

# Search Solutions – The Path to Successful Search

## Search for new drug approvals (NDA) and abbreviated new drug applications (ANDA)

**TOPIC:** Summaries of drug approval for prescription and generic drugs appear about every two weeks and are covered by [FDAnews](#), which is a good file for current awareness since it updates daily. FDAnews on ProQuest Dialog has coverage of U.S. and international regulatory, legislative, and business news and information for those companies and organizations that are regulated by the FDA and the European commission.

Approval contains the applicant, ingredients of the drug, the drug name (lab code) and indications. It also includes both ANDA and NDA approvals and type of approval. Some may be tentative approvals and will list the reason for the caution. Additionally, other articles are also included for drugs where there may be a potential problem (e.g., “Teva Wins Tentative Approval...”).

### COMMAND SUMMARY

**Topic:** Look for ANDA and NDA drug approvals issued by the FDA for the pharmaceutical company Mylan in the last three years

**Database:** FDAnews

### Search strategy

- Enter “drug approval” or anda or nda and mylan
- Use the date slider to narrow to last three years
- Sort the records by date, most recent first
- Preview/select records

## SOLUTION – ADVANCED SEARCH

1. Scroll down to **Pharmaceutical & Biomedical** databases. Click **FDAnews** to select the database to search.

### Pharmaceutical & Biomedical Search >



#### Databases

- Adis Clinical Trials Insight
- Adis Pharmacoeconomics & Outcomes News
- Adis R&D Insight
- Adis Reactions Database
- Allied & Complementary Medicine™
- Analytical Abstracts
- BIOSIS Previews®
- British Library Inside Conferences
- British Nursing Index
- CAB ABSTRACTS
- Chemical Engineering & Biotechnology Abstracts
- Chemical Safety Newsbase
- Current Contents® Search
- Derwent Biotechnology Resource
- Derwent Drug File
- Derwent Drug Registry
- DIOGENES® FDA Regulatory Updates
- Drug Information Fulltext
- Ei Compendex®
- Embase®
- Embase® Alert
- EMCare®
- ESPICOM Pharmaceutical & Medical Device News
- FDAnews**

2. The top line now shows you are in one database. Click **Advanced search**.

You are searching: 1 database (See list | Change >)

< All databases | Pharmaceutical & Biomedical databases

0 Recent searches | 2 Selected items | My Research | Exit

Cost Estimate | Preferences | English | Help ?

ProQuest  
Dialog DataStar

## FDAnews

Basic Search | Advanced | Command Line

Advanced search

Want to Learn More?

Try one of these options:

- Search the online Help.
- Sign up for a training webinar.
- Discover answers to common questions at ProQuest's Product Support Center.
- Got an uncommon question? Contact our Customer Support Team.

Search tip

By default, we will look for documents with all the terms entered.

Use "quotation marks" to search for exact phrases. Separate terms with OR to find any of the words entered.

FDAnews

FDAnews provides both U.S. and international regulatory, legislative, and business news and information for those companies and organizations that are regulated by the FDA and the European commission. The file contains newsletters, books, reports, and conference documents that pharmaceutical and medical device professionals can use to stay in compliance with international standards and the FDA's regulations.

Coverage: 2004 - current

**3. Enter search terms.** Use quotation marks around search terms you want to search as a phrase. There are three rows, and you can add more rows if needed. Each line has a drop-down fields list available. For this search we are doing a search in All fields (no full text).

*Note:* Depending on your search needs, you can use the drop-down operator list to change from AND to OR or NOT.

Press the **Search** button.

You are searching: 1 database (See list | Change >)

0 Recent searches | 0 Selected items | My Research | Exit

< All databases | Pharmaceutical & Biomedical databases

Cost Estimate | Preferences | English | Help

ProQuest Dialog DataStar **FDAnews**  
Basic Search | Advanced | Command Line

### Advanced Search

Look Up Citation

Field codes | Tips

"drug approval" or anda or nda in All fields (no full text) - ALL

AND mylan in All fields (no full text) - ALL

AND in All fields (no full text) - ALL

Add a row | Remove a row

Show number of results and stay on this page

Search Clear form

**4. Results return.** Narrow results by publication year or date. Hover over a bar to see the number of records in a certain range. Drag the handles or click a bar, or enter a specific date range by clicking the link to Enter a specific date range (not shown).

