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1 Introduction

1.1 Organization Overview

This document is organized into seven main sections.

- **Section One (Introduction)** discusses the background, scope, and organization.
- **Section Two (Getting Started)** contains instructions on connecting to the system, logging on, requesting accounts, and navigation from the home page.
- **Section Three (Settings for All Users)** provides information on system wide settings available to all POCA user roles.
- **Section Four (Advanced Settings for Business and System Admin. Users)** describes information on system wide settings available to System Administrators and Business Administrators users.
- **Section Five (Advanced Settings – System Administrators)** provides information on system wide settings accessible to the System Administrators user group.
- **Section Six (Advanced Settings – Business Administrators)** provides information on system wide settings accessible to the Business Administrators user group.
- **Section Seven (Drug Name Searches – All Users)** provides information about how to perform drug name searches.

1.2 Background

A vital part of the Food and Drug Administration (FDA) and Center for Drug Evaluation and Research (CDER)'s mission is to develop new standards to prevent medication errors due to proprietary name confusion. The Office of Surveillance and Epidemiology (OSE), Division of Medication Errors Prevention and Analysis (DMEPA) contributes to this effort by evaluating all proprietary names submitted to CDER 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) is a web application developed to determine written (orthographic) and spoken (phonetic) similarities between proposed drug names.

1.3 Document Scope

This User Guide provides information about all of the features in the application. It is not a technical developer's manual, nor does it provide in-depth information on the database or operating systems.

This document was written for the FDA and refers to three types of users, namely *Safety Evaluator*, *Business Administrator*, and *System Administrator*. The scope of their access to the system is as described below.

Safety Evaluator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Personal settings

Settings for safety evaluators include as per the screen below:

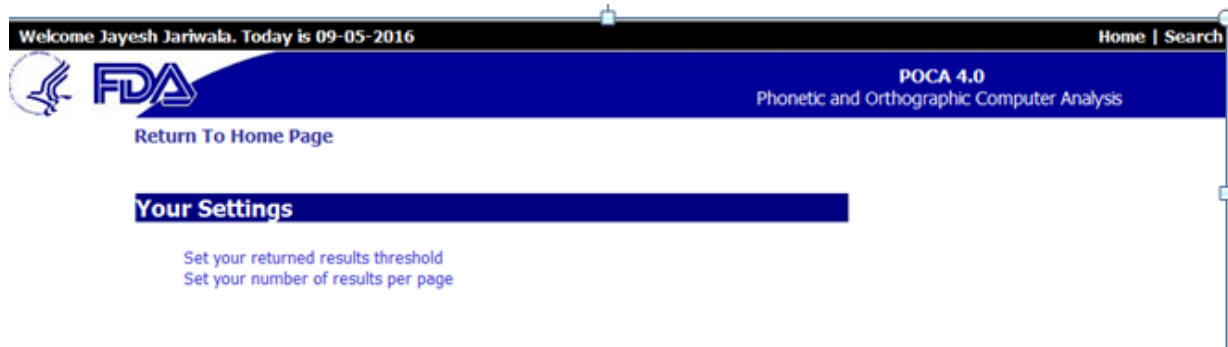


Figure 1: Settings Page for Safety Evaluators

Business Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Personal settings
- Manually Add Drug Names To Database
- Delete Drug Names from Database
- Add/Edit users
- UAR Report

Settings for business administrators include as per the screen below:

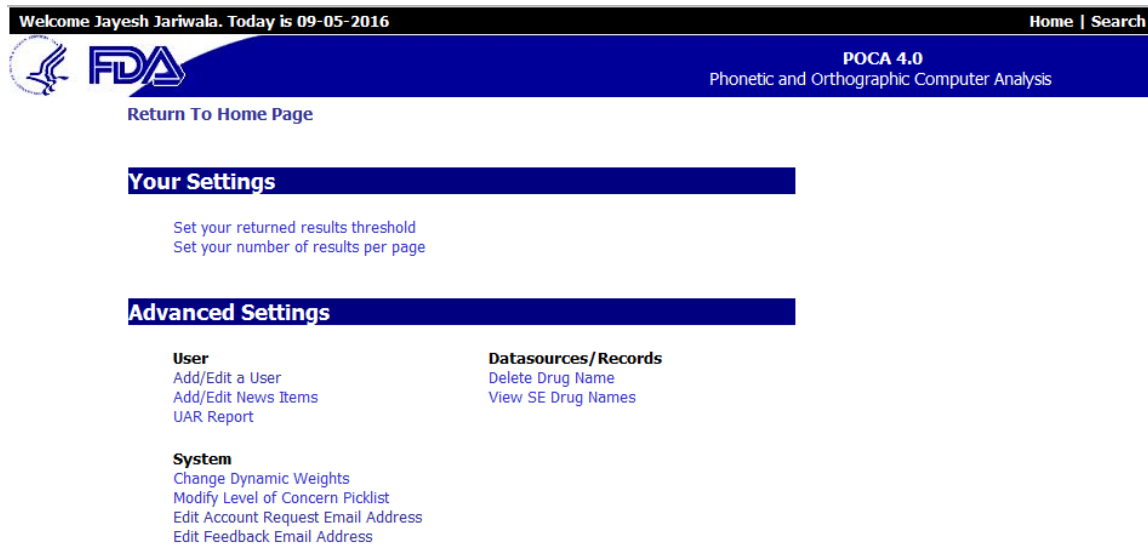


Figure 2: Settings Page for Business Administrators

System Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Search
- Personal settings
- Databases Maintenance
- Add/Edit users
- UAR Report

Settings for System Administrators include as per the screen below:

