PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

POCA v4.3 USER GUIDE



Version 1.3

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Version History

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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 INTRODUCTION

1.1 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, as well as other proposed names currently under review. 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 way 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.

1.2 DOCUMENT SCOPE

This User Guide provides information for safety evaluators, business administrators, 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 user groups and the scope of their access to the database as described below:

Safety Evaluator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches

Settings for safety evaluators include as per the screen below:

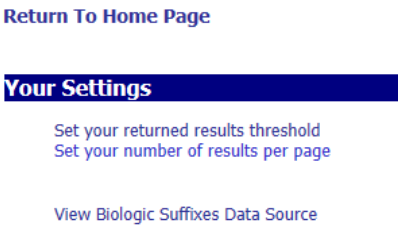


Figure 1: Settings Page for Safety Evaluators

Business Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Searches
- Manually Add Drug Names To Database
- Manage Biologic Suffixes Data Source
- Delete Drug Names from Database
- Add/Edit users
- UAR Report

Settings for business administrators include as per the screen below:

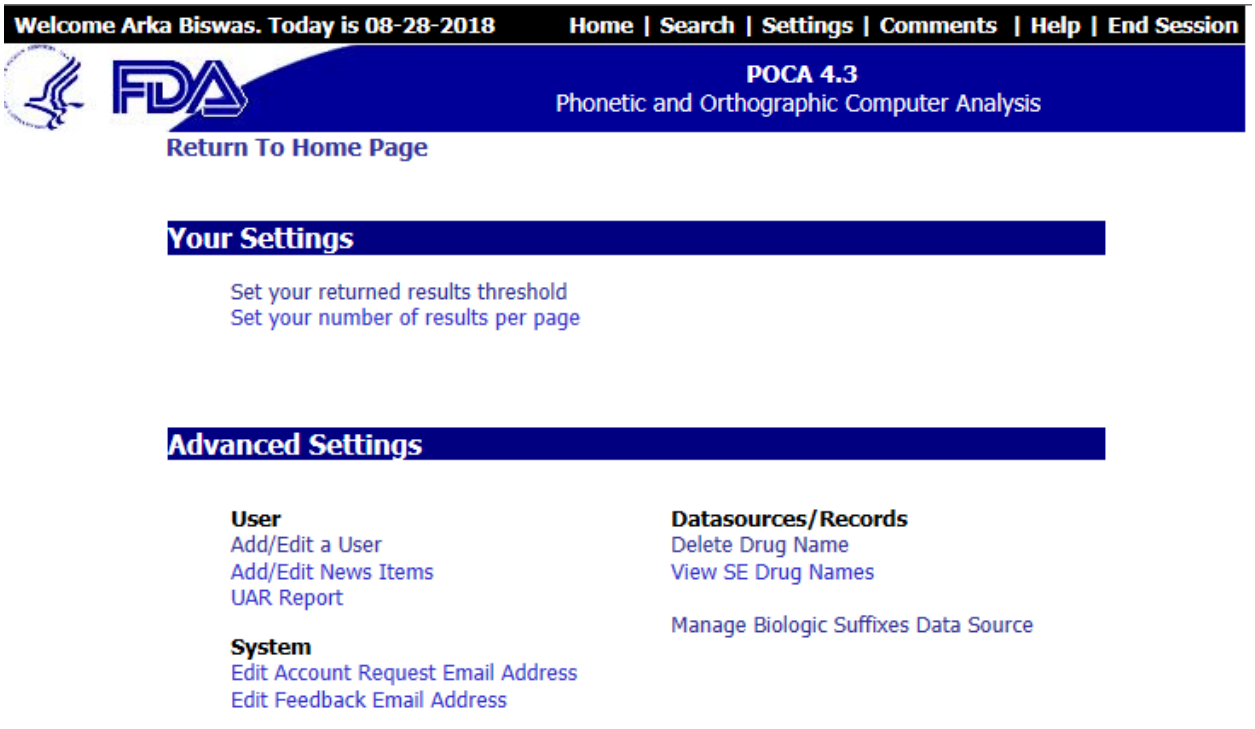


Figure 2: Settings Page for Business Administrators

System Administrator User Group

Access Level includes:

- Conduct Searches
- Retrieve Archived Search
- Datasources Maintenance
- Modify Datasource Names
- Add/Edit users
- UAR Report

Settings for System Administrators include as per the screen below:

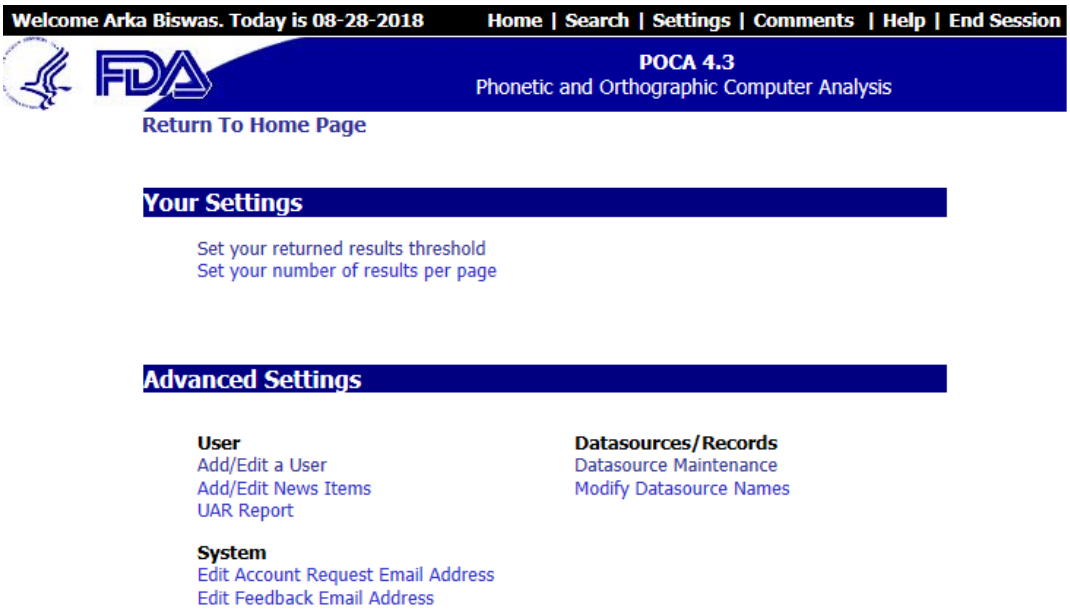


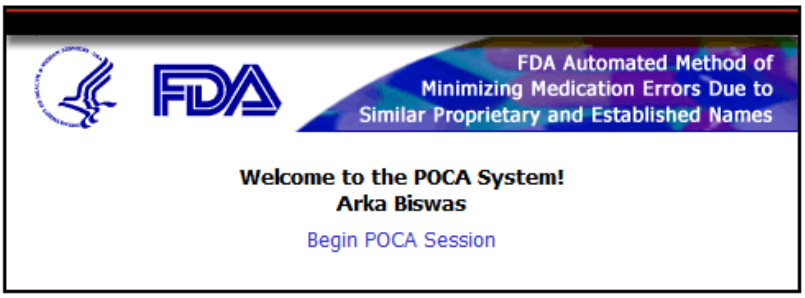
Figure 3: Settings Page for System Administrators

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 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 https://poca.fda.gov/poca.

You will need a user account to access POCA. If an account has been created for you, then the Login screen will appear as shown below with "*Begin POCA Session*" link. Since the POCA system is Single Sign-On (SSO) enabled, and does not require users to enter a user name and password. Click on the link "Begin POCA Session" to login to POCA. After successful login,

POCA Home page will be displayed as in section 2.2.



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

If you do not have a POCA account, then the Login Screen will appear as shown below with "Request Account" link. Please click on the "Request Account" link and follow the steps below to request an account.

2.1 REQUESTING AN ACCOUNT

You may request a POCA account by clicking on the "Request Account" link on the login screen. The *Request an Account* screen will be displayed.



Figure 5: Request Account Screen

Enter your name and FDA 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. The POCA administrator will contact you via e-mail with your login information and you will also receive POCA email after your account is created. At that point, you may log in by typing https://poca.fda.gov/poca in your browser. Upon successful log in, the home page is displayed for the assigned role to you.

2.2 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.

