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1 Introduction

1.1 Background

A vital part of FDA and CDER's mission is to develop new standards to prevent medication errors due to proprietary name confusion. The Office of Drug Safety (ODS), Division of Medication Errors and Technical Support (DMETS) contributes to this effort by evaluating all proprietary names submitted to the Center for Drug Evaluation and Research for similarity to other marketed names. In December 1999, the Institute of Medicine (IOM) Report recommended testing of proposed proprietary names to prevent confusion and medication errors with existing drug names. The Quality Interagency Coordination Task Force (QuIC) reporting to the President in February 2000 endorsed the IOM recommendation.

In response to these reports, FDA devoted greater resources to the area of drug name confusion analysis. Proprietary name confusion may stem from the manner in which a name is pronounced or scripted. The Phonetic and Orthographic Computer Analysis System (POCA) system is a web application developed to determine written and phonetic similarities between proposed drug names.

1.2 Document Scope

This User Guide provides information for study participants, safety evaluators, and system administrators. It is not a technical developer's manual nor does it provide in-depth information on the database or operating systems.

This document refers to three types of users, namely *Safety Evaluator, Consult Coordinator,* and *System Administrator*. *Safety Evaluators* have the lowest level of permissions, with rights to conduct searches, maintain watch lists, and access personal settings. *Consult Coordinators* have all the capabilities of safety evaluators with the added abilities to add/edit news items, change dynamic weights, edit account request email addresses, edit feedback/comments email addresses, assign consults, view assigned consults, consolidate watch lists, view all watch lists. *System Administrators* have all the capabilities of *Safety Evaluators* and *Consult Coordinators* with the added abilities of adding new data sources, adding/editing users, and modifying text for the levels of concern. The functions available to each user type are described in more detail throughout this document.

1.3 Organization

This document is organized into five main sections.

- Section One discusses the background, scope and organization.
- Section Two contains instructions on connecting to the system, logging on, requesting accounts, and navigation from the home page.
- Section Three provides information on account settings available to all POCA users.

- Section Four provides information on system wide settings accessible to the *Consult Coordinators* user group.
- Section Five provides information on system wide settings accessible to the *System Administrators* user group.
- Section Six contains information about the POCA search modules.

2 Getting Started

To access POCA, open your web browser by double clicking on the icon on your desktop or selecting Start, Programs, and Internet Explorer. In the address bar of your web browser, type the universal resource locator (URL) for POCA – http://pocastage.ppc.com/. The Login screen will appear as shown below.

Disclaimer
This is a Federal computer system and is the property of the United States Government. It is for authorized use only. Users (authorized or unauthorized) have no explicit or implicit expectation of privacy.

Any or all use of this system and all files on this system may be intercepted, monitored, recorded, copied, audited, inspected, and disclosed to authorized site, Food and Drug Administration, and law enforcement personnel, as well as authorized officials of other agencies, both domestic and foreign. By using this system, the user consents to such interception, monitoring, recording, copying, auditing, inspection, and disclosure at the discretion of authorized site or Food and Drug Administration personnel.

Unauthorized or improper use of this system may result in administrative disciplinary action and civil and criminal penalties. By using this system you indicate your awareness of and consent to these terms and conditions of use.

Figure 1 - Login Screen

You will need a user account to access POCA. If an account has been created for you, enter your email address and password and click the Login button.

2.1 Resetting Your Password

If you do not remember your password, click the "Reset Password" link. The *Reset Password* screen, shown below, will be displayed.

Type your username and click "Submit." POCA will assign a temporary password to your account and send you an automated e-mail message with the temporary password. You will be required to change your password upon login.

2.2 Changing Your Password

If you wish to change your password, click on the "Change Password" link on the POCA login page. The *Change Password* screen will display, as seen below.

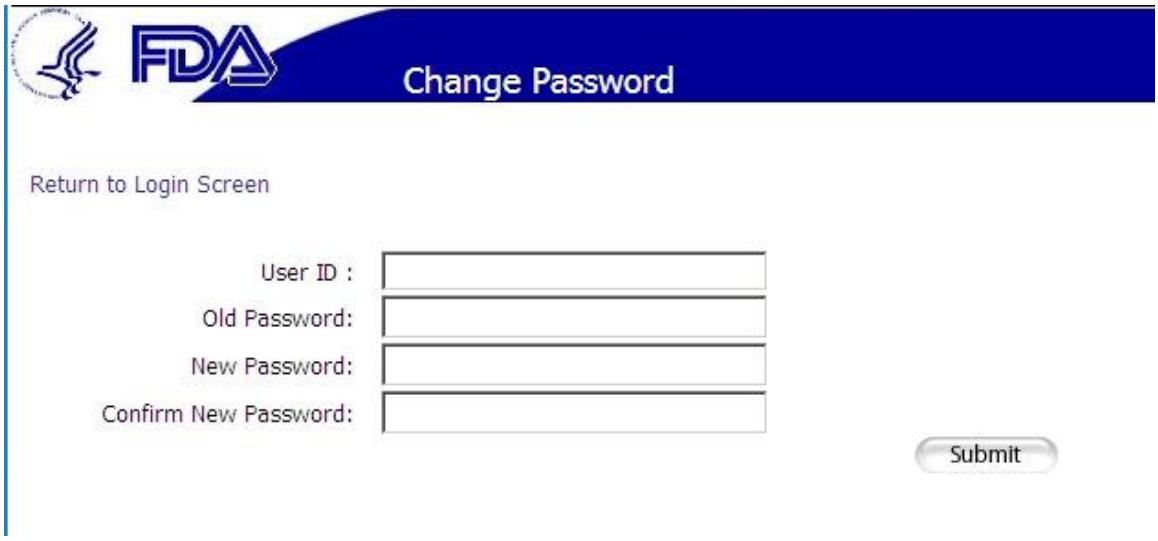


Figure 2 - Change Password Screen

Enter your current login credentials in the text boxes labeled "User ID" and "Old Password" to allow POCA to verify your identity. Enter your desired password into the text boxes labeled "New Password" and "Confirm New Password," and click the "Submit" button. If the current login information you entered is incorrect, your passwords do not match, or your new password does not comply with POCA password requirements, you will be asked to correct your inputs.

2.3 Requesting an Account

If you do not have a POCA account, you may request one by clicking on the "Request Account" link on the login screen. The *Request an Account* screen will be displayed.

Figure 3 - Request Account Screen

Enter your name and email address in the text boxes provided, and click the "Submit" button. A POCA system administrator will contact you via e-mail with your login information. You may now log in using your email address and password. Upon successful log in, the home page is displayed.

2.4 Home Page and Navigation

The home page is the main control panel for the system. From the homepage users can access all of the functionality of the system. Specific sections of the home screen and their purpose are described below.

