirements that must be met before the record can be created. See New Record Requirements by Concept Type for additional information.

New Record Requirements by Concept Type

Some records have specific requirements for new records that are not indicated by the Required label.

Drug-Drug Interaction

• For a completely new record, the interacting drugs must be separated by a forward slash (/) character.

Professional Monograph

 Custom Professional Monographs can be associated with Drug-Drug Interactions once they are Approved.

Dose Range

- Concept Type can only be 6
- The Concept ID Number must correspond to an existing FDB record for Concept Type 6

Duplicate Therapy

• New Duplicate Therapy records *cannot* be created using this method. A new Duplicate Therapy customization must be made on the Advanced Query/Customization page.

Drug Pairs

• New Drug Pair records *cannot* be created using this method. A new Drug Pair can be added by selecting routed generic drugs associated with a drug-drug interaction.

(This page included for two-sided copying.)

13 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.

13.1 Duplicate Therapy Modification

Sample case: You are making a Duplicate Therapy customization for Topical Pine Tar.

13.1.1 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 Edit button to edit the record.
- 9. Click the drop down arrow on Custom Dup Allowance (required) and select another number.
- 10. Enter a Description (required).
- 11. Enter the Current Action Reason (required).
- 12. Add any reference text you think is needed (optional).
- 13. Click the Customize button.

13.2 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.

13.2.1 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. Click the Edit button to edit the record.
- 7. Select the next business reviewer's name in Request Assigned To (optional) field.
- 8. Indicate the action reason in Current Action Reason (optional) field.
- 9. Click the Submit As Reviewed button.

13.3 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.

13.3.1 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.

13.4 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.

13.4.1 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: Fields=Interaction Description; Filter=contains; Value=cyclosporine; And/Or=Or.
- 4. Build Query: Column=Interaction Description; Constraints=contains; Value=tolterodine.
- 5. Click the Query button.
- 6. Look at the query results at the bottom of the page.
- 7. Click the Open link for desired Interaction Description.
- 8. Click the Edit button to edit the record.
- 9. Click the drop down arrow on Severity Level Code (required).
- 10. Select the new desired severity level code (1).
- 11. Indicate the action reason in the free text Current Action Reason (required) field.
- 12. Click the Customize button.
- 13. Click Drug Pairs button.
- 14. Click the Edit button to edit the Drug Pairs.
- 15. If the section is not expanded, click the plus sign on Select Drug Pairs to add to the above VA Custom interaction bar.
- 16. If the radio button is not selected, 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 (required) field.
- 19. Click the Customize button.

To Submit as Reviewed:

- 1. From the home page, look at My Request History.
- 2. Click the NEW Drug-Drug Interactions link.
- 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 Drug Pairs button.
- 6. Click the Edit button.
- 7. Scroll down to Drug Pairs section, and select the newly added Drug Pair
- 8. Click the Submit as Reviewed button.
- 9. Click the link at the top of the page for the VA interaction
- 10. Click the Edit button.
- 11. Review the information.
- 12. Indicate the Action Reason in the free text Current Action Reason (required) field.
- 13. Click the Submit as Reviewed button.

13.5 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.

13.5.1 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: Fields=Interaction Description; Filter=contains; Value=digoxin; And/Or=And.
- 4. Build the Query: Fields=Interaction Description; Filter=contains; Value=metoclopramide.
- 5. Click the Query button.
- 6. Look at the query results at the bottom of the page.
- 7. Click the Active link for the desired Interaction Description.
- 8. Click the Edit button.
- 9. Click the drop down arrow on Severity Level Code (required).
- 10. Select the desired new severity level code (2).
- 11. Indicate the action reason in the free text Current Action Reason (required) field.
- 12. Click the Customize button.
- 13. Click Drug Pairs button.
- 14. Click the Edit button.
- 15. If the section is not expanded, click the plus sign on Select Drug Pairs to add to the above VA Custom interaction bar.
- 16. If the radio button is not selected, 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 (required) 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. Scroll to the Drug Pairs Bar
- 26. Click the Edit button
- 27. Click the checkbox for 'Select/Deselect All Drug Pairs Displayed from VA Custom Interaction'
- 28. Click the Submit as Reviewed button.