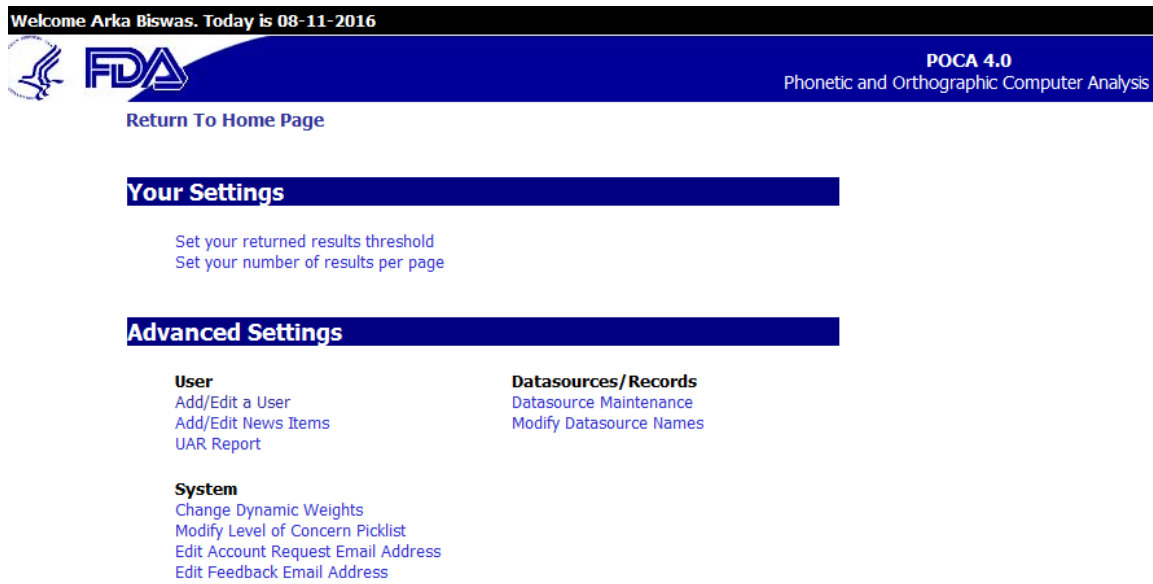


Figure 3: Settings Page for System Administrators

2 Getting Started

To access POCA, open your web browser (Internet Explorer, Chrome, Firefox or any other browser). Internet Explorer is opened by double clicking on the IE browser icon on your desktop or by selecting Start, Programs, and Internet Explorer from the start menu. In the address bar of your web browser, type the universal resource locator (URL) for POCA as <http://poca.pub.com/>. The Login screen will appear as shown below.

The screenshot shows the POCA login interface. At the top left is the FDA logo. To its right is a blue banner with white text that reads "FDA Automated Method of Minimizing Medication Errors Due to Similar Proprietary and Established Names". Below the banner are two input fields: "User ID:" and "Password:". To the right of the "Password:" field is a "Login" button. At the bottom of the form are three links: "Reset Password", "Change Password", and "Request Account".

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 4: Login Screen

You will need a user account to access POCA. If an account has been created for you, enter your user ID 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.



Figure: Reset Password Screen

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 be displayed, as seen below.

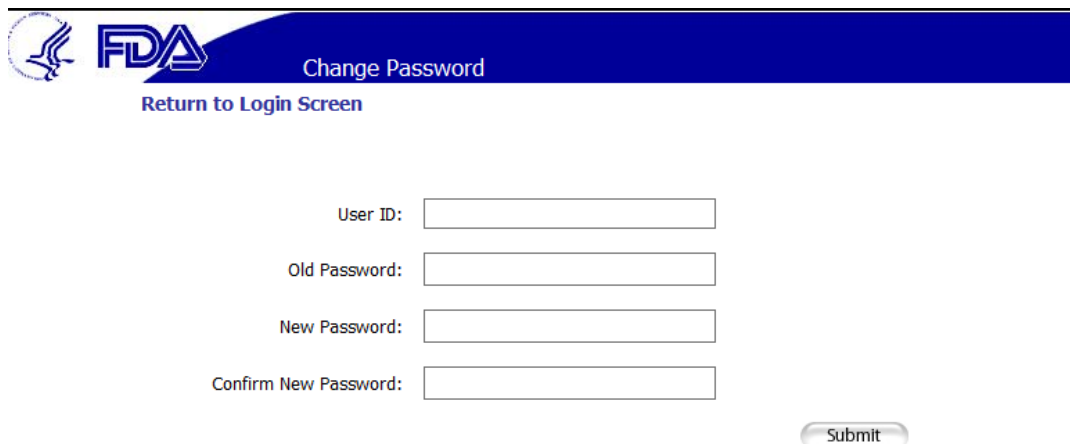


Figure 5: Change Password Screen

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 textboxes 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 the POCA account by clicking on the “Request Account” link on the login screen. The *Request an Account* screen

will be displayed.