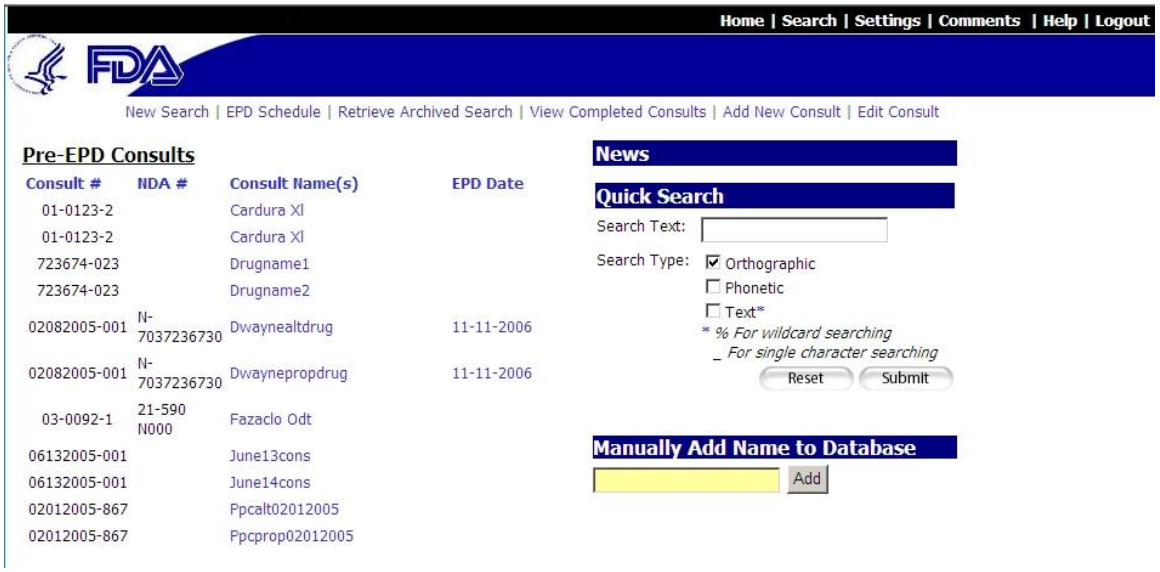


Figure 4 - The Home Page

2.4.1 Navigation Bar

At the top right hand portion of the home page you will find a navigation bar with links for accessing major parts of the POCA application, such as the home page, search pages, and personal settings. This navigation bar is accessible on all POCA pages.

2.4.2 Options Bar

An options bar with options available based on user type is provided at the top of the home page, below the FDA banner.

The EPD Schedule is available for all users. This page displays a calendar for the current month. EPD dates are highlighted with the consults which will be discussed. A user can view their watch list for the consult by clicking on the consult name on the EPD date.

The Retrieve Archive Search link is available for all users. Clicking the link will display a search page that can be used to search for a previously conducted search.

The Add New Consult link is provided for consult coordinators and system administrators only. The target page displays an input screen for creating new consults.

The Edit Consult link is provided for consult coordinators and system administrators only. The target page will display a list of consults available for edit. Once a consult is selected, all known information about the consult is displayed on screen for editing.

2.4.3 The Pre-EPD consults list

This list gives consults that have not been through an EPD. A user can view a watch list by clicking on a consult in this list. This list is provided for all users.

2.4.4 The Pre-Marketing Assigned Consult List

This list consists of consults that have been through an EPD and are assigned to a user. Safety evaluators can only see the consults to which they are assigned. Consult coordinators and system administrators can view all consults.

2.4.5 News and announcements

News and announcements are displayed for all users. To view more information about the news item, the user can click on the title.

3 Personal Settings

All personal settings for your POCA account can be accessed from the *Your Settings* section on the *Personal Settings* screen. To access the *Personal Settings* screen, click on the 'Settings' link found in the navigation bar.

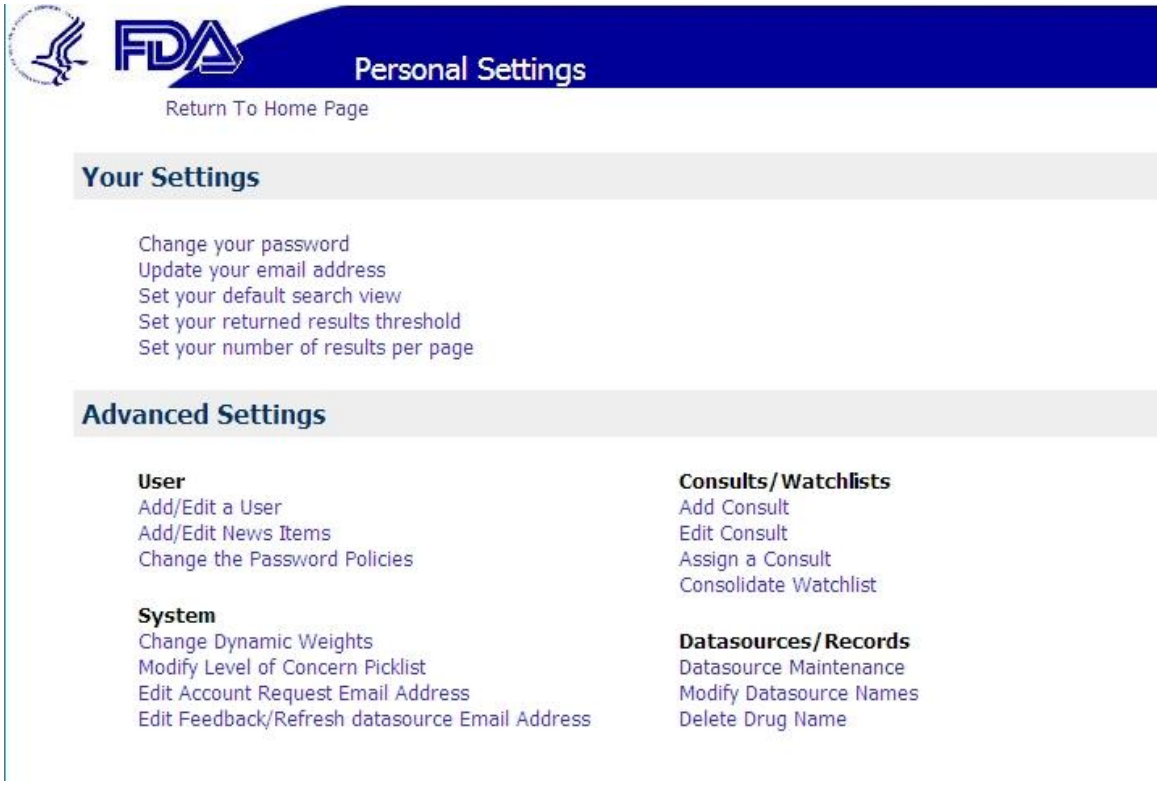


Figure 5 - Personal Settings Screen

The following settings are available to all users.