- 29. Click on the VA Interaction ID at top of page to navigate to Drug Interaction Detail page
- 30. Click the Submit as Reviewed button.

13.6 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.

13.6.1 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 Query button.
- 5. Look at the query results at the bottom of the page.
- 6. Select the Active link for the desired Interaction Description.
- 7. Click the Edit button.
- 8. Click the Drug Pairs button.
- 9. Click the Edit button to edit the drug pairs.
- 10. Click the plus sign on 'Drug Pairs' bar.
- 11. Click on the checkbox associated with Sumatriptan Nasal and Tranyleypromine Sulfate Oral.
- 12. Click the Submit for Delete button.
- 13. Alert another Approver that the drug pair needs to be deleted.

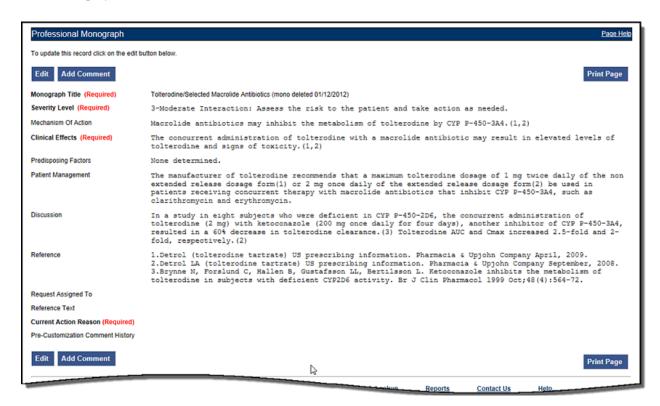
13.7 Create Professional Monograph

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.

13.7.1 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 OR from the And/Or 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. Click the Edit button to edit the record.
- 10. Change the Severity level to 1 Critical.
- 11. Indicate the action reason in the free text Current Action Reason (required) field.
- 12. Click the Customize button.

14 Contact Us

The Contact Us page contains a list of PECS Project Contacts should you need additional information about the PECS product. The content of the Contact Us page is decided by users with the Administrator role. Click the link associated with the name to send that person (or group) an email.

Note: Clicking the link opens your mail application and a new email message to the person specified in the properties of the link. This may produce a warning message. This is normal.

Contact Us

For general questions or comments about PECS, please contact <u>PECS Product Manager</u> - (000) 000-0000 Contact the PECS Workgroup

Key Members:

<u>Clinical Pharmacist</u> - (999) 888-7777 <u>Pharmacist Specialist</u> - (666) 555-4444 <u>PBM Lead</u> - (333) 222-1111

Figure 114: Contact Us Example

14.1 Editing Contact Us

Administrator users can edit the content of the Contact Us page. To edit the Contact Us page:

1. Click the Edit Content link on the right side of the page. This will display a word processor-like editor.

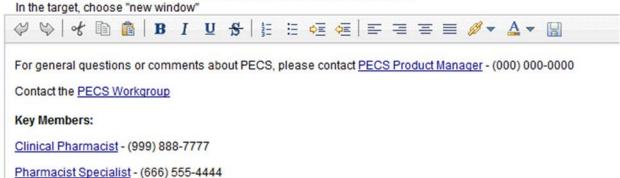


2. Add or change the content on the page. To add or edit a link, see the appropriate sections below.



To edit the contact information, type in the box below. Use the icons on the taskbar for general formatting. To add an email address link:

Click
In the URL type, mailto:somebody@va.gov
In the description, type the name of the person you want to appear in the link



3. When the edits are complete, click the Save button.



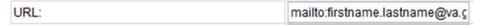
14.2 Add a Contact Link

To add a link while editing the Contact Us page:

1. Click the Create Link button. This will display the Link Properties dialog box.



2. Enter the mailto URL for the person whose contact information you are adding in the URL field. A mailto URL is the word "mailto" followed by a colon followed by the appropriate email address. VA email addresses are usually (but not always) firstname.lastname@va.gov. Verify the contact information in the Outlook Global Address List (GAL) for the correct email address. Example: mailto:firstname.lastname@va.gov.



