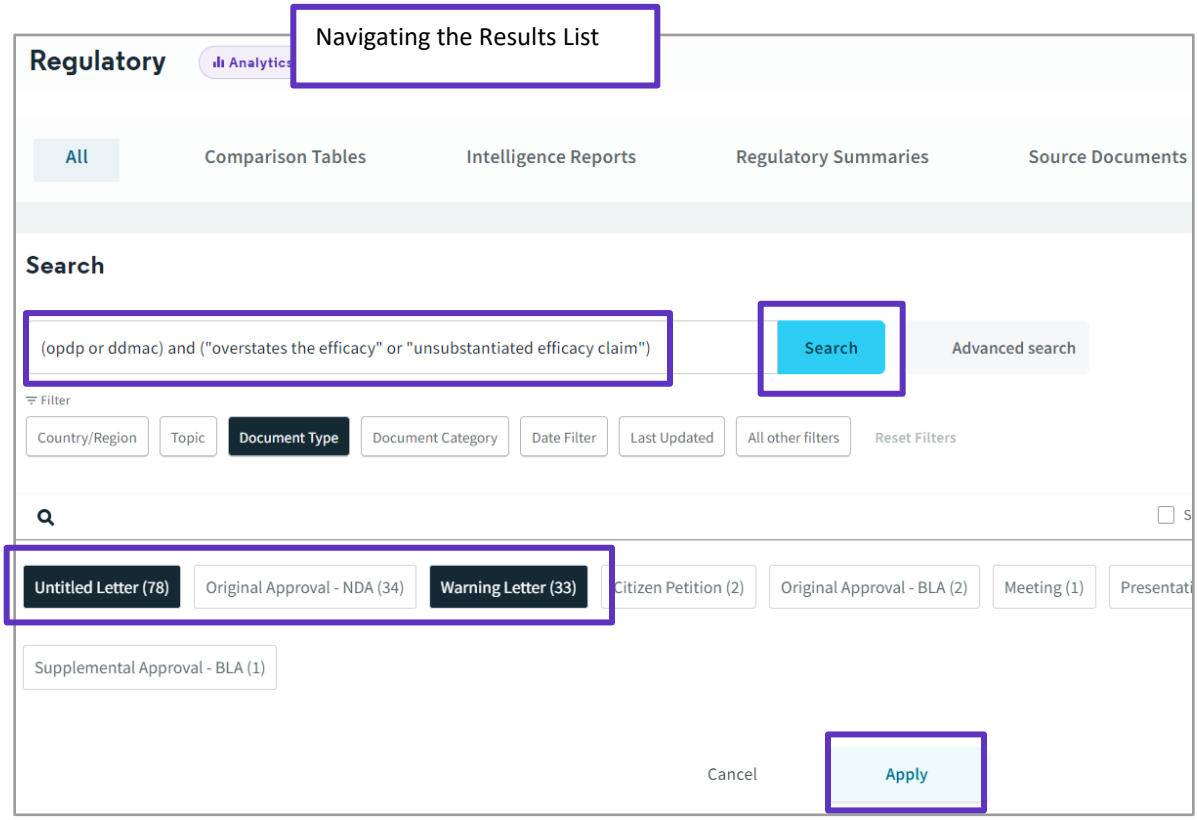
Searching FDA Warning and Untitled Letters in Cortellis