3.1 Set Threshold for Returned Results

Users can set the threshold for returned results by clicking the 'Set your returned results threshold' option under *Your Settings*.

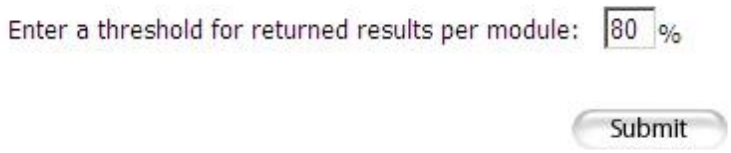


Figure 6 - Threshold for Returned Results

The threshold is the percentage match required for a result to be returned by the search engine. For example: If the threshold is set to 80%, only results with a match percentage of 80% or higher will appear in the result set.

3.2 Set Your Number of Results per Page

POCA allows users to set the default number of results displayed per page by clicking on the 'Set Your Number of Results per Page' link under *Your Settings*. When a user conducts a search, the default number of results will be displayed per page. If there are more results returned than the default number of results, the user will have the ability to scroll through the pages of results.

3.3 Set Default Search View

The POCA system allows users to set their default search view by clicking the 'Set your default search view' option under *Your Settings*. The current setting will be selected in the display. The selected view will be the initial start point for every search. Access to the other view is always provided by a link on the search screen.

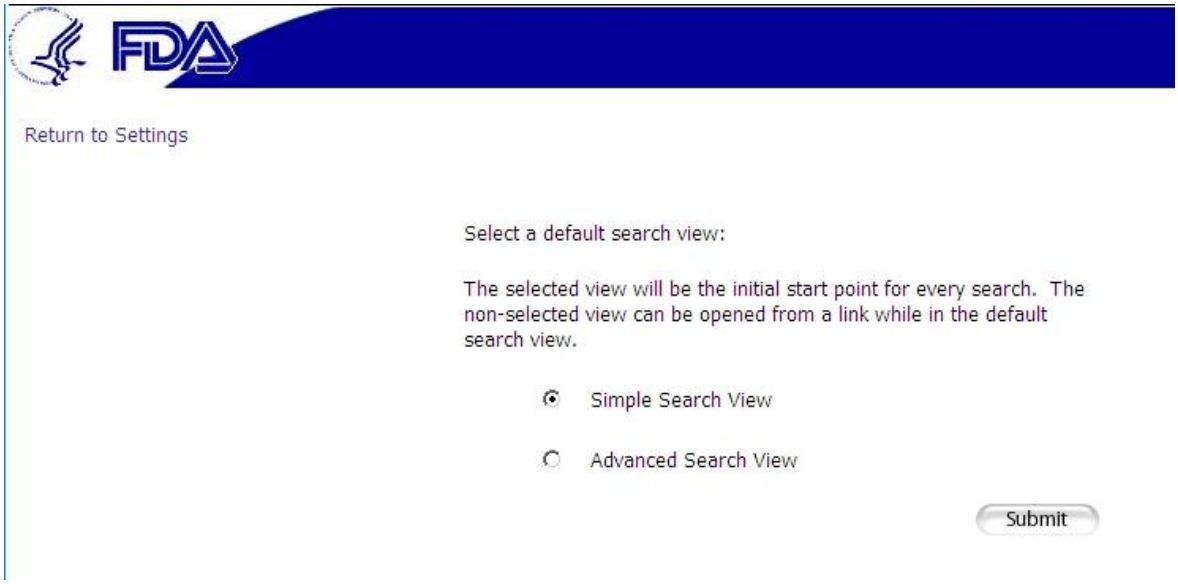


Figure 7 - Set Default Search View Screen

3.4 Update Email Address

This option enables users to update their email address in the POCA database. The current email address that is stored in the POCA database is displayed near the top of the screen. Enter the new email address in the text box provided, and click the 'Submit' button to commit changes to the POCA database.

4 Advanced Settings – Consult Coordinators

The following options are available to the *Consult Coordinators* user group.

4.1 Add/Edit News Items

News Items display on the login screen and home page of the POCA system. Existing news items can be edited, and additional news items can be created by clicking the *Add/Edit News Items* link in the list of *Advanced Settings* on the *Personal Settings* screen. To add a news item, populate the *Headline, News Teaser, News Item,* and *Expire Date* fields in the form that appears below, and click the 'Submit/Update' button. Click 'Reset' to clear the form.

Figure 8 - Add/Edit News Items screen

The fields on this form are described below.

Field Name	Definition/Description	Field Type

Headline	This is the title that will identify the news item.	**Edit**
News Teaser	Text entered here will appear below the headline on the home and login pages.	**Edit**
News Item	This is the main text of the news item. This field is required.	**Edit**
Expire Date	The expire date determines when a news item will no longer be displayed on the home and login screens. Enter a date in the format MM-DD-YYYY. This field is required.	**Edit**

To edit an existing news item, select a news item in the drop down list at the top of the screen, and click the *'Get News Item'* button. Edit the information that appears in the form, and click 'Submit/Update' when you are satisfied with the information you entered.

4.2 Assign a Consult

Consults in the POCA system can be assigned to any user. When the *Assign a Consult* link is clicked, a list of unassigned consults will be displayed. Select a consult by clicking on a name, and then click the 'Submit' button. A drop down list of user names will display, as shown below.

Figure 9 - Assign a Consult Screen

Select a user from the list and click the 'Assign' button. The assigned user will automatically be sent an email as notification of the assignment.

4.3 Add New Consult

Clicking on the *Add New Consult* link will display a form for submitting a new consult. Fill out the form by filling in all necessary fields, and click 'Submit' to store the

information. Click ‘Reset’ to clear the form. Each field on the form is described in the table below. An image of the Add New Consult form is provided below the table.