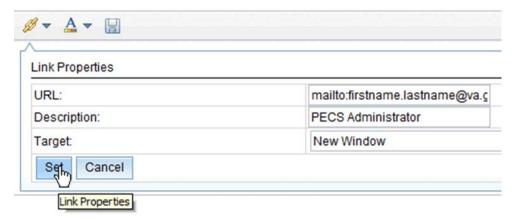
3. Enter the contact name in the Description field. This is the text the user will actually see on the Contact Us page.



4. On the Target list, select New Window.



5. Click the Set button.



14.3 Edit a Contact Link

To modify an existing contact link while editing the Contact Us page:

- 1. Double-click the existing link.
- 2. Make the necessary adjustments in the Link Properties dialog box.
- 3. Click the Set button.

(This page included for two-sided copying.)

15 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.

Note to Assistive Technology Users: Please refer the documentation included with your screen reader for commands related to reading column and row headers.

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).

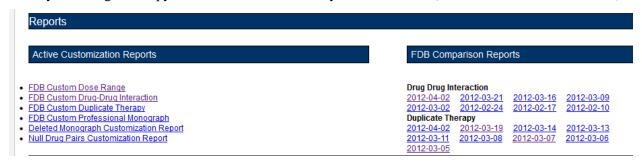


Figure 115: List of Reports

There are two types of Reports:

- Active Customization Reports
- FDB Comparison Reports

15.1 Active Customization Reports

The Active Customization Reports are:

- FDB Custom Dose Range Report
- FDB Custom Drug-Drug Interaction Report
- FDB Custom Duplicate Therapy Report
- FDB Custom Professional Monograph Report
- Deleted Monograph Customization Report
- Null Drug Pairs Customization Report

The first four Active Customization Reports, FDB Custom Dose Range, FDB Custom Drug-Drug Interaction, FDB Custom Duplicate Therapy, and FDB Custom Professional Monograph, display concept records in an Approved status along with their corresponding FDB record data. See the sample below.

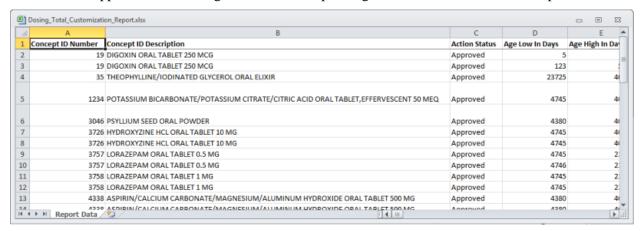


Figure 116: Sample Active Customization Report

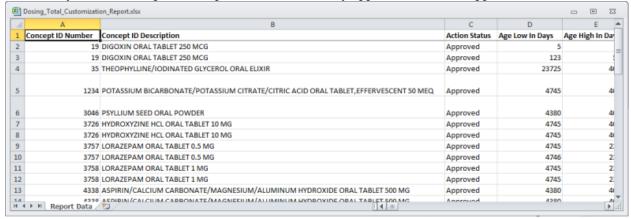
The last two reports on the list, Deleted Monograph Customization Report and Null Drug Pairs Customization Report, look for problems. The Deleted Monograph Customization Report displays DDIs with an associated PM that has been deleted (e.g., the FDB update deleted an FDB PM, and that FDB PM is associated to a custom DDI). The Null Drug Pairs Customization Report displays custom DDIs that have an associated DP in which one or both routed generics is null because an FDB update deleted the routed generic(s).