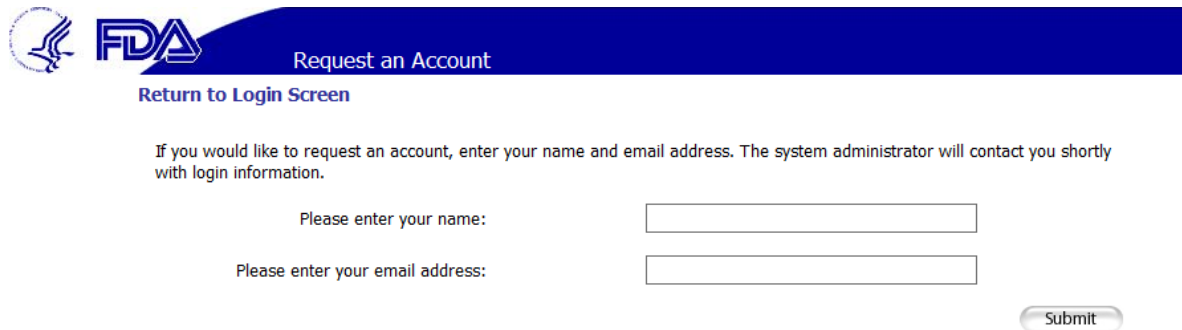
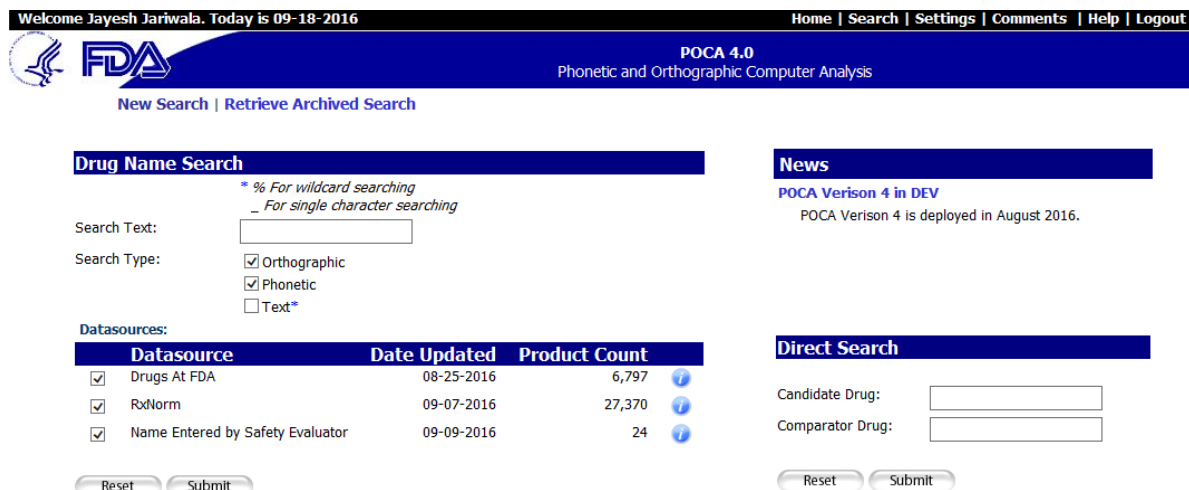


Figure 6: Request Account Screen

Enter your name and email address in the text boxes provided, and click the “Submit” button. An email will be sent to a POCA administrator stating that a POCA account is being requested for you. The POCA administrator will add your account to POCA with the Safety Evaluator user role unless a different role is requested. You will receive POCA email after your account is created. At that point, you may log in by typing <http://poca.pub.com> in your browser. 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.



Welcome Jayesh Jariwala. Today is 09-18-2016

Home | Search | Settings | Comments | Help | Logout

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New Search | Retrieve Archived Search

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic
☒ Phonetic
☐ Text*

Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	08-25-2016	6,797	
<input checked="" type="checkbox"/>	RxNorm	09-07-2016	27,370	
<input checked="" type="checkbox"/>	Name Entered by Safety Evaluator	09-09-2016	24	

Reset Submit

News

POCA Verison 4 in DEV
POCA Verison 4 is deployed in August 2016.

Direct Search

Candidate Drug:

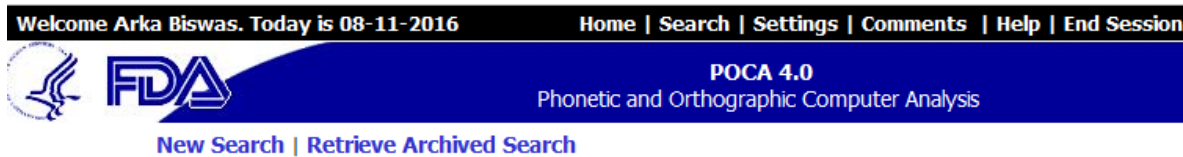
Comparator Drug:

Reset Submit

Figure 7: Home page

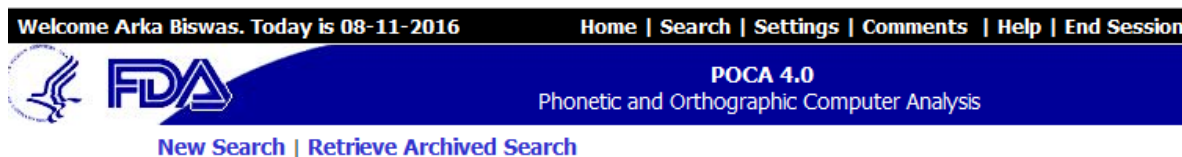
2.4.1 Navigation Bar

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 page and settings page. The navigation bar has other links such as comments and help. This navigation bar is accessible on all POCA pages.



2.4.2 New Search/Retrieve Archived Search Bar

Another option to navigate to the search page is the “New Search” link located at the top of the home page, below the FDA banner.



The *New Search link* is available for all users. This will allow you to search for a drug name.

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 previously conducted searches.

2.4.3 News

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

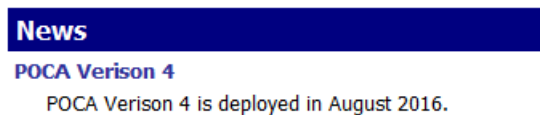


Figure 8: News

2.4.4 Drug Name Search

Drug Name Search is displayed for all users. The User can perform Orthographic, Phonetic or Text searches for any drug name with in the selected data sources. More about how to use the *Drug Name Search* feature is described in section 7.

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic
☒ Phonetic
☐ Text*

Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	11-16-2016	5,899	
<input checked="" type="checkbox"/>	RxNorm	11-14-2016	26,321	
<input checked="" type="checkbox"/>	Name Entered by Safety Evaluator			

Figure 9: Drug Name Search Section in Home Page

2.4.5 Direct Search

The direct search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and Comparator Drug Names. After entering those 2 drug names and pressing the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed for those 2 drug names.