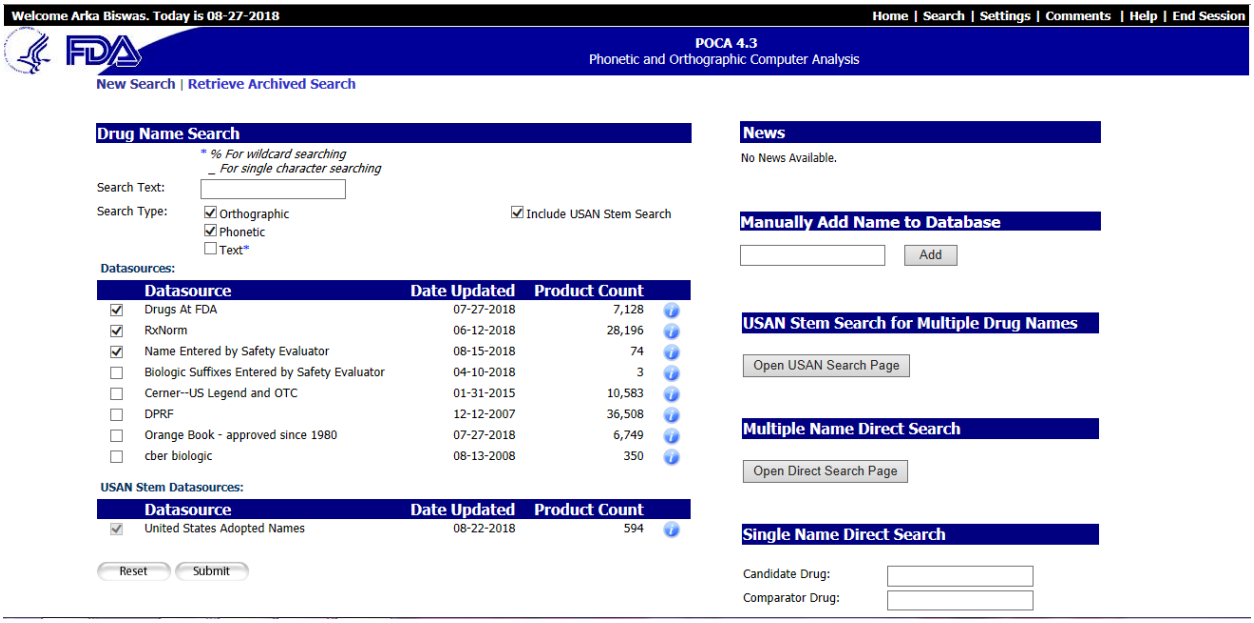
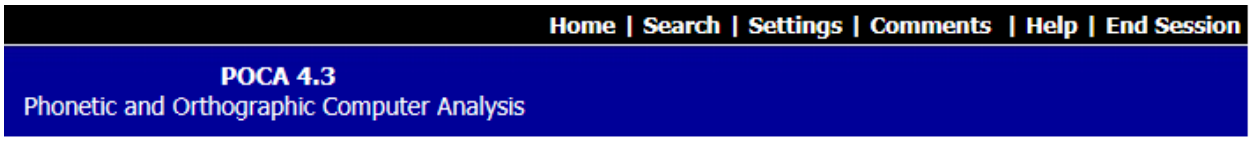


Figure 6: Home Page

2.2.1 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.



2.2.2 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.

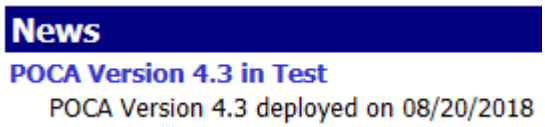


The *New Search link* is available for all users. This will allow you to search for a drug name.

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.

2.2.3 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.



2.2.4 Drug Name Search

Drug Name Search is displayed for all users. Users 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.

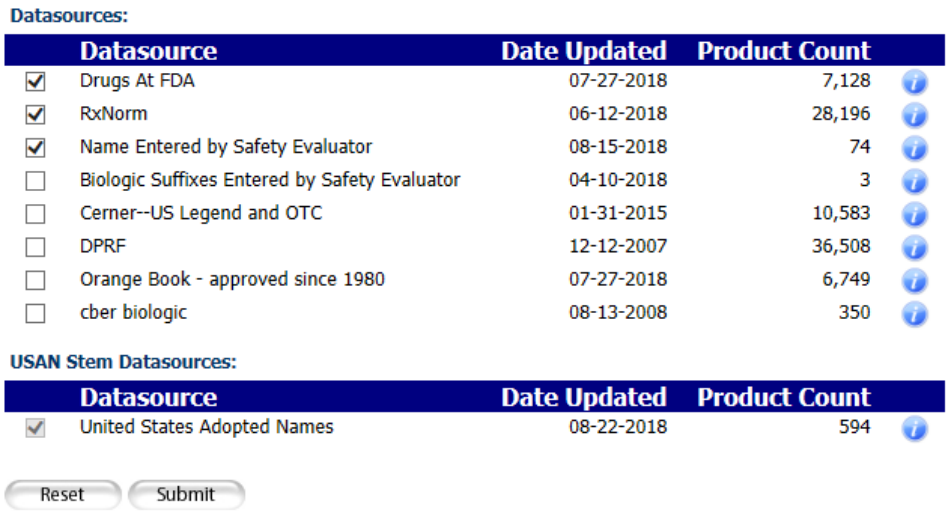


Figure 7: Drug Name Search Section in Home Page

2.2.5 Single Name 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 displayedfor those 2 drug names.

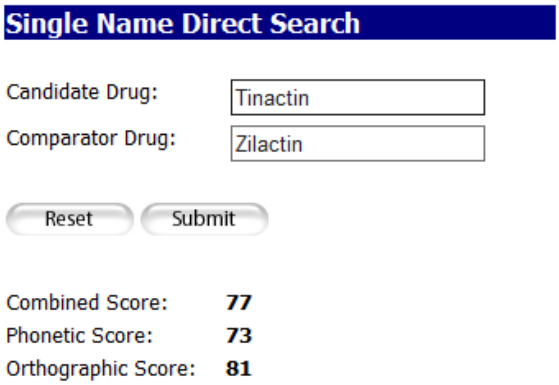


Figure 8: Direct Search section in Home Page

2.2.6 Multiple Direct Search

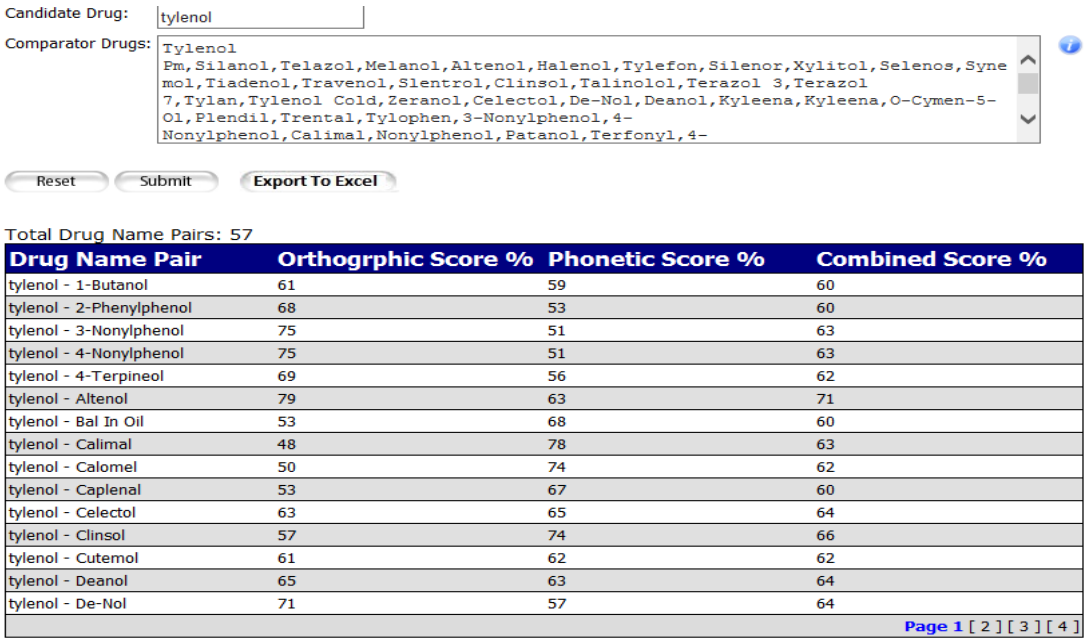
The Multiple Direct Search functionality is available to all users. This feature provides users the ability to perform direct searches between Candidate Drug Names and multiple Comparator Drug Names. Click on "Open Direct Search Page" under the “Multiple Name Direct Search” section.



A new page will appear with Candidate Drug and Comparator Drugs text fields. To use this search function, follow the instructions below:

- Enter a name in the Candidate Drug text field
- Enter multiple drug names in the Comparator Drugs text field, each separated by commas. Click on the "information" button - that will display popup message about Comparator Drugs text field format.
- Click the Submit button once all names have been entered in the text fields.

After clicking on the Submit button, the Combined, Phonetic and Orthographic search result scores will be displayed as illustrated in below figure.



Drug Name Pair	Orthogrphic Score %	Phonetic Score %	Combined Score %
tylenol - 1-Butanol	61	59	60
tylenol - 2-Phenylphenol	68	53	60
tylenol - 3-Nonylphenol	75	51	63
tylenol - 4-Nonylphenol	75	51	63
tylenol - 4-Terpineol	69	56	62
tylenol - Altenol	79	63	71
tylenol - Bal In Oil	53	68	60
tylenol - Calimal	48	78	63
tylenol - Calomel	50	74	62
tylenol - Caplenal	53	67	60
tylenol - Celectol	63	65	64
tylenol - Clinsol	57	74	66
tylenol - Cutemol	61	62	62
tylenol - Deanol	65	63	64
tylenol - De-Nol	71	57	64

Figure 9: Multiple Direct search home page

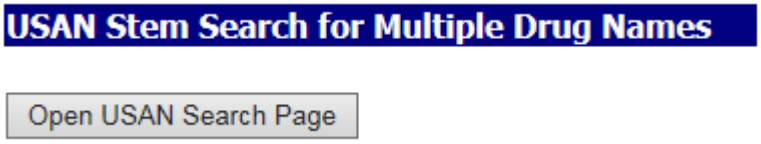
2.2.7 Manually Add Drug Name to Database

This functionality is available to business administrator users only and allows them to manually add drug names to "Name Entered by Safety Evaluator" data source. Please see Section 6.1 for more information.