15.1.1 FDB Custom Dose Range Report

The FDB Custom Dose Range Report contains active VA custom Dose Range records in an Approved status. The default file name is Dosing_Total_Customization_Report.xlsx.

To Run the FDB Custom Dose Range Report

- 1. Click the Reports tab on the PECS Application Window.
- 2. Click the FDB Custom Dose Range 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). The file name is Dosing_Total_Customization_Report.xlsx.
- 4. If you selected Open, the report will automatically appear in the Excel application.

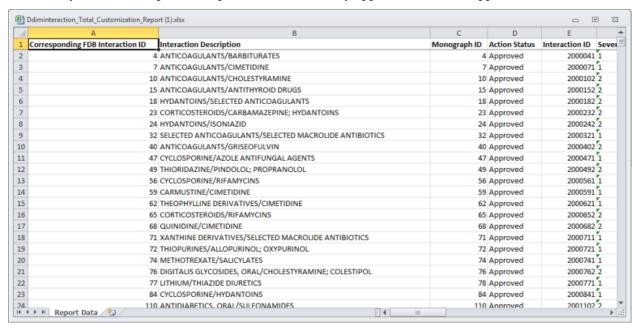


15.1.2 FDB Custom Drug-Drug Interaction Report

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

- 1. Click the Reports tab on the PECS Application Window.
- 2. Select the FDB Custom Drug-Drug Interaction 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). The file name is Ddiminteraction Total Customization Report.xlsx.
- 4. If you selected Open, the report will automatically appear in the Excel application.

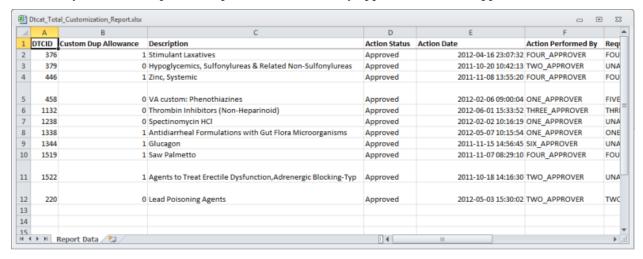


15.1.3 FDB Custom Duplicate Therapy Report

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.

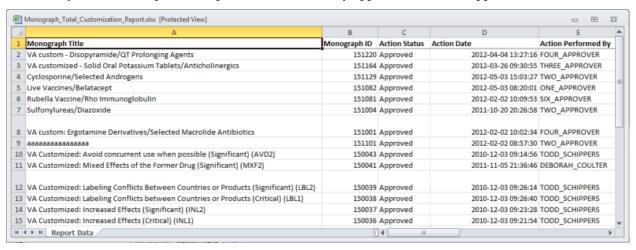


15.1.4 FDB Custom Professional Monograph Report

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.

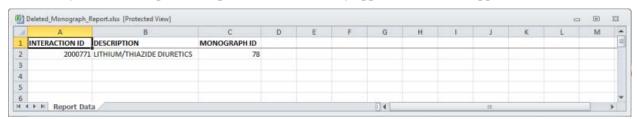


15.1.5 Deleted Monograph Customization Report

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.



15.1.6 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. The report will not display drug pairs with Deleted status.

If this report contains any entries, a user in the Administrator role should initiate the Null Drug Pair Removal Process, which deletes Null Drug Pairs listed on the report. After the Null Drug Pair Removal process is complete, the Administrator may want to run the report to verify that these drug pairs have been removed. The null Drug Pairs listed on this report are the ones that will be deleted during 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.

A	Α	В	С	D
1	INTERACTION ID	RTGENID1	RTGENID2	DRUGMISSING
2	2011952	1052699	1069042	2
3	2011952	1052700	1069042	2
4	2011952	1054611	1069042	2
5	2011952	1054983	1069042	2
6	2011952	1060960	1069042	2
7	2011952	1062022	1069042	2
8	2011952	1081458	1069042	2
9	2011952	23072796	1069042	2
10	2011952	23081056	1069042	2
11	2018222	1084565	1069042	2
12	2020315	1054617	1069042	2
13	2020315	1054617	1083895	2
14	2020315	10489662	1069042	2
15	2020315	10489662	1083895	2
16	2020513	10403002	1003033	_

Note: This report can be used to identify approved VA Drug-Drug Interactions that contain null Drug Pairs.