Direct Search

Candidate Drug:

Comparator Drug:

Combined Score: **77**
Phonetic Score: **73**
Orthographic Score: **81**

Figure 10: Direct Search section in Home Page

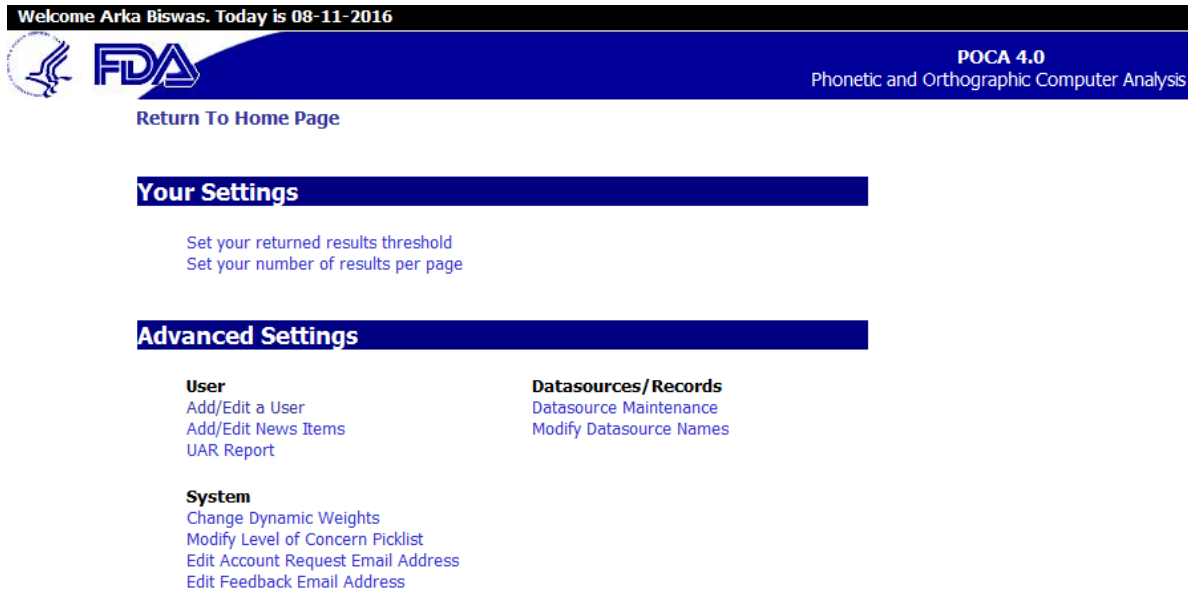
2.4.6 Manually Add Drug Name to Database

This functionality is available to business administrator users only. It allows users to add drug name manually to “Name Entered by Safety Evaluator” data source. Please see Section 6.1 for more information.

Manually Add Name to Database

3 Settings for All Users

All personal settings for your POCA account can be accessed from *Your Settings* section on the *Settings* screen. To access the *Your Settings* screen, click on the “Settings” link found in the navigation bar. Each role will see different functionality in Settings page as described in section 1.3.



Welcome Arka Biswas. Today is 08-11-2016

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[Return To Home Page](#)

Your Settings

[Set your returned results threshold](#)
[Set your number of results per page](#)

Advanced Settings

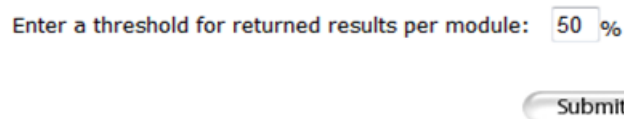
User Add/Edit a User Add/Edit News Items UAR Report	Databases/Records Database Maintenance Modify Database Names
System Change Dynamic Weights Modify Level of Concern Picklist Edit Account Request Email Address Edit Feedback Email Address	

Figure 11: Personal Settings for a System Administrator

The following settings are available to all users.

3.1 Set your Returned Results Threshold

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



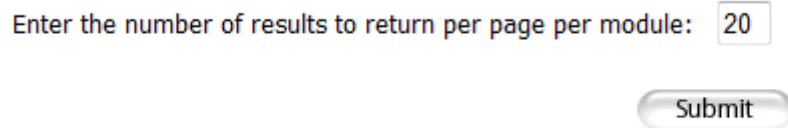
Enter a threshold for returned results per module: %

Figure 12: Setting the 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 50%, only results with a match percentage of 50% 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.



Enter the number of results to return per page per module:

Figure 13: Number of results per page

4 Settings for Business and System Administrator Users

Business Administrators and System Administrators user groups have the same advanced settings except for their level of access to ‘Datasource/Records’. The table below shows the level of access for each type of administrator under Datasource/Records:

Administrator User Group	Datasources/Records Level of Access
System Administrator	Datasource Maintenance Modify Datasource Name
Business Administrator	Delete Drug Name View SE Drug Names

The following settings are available to all business and system administrator users.

4.1 Add/Edit a User

To add or edit a user profile, click the “*Add/Edit a User*” link under *Advanced Settings* on the *Settings* page. To access the *Advanced Settings* screen, click on the “*Settings*” link found in the navigation bar. The User Administration page will be displayed as shown below.

Welcome Jayesh Jariwala2. Today is 09-05-2016

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[Return to Settings](#)

Edit User:

Select a user from the list below to edit their details.

Enabled Users:

Disabled Users:

Add a new user:

User Name:

First Name:

Last Name:

Email:

User Group:

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
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 <i>Safety Evaluator</i> , <i>Business Administrator</i> or <i>System Administrator</i> .	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 *arka.biswas1* for editing appears as below.

Edit User

User Name:	arka.biswas1
First Name:	<input type="text" value="Arka"/>
Last Name:	<input type="text" value="Biswas"/>
Email:	<input type="text" value="arka.biswas@fda.hhs.gov"/>
User Group:	<input type="text" value="Business Administrator User Group"/> ▼

<input type="button" value="Update User"/>	<input type="button" value="Disable User"/>
--	---

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 for the enabled user account can be used to disable user

accounts. To disable the enabled user 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.

Similarly, the *Edit User* form for the disabled user account can be used to enable user accounts. To enable the disabled user account, simply click the “Enable User” button on the *Edit User* page.

4.2 Add/Edit News Items

News Items display on the home page of the POCA system under News section. 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 *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.

Welcome Arka Biswas. Today is 08-11-2016

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[Return to Settings](#)

Select a news item from the list to edit it:

Headline:

News Teaser:

News Item:

Expire Date:

Figure 16: Add/Edit News Item page

The fields on this form are described below table.

