

DIOGENES® FDA Regulatory Updates

FILE DESCRIPTION

DIOGENES FDA Regulatory Updates provides access to the Food and Drug Administration (FDA) regulatory information and is the database of choice for those researching the market status of FDA-approved pharmaceuticals and medical devices. The database includes:

- **Premarket Notifications [510(k)s].** Every device ever declared substantially equivalent and therefore allowed onto the market under the Premarket Notification provisions of the Medical Device Amendments of 1976, including device name and classification, regulating advisory committee, sponsoring company, date of FDA decision, and 510(k) number.
- **Premarket Approvals (PMAs).** All medical devices approved under the Premarket Approval provisions of the Medical Device Amendments of 1976. Individual entries include device name and manufacturer, date of approval, and regulating advisory committee.
- **Medical Device Reports (MDRs).** Includes a record describing each adverse device experience submitted to the FDA from the beginning of the Medical Device Reporting plan in 1985.
- **New Drug List (NDL).** A listing of every drug ever allowed onto the U.S. market since approval requirements began in 1938. Individual records include drug generic and trade names, Abbreviated New Drug Approval (ANDA) number, and data of approval. For affected drugs, date of market withdrawal, date of withdrawal of FDA permission to market Waxman-Hatch patent number, patent expiry, and patent exclusivity dates are also included.
- **The Enforcement Report.** Covering back to 1984, each record of The Enforcement Report describes an instance of FDA-recorded field corrections and product recalls, indexed by company, product, recall number, extent of recall, and recall narrative. It describes pharmaceuticals, medical devices, biologics, foods, radiological products, veterinary medical products, and cosmetics.

All material is acquired directly from the FDA and describes the approval and regulation of these

products.

SOURCES

DIOGENES FDA Regulatory Updates is made up of unpublished U.S. FDA documents acquired under the Freedom of Information Act, including: Advisory Committee minutes, drug and device approval information, regulatory letters, Establishment Inspection reports, Industry/FDA correspondence, and recall documentation.

TIPS

USE FILE 158

to monitor regulatory milestones for the pharmaceutical and medical device industry.

EXPAND ON AC=, DT=, AND SO=

to choose Advisory Committee, Device, or Source:

E AC=ADVISORY COMMITTEE

E DT=DEVICE

E SO=510K

ENTER SELECT STATEMENT AND RANK CO

to see which companies are working in an area of interest:

S (SO=510K AND (IMMUNO(W)ASSAY? OR IMMUNOASSAY?))/1996

RANK CO

DIALOG FILE DATA

Inclusive Dates:

510(k)s and PMAs from 1976, MDRs from 1985,
NDL from 1938, Reports from 1984

Update Frequency: Closed

File Size:

More than 2,315,140 records as of January 2012

CONTACT

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SAMPLE RECORD

DIALOG(R)File 158:DIOGENES(R)
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AA= 02530132 DIOGENES RECORD NUMBER: E0146083
 /TI NCS Healthcare of Kentucky CLASS II RECALL 11/30/04 & 12/01/04:
 Metoclopramide Tablets, 5mg;
 Folic Acid Tablets, 1mg.
 /TN,/NA,NA= DRUG NAME: Metoclopramide tablets, 5mg & folic acid tablets, 1mg.
 /CO,CO= COMPANY NAME: NCS Healthcare of Kentucky, Inc., Glasgow, KY.
 SO= SOURCE: FDA ENFORCEMENT REPORT 02/02/2005.
 PD= PUBLICATION DATE: November 30, 2004 ((20041130)December 01, 2004
 ((20041201))
 RT= RECORD TYPE: Fulltext
 WD=,LT= WORD COUNT: 143 (Short)
 DT= DOCUMENT TYPE: DRUG (DRG)
 LA= LANGUAGE: English
 /TX PRODUCT
 a) Metoclopramide Tablets, USP, 5 mg tablets, Rx only, packaged in 30 and 31
 count grid cards. NDC
 0615-3546-39 and NDC 0615-3546-31. Recall #D-107-5;
 b) Folic Acid Tablets, USP, 1 mg, Rx only, packaged in 30 and 31 count grid
 cards. NDC 0615-0664-39 and
 NDC 0615-0664-31. Recall # D-108-5.
 CODE
 a) Lot 3546-4009, exp. Date 10/31/05 and Lot 3546-4009, exp. Date 10/31/05;
 b) Lot 0664-4010, exp. Date 10/31/05 and Lot 0664-4010, exp. Date 10/31/05.
 RECALLING FIRM/MANUFACTURER
 NCS Healthcare of Kentucky, Inc., Glasgow, KY, by facsimile on November 30,
 2004 and by letter on
 December 1, 2004. Firm initiated recall is ongoing.
 REASON Mislabeled, the outside grid card package is labeled as
 Metoclopramide,5 mg, however,
 individual blister packages contained within the
 grid cards are labeled as, and contain, Folic Acid, 1 mg.
 VOLUME OF PRODUCT IN COMMERCE
 38,354 packages.
 DISTRIBUTION
 Nationwide.

