

# FDAnews

## FILE DESCRIPTION

**FDAnews** provides domestic and international regulatory, legislative, and business news and information for executives in industries regulated by the U.S. Food and Drug Administration and The European Commission.

The database provides pharmaceutical and medical device professionals print and electronic newsletters, books, special reports, documents, and conferences that will help them stay in compliance with international standards and FDA's complex and ever-changing regulations to get their products to market faster and boost profits.

## SOURCES

FDAnews is particularly strong in its coverage of clinical trials and generic drugs.

Some of the titles covered in the database include:

- *FDAnews Biodefense Alert*
- *Clinical Trials Advisor*
- *Daily International Pharma Alert*
- *Devices & Diagnostics Letter*
- *Drug GMP Report Monthly*
- *Drug Industry Daily*
- *FDAnews Device Daily Bulletin*
- *FDAnews Drug Daily Bulletin*
- *FDAnews Drug Pipeline Alert*
- *FDAnews Nutraceutical Weekly Bulletin*
- *The Food & Drug Letter*
- *Generic Line*
- *The GMP Letter*
- *Part 11 Compliance Report*
- *Washington Drug Letter*

## TIPS

### USE FILE 182

to track regulatory and legislative information about the U.S. FDA and The European Commission.

### USE /TI

to search for article titles.

### USE THE PY=

prefix to restrict retrieval to records from certain years.

SELECT PY=2004

### EXPAND JN=

to see the latest list of publications in the database.

## DIALOG FILE DATA

Inclusive Dates: 2000 to the present

Update Frequency: Daily

File Size: Over 25,000 records as of March 2005

## CONTACT

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## SAMPLE RECORD

DIALOG(R)File 182:FDAnews  
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AA= 0000002241 IE44B4BA06E2711D9BA549F056E469BC9 (THIS IS THE FULLTEXT)  
/TI COURT REJECTS MYLAN'S CHALLENGE TO DURAGESIC  
JN= Generic Line, v22, n1  
DY=,PD=,PY= Tuesday, January 11, 2005  
JC=,LA=,RT= JOURNAL CODE: GELI LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT  
DT= DOCUMENT TYPE: Newswire  
WORD COUNT: 448

TEXT:  
/LP,/TX Generic drugmaker Mylan Laboratories last month lost another round in its legal battle to market a generic version of Johnson & Johnson's (J&J's) Duragesic transdermal pain patch before J&J's pediatric exclusivity period ends later this month and the patent on the product expires.

The U.S. Court of Appeals for the Federal Circuit rejected Mylan's challenge to the validity of the patent on Duragesic (fentanyl) held by Alza, a subsidiary of J&J in December 2004, effectively blocking Mylan from entering the market with a generic version of the product before Alza's pediatric exclusivity period ends.

/TX "Because the district court correctly construed the claim term 'skin permeable form' to exclude fentanyl citrate, we affirm its validity determinations," the court said. "Further, because we discern no error in the district court's, finding of a lack of intent to deceive, we affirm the district court's holding that the '580 patent is not unenforceable due to inequitable conduct."

Other Hurdles Facing Mylan

Earlier in December 2004, the U.S. Court of Appeals for the District of Columbia upheld a ruling by a lower court that affirmed an FDA decision to grant pediatric exclusivity to Alza. The pediatric exclusivity delays the date of entry for Mylan's generic product to January 2005.

Mylan said it expected to launch its generic product no later than July 23, 2004, when the drug's patent was initially set to expire. Mylan had received final FDA approval for its generic product, and the company believed that neither a 30-month stay nor a pediatric exclusivity period would apply.

Mylan asserted that because Alza didn't sue for patent infringement within 45 days of receiving Mylan's abbreviated new drug application (ANDA) with a Paragraph IV certification, Alza is not allowed two exclusivity extensions under the Hatch-Waxman Act.

Mylan sued the FDA when it granted six months of pediatric exclusivity to Alza and converted approval status for Mylan's ANDA from final to tentative for Duragesic (Generic Line, June 30, 2004, Page 1). Mylan then sought an emergency court order to block this decision (Generic Line, July 28, 2004, Page 2). But in August, the U.S. District Court for the District of Columbia ruled against Mylan saying that the FDA had not acted improperly when it withdrew the firm's ANDA for the Duragesic patch (Generic Line, Aug. 25, 2004, Page 1).

Mylan is incurring substantial revenue losses as it pushes to market generic Duragesic. The company spent hundreds of thousands of dollars on perishable adhesive for the transdermal patches that will expire this month. Mylan also spent money to hire security to support the production of the patches and employees to produce them, as well as \$14 million for facilities, manufacturing, and lab equipment.