Field Name	Definition/Description	Field Type
Proprietary Name	Type the proprietary product name of the consult. This field is required.	**Edit**
Alternative Name	Enter an alternative name here. This field is optional.	**Edit**
Established Name	This is the main text of the news item. This field is required.	**Edit**
Product Modifier	Enter the product modifier here. This field is optional.	**Edit**
Date Received	Enter the date received in the format MM-DD-YYYY. This field is optional.	**Edit**
EPD Date	Enter the EPD date in the format MM-DD-YYYY. If an EPD date is entered, the new consult will appear on the EPD schedule. This field is optional.	**Edit**
Consult Number	Enter the consult number. This field is required.	**Edit**
Application Number	Type the application number here. This field is optional.	**Edit**
Application Type	Select an application type. The options available in the drop down list are: *Abbreviated New Drug Application, Investigational New Drug, New Drug Application, Unknown.* This field is optional.	**Pick List**
Comments	Type any comments related to the new consult here. This field is optional.	**Edit**

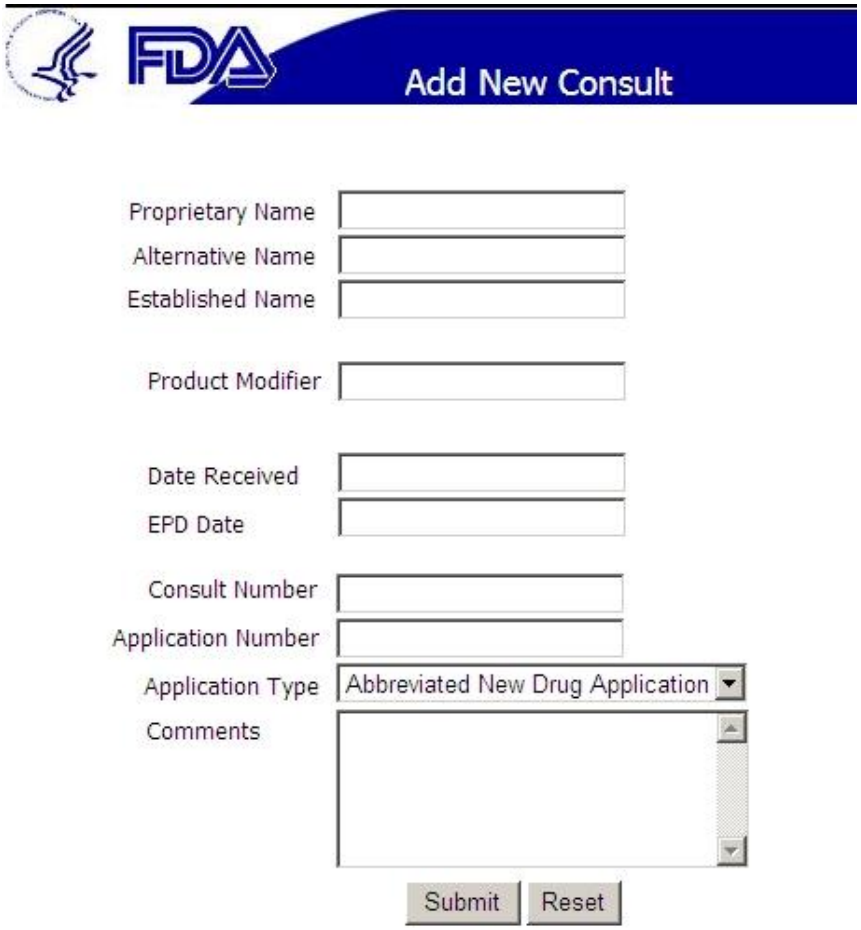


Figure 10 - Add New Consult Screen

4.4 Change Dynamic Weights

The POCA system supports the capability to modify the weighted average used to calculate the combined score in search results using the *Dynamic Weights Settings* page, shown below.

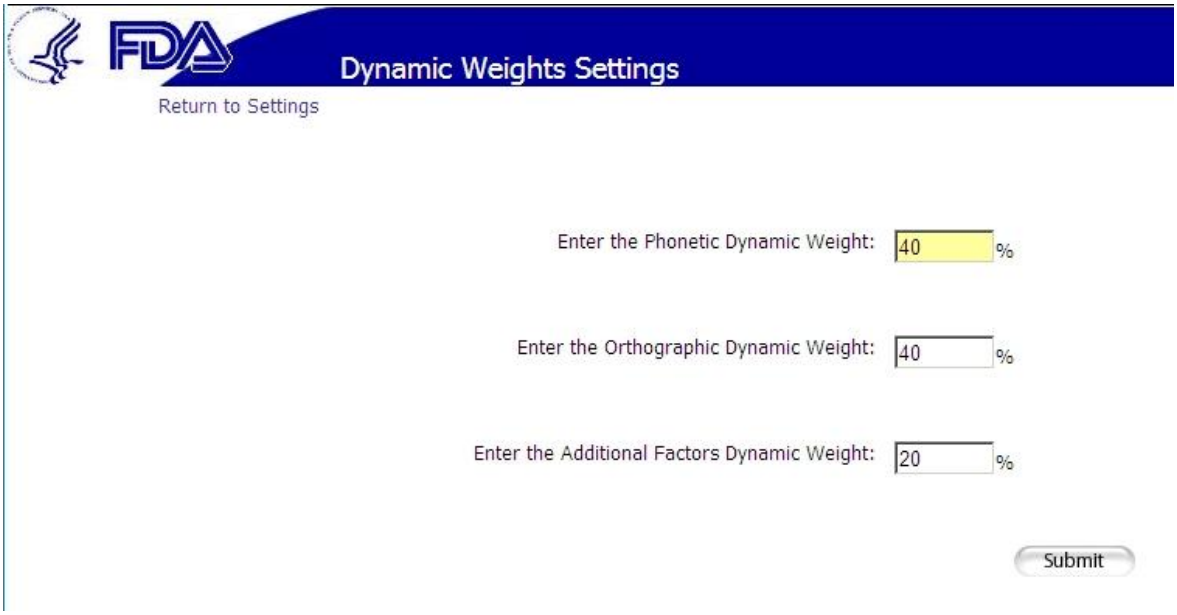


Figure 11 - Change Dynamic Weights Screen

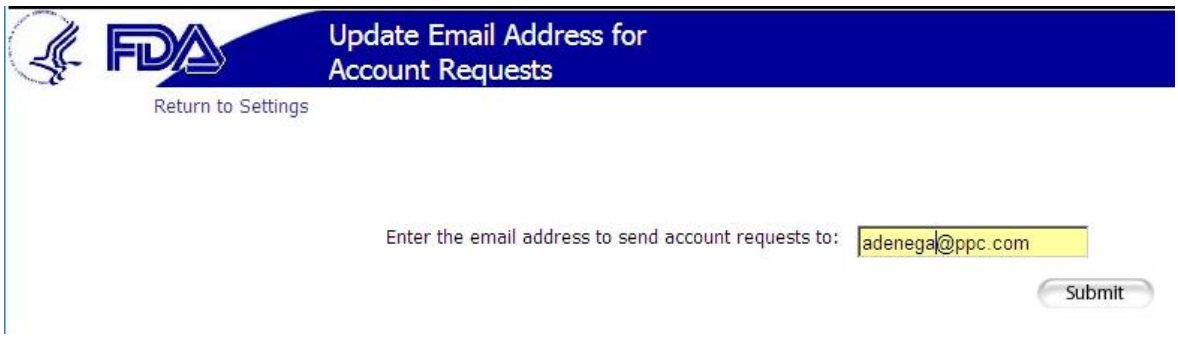
Enter weights for phonetic, orthographic, and additional factors in the text boxes provided, and click the 'Submit' button. Note that when combined, the entered percentages must equal 100, and a percentage for orthographic, phonetic, and additional factors must be set.