Press **Update**.

all("drug approval" or anda or nda) AND all(mylan)

Modify search | Tips

54 Results\* Search within

Create alert Create RSS feed Save search Download all results

0 Selected items [Clear] Save to My Research Email Print Cite Export Save as file

Select 1-20 Brief view Detailed view

1 FDA GRANTS MYLAN'S GENERIC ZOFRAN ANDA TENTATIVE APPROVAL RxTrials Institute Preview  
Drug Pipeline Alert 4. 42 (Feb 27, 2007)  
Found in: FDAnews (2004 - current)

2 Mylan: Past Errors from Drugmaker Nullify ANDA for Generic Lipitor Generic Preview  
Line 28. 7 (Mar 29, 2011)  
Found in: FDAnews (2004 - current)

3 Mylan Sued Over Generic Cholesterol Drug ANDA Drug Industry Daily 8. 248 (Dec 22, 2009) Preview  
Found in: FDAnews (2004 - current)

4 Mylan Says FDA Should Deny Ranbaxy Lipitor ANDA Washington Drug Letter 43. 13 (Mar 25, 2011) Preview  
Found in: FDAnews (2004 - current)

5 Mylan Says Past Lapses Nullify Ranbaxy's ANDA for Generic Lipitor Drug Industry Daily 10. 57 (Mar 21, 2011) Preview  
Found in: FDAnews (2004 - current)

6 FDA APPROVES MYLAN'S ANDA FOR GENERIC BETAPACE RxTrials Institute Drug Pipeline Alert 4. 30 (Feb 9, 2007) Preview  
Found in: FDAnews (2004 - current)

Sort results by: Relevance Sort

Narrow results by

- Publication title
- Publication date 2005 - 2011 (years)

Update

5. **Sort results by** offers options for relevance (default) and date.

Click option for **Publication date (most recent first)** and press **Sort**.

all("drug approval" or anda or nda) AND all(mylan)

35 Results\* Search within

0 Selected items [Clear] Save to My Research Email Print Cite Export Save as file

Select 1-20 Brief view Detailed view

Narrowed by  
Date: 2009-2011

- 1 **Mylan: Past Errors from Drugmaker Nullify ANDA for Generic Lipitor**. Generic Line 28. 7 (Mar 29, 2011)  
Found in: FDAnews (2004 - current)
- 2 **Mylan Sued Over Generic Cholesterol Drug ANDA**. Drug Industry Daily 8. 248 (Dec 22, 2009)  
Found in: FDAnews (2004 - current)
- 3 **Mylan Says FDA Should Deny Ranbaxy Lipitor ANDA**. Washington Drug Letter 43. 13 (Mar 25, 2011)  
Found in: FDAnews (2004 - current)
- 4 **Mylan Says Past Lapses Nullify Ranbaxy's ANDA for Generic Lipitor**. Drug Industry Daily 10. 57 (Mar 21, 2011)  
Found in: FDAnews (2004 - current)
- 5 **Vytorin Cholesterol Drug ANDA Leads to Mylan Patent Dispute**. Generic Line 27. 1 (Jan 5, 2010)  
Found in: FDAnews (2004 - current)

Sort results by:  
Publication date (most recent first) [v]  
Sort

Narrow results by  
Publication title  
Publication date Clear

2009 - 2011 (years)

6. Results display. Preview records by clicking the **Preview** button.

**Note:** Under **Narrow results by** you can view publication titles for these results and refine further by clicking a publication title.

all("drug approval" or anda or nda) AND all(mylan)