FDA Citation:

DIALOG(R)File 158:DIOGENES(R)
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AA= 01881292 DIOGENES RECORD NUMBER: 733368
 /TI USI AUTOJECT INSULIN SYRINGE; FOI SUMMARY NOT AVAILABLE.
 /DC DEVICE CLASSIFICATION: (FMF) SYRINGE, PISTON. CLASS: 2. 21CFR: 880.586
 SD= SUBMISSION DATE: 19861205
 EQ= EQUIVALENCE CODE: (SE) SUBSTANTIALLY EQUIVALENT
 /CO,CO= COMPANY NAME: ULSTER SCIENTIFIC
 /AC,AC= ADVISORY COMMITTEE: GENERAL HOSPITAL AND PERSONAL USE DEVICE PANEL
 (DVGENPERS)
 DN= DEVICE/DRUG NO.: K864761
 SO= SOURCE: FDA 510(K) LIST (510K). LIST EDITION: January 2000
 PD=,PY= PUBLICATION DATE: December 16, 1986 (19861216)
 RT= RECORD TYPE: Citation
 DT= DOCUMENT TYPE: DEVICE (DEV) \$\$\$DC
 LA= LANGUAGE: English

SEARCH OPTIONS

BASIC INDEX

SEARCH SUFFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
—	—	All Basic Index Fields	Word	S CIBA
/AC	AC	Advisory Committee ¹	Word	S IMMUNOLOGY(W)DEVICE(W)PANEL/AC
/CO	CO	Company Name ¹	Word	S ULSTER(W)SCIENTIFIC/CO
/DC	DC	Device Class	Word	S SYRINGE(W)PISTON?/DC
/ID	ID	Identifier ²	Word & Phrase	S INJECTABLE(W)DRUG?/ID S INJECTABLE DRUG?/ID
/NA	NA	Drug Name ¹	Word	S METOCLOPRAMIDE(W)TABLETS/NA
/TI	TI	Title	Word	S INSULIN(W)SYRINGE/TI
/TN	TN	Drug Brand Name ¹	Word	S LOTREL/TN
/TX	TX	Text	Word	S FOLIC(W)ACID(W)TABLET?/TX
/XF	XF	All Basic Index Fields Except Full Text	Word	S CONTROLLED(W)RELEASE/XF

¹ Searchable in the Basic Index and in the Additional Indexes.

² Also /IF.

ADDITIONAL INDEXES

SEARCH PREFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
AA=	AA	DIOGENES Accession Number	Phrase	S AA=02530132
AC=	AC	Advisory Committee ¹	Phrase	S AC="GENERAL HOSPITAL AND PERSONAL USE"?
—	AZ	DIALOG Accession Number		
CO=	CO	Company Name ¹	Phrase	S CO=ULSTER SCIENTIFIC?
DN=	DN	Drug/Device Number	Phrase	S DN=K864761
DT=	DT	Document Type	Word	S DT=DEVICE
EQ=	EQ	Equivalence Code	Phrase	S EQ=SE
FD=	FD	FDA Number	Phrase	S FD=D1411365-2000-00009
LA=	LA	Language	Phrase	S LA=ENGLISH
LT=	LT	Length of Text	Phrase	S LT=SHORT S LT=LONG
ME=	ME	Market Exclusivity Reason	Word & Phrase	S ME=(ANTIGEN(W)REACTION) S ME=(U-304)?
NA=	NA	Drug Name ¹	Phrase	S NA=METOCLOPRAMIDE TABLET?
PD=	PD	Publication Date	Phrase	S PD=20041130
PE=	PE	Patent Expiration Date	Phrase	S PE=20051018?
PN=	PN	Patent Number	Phrase	S PN=US 4410520
PY=	PY	Publication Year	Phrase	S PY=2004
RT=	RT=	Record Type	Phrase	S RT=FULLTEXT
SD=	SD	Submission Date	Phrase	S SD=19861205
SO=	SO	Source Information	Word	S SO=(FDA(W)ENFORCEMENT(W)REPORT)
TN=	TN	Drug Brand Name ¹	Phrase	S TN=LOTREL
UD=	—	Update	Phrase	S UD=9999
WD=	WD	Word Count	Phrase	S WD=143

SPECIAL FEATURES

For command descriptions, enter HELP LIMIT, HELP SORT, HELP RANK, HELP MAP, HELP DUP online.

LIMIT	/DEVICE -- Medical Device Record /DRUG -- Drug Record /YYYY -- Publication Year	S S2/DEVICE S S2/DRUG S S3/2005
SORT	AC, CO, PD, PY, TI	SORT S6/ALL/AC/PD,D PRINT S3/5/1-24/CO
RANK	All phrase- and numeric-indexed fields in the Additional Indexes can be ranked. Other RANK codes include: ID	RANK ID
MAP	PN	MAP PN TEMP S2
RD, ID	Remove duplicates (RD) or identify duplicates (ID,IDO).	RD S5

PREDEFINED FORMAT OPTIONS

NO.	DIALOGWEB FORMAT	RECORD CONTENT
1	--	DIALOG Accession Number
2	--	Bibliographic Citation and Indexing
3	Medium	Bibliographic Citation
4	--	Full Record with Tagged Fields
5	--	Full Record except Fulltext
6	Free	Title and Word Count
7	--	Bibliographic Citation and Text
8	Short	Title 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.

USER DEFINED FORMATS	User-defined formats may be specified using the display codes indicated in the Search Options tables.	TYPE S3/AC,TI,SO/1-5
TAG	TAG may be used for tagged fields.	TYPE S3/3/1-5 TAG
DIRECT RECORD ACCESS	DIALOG Accession Number	TYPE 02531330/5 DISPLAY 02530889/TI,TN PRINT 02529638/3

FOR ONLINE HELP:

See HELP FIELDS 158 for searchable fields; HELP FORMAT 158 for output formats; HELP LIMIT 158 for limits; HELP RATES 158 for cost information; HELP SORT 158 for sorts.