For more information, see the section Null Drug Pair Removal Process under Administrator.

15.2 FDB Comparison Reports

The FDB Comparison Reports display the changes to existing data included in the Incremental FDB updates. The reports inform an Approver or Administrator of the latest FDB changes for the Duplicate Therapy, Drug-Drug Interaction, Drug Pair, and Dose Range concepts and provide data that helps the these users decide whether or not 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.

Changed data is marked with an asterisk (*) and colored red. The reports are organized by type and the date of the FDB Incremental Update.

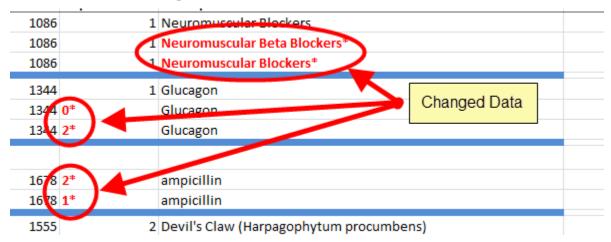


Figure 117: Changed Data in Report

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

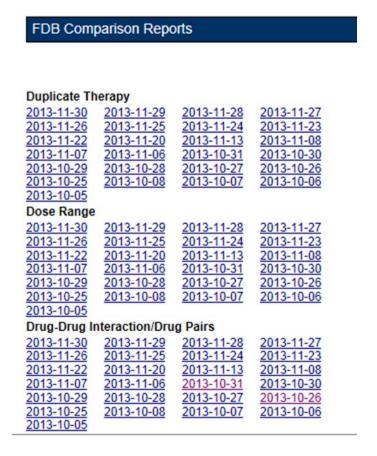


Figure 118: FDB Incremental Update Date Samples

15.2.1 Structure of the FDB Comparison Report

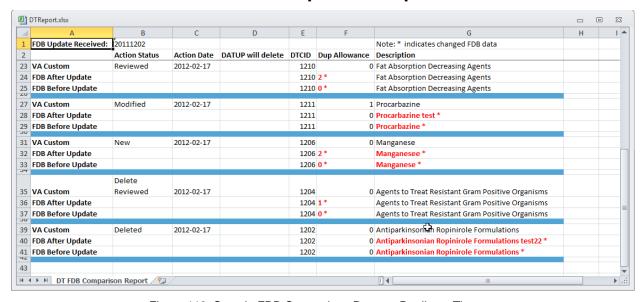


Figure 119: Sample FDB Comparison Report - Duplicate Therapy

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:

Row Name	Row Description
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:

Column Name	Column Description
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.

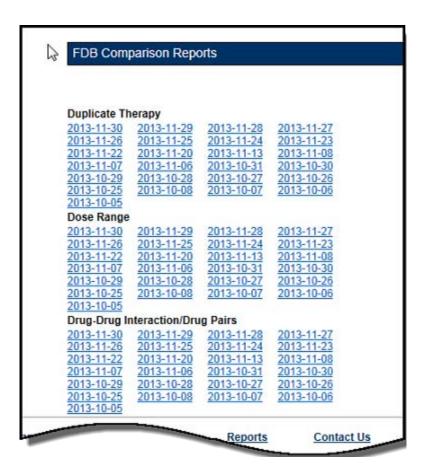


Figure 120: FDB Incremental Updates

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.

