

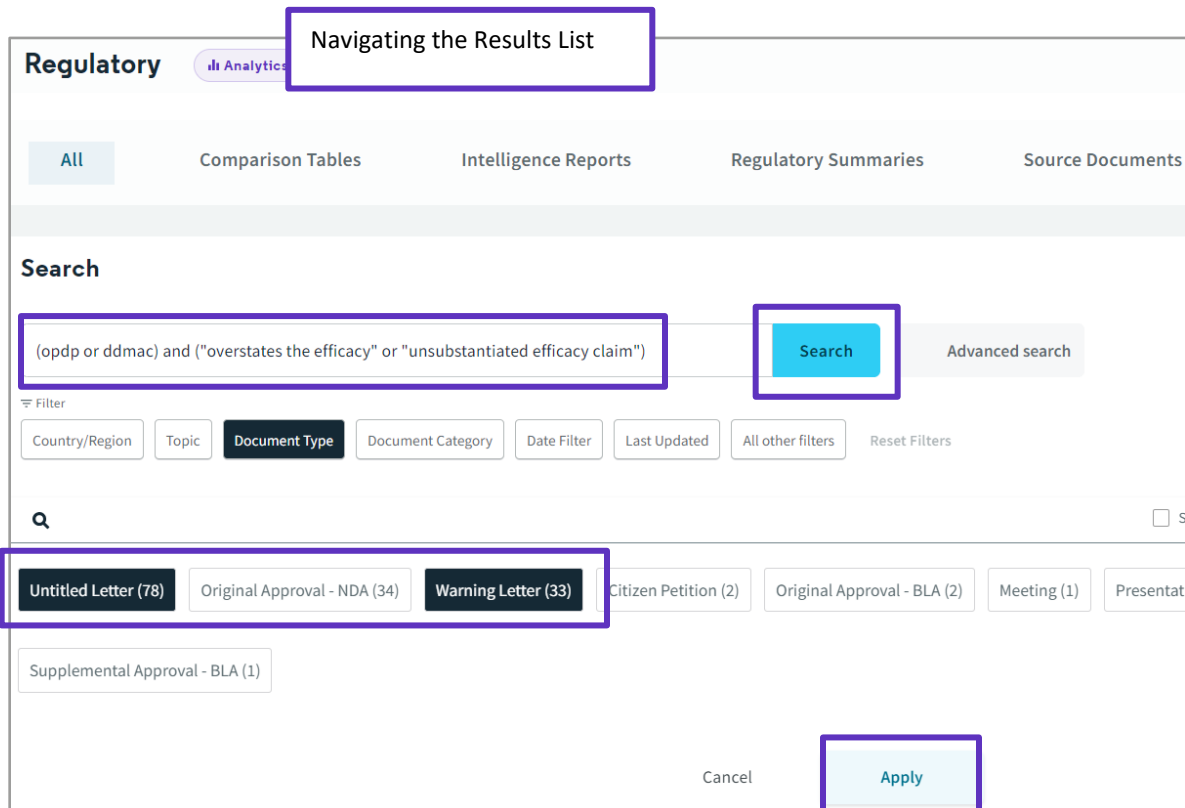
Searching FDA Warning and Untitled Letters in Cortellis

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.



The screenshot shows the Cortellis Regulatory Intelligence search interface. At the top, there is a navigation bar with "Regulatory" and "Analytics" tabs. Below this is a search bar containing the query: "(opdp or ddmac) and ("overstates the efficacy" or "unsubstantiated efficacy claim")". A blue "Search" button is highlighted. Below the search bar is a filter section with a "Filter" dropdown and several filter buttons: "Country/Region", "Topic", "Document Type", "Document Category", "Date Filter", "Last Updated", "All other filters", and "Reset Filters". The "Document Type" filter is expanded, showing a list of document types: "Untitled Letter (78)", "Original Approval - NDA (34)", "Warning Letter (33)", "Citizen Petition (2)", "Original Approval - BLA (2)", "Meeting (1)", and "Presentati". The "Untitled Letter (78)" and "Warning Letter (33)" options are highlighted. At the bottom right, there are "Cancel" and "Apply" buttons.