4.5 Consolidate Watch Lists

To consolidate a watch list, click on the *Consolidate Watch Lists* link under *Advanced Settings*. A list of consults will display. Click on the desired consult to consolidate the watch list. Once consolidation is complete, members of the *Consult Coordinators* and *System Administrators* will be able to view the consolidated list by clicking on the consult name on the Home Screen.

4.6 Edit Account Request Email Address

When a user account is requested, an automatically generated email is sent to the *account request email address* stored in the POCA database. This email address can be changed using the *Edit Account Request Email Address* page, shown below.



To have POCA send account requests to multiple email addresses, enter the email addresses separated by semicolons (;). Click 'Submit' to store your changes to the POCA database.

4.7 Edit Consult

To edit an existing consult, begin by clicking the *Edit Consult* link under *Advanced Settings*. A list of consults will display. Locate the consult you wish to edit, and selected by clicking the consult name. The Edit Consult page, with input fields seeded by all available information, will display. A sample *Edit Consult* form, with *Aerospan* as the selected consult, is shown below.

Figure 12 - Edit Consult Screen

Edit and/or fill in the form as necessary. All input fields available are described in the table below.

Field Name	Definition/Description	Field Type
Proprietary Name	Type the proprietary product name of the consult. This field is required.	**Edit**
Alternative Name	Enter an alternative name here. This field is optional.	**Edit**
Established Name	This is the main text of the news item. This field is required.	**Edit**
Product Modifier	Enter the product modifier here. This field is optional.	**Edit**
Date Received	Enter the date received in the format MM-DD-YYYY. This field is optional.	**Edit**
EPD Date	Enter the EPD date in the format MM-DD-YYYY. If an EPD date is entered, the new consult will appear on the EPD schedule. This field is optional.	**Edit**
Application	Type the application number here. This field is	**Edit**

Number	optional.	
Application Type	Select an application type. The options available in the drop down list are: *Abbreviated New Drug Application, Investigational New Drug, New Drug Application, Unknown.* This field is optional.	**Pick List**
Comments	Type any comments related to the new consult here. This field is optional.	**Edit**

Note that editing the consult number is not permitted. While you are editing, you may revert to the data stored in the POCA database at any time by clicking the 'Reset' button. When you are done, click 'Submit' to store your changes to the POCA database.

4.8 Edit Feedback Email Address

When a user fills out and submits the *Comments and Feedback* form, POCA will send an automatically generated email to the *Feedback Email Address* stored in the database. This email address can be changed using the *Edit Feedback Email Address* page, shown below.

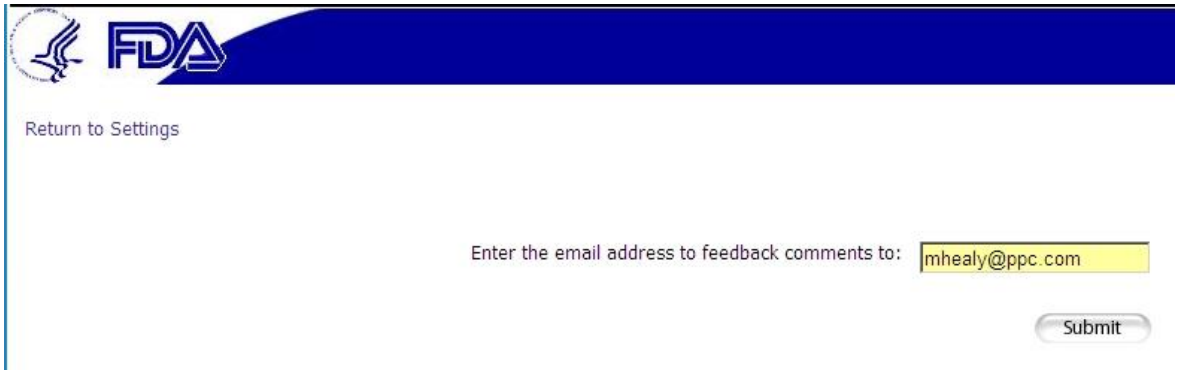


Figure 13 - Edit Feedback Email Address Screen

To have POCA send feedback and comments to multiple email addresses, enter the email addresses separated by semicolons (;). Click 'Submit' to store your changes to the POCA database.

5 Advanced Settings – System Administrators

5.1 Add/Edit a User

To add or edit a user profile, click the *Add/Edit User* link under *Advanced Settings* on the settings page. The User Administration page will display, as shown below.