Field Name	Definition/Description	Field Type
Headline	This is the title that will identify the news item. This field Is required.	Edit

News Teaser	Text entered here will appear below the headline on the home and login pages. This field is required.	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.

Return to Settings

Select a news item from the list to edit it: POCA Verison 4 ▼ Get News Item

Headline: POCA Verison 4

News Teaser: POCA Verison 4 is deployed in August 2016.

News Item:

Expire Date:

Submit/Update Reset

Figure 17: Edit a New Item

4.3 User Access Report (UAR)

Administrator users can view a list of all users, enabled users and disabled users with their full name, e-mail addresses, status, and user group assignment from this feature. You can export the user’s list into a Microsoft Excel by clicking on the ‘Export to Excel’ button. You also can filter user’s list for a specific time frame.

User Access Report

Enter Begin Date: (mm/dd/yyyy)

Enter End Date: (mm/dd/yyyy)

All **Enabled** **Disabled**

Total Enabled Users: 68

User Name	Full Name	Email	User Group	Status	Create/Update Date
winiarskia	Aleksander Winiarski	Aleksander.Winiarski@fda.hhs.gov	Safety Evaluators	Enabled	05/29/2012
tuc	Alice Tu	chi-ming.tu@fda.hhs.gov	Safety Evaluators	Enabled	05/22/2013
POPATA	Alpita Popat	Alpita.Popat@fda.hhs.gov	Safety Evaluators	Enabled	03/12/2015
Arka.Biswas	Arka Biswas	Arka.Biswas@fda.hhs.gov	Business Administrators	Enabled	09/20/2016
Vicky.Borders-Hemphill	Brenda Borders-Hemphill	Vicky.Borders-Hemphill@fda.hhs.gov	Safety Evaluators	Enabled	06/03/2013

Figure 18: UAR Report

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.

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Phonetic and Orthographic Computer Analysis

[Return to Settings](#)

Enter the Phonetic Dynamic Weight: %

Enter the Orthographic Dynamic Weight: %

Enter the Additional Factors Dynamic Weight: %

Figure 19: 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 to 100. Also, a percentage for orthographic, phonetic, and additional factors must be set.

4.5 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*” link in Settings page. It will display the page as shown below.



Figure 20: Edit Account Request Email Screen

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.

4.6 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*” link in Settings page. It will display the page as shown below.

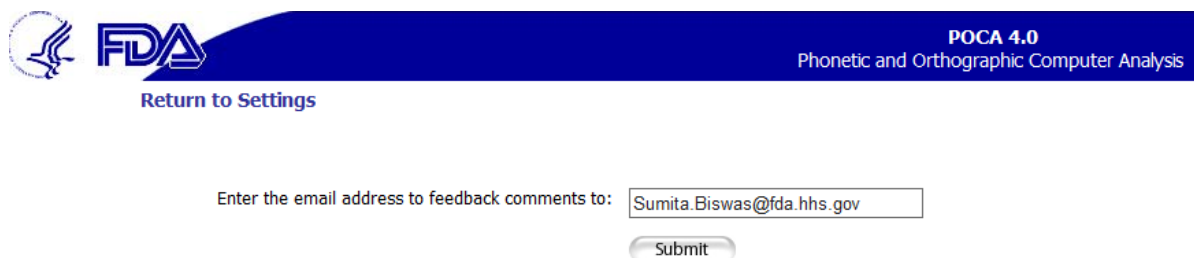


Figure 21: Edit Feedback Email Address Screen

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.

4.7 Modify the level of Concern Picklist

User can modify the level of concern picklist using the below screen.

Modify the Level of Concern Picklist

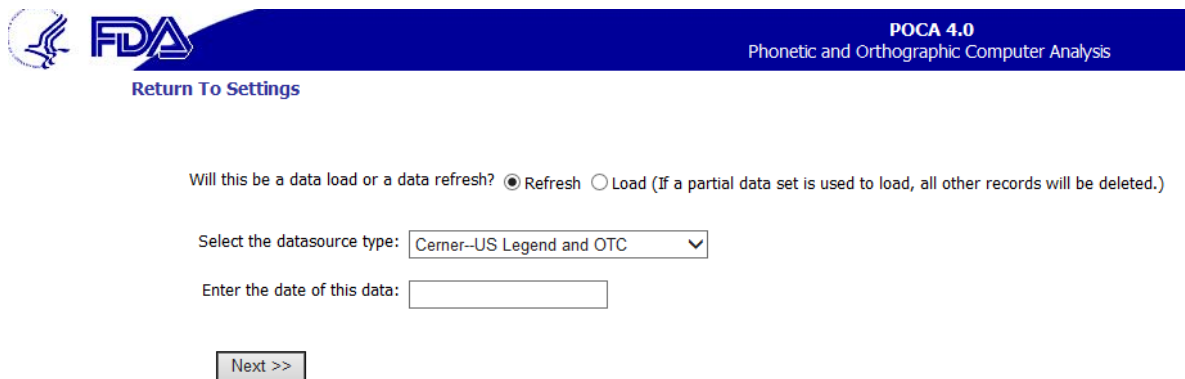
Description	
<input type="button" value="Edit"/>	Undetermined
<input type="button" value="Update"/> <input type="button" value="Cancel"/>	List Item 2: Low
<input type="button" value="Edit"/>	Moderate
<input type="button" value="Edit"/>	high

Figure 22: Modify the level of concern picklist

5 Advanced Settings – System Administrators

5.1 Datasource 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 *Settings* page.



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[Return To Settings](#)

Will this be a data load or a data refresh? ☒ Refresh ☐ Load (If a partial data set is used to load, all other records will be deleted.)

Select the datasource type: Cerner--US Legend and OTC

Enter the date of this data:

Next >>

Figure 23: Data Source Maintenance Screen

Select the datasource 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.

5.2 Modify Datasource Names

To rename datasource in POCA database and also to add new datasources click on the “Modify Datasource Names” link in the *Advanced Settings* section of the *Settings* page. You will see below page in the following screen. Select the “Edit” button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the “Update” button to successfully update the data.