111 results for '(opdp or ddmac) and ("overstates the efficacy" or "unsubstantiated efficacy claim")'

Switch to Comparison Tables

Refine Search ^

(opdp or ddmac) and ("overstates the efficacy" or "unsubstantiated efficacy claim") **Search**

Filter

Country/Region Topic **Document Type** Document Category Date Filter Last Updated All other filters **Reset Filters**

Side by Side Viewer Showing 1-10 of 111 results

Customize Columns ? Sorted by Date

Summary	Relevance	Title	Abstract	Reason for Update
<input checked="" type="checkbox"/> 22-May-2019 EN RD	Highest to Lowest	A to Z	This letter Vivus, Inc. (Campbell, California) that FDA's Office of Prescription Drug Promotion (OPDP) reviewed the homepage	N/A
<input checked="" type="checkbox"/> 14-Dec-2015 EN RD	Date Most Recent	A to Z	Pharmaceuticals, (se), that the g Promotion	This Warning letter re 14-Dec-2015
<input checked="" type="checkbox"/> 12-Mar-2015 EN RD	Highest to Lowest	Untitled Letter: Protein Sciences Corporation, 12-Mar-2015		N/A

Change sorting to view the most recent at the top.

Click the links to view the documents

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.

The image shows the process of setting up an alert. It starts with a search result icon in the top right corner. This leads to a 'Save and Alert on' dialog box where 'Query' is selected. The next step is a 'Save Search Query' form where the user can enter a title, query details, content set, and filters, and then click 'Create Alert'.

Document navigation and management

Read the abstracts to quickly understand the FDA claims.

Summary

This letter informs Pacira Pharmaceuticals, Inc. (Parsippany, New Jersey), that the Office of Prescription Drug Promotion (OPDP) of the US FDA has reviewed "educational technique flashcards and a journal ad" for "EXPAREL (bupivacaine liposome injectable suspension)." FDA claims that, the promotional materials are false or misleading because it lacks approval, adequate directions for use and it overstates the efficacy.

The "educational technique flashcards and a journal ad" therefore violates the Federal Food, Drug and Cosmetic Act and FDA regulations as per sections 21 CFR 201 & (v)

Reason for Update

This Warning letter received a rescission on 14-Dec-2015

Last Updated Date	Authority Acceptance Date	Source Publication Date
16-Dec-2015	14-Dec-2015	15-Dec-2015

Document

None English

Use the Find in Document tool to locate your word or phrase in the letter

Click to download to PDF to take offline

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Expand

overstates the efficacy

1 of 16

Automatic Zoom

WARNING LETTER
PROMOTIONAL MATERIAL
RESCISSION LETTER

ing does not provide adequate... e meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and make its distribution violative. See 21 U.S.C. 355(a), 352(f); 331(a), (d); 21 CFR 201.5; 201.100; 201.115; 201.128. In addition, the journal ad is false or misleading because it overstates the efficacy of Exparel. Thus, the journal ad misbrands the drug within the meaning of the FD&C Act, and makes its distribution violative. 21 USC 352(n), 331(a); 21 CFR 202.1(e)(6)(i). These violations are extremely concerning from a public health perspective because they provide evidence of the intended use of Exparel in surgical procedures other than those for which the drug has been shown to be safe and effective and they suggest that Exparel is more effective than has been demonstrated.

Background

Below are the indication and summary of the most serious and most common risks associated with the use of Exparel.¹

¹ This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional pieces cited in this letter.

Reference ID: 3631775

Mentioned Documents (9)

- Form FDA 2253 (04/21): Transmittal of Advert...
- 21 CFR Part 201: General Labeling Provisions...
- Warning Letter: Pacira Pharmaceuticals, Inc....
- New Drug Application (NDA) 22496: EXPAREL (b...
- 21 CFR Part 201: Exemptions from Adequate Di...
- 21 CFR Part 202: Prescription Drug Advertisi...
- Federal Food, Drug, and Cosmetic Act (1997),...
- Federal Food, Drug, and Cosmetic Act (1997),...
- Food, Drug, and Cosmetics Act (Table of Cont...

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