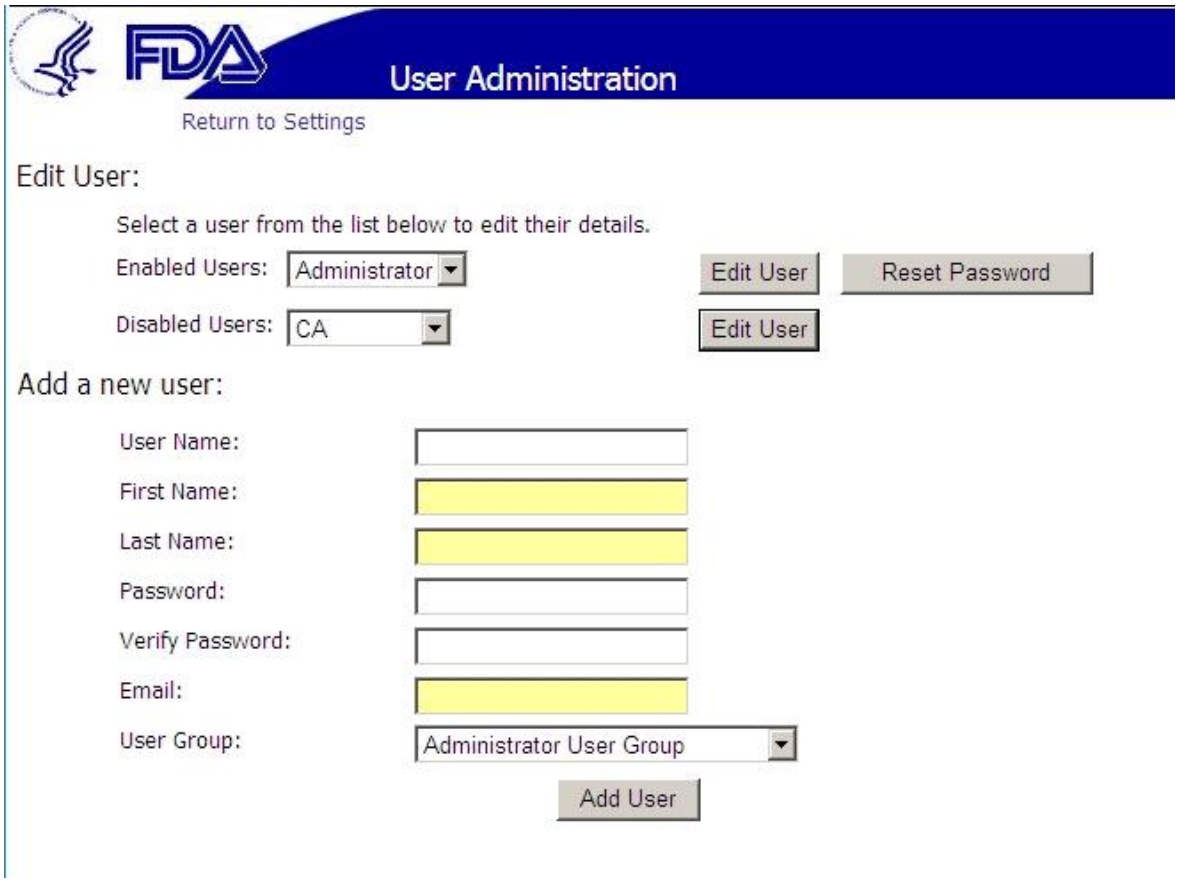


Figure 14 - User Administration Page

To add a new user profile, fill out the form that appears under the *Add a new user* heading. All input fields available on the form are described in the table below.

Field Name	Definition/Description	Field Type
User Name	Enter a username for the new account. The username will be used by the user to log in to POCA. This field is required.	**Edit**
First Name	Enter the first name of the user. This field is required.	**Edit**
Last Name	Enter the last name of the user. This field is required.	**Edit**
Password	Enter a password that conforms to the system password complexity requirements. This field is required.	**Edit**

Verify Password	Enter the password again for verification. This field is required.	**Edit**
Email	Enter the email address of the user, and be sure to check for typos. It is important to type this field correctly. The application will use this field to send electronic notifications to the user. This field is required.	**Edit**
User Group	Select from the list if the user is a *Safety Evaluator*, *Consult Coordinator*, or *Administrator*.	**Pick list**

When editing a user profile, please note that there are two pick lists for existing user profiles, one for enabled accounts, and another for disabled accounts. You can choose an account to edit by selecting from either list the username corresponding to the user profile you wish to edit, and clicking the "Edit User" button. Once a user is selected for editing, the *Edit User* form, seeded with all available information, will display. An example of the *Edit User* form following the selection of username *test_user11* for editing appears below.

Figure 15 - Edit User Screen

The *Edit User* form allows the editing of the First Name, Last Name, Email, and User Group associated with a user. When you are done editing these fields, click 'Update User' to submit these changes to the POCA database.

In addition, the *Edit User* form can be used to disable user accounts. To disable an account, simply click the 'Disable User' button on the *Edit User* page. A disabled account cannot be used to log in to POCA, but all data associated with the disabled user will be preserved.

5.2 Change the Password Policies

POCA allows administrators to edit password policies enforced by the application. You may edit the number of required special characters (e.g., !@#$%^&), minimum password length, maximum password age in days, minimum number of days before a user is allowed to change their password, number of failed login attempts that will cause a user account to be locked, and number of passwords to be kept in the password history to prevent frequent password reuse. To edit password policies, navigate to the home page, scroll to the Administrative Options section, and click the "Edit Password Policies" link. POCA will display the Password Policies screen, shown below.

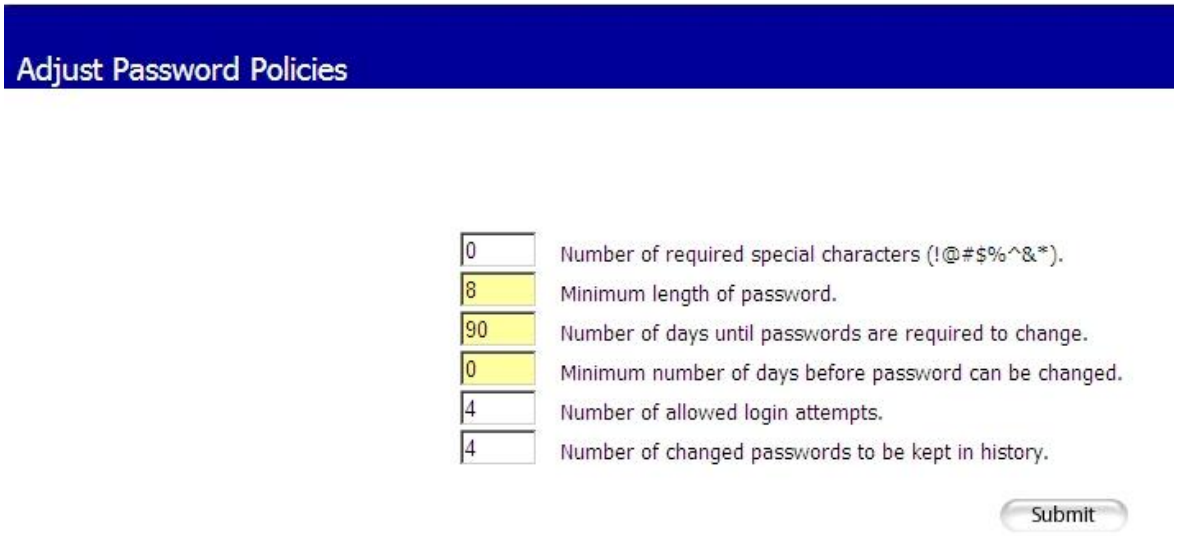


Figure 16 - Adjust Password Policies Screen

Edit this screen as needed and click the "Update" button to apply new policies.

5.3 Data Source Maintenance

For members of the *System Administrators* group, the POCA system supports capability to identify, load, refresh, and delete data sources from the POCA database. The data access process begins with the *Datasource Maintenance* screen, which can be accessed by clicking the 'Datasource Maintenance' link in the *Advanced Settings* section of the *Personal Settings* page.