Select the "Edit" button to the left of the Datasource Name that you wish to edit. Once the name change is complete, make sure to select the "Update" button to successfully update the data.

Datasource Name	
<input type="button" value="Edit"/>	Cerner--US Legend and OTC
<input type="button" value="Edit"/>	DPRF
<input type="button" value="Edit"/>	Drugs At FDA
<div><div><input type="button" value="Update"/><input type="button" value="Cancel"/></div><div><div><div>Name: <input type="text" value="Orange Book - approved since 1980"/></div><div>Description: <div></div></div></div><div><input type="button" value="Delete"/></div></div></div>	
<input type="button" value="Edit"/>	RxNorm

Figure 24: Modify datasource names

6 Advanced Settings – Business Administrators

6.1 Manually Add Drug Name to Database

In Home Page, “Manually Add Name to Database” section is only available to Business Administrator users. This field allows Business Administrators to add proposed proprietary names to the POCA database which updates the data source entitled 'Name Entered by Safety Evaluator'. Each proposed proprietary name assigned to a safety evaluator should be entered into the POCA database by a business administrator. This enables all safety evaluators to search the 'Name Entered by Safety Evaluator' data source to find other proposed names submitted to the Agency for review which may have orthographic or phonetic similarity to the proposed name they are assigned to evaluate.

If the name is entered manually in error or spelled it incorrectly, please contact business administrator to delete the incorrect entry and re-enter the correct name once the incorrect name is deleted.



Figure 25: Manually Add Name to Database

6.2 Delete Drug Name

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

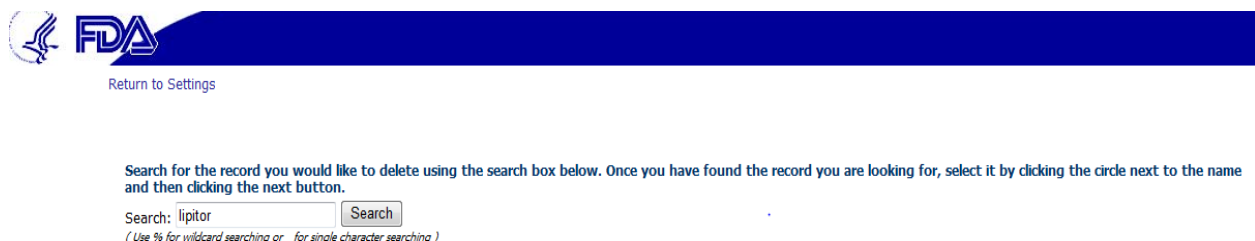
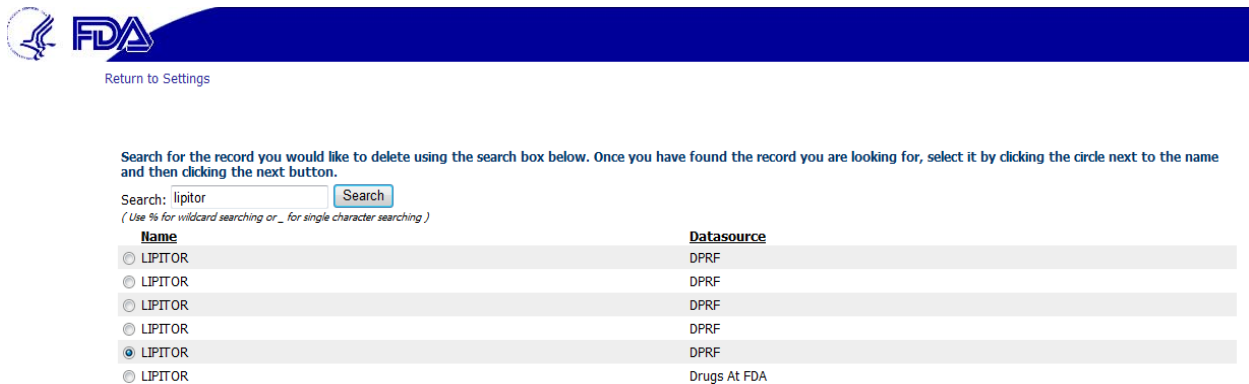


Figure 26: Delete a Record Screen (1 of 2)

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



Return to Settings

Search for the record you would like to delete using the search box below. Once you have found the record you are looking for, select it by clicking the circle next to the name and then clicking the next button.

Search:

(Use % for wildcard searching or _ for single character searching)

Name	Datasource
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	DPRF
<input checked="" type="radio"/> LIPITOR	DPRF
<input type="radio"/> LIPITOR	Drugs At FDA

Figure 27: 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. At the “Delete Confirmation” page, press the “Yes” button to remove the record from the POCA database or “No” button to not remove the record from the POCA database.

6.3 View SE Drug Names

To view the drugs entered by safety evaluators, click on the “View SE Drug Names” link under *Advanced Settings* in Settings page. In the following screen, select the date range from the drop down and you will see the drug names, similar to the figure below.

Select the Date Range you would like to view from the list below.

Show Last Month ▼

Drug Name	Date Entered	Entered By
Abasria	6/3/2013 1:30:04 PM	Walter Fava
Acticlate	6/3/2013 1:32:30 PM	Walter Fava
Aloftyn	6/3/2013 1:29:28 PM	Walter Fava
Avlina	5/31/2013 12:03:26 PM	Walter Fava
Cerinta	6/3/2013 1:31:17 PM	Walter Fava
Elifemme	6/3/2013 1:31:02 PM	Walter Fava
Hemangiol	6/3/2013 1:32:13 PM	Walter Fava
Jarbina	5/31/2013 6:59:35 AM	manizheh siahpoushan
Levemir FlexTouch	6/3/2013 2:07:37 PM	Walter Fava
Lorseva	6/3/2013 1:33:01 PM	Walter Fava
Mitigo	6/3/2013 2:06:28 PM	Walter Fava
Novolog FlexTouch	6/3/2013 2:07:16 PM	Walter Fava

Figure 28: View SE Drug Names screen

7 Drug Name Searches - All Users

7.1 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. Orthographic search algorithm is updated in POCA 4.0 to take more confuse pairs matrix into account. The update has been tested thoroughly by FDA team.