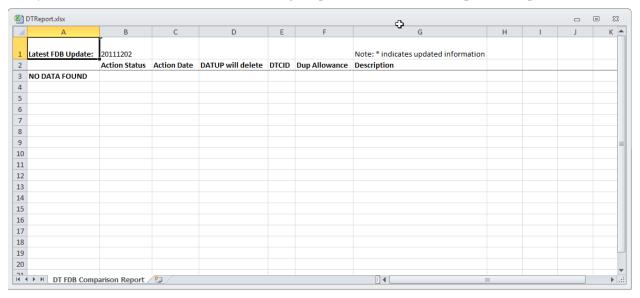


Figure 121: Report with No Differences

15.2.2 FDB Comparison Drug-Drug Interaction/Drug Pair Report

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:

Field	Description
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.

Field	Description
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 for more information.
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 id="" interaction="" number="">-DP." If a DDI record in the incremental FDB update file does not have added or drug pairs, this column will remain blank.</fdb>

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".

Each record consists of at least three lines and individual records are by a blank row (blue). There will be more than three lines if there are more than one VA Customization for the described interaction.

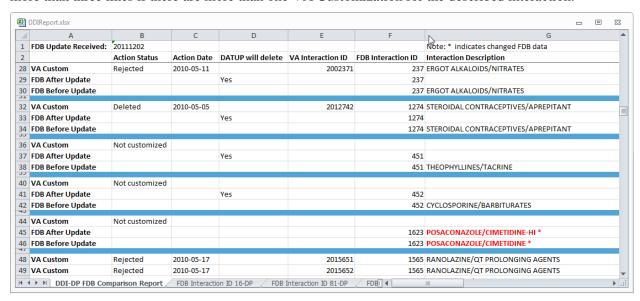


Figure 122: DDI-DP FDB Comparison Report

- VA Custom Custom VA information about the Drug-Drug Interaction record(s). If the DDI has not been customized, the record will state "Not customized".
- Latest FDB Indicates changes to the Drug-Drug Interaction record that appeared on the incremental FDB update you selected.
- Previous FDB Displays the value for the Drug-Drug Interaction record in the incremental FDB update immediately prior to the incremental FDB update you selected.

The following fields are included in the report:

Field	Description
Action Status	The current state of the record based on the most recent action performed on the associated record.
Action Date	The date the current action (Action Status) was performed.

Field	Description
DATUP will delete	 YES in this column Indicates the associated record will be deleted by DATUP.
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 for more information

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".

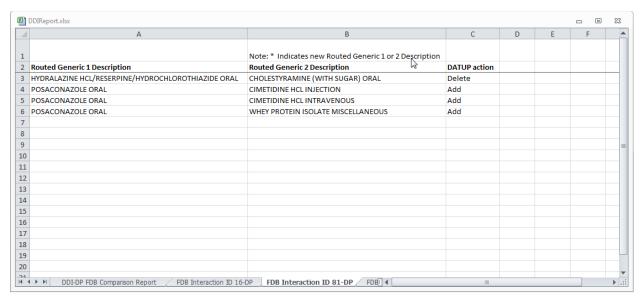


Figure 123: FDB Interaction ID-Drug Pairs Tab

The following fields are included in the report:

Field	Description
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. Either DATUP will 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.

15.2.3 FDB Comparison Duplicate Therapy Report

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:

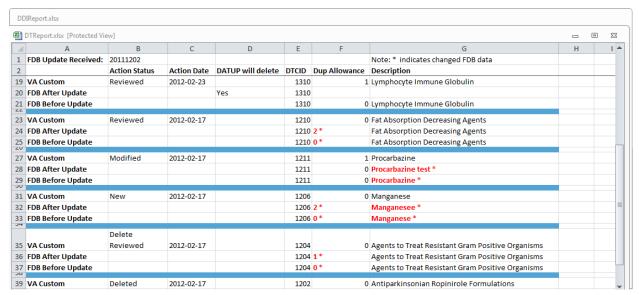


Figure 124: FDB Comparison Duplicate Therapy Report

The three lines display the following fields:

Field Name	Field Description
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.

To run the Duplicate Therapy FDB Comparison report, click the desired date of an FDB Incremental Update under the appropriate Duplicate Therapy heading.