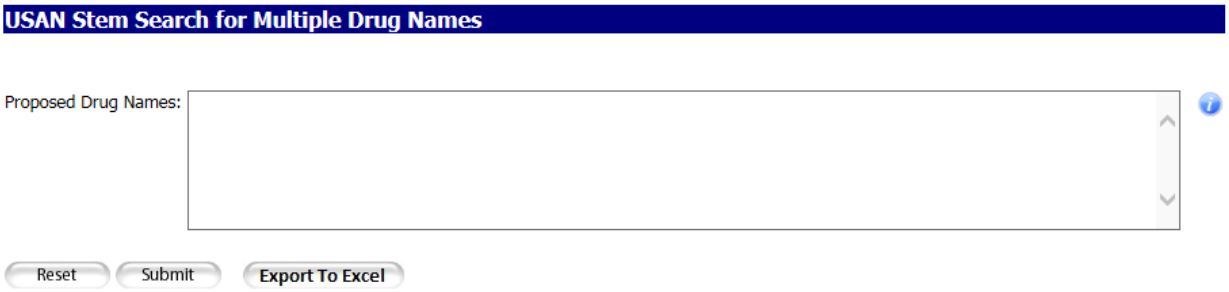


2.2.8 USAN stem search page

The USAN stem search functionality is available to all users. This feature provides users the ability to perform direct searches for the presence of USAN stems withinmultiple drug names. Click on "Open USAN Search Page" under the “Multiple Name Direct Search” section.

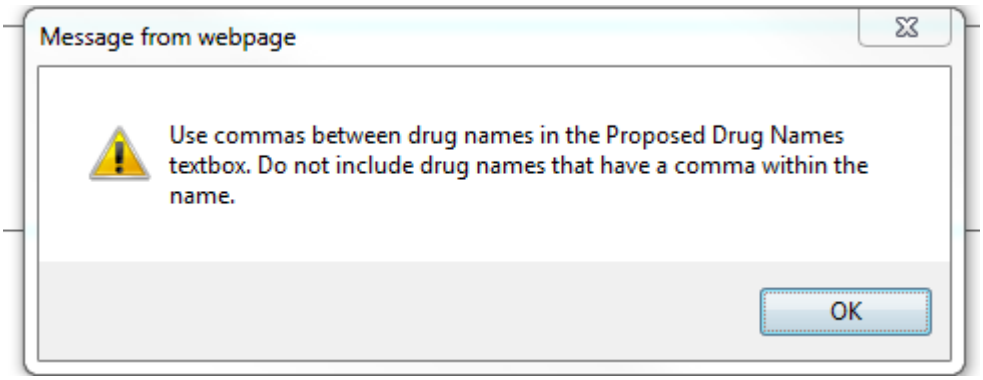


A new page will appear with a Proposed Drug Names text field as illustrated below in Figure (?).



To use this search function, follow the instructions below:

Enter multiple drug names in the Proposed Drug Names text field, and separate each name with acomma. Users may also click on the Click on the “information” button located to the right of the Proposed Drug Names text field to display a popup message explaining the correct format for entering multiple drug names as illustrated in Figure (?) below:



- Once all names have been entered in the text field, click on the 'Submit' button.

The search results will be displayed as illustrated in Figure (?) below:

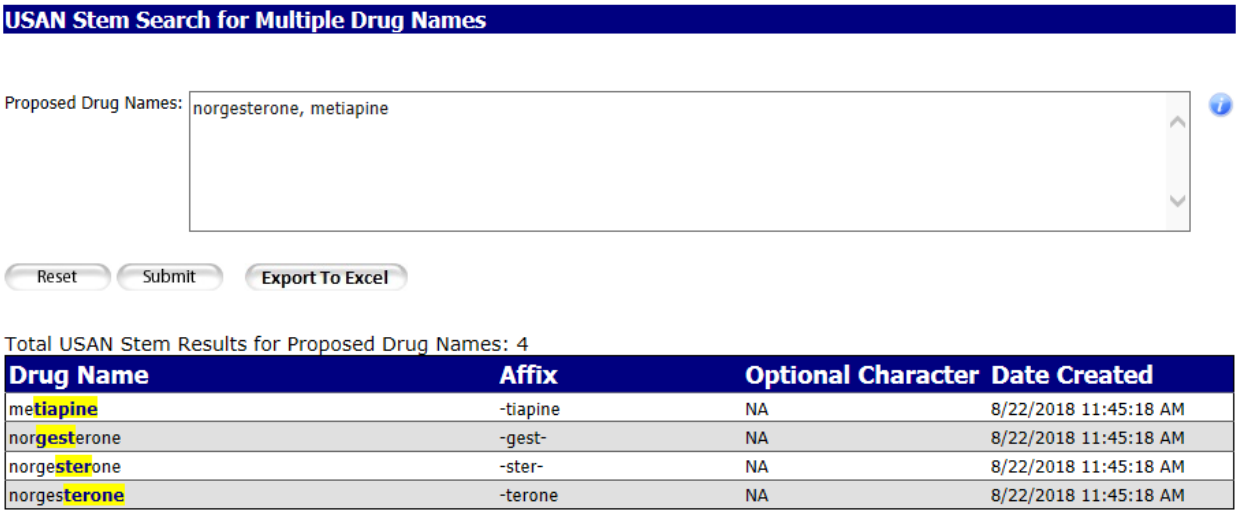


Figure 10: USAN search result

The first column of the results table displays each name searched with the identified USAN stem highlighted in yellow with bold font.
The second column of the results table displays the type of affix assigned to the USAN stem based on its position in the name (prefix, infix, or suffix).
The third column indicates if any letters in the USAN stem are considered 'optional' characters which may or may not be included in a recognized USAN stem.
The fourth column documents the date and time the results were retrieved.

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 1.2.



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*.

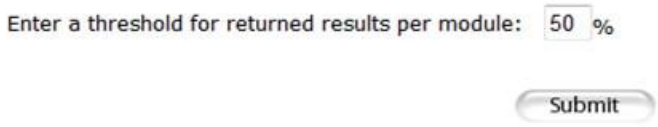


Figure 12: Setting the Threshold for Returned Results

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 can scroll through the pages of results.

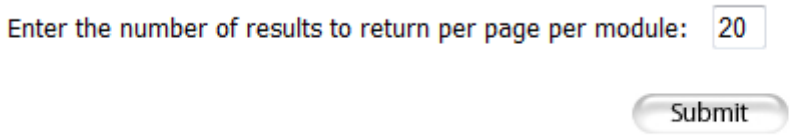


Figure 13: Number of results per page

4 SETTINGS FOR BUSINESS AND SYSTEM ADMIN 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 Manage Biologic Suffixes Data Source

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.

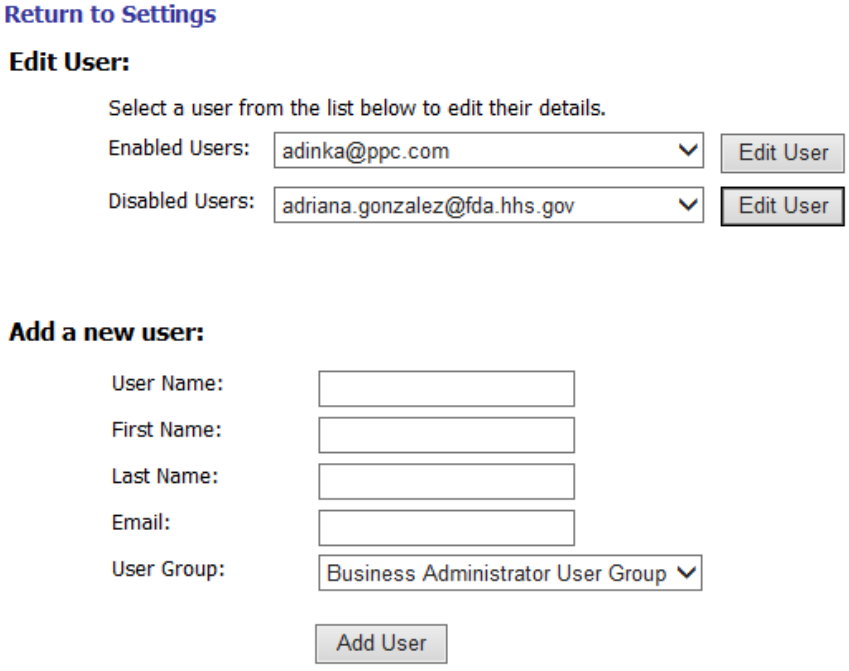


Figure 14: Add/Edit user

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 *Safety Evaluator*, *Business Administrator* or System *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 will be displayed with all the information available. An example of the *Edit User* form following the selection of username *arka.biswas1* for editing appears as illustrated in Figure 14 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 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.

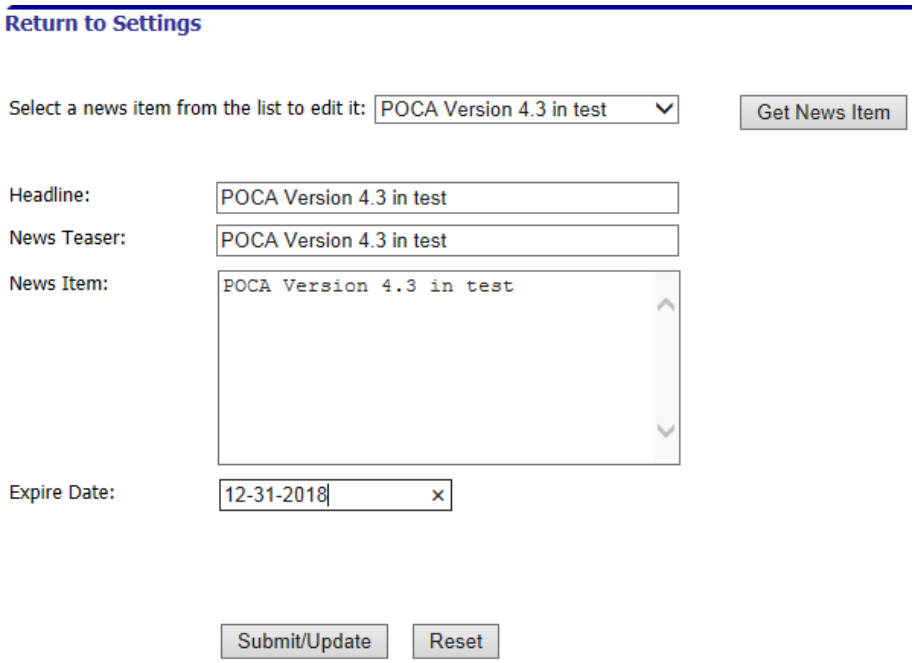


Figure 16: Add/Edit News Item page

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.