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 phonetic search engine ignores the numeric and special characters in the drug name.

The combined score is calculated as the average of the orthographic and phonetic scores.

Note that both the orthographic and phonetic search engines ignore numeric and special characters included in drug names. For example, the orthographic and phonetic similarity score for 'Drug-2' and 'Drug-25' will be 100%. See the below screen shots for examples.

Direct Search		Direct Search	
Candidate Drug:	tylenol	Candidate Drug:	Otezla
Comparator Drug:	tylenol @\$45	Comparator Drug:	Otezla 4566
<input type="button" value="Reset"/> <input type="button" value="Submit"/>		<input type="button" value="Reset"/> <input type="button" value="Submit"/>	
Combined Score:	100	Combined Score:	100
Phonetic Score:	100	Phonetic Score:	100
Orthographic Score:	100	Orthographic Score:	100

Figure 29: Direct Search

The text search module is implemented using comparison methods for text matching built in to the Oracle 11g 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, fluaxol, flavocoxid

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 underscore characters ('_') were used to match any two (2) characters at the end of a name.

7.2 Accessing the Search

The “*Drug Name Search*” section in Home page provides easy interface to conduct searches in POCA. The Search page can also be accessed by clicking the “*Search*” link in the Navigation Bar or by clicking the “*New Search*” link in the *Options* Bar.

The “*Direct Search*” functionality is available to all users under “Direct Search” section in Home page as well as in Search page. This feature provides user the ability to do direct search between Candidate Drug and Comparator Drug. After entering those 2 drug names and pressing Submit button, the Combined, Phonetic and Orthographic score search results will be displayed for those 2 drug names.

7.3 Search View

The “*Drug Name Search*” view allows users to search the POCA drug databases for a drug name using a combination of Orthographic, Phonetic, and Text algorithms. The *Drug Name Search* is accessible directly from the Home page, or by clicking on the “Search” link in the header.

By default, orthographic and phonetic searches will run. However, you may also choose by checking or unchecking any one or any combination of the orthographic, phonetic and text searches. When performing a text search, the underscore '_' character may be used to match any single character or the percentage '%' character may be used to match any string of characters.

Drug Name Search

* % For wildcard searching
_ For single character searching

Search Text:

Search Type: ☒ Orthographic
☒ Phonetic
☐ Text*

Datasources:

	Datasource	Date Updated	Product Count	
<input checked="" type="checkbox"/>	Drugs At FDA	11-16-2016	5,899	
<input checked="" type="checkbox"/>	RxNorm	11-14-2016	26,321	
<input checked="" type="checkbox"/>	Name Entered by Safety Evaluator			

Figure 30: Drug Name Search

By default, the drug name search will run against the Drugs At FDA, RxNorm and Name Entered by Safety Evaluator datasources. You may choose by checking or unchecking any combination of the datasources you wish to include in your search.

Enter the drug name to search in the “Search” Textbox and click on “Submit” button or press “Enter” key. The “Reset” button is provided to bring the “Drug Name Search” view in the default selection of Search Text, Search Type and Datasources.

The search results will be calculated and filtered with the scores that are equal to and greater than “user’s results threshold” value. The “Search Results” page will be displayed with the table of results with pagination and “Export to Excel” button.

7.4 Search Results

The *Search Results* page displays the results of every search. It displays a table containing drug names that matched the search criteria for every search module specified in the search.

Note that if the phonetic and orthographic search types are specified for the search, the results will display in a table that contains tabs which will allow users to display scores for each search type separately for the ‘combined’ results, ‘phonetic’ results, and ‘orthographic’ results. There is also a tab that allows user to display all three types of search results on one page. An overview of the result tabs is illustrated in Figure 28 below. It shows the *Search Results* page displaying the results of a search for *lipitor* using the orthographic and phonetic search types.

New Search

Search Results

Search Term: *lipitor*

Export To Excel

Combined	Phonetic	Orthographic	All
Orthographic & Phonetic Matches greater than 50%: Results 1 - 20 of 277 70% and Higher: 4 Between 55% and 69%: 98 54% and Lower: 175			
Name of Concern	Match % -	Datasource	
LIPITOR	100	RxNorm; Drugs At FDA	
LIPIDRO	78	RxNorm	
LIPIDIL	72	Drugs At FDA	
LIPIODOL	70	RxNorm	
EPITOL	68	RxNorm; Drugs At FDA	
ZADITOR	68	RxNorm; Drugs At FDA	
ZIPSOR	68	RxNorm; Drugs At FDA	
CLINITAR	66	RxNorm	
EPICORT	66	Drugs At FDA	
EPIKLOR	66	RxNorm	
KALBITOR	66	RxNorm; Drugs At FDA	
LIDOCORT	66	RxNorm	
LIDOPRO	66	RxNorm	
RELISTOR	66	RxNorm; Drugs At FDA	
DOMITOR	65	RxNorm	

Figure 31: Search Results Example

For Text search type, the Search Results page will display the Text tab with the table of exact text match.

All table columns on the *Search Results* page can be sorted by clicking on the column header.

If you would like to see additional information about any names returned by the search, simply click on the drug name of concern. “Product Details” page will be displayed in new window or new tab with all product details about the drug name stored in the POCA database, including the data sources. The Product Details page will be similar to the screen below. Please be aware that some results identified from RxNorm will not contain all information in Product Details page.