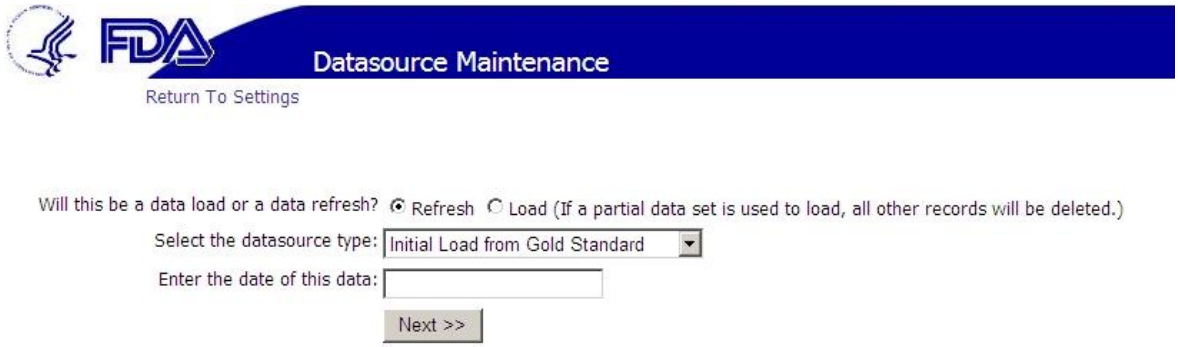


Figure 17 - Data Source Maintenance Screen

Select the data source type, enter the date of the data in the format 'MM-DD-YYYY', and check if you wish to load or refresh the data source. Click the 'Next >>' button, and follow the directions provided.

5.4 Delete Drug Name

To delete a drug name from the POCA database, click the *Delete Drug Name* link under *Advanced Settings*. The first screen in the *Delete a Record* wizard, shown below, allows you to search for a drug record in the POCA database. Type the name of the drug you wish to delete in the text box provided, and click the 'Search' button. In the sample below, we search for the name *celebrex*.

Figure 18 - Delete a Record Screen (1 of 2)

Our search returns a list of records composed of drug names and their associated data sources, as shown in the screen capture below.

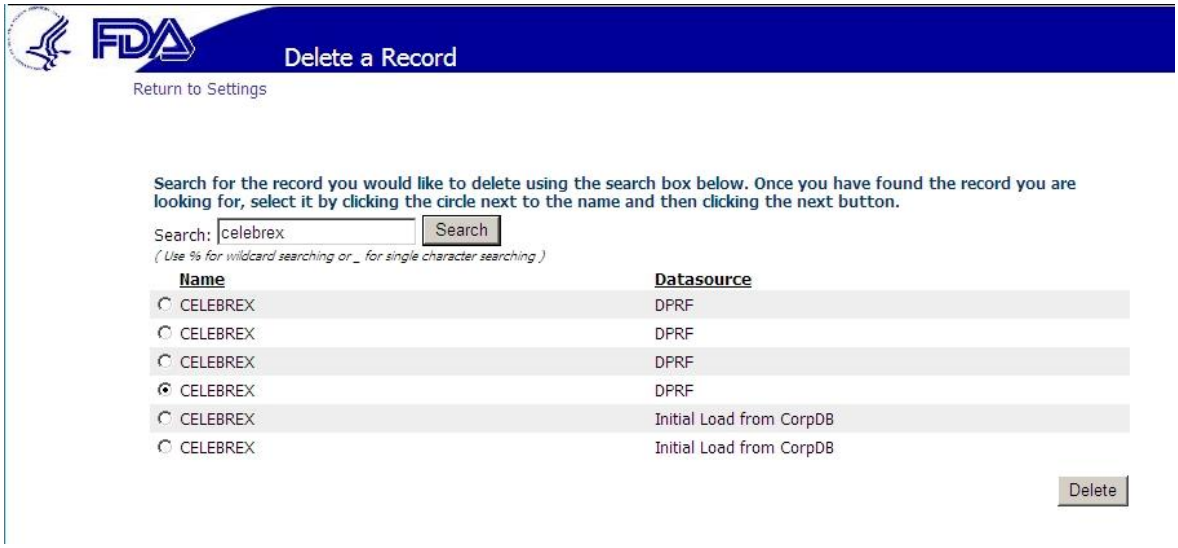


Figure 19 - Delete a Record Screen (2 of 2)

Find the record you wish to delete and mark it for deletion by clicking the radio button to the left of the drug name. Click the 'Delete' button to remove the record from the POCA database.

6 Searching

6.1 Search Algorithms

The POCA system has three search modules, namely *orthographic*, *phonetic*, and *text*. The orthographic search module is implemented using an ALINE algorithm modified for orthographic purposes. The orthographic search engine does not accept wild cards, as the algorithm takes each part of a written name into account when matching against names stored in the POCA database.

The phonetic search module is implemented using an ALINE algorithm for phonetic matching. The phonetic search engine does not accept wild cards because each sound of a name is taken into account when matching against names in the POCA database.

The text search module is implemented using comparison methods for text matching built into the Oracle 9i Database Management System. Several wildcards are available for the text search engine. The percent sign (%) is a wildcard character that will match any sequence of consecutive characters.

For example:
Search Term: flo%in
Results: floucin, floxin

The underscore character (_) is a wildcard that will match any single character.

For example:
Search Term: flo_in
Results: floxin

Wildcard characters can be used in conjunction with each other for matching a wider variety of patterns.

For example:
Search Term: fl%x__
Results: flexin, flexon, floxin

In the above example, both types of wild cards were used. A ‘%’ character was used to match any sequence of characters after the ‘l’ character and before the ‘x’ character in the search term. Two underscores (‘_’) were used to match any two (2) characters at the end of a name.

6.2 Accessing the Search

The search pages can be accessed by clicking the Search link in the Navigation Bar, by clicking the New Search link in the Options Bar, by entering a term into the Quick Search area of the Home Screen, or by entering a term into the Quick Search area included on the bottom of a search results screen. If the search is conducted from the results screen, the search criteria will be pre-populated from the search conducted.

6.3 Search Views

The *Quick Search* view allows users to search the database for a drug name using a combination of Orthographic, Phonetic, and Text algorithms. The *Quick Search* is accessible directly from the home page, or by clicking on the 'Search" link in the header. By default, only the orthographic search will run. However, you may also check the phonetic and text searches. When performing a text search, the '_'character may be used to match any single character. The '%' character will match any string of characters.

Figure 20 - Quick Search View

To switch to the *Advanced Search*, click the "Switch to advanced search view" link at the bottom of the screen. The *Advanced Search* allows a user to specify data sources for the search in addition to search criteria supported by the *Quick Search*.