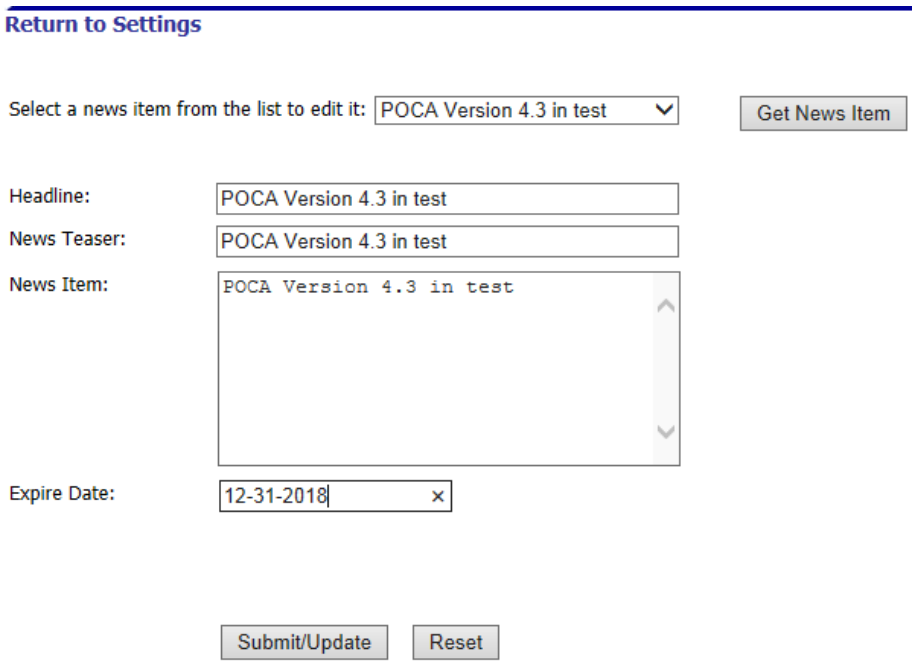
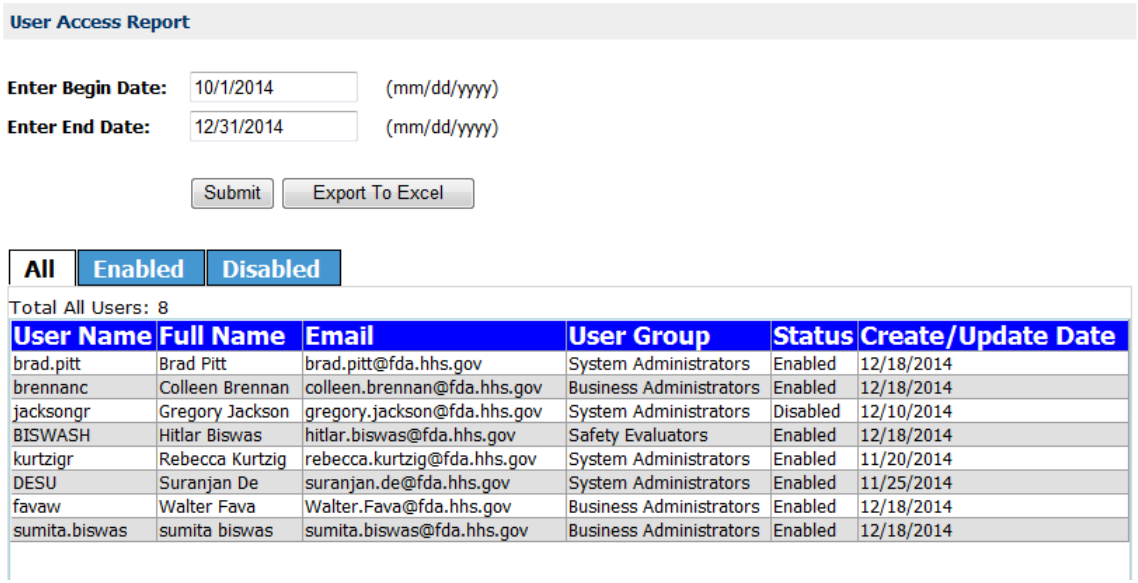


Figure 17: Edit a New Item

4.3 UAR REPORT

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 Name	Full Name	Email	User Group	Status	Create/Update Date
brad.pitt	Brad Pitt	brad.pitt@fda.hhs.gov	System Administrators	Enabled	12/18/2014
brennanc	Colleen Brennan	colleen.brennan@fda.hhs.gov	Business Administrators	Enabled	12/18/2014
jacksongr	Gregory Jackson	gregory.jackson@fda.hhs.gov	System Administrators	Disabled	12/10/2014
BISWASH	Hitlar Biswas	hitlar.biswas@fda.hhs.gov	Safety Evaluators	Enabled	12/18/2014
kurtzigr	Rebecca Kurtzig	rebecca.kurtzig@fda.hhs.gov	System Administrators	Enabled	11/20/2014
DESU	Suranjan De	suranjan.de@fda.hhs.gov	System Administrators	Enabled	11/25/2014
favaw	Walter Fava	Walter.Fava@fda.hhs.gov	Business Administrators	Enabled	12/18/2014
sumita.biswas	sumita biswas	sumita.biswas@fda.hhs.gov	Business Administrators	Enabled	12/18/2014

Figure 18: UAR Report

4.4 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 in Figure 19 below.



Figure 19: 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.

4.5 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.

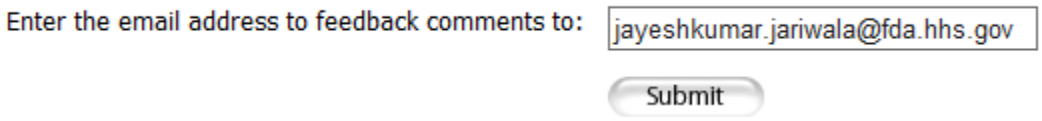


Figure 20: Edit feedback email address

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 DATASOURCE MAINTENANCE

For members of the System Administrators group, the POCA system supports capability to identify, load, refresh, and delete datasources from the POCA database. The data access process begins with the Datasource Maintenance screen, illustrated in Figure 21 below, which can be accessed by clicking the "Datasource Maintenance" link in the Advanced Settings section of the Settings page.

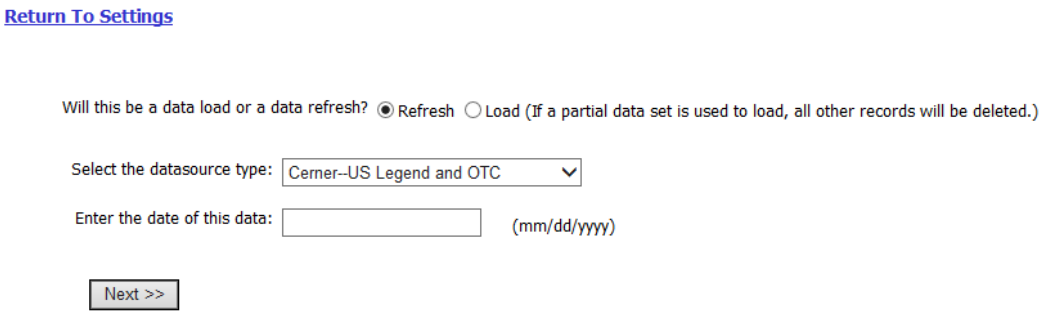


Figure 21: Data Source Maintenance Screen

Select the datasource type, enter the date of the data in the format "MM-DD-YYYY" or "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 a datasource in the POCA database and to also add new datasources, click on the "Modify Datasource Names" link in the *Advanced Settings* section of the *Settings* page, as illustrated in Figure 22 below. 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.

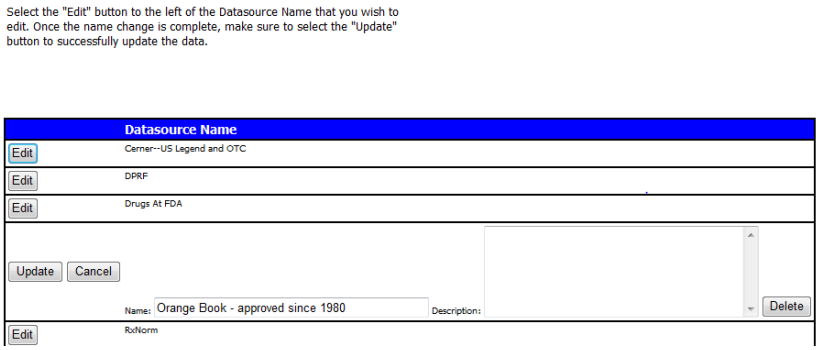


Figure 22: Modify datasource names

6 ADVANCED SETTINGS – BUSINESS ADMINISTRATORS

6.1 MANUALLY ADD NAME TO DATABASE

On the Home Page, "Manually Add Name to Database" section is only available to users assigned the role of Business Administrator and is illustrated in Figure 23 below. This field allows Business Administrators to add proposed proprietary names to the POCA database which updates the datasource entitled 'Name Entered by Safety Evaluator'. Each proposed proprietary name assigned to a safety evaluator should be entered the POCA database by a business administrator. This enables all safety evaluators to search the 'Name Entered by Safety Evaluator' datasource 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 incorrectly, please contact business administrator to delete the incorrect entry and re-enter the correct name once the incorrect name is deleted.