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/CO,CO= COMPANY NAMES: JOHNSON AND JOHNSON  
/DE DESCRIPTORS: exclusivity; pediatric; courts  
DIALOG UPDATE DATE: 20050202; 13:36:32 EST  
/DE,EN= EVENT NAMES: LEGAL  
GN= GEOGRAPHIC NAMES: DISTRICT OF COLUMBIA; USA; AMERICAS; NORTH AMERICA  
/PN,PN= INDUSTRY NAMES: PHARMACEUTICAL INDUSTRY  
NO= SUPPLIER NUMBER: 3057.34309.a

SEARCH OPTIONS

BASIC INDEX

SEARCH SUFFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
—	—	All Basic Index Fields	Word	S PAIN(W)PATCH
/CO	CO	Company Name <sup>1</sup>	Word	S JOHNSON(1W)JOHNSON/CO
/DE	DE	Descriptor <sup>2,3</sup>	Word & Phrase	S EXCLUSIVITY/DE S PEDIATRIC/DE
/GN	GN	Geographic Name <sup>1</sup>	Word	S USA/GN
/LP	LP	Lead Paragraph	Word	S MYLAN(W)LAB?/LP
/PN	PN	Industry/Product Name <sup>1</sup>	Word	S PHARMACEUTICAL/PN
/TI	TI	Title	Word	S MYLAN(1W)CHALLENGE/TI
/TX	TX	Text	Word	S PATENT(S)DURAGESIC/TX

<sup>1</sup> Searchable in the Basic Index and in the Additional Indexes.

<sup>3</sup> Includes Event Names.

<sup>2</sup> Also /DF.

ADDITIONAL INDEXES

SEARCH PREFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
AA=	AA	Supplier Accession Number	Phrase	S AA=IE44B4BA06E2711?
—	AZ	DIALOG Accession Number		
CO=	CO	Company Name <sup>1</sup>	Phrase	S CO="JOHNSON AND JOHNSON"
DT=	DT	Document Type	Phrase	S DT=NEWSWIRE
DY=	DY	Publication Day	Phrase	S DY=TUESDAY
EN=	EN	Event Name <sup>1</sup>	Phrase	S EN=LEGAL
GN=	GN	Geographic Name <sup>1</sup>	Phrase	S GN=DISTRICT OF COLUMBIA
JC=	JC	Journal Code	Phrase	S JC=GELI
JN=	JN	Journal Name	Phrase	S JN=GENERIC LINE?
LA=	LA	Language	Phrase	S LA=ENGLISH
MO=	MO	Month	Phrase	S MO=JANUARY
NO=	NO	Source Number	Phrase	S NO=3057.343?
PD=	PD	Publication Date	Phrase	S PD=20050111
PN=	PN	Industry/Product Name <sup>1</sup>	Phrase	S PN=PHARMACEUTICAL?
PY=	PY	Publication Year	Phrase	S PY=2005
RT=	RT	Record Type	Phrase	S RT=FULLTEXT
—	SO	Source Information		
UD=	—	Update	Phrase	S UD=9999
—	WD	Word Count		

SPECIAL FEATURES

For command descriptions, enter HELP LIMIT, HELP SORT, HELP RANK, HELP CURRENT online.

<b>LIMIT</b>	/ENG -- English Language Record /FULLTEXT -- Fulltext Record /LONG -- Record is > 1,000 Words /NONE -- Publication Year /NONENG -- Non-English Language Record /SHORT -- Record is < 1,000 Words	S S2/ENG S S3/FULLTEXT S S2/LONG S S2/2003 S S2/NONENG S S2/SHORT
<b>SORT</b>	AA, JN, PD, PY, TI	SORT S6/ALL/JN PRINT S3/5/1-24/PD,D
<b>RANK</b>	All phrase- and numeric-indexed fields in the Additional Indexes can be ranked.	RANK JN
<b>CURRENT</b>	Search only the most recent year plus one (CURRENT1) to five (CURRENT5) years.	B 182 CURRENT2

**PREDEFINED FORMAT OPTIONS**

NO.	DIALOGWEB FORMAT	RECORD CONTENT
1	--	DIALOG Accession Number
2	--	Full Record except Text
3	Medium	Bibliographic Citation
4	--	Bibliographic Citation, Lead Paragraph, and Word Count
5	Long	Bibliographic Citation, Indexing, Lead Paragraph, and Word Count
6	Free	Title, Publication Date, and Word Count
7	--	Full Record except Indexing
8	Short	Title, Publication Date, Word Count, and Indexing
9	Full	Full Record
K	--	KWIC (Key Word In Context) displays a window of text; may be used alone or with other formats

**OTHER OUTPUT OPTIONS**

For an explanation, enter HELP TYPE, HELP UDF, HELP TAG online.

<b>USER DEFINED FORMATS</b>	Display codes listed in the Search Options tables can be used to customize output.	TYPE S3/TI,PD/1-5
<b>TAG</b>	Output can be displayed with tags identifying each display field.	TYPE S2/TI,PD/1-5 TAG
<b>DIRECT RECORD ACCESS</b>	If the accession number of a specific record is known, it can be used to display the record directly.	TYPE 00004724/5 DISPLAY 00004704/CO,PN PRINT 00004392/2

**FOR ONLINE HELP:**

See HELP FIELDS 182 for searchable fields; HELP FORMAT 182 for output formats; HELP LIMIT 182 for limits; HELP RATES 182 for cost information; HELP SORT 182 for sorts.