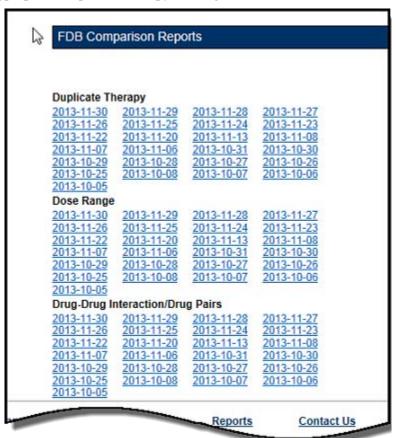


Figure 125: FDB Incremental Update Dates

15.2.4 FDB Comparison Dose Range Report

The Dose Range FDB Comparison Report displays the differences between the PECS FDB data and the data in the Incremental FDB Update file for the Dose Range (DR) concept.

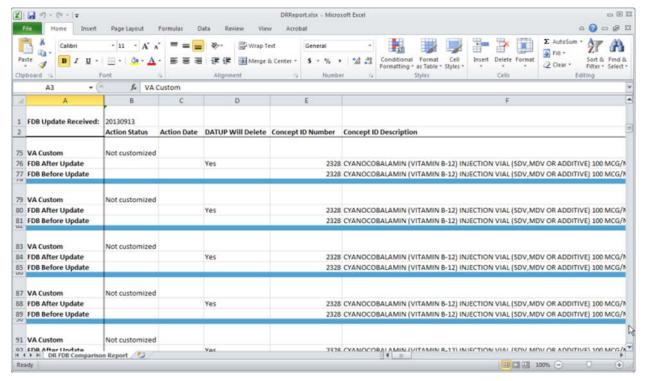


Figure 126: FDB Comparison Dose Range Report

Only records where the Concept Type = 6 will display on the report. If the DR FDB record has not been customized, it will display on the report if the following conditions were met:

- Data in all of the first seven fields (Concept ID Number, Age Low in Days, Age High in Days,
 Dose Route ID, Dose Type ID, FDBDX, HITTYPE) is identical in the PECS FDB record and the
 latest incremental FDB update
- Data in at least one other field is different in the PECS FDB record and the latest incremental FDB update

If a DR FDB record has been customized, it will display on the report if all the conditions mentioned above have been met and the active VA custom record and the PECS FDB record are cross-referenced, thus indicating that the active VA custom record was created from the FDB record.

Fields

Field Name	Field Description
Concept ID Number	Number identifying the drug. Identifies a specific drug within a given concept type.
Age Low in Days	Lowest patient age in days to which dosing information applies
Age High in Days	Highest patient age in days to which dosing information applies
Dose Route ID	Dose Route Identifier. Refers to the route of administration, which is the site or method by which a drug is administered
Dose Type ID	Dose type identifier
FDBDX	FDBDX type code to identify a Medical Condition