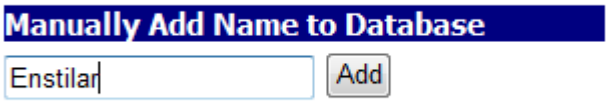


Figure 23: Manually Add Name to Database

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 as illustrated in Figure 24 below. Users can only delete drug names from "Name Entered by Safety Evaluator" data source. The first screen in the *Delete a Record* wizard, shown below, allows you to search for a drug record in the "Name Entered by Safety Evaluator". 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 24: Delete drug name (1 of 2)

Our search returns a set of records composed of drug names as shown in the screen capture below.

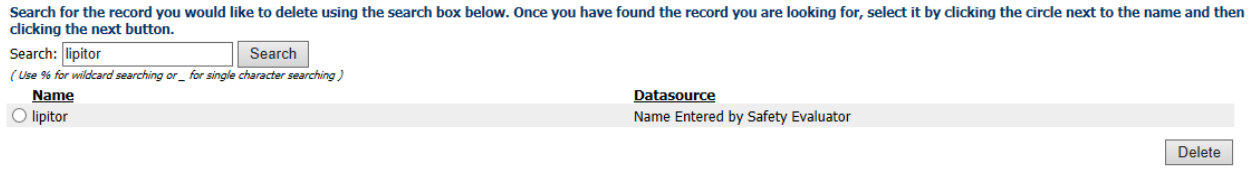


Figure 25: Delete a Record Screen (2 of 2)

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. Using the dropdown menu that appears on the screen, select the date range as illustrated in figure 26 below.



Figure 26: View SE Drug Names screen

6.4 MANAGE BIOLOGIC SUFFIXES DATA SOURCE

"Manage Biologic suffixes data source" section is only available to users assigned the role of Business Administrator. Click on the "Manage Biologic Suffixes Data Source" link under

Advanced Settings in Settings page. It will display the page as illustrated in Figure 27 below. This page allows Business Administrators to add proposed four-characters Biologic Suffixes to the POCA database which updates the datasource entitled 'Biologic Suffixes Entered by Safety Evaluator'. This enables all users to search the 'Biologic Suffixes Entered by Safety Evaluator ' datasource to find all stored suffixes submitted to the Agency for review which may have orthographic or phonetic similarity to the proposed names or other suffixes they are assigned to evaluate.

This page also allows Business Administrators to view the stored suffixes for specified period selected using a dropdown menu as illustrated below. By default, all suffixes that have been added during last week are displayed. The displayed suffix can be exported to a Microsoft Excel file by clicking the "*Export To Excel*" button.

The page also allows users to update the application number and status of the suffix as well as delete the suffix.

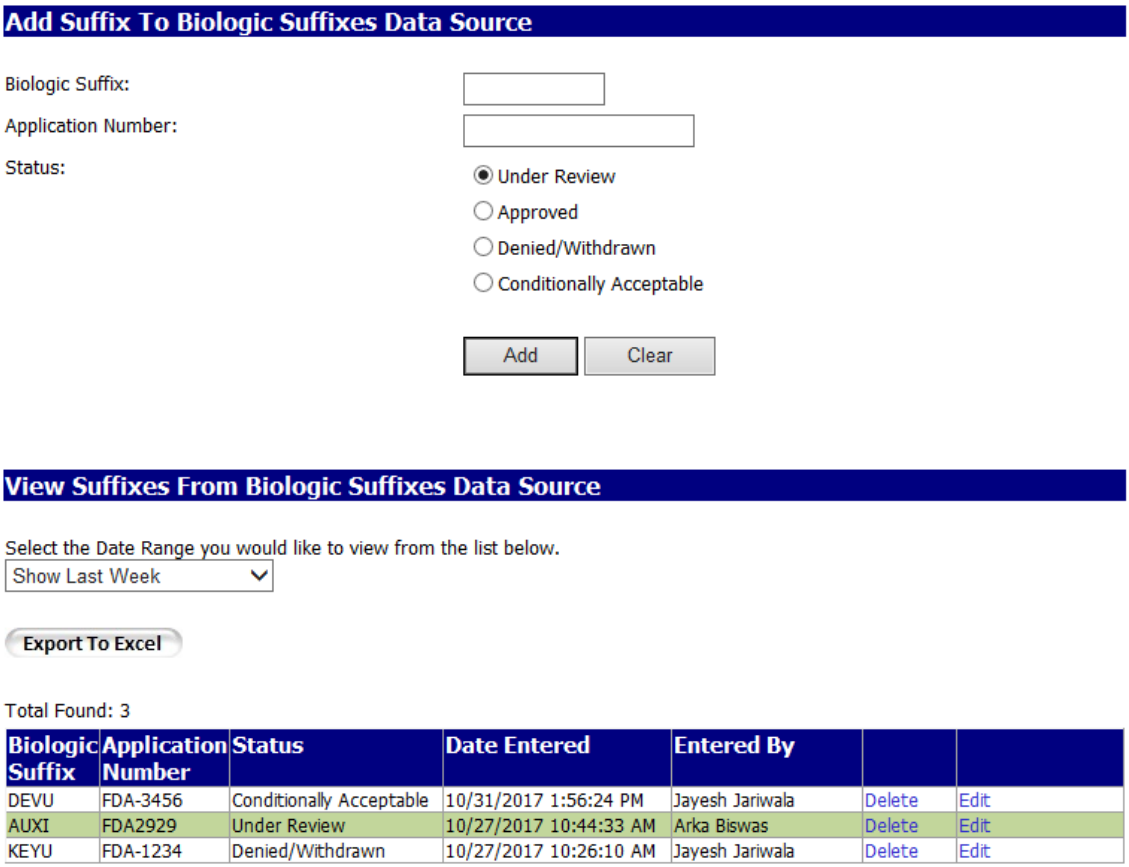


Figure 27: Manage Biologic Suffixes Data Source Page

To add suffix to the datasource:

- Click on the "Manage Biologic Suffixes Data Source" link under the "Advanced Settings" tab.
- Put the suffix in "Biologic Suffix" text box as illustrated in Figure 28.

- Put the correct "Application Number" and select the correct "Status"
- Click "Add" button
- New Suffix name will be updated to the database and it will be displayed in View section.

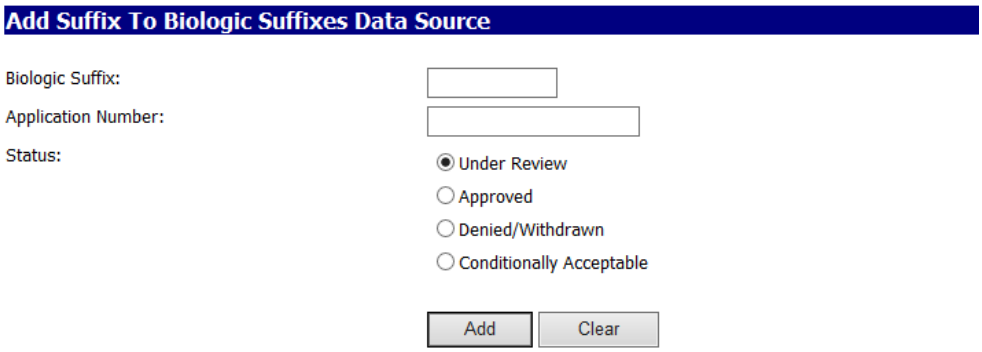


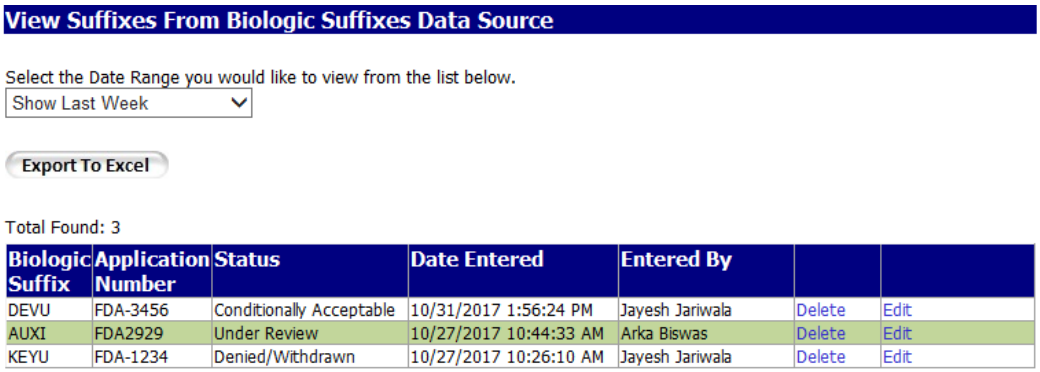
Figure 28: Adding Biologic suffix

To modify the existing suffix:

- Select the suffix and click on the "Edit" button as illustrated in Figure 29.
- Application number will be changed to Text box and Status will be changed to radio choices. Change the application number and status of the existing suffix.
- Click on the "Update" button to save the changes. You may click on the "Cancel" button to cancel the changes.