35 Results\* Search within

0 Selected items [Clear] Save to My Research Email Print Cite Export Save as file

Select 1-20 Brief view Detailed view

Narrowed by  
Date: 2009-2011

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- 2 **Mylan Sued Over Generic Cholesterol Drug ANDA**. Drug Industry Daily 8. 248 (Dec 22, 2009)  
Found in: FDAnews (2004 - current)
- 3 **Mylan Says FDA Should Deny Ranbaxy Lipitor ANDA**. Washington Drug Letter 43. 13 (Mar 25, 2011)  
Found in: FDAnews (2004 - current)
- 4 **Mylan Says Past Lapses Nullify Ranbaxy's ANDA for Generic Lipitor**. Drug Industry Daily 10. 57 (Mar 21, 2011)  
Found in: FDAnews (2004 - current)
- 5 **Vytorin Cholesterol Drug ANDA Leads to Mylan Patent Dispute**. Generic Line 27. 1 (Jan 5, 2010)  
Found in: FDAnews (2004 - current)
- 6 **Mylan ANDA for Copaxone Accepted by FDA**. FDAnews Drug Daily Bulletin 6. 184 (Sep 21, 2010)  
Found in: FDAnews (2004 - current)

Preview

**Mylan: Past Errors from Drugmaker Nullify ANDA for Generic Lipitor** Generic Line 28. 7 (Mar 29, 2011)  
Brief citation Full text

**Abstract (summary)**  
Generic-drug maker **Mylan** Pharmaceuticals says a competitor's **ANDA** for Pfizer's blockbuster cholesterol drug Lipitor is invalid due to past submission of false data to the FDA.

**Subject** Generic Line  
**Found in:** FDAnews (2004 - current)

Save to My Research Email Print Cite Export Save as file

Sort results by:  
Publication date (most recent first) [v]  
Sort

Narrow results by  
Publication title  
Publication date Clear

2009 - 2011 (years)

Update

7. Click check boxes before records you want to view and then click **Selected items**.

A popup box displays. Choose how much of the records you wish to view, or click a title to view a full record.

Then press **Display**.

The screenshot shows a search results page with 35 results. Two items are selected, indicated by red circles around their checkboxes. A dialog box titled "Display format for selected items" is open, showing options for how to display the selected items. The "Full text (full indexing, abstract, full text, images)" option is selected. The dialog box has "Display" and "Cancel" buttons. The background shows a list of search results with titles like "Mylan: Past Errors from Drugmaker Nullify ANDA for Generic Lipitor" and "Mylan Sued Over Generic Drug".

8. A full record displays. This record has both an abstract and the full text, as well as indexing.

To go to the next record, you can scroll down through the records you selected or click **Next**.

You can email, print, cite, export to a software application such as Excel or Save as file in PDF, HTML, Rich Text Format or text. You can also easily create an Alert, RSS feed or Saved search based on your search strategy.

The screenshot shows the full record view for the selected item. The title is "Mylan: Past Errors from Drugmaker Nullify ANDA for Generic Lipitor". The record includes an abstract (summary) and full text. The abstract states: "Generic-drug maker Mylan Pharmaceuticals says a competitor's ANDA for Pfizer's blockbuster cholesterol drug Lipitor is invalid due to past submission of false data to the FDA." The full text provides more details: "Generic-drug maker Mylan Pharmaceuticals says a competitor's ANDA for Pfizer's blockbuster cholesterol drug Lipitor is invalid due to past submission of false data to the FDA. In a complaint filed March 18 in federal court in Washington, D.C., Mylan is asking a judge to force the FDA to rule on Ranbaxy Laboratories' ANDA for generic Lipitor (atorvastatin). The India-based drugmaker has first-to-file status. Mylan claims Ranbaxy submitted falsified data to the FDA for several other ANDAs, making them invalid. The company says the FDA isn't authorized to approve ANDAs where the application contains untrue statements. 'As FDA has publicly stated, FDA found that Ranbaxy engaged in a pattern and practice of submitting to FDA drug applications containing false and unreliable data generated from Ranbaxy's Paonta Sahib, India manufacturing site, where upon information and belief, Ranbaxy manufactures its generic Lipitor,' the suit states." The page also features a "Selected items" header, navigation buttons like "Next", and a "Display format" sidebar on the right.