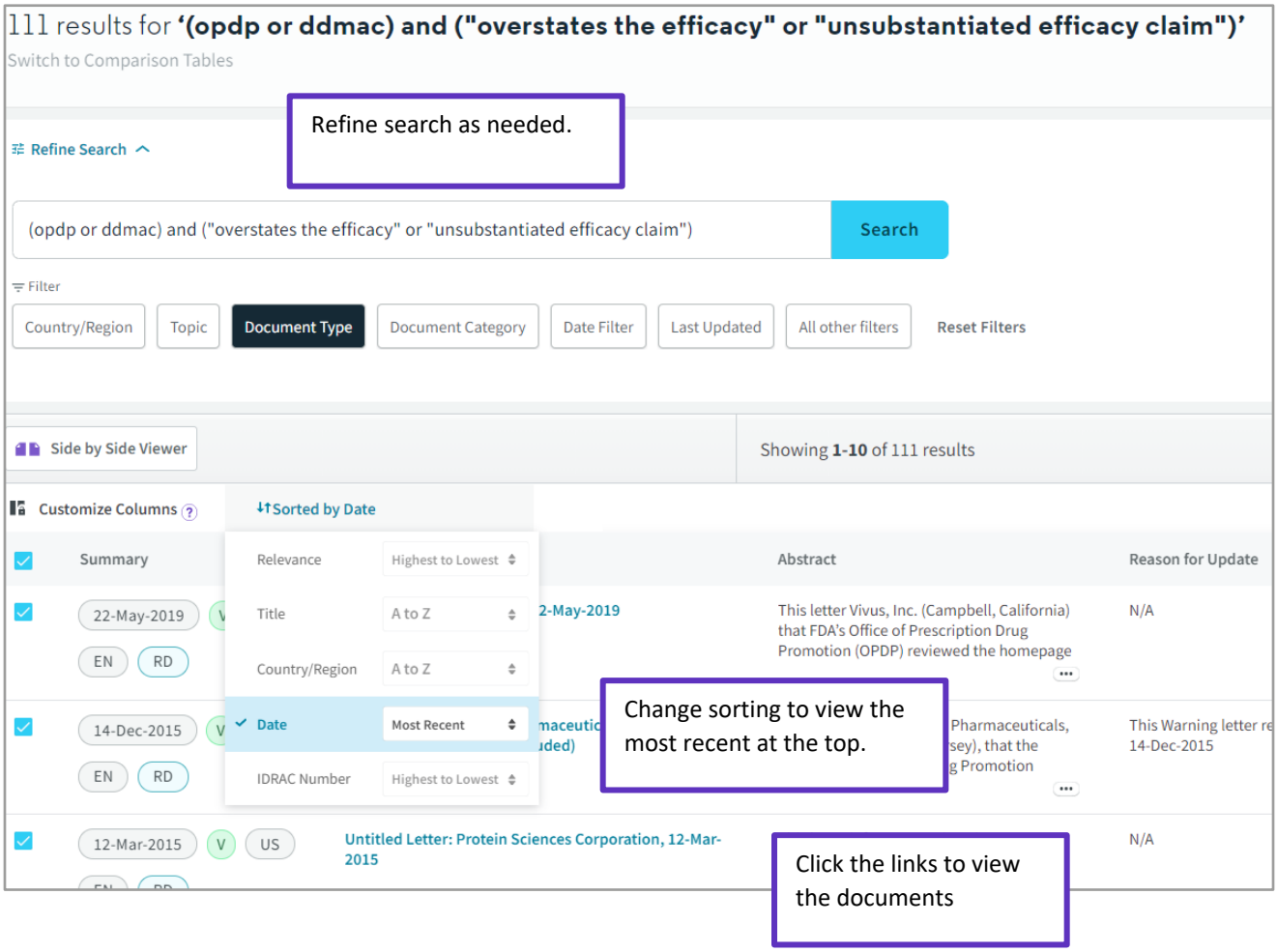
In Cortellis Regulatory Intelligence you can search by combining keywords and filters to find the documents you need. This guide discusses how to find FDA Warning and Untitled Letters of interest.

To find more general classifications of FDA Warning and Untitled Letters be sure to consult the Regulatory Intelligence Reports: FDA Inspector's Table: Inventory of EIR, FDA 483 and Correspondence (IDRAC 71070) and Drugs and Biologics Warning Letters Overview (IDRAC 260064) and Medical Devices Warning Letters Overview (IDRAC 262568). Simply type the IDRAC number into the search bar to find these reports.

Example: Find FDA Warning and Untitled Letters issued by OPDP (formerly DDMAC) that were issued due to unsubstantiated efficacy claims.

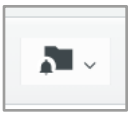
1. Using Regulatory Home Page Search, consider your keywords or phrases and any synonyms that might be beneficial for complete results. For example, for "unsubstantiated efficacy claim" you would want to include, "overstates the efficacy". For OPDP include the former name DDMAC. Once you have considered all possible synonyms and phrases, add them to the keyword search bar with OR between them. Use double quotes around any phrases. You may also nest using parentheses and utilize the operators AND and NOT as per below.
2. Open the Document Type filter and select Untitled Letter and Warning Letter and click Apply.
3. Click the blue Search button.