To delete an existing suffix:

- Select the suffix.
- Click on the "Delete" button as illustrated in Figure 29.
- A pop-up will be displayed there to confirm the delete suffix.
- Click OK to confirm.
- The suffix will be deleted.



Biologic Suffix	Application Number	Status	Date Entered	Entered By		
DEVU	FDA-3456	Conditionally Acceptable	10/31/2017 1:56:24 PM	Jayesh Jariwala	Delete	Edit
AUXI	FDA2929	Under Review	10/27/2017 10:44:33 AM	Arka Biswas	Delete	Edit
KEYU	FDA-1234	Denied/Withdrawn	10/27/2017 10:26:10 AM	Jayesh Jariwala	Delete	Edit

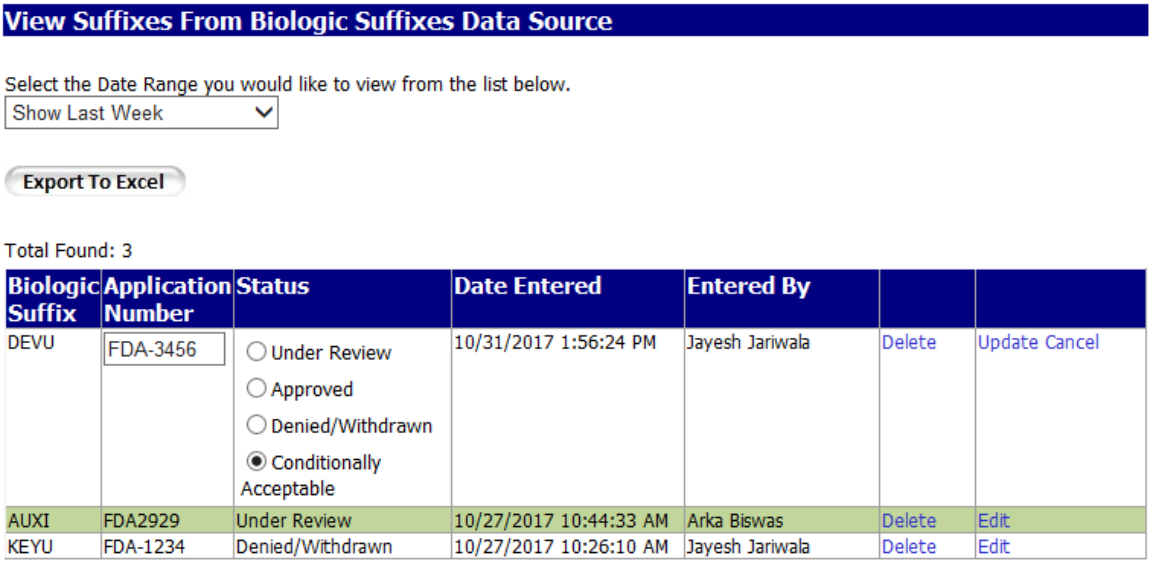
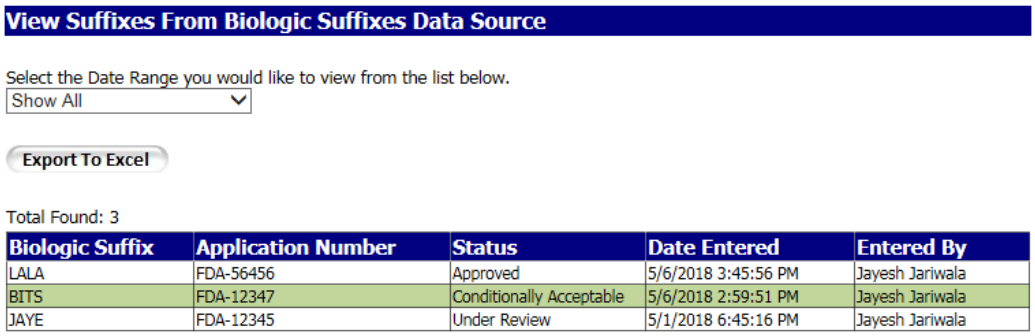


Figure 29: Modify Biologic Suffix

7 ADVANCED SETTINGS – SAFETY EVALUATOR

7.1 VIEW BIOLOGIC SUFFIXES DATA SOURCE

On the Settings page, Safety Evaluators can view the Biologic Suffixes Data Source as in the figure below.



Biologic Suffix	Application Number	Status	Date Entered	Entered By
LALA	FDA-56456	Approved	5/6/2018 3:45:56 PM	Jayesh Jariwala
BITS	FDA-12347	Conditionally Acceptable	5/6/2018 2:59:51 PM	Jayesh Jariwala
JAYE	FDA-12345	Under Review	5/1/2018 6:45:16 PM	Jayesh Jariwala

Figure 30: View Biologic Suffix data – SE

This allows safety evaluators access to the list of biologic suffixes in POCA without the ability to make any edits to the contents. Safety evaluators can see each biologic suffix entered into POCA along with its associated Application Number, Status, Date Entered, and who entered the suffix.

8 DRUG NAME SEARCHES - ALL USERS

8.1 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 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 Figure 30 below.

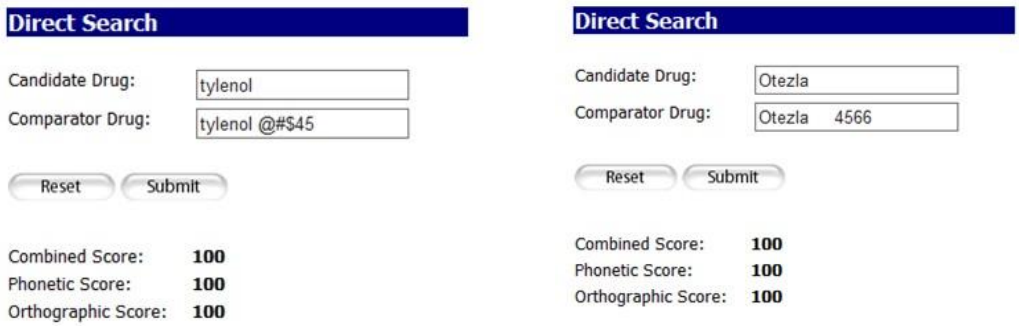


Figure 31: search algorithm

The text search module is implemented using comparison methods for text matching built in to the Oracle 12c 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, fluanxol, 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.

8.2 ACCESSING THE SEARCH

The "*Drug Name Search*" section in Home page provides an 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.

8.3 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 as shown in Figure 31 below.

By default, the orthographic and phonetic search options are preselected to run. However, you may also customize the type of search you need to run by selecting or unselecting any of the choices for Orthographic, Phonetic, or Text searches. Please note that Text searches cannot be run in combination with the two other search types, orthographic and phonetic, and must be selected by itself in order to run a text search. 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. Placing the '%' character before a letter string will identify any name ending in that exact letter string, and placing the '%' character after a letter string will identify any names beginning with that exact letter string.

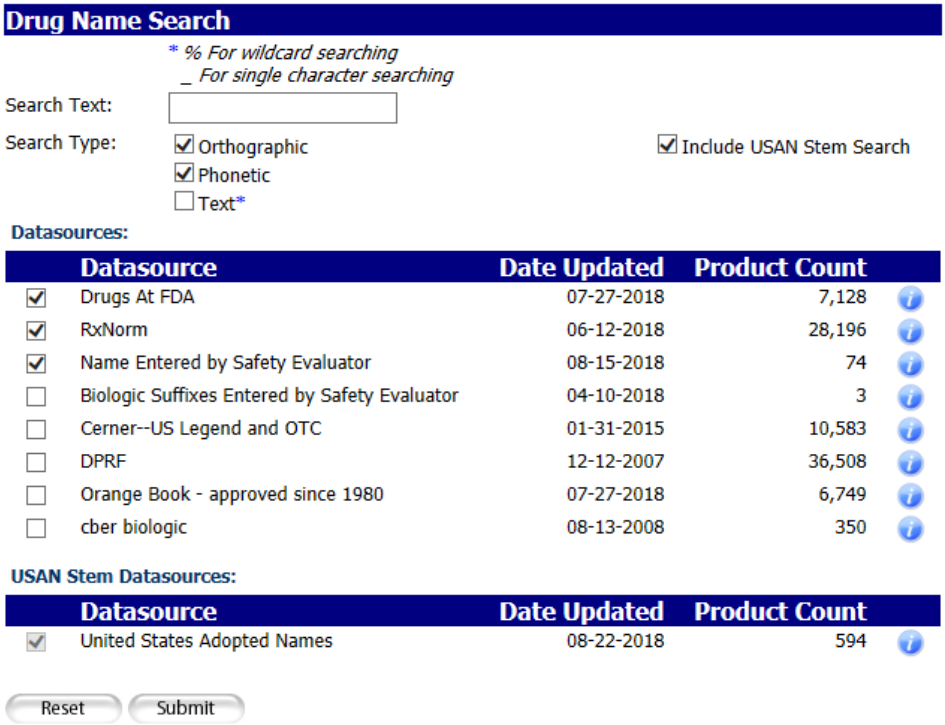


Figure 32: Drug Name Search

Drugs@FDA, RxNorm, Name Entered by Safety Evaluator and United States Adopted Names are pre-selected and by default, name searches will be run against these three datasources. User cannot uncheck the "United States Adopted Names" data sources during search, but they can uncheck the "Include USAN STEM search" on the top right of the search box. If the box is unchecked the results will be shown without USAN tab. Users may customize their search by unselecting or selecting any combination of datasources under the datasource column.