Product Details for LIPITOR

Data Source	Dosage Form	Potency	Route	Active Ingredient
Drugs At FDA	TABLET; ORAL	EQ 80MG BASEN/A	N/A	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 80 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 80MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	20MILLIGRAM(S)	ORAL	ATORVASTATIN
Drugs At FDA	TABLET; ORAL	EQ 20MG BASEN/A	N/A	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 40 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 40MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	80MILLIGRAM(S)	ORAL	ATORVASTATIN
DPRF	TABLET	EQ 80MG BASE	ORAL	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 20 MG ORAL TABLET [LIPITOR]
Cerner--US Legend and OTC	TABLET	10MILLIGRAM(S)	ORAL	ATORVASTATIN
Orange Book - approved since 1980	TABLET; ORAL	EQ 20MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Drugs At FDA	TABLET; ORAL	EQ 40MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Drugs At FDA	TABLET; ORAL	EQ 10MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Cerner--US Legend and OTC	TABLET	40MILLIGRAM(S)	ORAL	ATORVASTATIN
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 10 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 10MG BASEN/A	N/A	ATORVASTATIN CALCIUM

Figure 32: Product Details Page

7.5 Export To Excel

The ‘Export To Excel’ button displayed above the search results table. It can be clicked to transfer search results into an Excel Spreadsheet. This feature will export the combined scores, the phonetic scores, and the orthographic scores, as well as any product information from the product details into the Excel spreadsheet.

Also, please note that when the tab for combined search results is selected and the results are exported to Excel, then the Excel spreadsheet will contain the combined, phonetic, and orthographic scores for all of the combined results.

Otezla_CombinedSearchResults_50Percentage.xls - Microsoft Excel							
Combined Search Result							
Search Term: otezla Search Date: 09/07/2016 10:14 AM							
Name of Concern	Orthographic Score	Phonetic Score	Combined Score	Data Sources	Active Ingredient	Strength	Dosage Form
Otezla	100	100	100	RxNorm; Drugs At FDA	APREMILAST	10MG 20MG 30MG	TABLET
Zotex La	85	60	72	RxNorm			
Otovel	71	67	69	RxNorm; Drugs At FDA	CIPROFLOXACIN HYDROCHLORIDE; FLUOCINOLONE ACETONIDE	EQ 0.3% BASE;0.025%	SOLUTION/DROPS
Teslac	67	70	68	RxNorm; Drugs At FDA	TESTOLACTONE	100MG/ML 250MG 50MG	INJECTABLE TABLET
Motazol	73	57	65	RxNorm	CLOTRIMAZOLE 10 MG/ML / GENTAMICIN 3 MG/ML / MIOMETASONE 1 MG/ML OTIC SUSPENSION [MOTAZOL]		
Atreza	71	57	64	Name Entered by Safety Evaluator; RxNorm	ATROPINE SULFATE 0.4 MG ORAL TABLET [ATREZA]		
Teflaro	69	52	60	RxNorm; Drugs At FDA	CEFTAROLINE FOSAMIL	400MG/VIAL 600MG/VIAL	POWDER
Telazol	81	40	60	RxNorm	TILETAMINE 50 MG/ML / ZOLAZEPAM 50 MG/ML INJECTABLE SOLUTION [TELAZOL]		
Entex La	65	55	60	RxNorm			
Savella	54	64	59	Name Entered by Safety Evaluator; RxNorm; Drugs At FDA	MILNACIPRAN HYDROCHLORIDE	100MG 12.5MG 25MG 50MG	TABLET

Name of Concern	Orthographic Score	Data Sources	Active Ingredient	Strength	Dosage Form	Route
Otezla	100	RxNorm; Drugs At FDA	APREMILAST	10MG 20MG 30MG	TABLET	ORAL
Zotex La	85	RxNorm				
Telazol	81	RxNorm	TILETAMINE 50 MG/ML / ZOLAZEPAM 50 MG/ML INJECTABLE SOLUTION [TELAZOL]			
Terazol 3	77	RxNorm; Drugs At FDA	TERCONAZOLE	0.80% 80MG	CREAM SUPPOSITORY	VAGINAL
Terazol 7	77	RxNorm; Drugs At FDA	TERCONAZOLE	0.40%	CREAM	VAGINAL
Oxtellar	75	RxNorm	24 HR OXCARBAZEPINE 150 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 300 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR] 24 HR OXCARBAZEPINE 600 MG EXTENDED RELEASE ORAL TABLET [OXTELLAR]			

Figure 33: Export to Excel examples

When you click on the 'Export to Excel' button, a pop up window appears at the bottom of the screen asking if you want to open or save your search results. If you click on the dropdown arrow next to the 'Save' tab, then a menu appears for you to select from either 'Save', 'Save as', or 'Save and Open'. Select 'Save as' and the data will be saved in a

POCA 4.0
Phonetic and Orthographic Computer Analysis

New Search

Search Results
Search Term: *lipitor*

Export To Excel

Combined Phonetic Orthographic All

Phonetic Matches greater than 10%: Results 1 - 50 of 17,256
70% and Higher: 9 Between 55% and 69%: 114 54% and Lower: 17133

Name of Concern	Match %	Datasource
LIPITOR	100	RxNorm; Drugs At FDA
LIPIDIL	76	Drugs At FDA
LIPIDRO	76	RxNorm
ZADITOR	76	RxNorm; Drugs At FDA
RIFATER	72	RxNorm; Drugs At FDA
FLECTOR	71	RxNorm; Drugs At FDA
LEVATOL	71	RxNorm; Drugs At FDA
LOPRESSOR	71	RxNorm; Drugs At FDA
ZIPSOR	70	RxNorm; Drugs At FDA
DEPODUR	69	RxNorm
LEVITRA	68	RxNorm; Drugs At FDA
LIPIODOL	68	RxNorm
REBETOL	68	RxNorm; Drugs At FDA
GLISTER	67	RxNorm
LIOSORB		

Do you want to open or save *lipitor_PhoneticSearchResults.xls* (10.9 MB) from *poca.preprod.fda.gov*?

Open Save Save as Save and open

Figure 34: Excel file 'Save as' in the local drive

file with a '.xls' extension appearing after the file name. This format will allow you to easily edit the information in your spreadsheet. If you choose only to open the spreadsheet, be aware that when you decide to save it, you will need to click on the 'File' tab in the upper left hand corner of toolbar, select 'Save as' and from the dropdown menu, choose the version of Excel with the file extension, '.xls'.