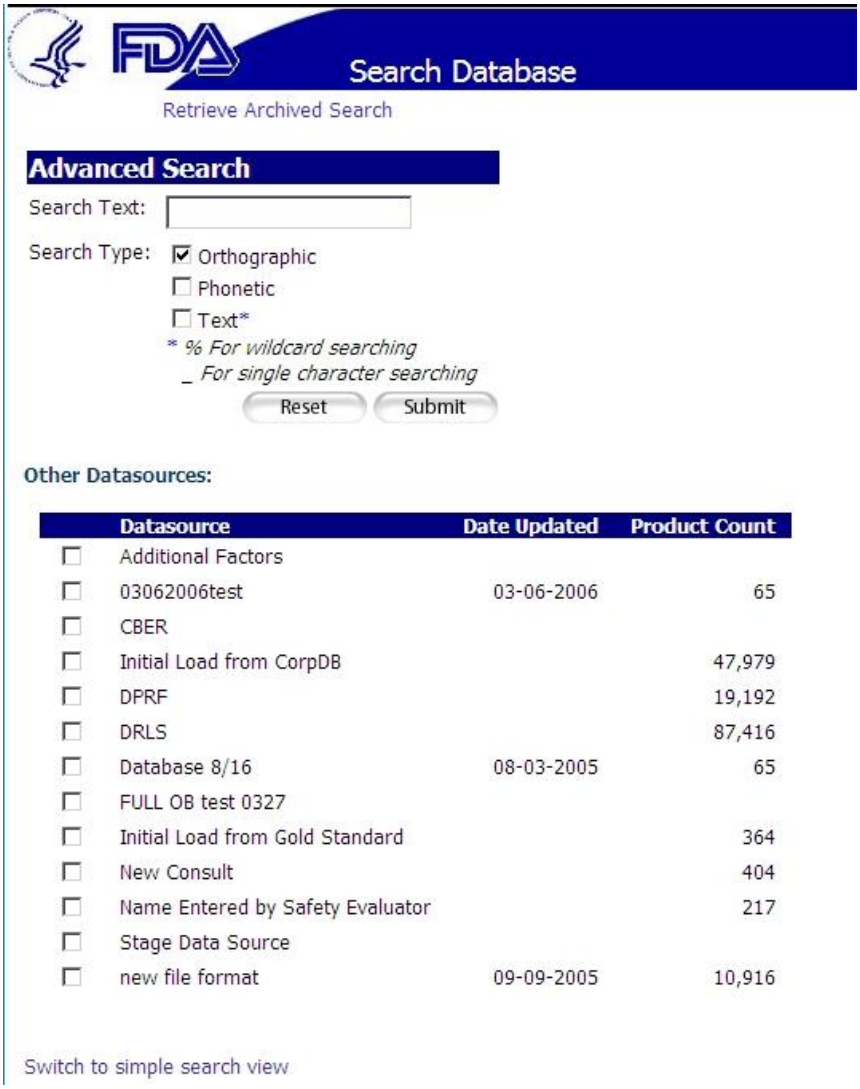


Figure 21 - Advanced Search View

Check all data sources you wish to include in your search, and click "Submit." To switch back to the *Quick Search*, click "switch to simple search view."

6.4 Search Results

The *Search Results* page displays the results of every search. The upper section of the *Search Results* page displays a table containing drug names that matched the search criteria for every search module specified in the search. The lower section displays a quick search pre-filled with the search criteria used in the previous search.

Note that if the phonetic, orthographic, and additional factors engines are all specified for the search, a table with matching drug names and a combined score will appear in the top table. The combined score is calculated by a weighted average of the returned results.

Individual matches will appear in separate tables under the combined score table. All table columns on the *Search Results* page can be sorted by clicking on the column header.

Shown below is the Search Results page displaying the results of a search for *lipater* using the orthographic, phonetic, and text search modules. Note a table with the combined scores for orthographic and phonetic matches, as well as separate tables for orthographic and phonetic results. Also note that there are no text matches.

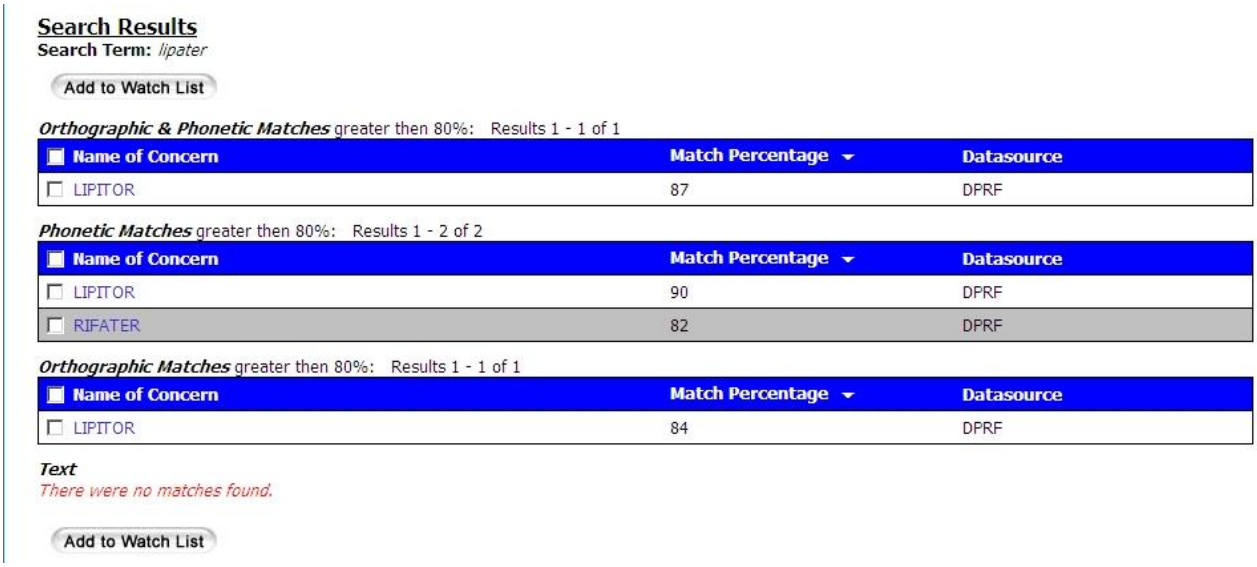


Figure 22 - Search Results Example

If you would like to see additional information about any names returned by the search, simply click on the name of interest. A details page will display all details about the name stored in the POCA database, including the data source.

Search results can be added to a watch list by selecting the checkbox next to the desired result and clicking the 'Add to Watch List' button. Clicking the 'Add to Watch List' button will bring up the Add to Watch List dialogue, as shown below.

Figure 23 - Add to Watch List Dialogue

Use the drop down lists provided to choose the watch list to which you would like to add you search result and, if necessary, the type of concern and level of concern. Type any comments in the *Narrative* text box, and click the 'Add' button. The search result will be added to the selected watch list.