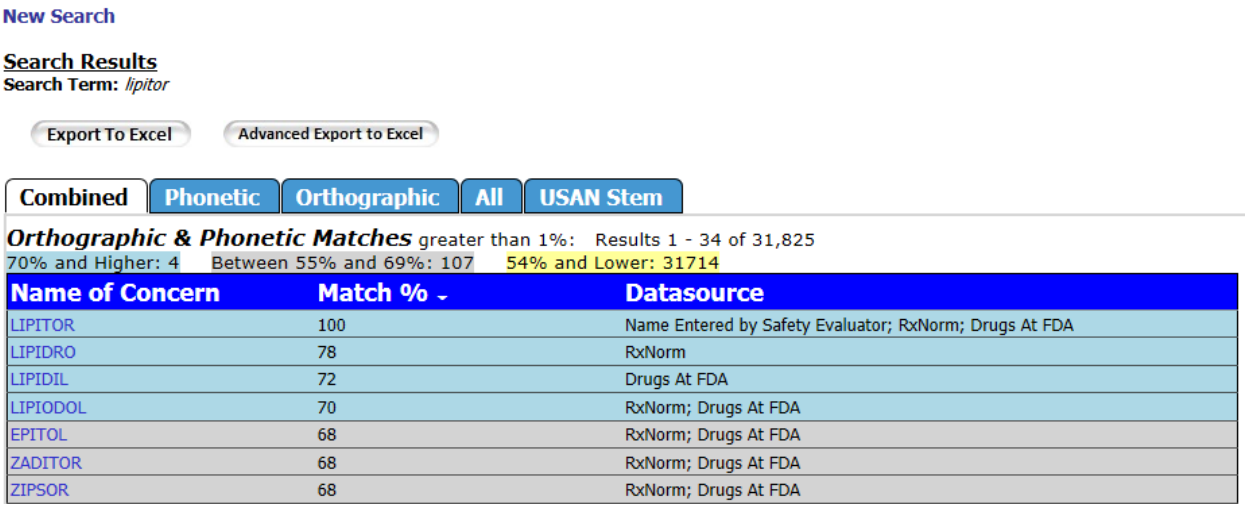
Once users have entered the drug name to search in the "Search" Textbox, and have selected the search type and datasources they can click on the "Submit" button or press the "Enter" key on their keyboard. If the search criteria need to be changed, users may use the "Reset" button. This feature allows users to revise their search criteria or their search name.

The search results will be calculated and filtered with the scores that are equal to and greater than the results threshold value entered by the user under the settings page in the "user's results threshold" value. The "Search Results" page will be displayed as described in Figure 32 below.

8.4 SEARCH RESULTS

The *Search Results* page displays the results of the search based on the search criteria entered. The results will display in a table that allows users to view the names within their defined threshold for combined scores, 'phonetic scores', 'orthographic scores', and 'all scores', by clicking the tabs at the top of the results table labeled 'Combined', 'Phonetic', 'Orthographic', and 'All'.

For example, 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 ('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. "USAN Stem" tab shows the STEM search result. An overview of the result tabs is illustrated in Figure 32 below. It shows the *Search Results* page displaying the results of a search for "*Lipitor"* using the orthographic and phonetic and USAN search types.



New Search

Search Results
Search Term: *lipitor*

Export To Excel | Advanced Export to Excel

Combined | Phonetic | Orthographic | All | USAN Stem

Orthographic & Phonetic Matches greater than 1%: Results 1 - 34 of 31,825
70% and Higher: 4 Between 55% and 69%: 107 54% and Lower: 31714

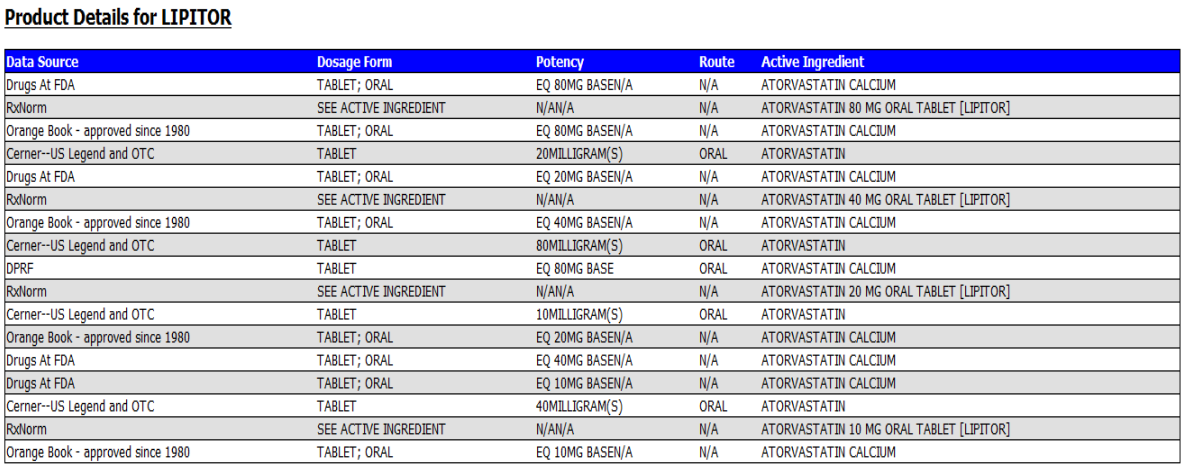
Name of Concern	Match %	Datasource
LIPITOR	100	Name Entered by Safety Evaluator; RxNorm; Drugs At FDA
LIPIDRO	78	RxNorm
LIPIDIL	72	Drugs At FDA
LIPIODOL	70	RxNorm; Drugs At FDA
EPITOL	68	RxNorm; Drugs At FDA
ZADITOR	68	RxNorm; Drugs At FDA
ZIPSOR	68	RxNorm; Drugs At FDA

Figure 33: Search Results Example

For searches conducted where users only select 'Text' as the search type, the Search Results page will display the exact text matches in a results table having only the Text tab at the top of the table.

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

If users would like to see additional information about any names returned by the search, click on the drug name of concern. A "Product Details" page will be displayed in new window with all product details stored in the POCA database, including the data sources, as illustrated in Figure 33 below. Please be aware that some results identified from RxNorm will not contain information in Product Details page.



Product Details for LIPITOR

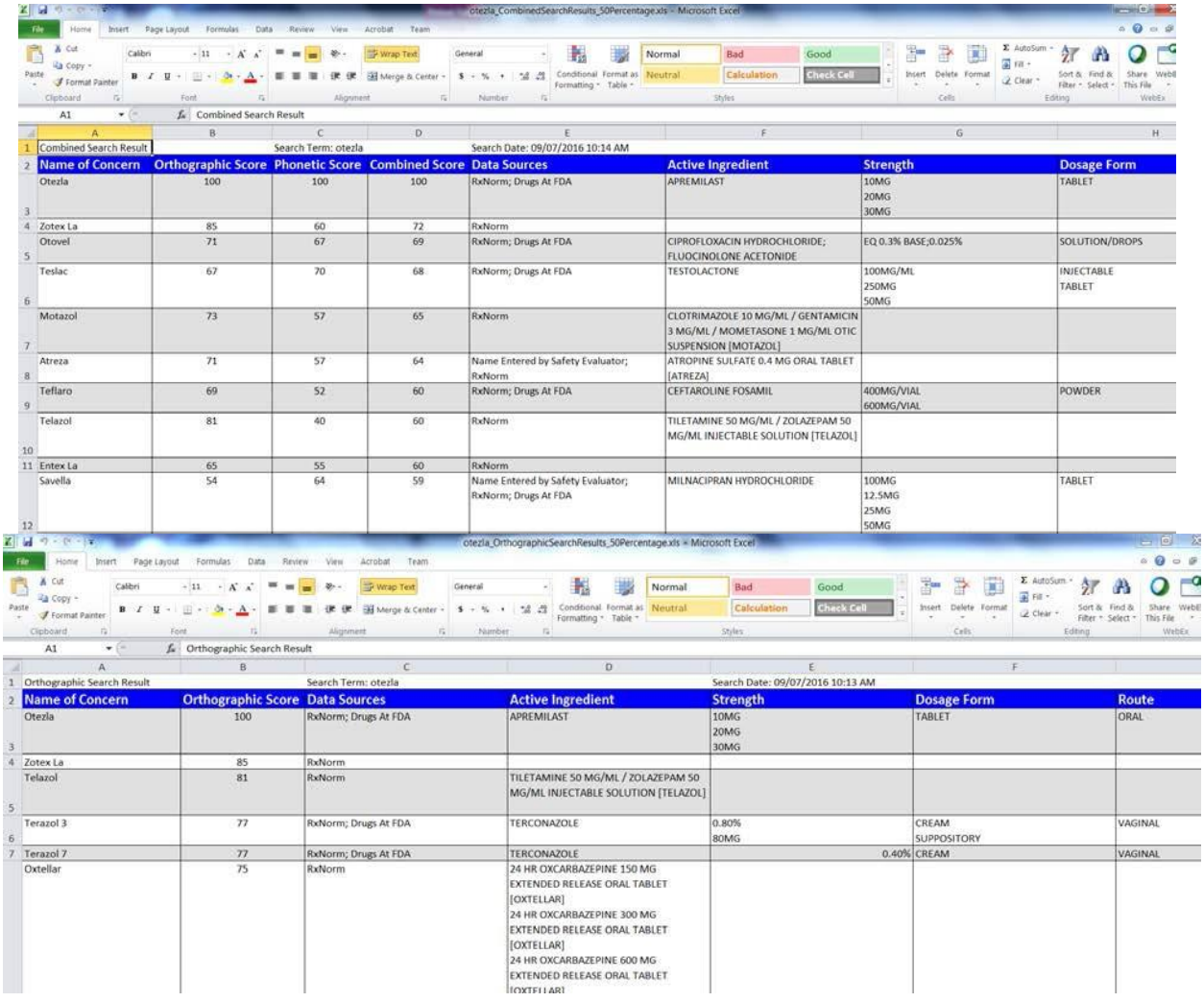
Data Source	Dosage Form	Potency	Route	Active Ingredient
Drugs At FDA	TABLET; ORAL	EQ 80MG BASEN/A	N/A	ATORVASTATIN CALCIUM
RxNorm	SEE ACTIVE INGREDIENT	N/AN/A	N/A	ATORVASTATIN 80 MG ORAL TABLET [LIPITOR]
Orange Book - approved since 1980	TABLET; ORAL	EQ 80MG BASEN/A	N/A	ATORVASTATIN CALCIUM
Cerner--US 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 34: Product Details Page