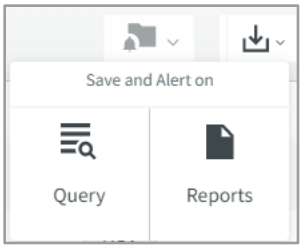


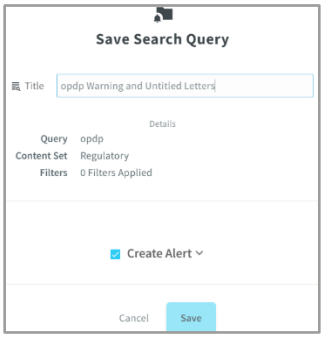


To set up an alert

1. Use the icon in the upper right-hand corner of the search result screen
2. Select Save and Alert on Query
3. Fill in the Alert pop and click Save.







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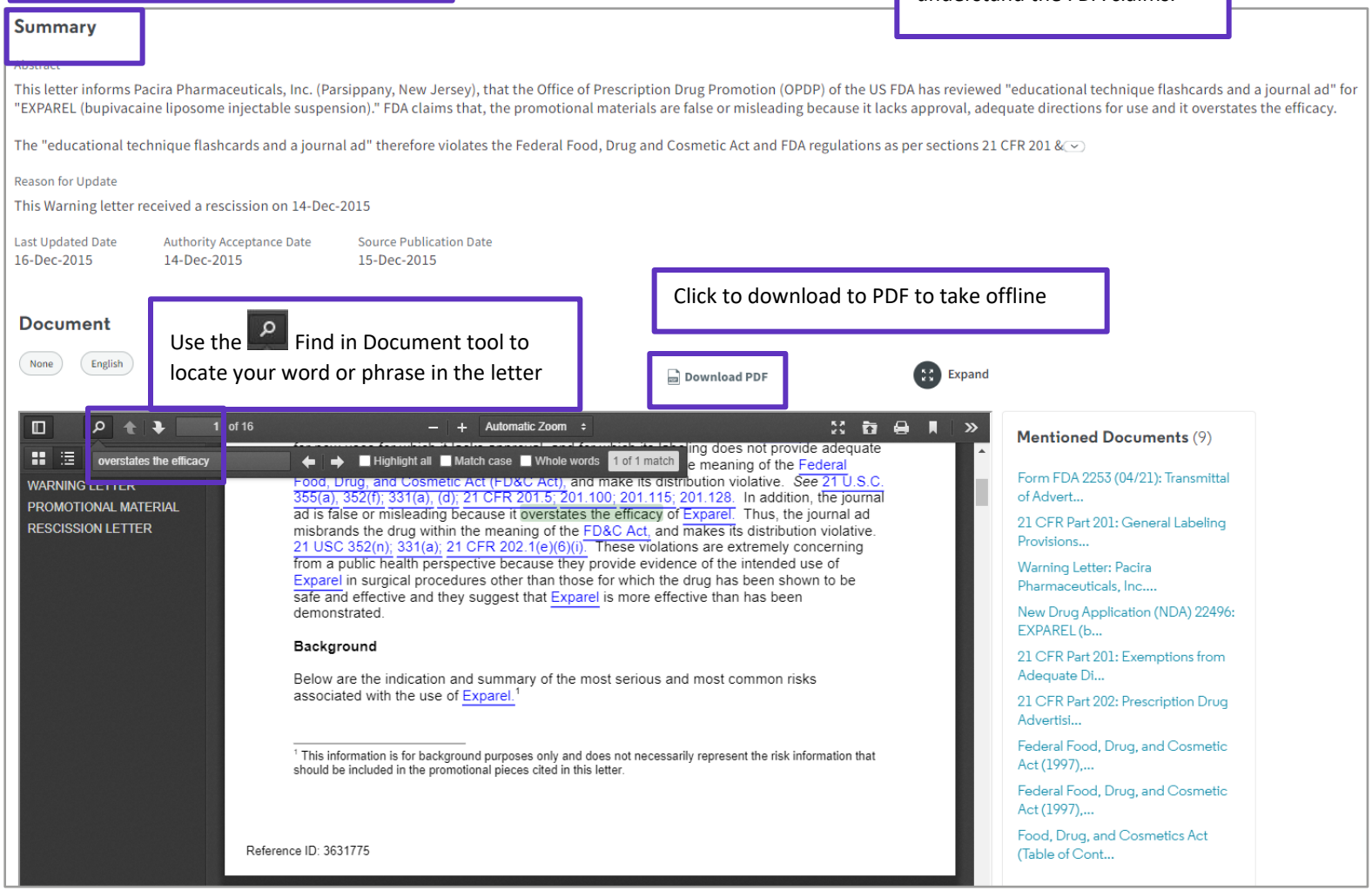
Document navigation and management

Read the abstracts to quickly understand the FDA claims.



For more information contact Customer Service at **LS Product Support.**