Field Name	Field Description
HITTYPE	Signifies whether the dose record came from the Dosage Range Check module or the Minimum/Maximum dosing module. There are 3 possible values: 1 – Dose Range Check; 2 – Dosing Not Established For This Age Range; 3 – Minimum/maximum dosing. HITTYPE is used to determine how to structure the dose alerts.
Concept ID Description	Text description of the Concept ID. Also defined as the drug name. For example, the Concept ID Description is GUAIFENESIN/PHENYLPROPANOLAMINE HCL/ACETAMINOPHEN/CAFFEINE ORAL TABLET and the Concept ID is 713.
DXID	First Databank Medical Lexicon (FML) Disease Identifier
Dose Low	Minimum amount to be administered per day
Dose Low Units	Unit of measure for low dose per day
Dose High	Highest amount to be administered per day
Dose High Units	Unit of measure for high dose per day
Dose Form Low	Low dose for a given dose form
Dose Form Low Units	Unit of measure for the dose form (EA/KG/DAY)
Dose Form High	High dose for a given dose form
Dose Form High Units	Unit of measure for the dose form (EA/KG/DAY)
Frequency Low	Low end of a drug's frequency of administration per day
Frequency High	High end of a drug's frequency of administration per day
Duration Low	Lowest recommended duration of therapy (in days)
Duration High	Highest recommended duration of therapy (in days)
Maximum Duration	Maximum recommended duration of therapy (in days)
Maximum Single Dose	Maximum amount to be administered in a single dose
Maximum Single Dose Units	Unit of measure for the maximum single dose
Maximum Single Dose Form	Maximum single dose for a given form
Maximum Single Dose Form Units	Unit of measure for the dose form (EA/KG/DAY)
Maximum Daily Dose	Maximum amount to be administered per day
Maximum Daily Dose Units	Unit of measure for the maximum daily dose
Maximum Daily Dose Form	Maximum daily dose for a dose form
Maximum Daily Dose Form Units	Unit of measure for the dose form (EA/KG/DAY)
Maximum Lifetime Dose	Maximum amount to be administered over a patient's lifetime, if available
Maximum Lifetime Dose Units	Unit of measure for maximum lifetime dose
Maximum Lifetime Dose Form	Maximum lifetime dose for a given dose form
Maximum Lifetime Dose Form Units	Unit of measure for the dose form (EA/KG/DAY)
Dose Rate Low	Minimum amount to be administered per dose rate (hours or minutes)
Dose Rate Low Units	Unit of measure for low dose rate (hours or minutes)
Dose Rate High	Highest amount to be administered per dose rate (hours or minutes)
Dose Rate High Units	Unit of measure for high dose rate (hours or minutes)
Dose Form Rate Low	Low dose for a given dose form rate (hours or minutes)

Field Name	Field Description
Dose Form Rate Low Units	Unit of measure for the dose form rate (hours or minutes)
Dose Form Rate High	High dose for a given dose form rate (hours or minutes)
Dose Form Rate High Units	Unit of measure for the dose form rate (hours or minutes)
Maximum Single Dose Rate	Maximum amount to be administered in a single dose rate (hours or minutes)
Maximum Single Dose Rate Units	Unit of measure for the maximum single dose rate (hours or minutes)
Maximum Single Dose Form Rate	Maximum single dose for a given dose form rate (hours or minutes)
Maximum Single Dose Form Rate Units	Unit of measure for the dose form rate (hours or minutes)
Maximum Daily Dose Form Rate	Maximum daily dose for a dose form rate (hours or minutes)
Maximum Daily Dose Rate	Maximum amount to be administered per dose rate (hours or minutes)
Maximum Daily Dose Form Rate Units	Unit of measure for the dose form rate (hours or minutes)
Maximum Daily Dose Rate Units	Unit of measure for the maximum daily dose rate (hours or minutes)
Max Single NTE Dose	Maximum Not-to-Exceed (NTE) amount to be administered in a single dose
Max Single NTE Dose Unit	Unit of measure for the maximum single NTE dose
Max Single NTE Dose Form	Maximum Unit of measure for the NTE dose form (EA/KG/DAY)
Max Single NTE Dose Form Unit	Maximum Not-to-Exceed amount to be administered in a single dose for a given dose form
Hepatic Impairment Indicator	Indicates that the drug's dosing information needs to be adjusted for a patient with hepatic impairment. This flag does not differentiate between mild, moderate, and severe hepatic failure.
Renal Impairment Indicator	Indicates whether the dosing information needs to be modified for any degree of renal impairment in the patient.
CRCL Threshold	Lowest Creatinine Clearance (CRCL) to which dosing applies.
CRCL Threshold Units	Unit of measure for the Creatinine Clearance (CRCL) threshold.
Low Elimination Half Life	Low end of the drug's half-life range
High Elimination Half Life	High end of the drug's half-life range.
Half Life Units	Unit of time for the half-life range of a drug.
Weight Required Indicator	Indicates whether weight is required for dosing.
BSA	Required Indicator Indicates whether Body Surface Area (BSA) is required for dosing