8.5 EXPORT TO EXCEL

As illustrated in Figure 33 above, the "Export to Excel" button displays above the search results table. Users can click on the Export to Excel button to transfer search results into an Excel Spreadsheet. This feature provides users with the ability to export the combined scores, the phonetic scores, he orthographic scores, and the USAN Stem results, as well as any product information from the product details into an Excel spreadsheet. Users can select a tab at the top of the results table to export those specific search results to an Excel Spreadsheet.

Also, please note that when the tab for combined search results is selected and the results are exported to Excel, the Excel spreadsheet will contain the combined, phonetic, and orthographic scores for all the combined results as illustrated in Figure 34 below.



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 / MOMETASONE 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	

otezla_OrthographicSearchResults_50Percentage.xls - Microsoft Excel

Orthographic Search Result		Search Term: otezla		Search Date: 09/07/2016 10:13 AM			
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 35: Export to Excel examples

When the tab labeled USAN Stem is selected from the results table, the USAN Stem search results may also be exported to an Excel spreadsheet as illustrated in Figure 36 below:

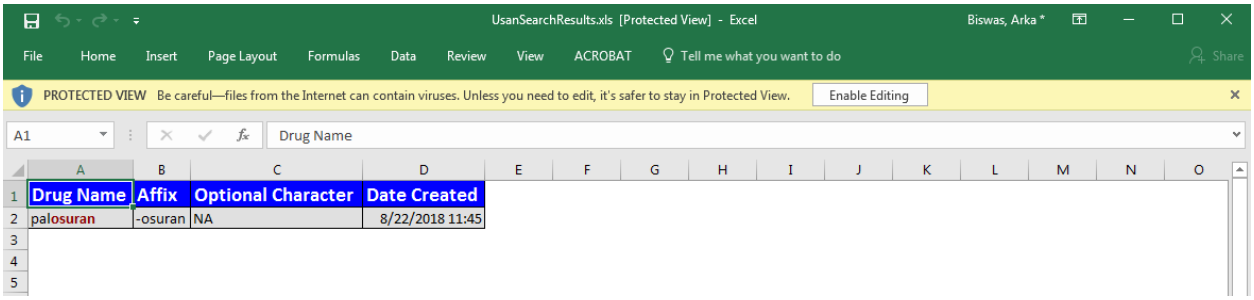


Figure 36: USAN export to excel

When users 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 as illustrated in Figure 37 below. If users click on the dropdown arrow next to the 'Save' tab, a menu appears for users to select from either 'Save', 'Save as', or 'Save and Open'. Select 'Save as' and the data will be saved in a file with a '.xls' extension appearing after the file name.

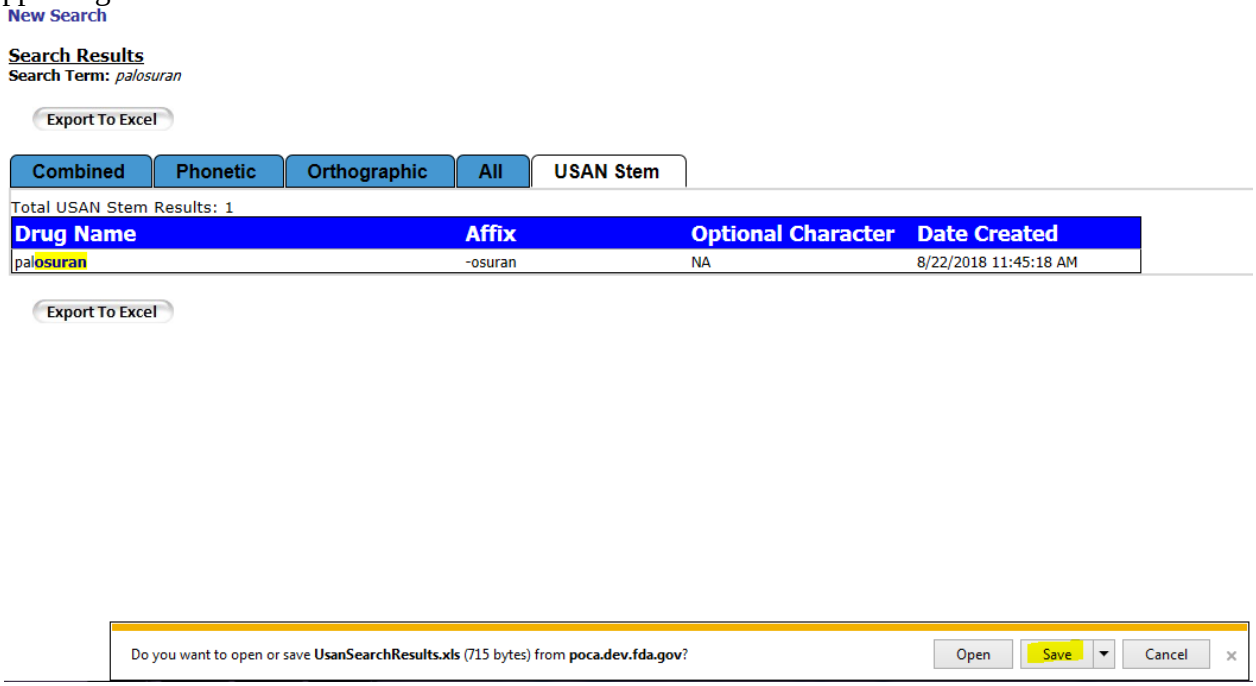


Figure 37: Excel file 'Save as ' in the local drive

This format will allow users to easily edit the information in the spreadsheet. If users choose only to open the spreadsheet, but later decide to save it, they 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' or the file extension compatible with the most current version of Excel in their computer.

8.6 ADVANCED EXPORT TO EXCEL

The "Advanced Export to Excel" button is displayed above the search results table, and provides advanced results for Combined search results tab. This button is not available when users click on the Phonetic, Orthographic, All, or USAN Stemsearch results tabs. When the 'Combined' results tab is highlighted, users can click on the "Advanced Export to Excel" button to transfer advanced search results into an Excel Spreadsheet. *This feature will export the all the drug names that have a combined score greater than or equal to 55%, as well as all drug names that have an individual phonetic score of 70% or greater, and all drug names that have an orthographic score of 70% or greater. Any product information from the product details will also export into the Excel spreadsheet*. The excel file name that is created will have default name "drugname_AdvancedSearchResults.xls".

The Excel spreadsheet will contain the combined, phonetic, and orthographic scores for exported drug names as illustrated in Figure 38 below.

Advanced Search Result		Search Term: zonalon		Search Date: 10/31/2017 04:04 PM		Combined Score >= 55 OR Phonetic Score >= 70 OR Orthographic Score >= 70	
Name of Concern	**Orthographic Score**	**Phonetic Score**	**Combined Score**	**Data Sources**	**Active Ingredient**	**Strength**	**Dosage Form**
Zonalon	100	100	100	RxNorm; Drugs At FDA	DOXEPIN HYDROCHLORIDE	5%	CREAM
Cinalog	64	77	70	RxNorm	TRIAMCINOLONE ACETONIDE 5 MG/ML TOPICAL CREAM [CINALOG]		
Zenavod	64	76	70	Drugs At FDA	DOXYCYCLINE	40MG	CAPSULE
Nalfon	81	57	69	RxNorm; Drugs At FDA	FENOPROFEN CALCIUM	EQ 200MG BASE EQ 300MG BASE EQ 400MG BASE EQ 600MG BASE	CAPSULE TABLET
Lanolin	64	71	68	RxNorm			
Zenalb	65	72	68	RxNorm			
Zevalin	61	75	68	Drugs At FDA	IBRITUMOMAB TIUXETAN	3.2MG/2ML	INJECTABLE
Zonegran	71	65	68	RxNorm; Drugs At FDA	ZONISAMIDE	100MG 25MG 50MG	CAPSULE
Sano Log	61	73	67	RxNorm	TRIAMCINOLONE ACETONIDE 40 MG/ML INJECTABLE SUSPENSION [SANO LOG]		
Zaleplon	77	57	67	RxNorm; Drugs At FDA	ZALEPLON	10MG 5MG	CAPSULE
Albalon	71	62	66	RxNorm; Drugs At FDA	NAPHAZOLINE HYDROCHLORIDE	0.1% **FEDERAL REGISTER DETERMINATION THAT PRODUCT WAS NOT DISCONTINUED OR WITHDRAWN FOR SAFETY OR E	SOLUTION/DROPS

Figure 38: Advanced Export to Excel example