

PharmApp - Drug Discovery and Development

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Animal Drugs @ FDA

Information

Animal Drugs @ FDA refers to the regulation and approval of animal drugs by the U.S. Food and Drug Administration (FDA). The FDA's Center for Veterinary Medicine (CVM) is responsible for overseeing the safety and effectiveness of veterinary drugs and feed additives used in animals. This includes:

- **Pre-Approval Review:** Before a new animal drug can be marketed in the U.S., the manufacturer must submit a New Animal Drug Application (NADA) to the CVM. This application includes extensive data demonstrating the drug's safety and effectiveness. The CVM reviews this data to determine whether the drug meets their standards.
- **Post-Market Surveillance:** After approval, the CVM continues to monitor the safety of animal drugs through post-market surveillance activities, including adverse event reporting and inspections of manufacturing facilities.
- **Regulation of Veterinary Drugs:** The FDA regulates not only the active pharmaceutical ingredients but also the manufacturing processes, labeling, and marketing claims for animal drugs. They set standards for drug quality, purity, and potency to ensure that they meet specific requirements.
- **Feed Additives:** The CVM also regulates feed additives that are used to enhance animal growth, health, and productivity. These additives must also undergo a rigorous pre-approval process.
- **Drug Residues:** The FDA has regulations to control drug residues in animal products (meat, milk, eggs) to ensure the safety of the food supply. They establish tolerance levels for drug residues that are allowed in these products to minimize any potential health risks to humans consuming the food.
- **Resources:** The CVM provides various resources for the public, veterinarians, and drug manufacturers such as the "Green Book" (officially known as "Summary Basis of Approval (SBA) for Veterinary Drugs"). This database contains information on approved veterinary drugs.

In essence, "Animal Drugs @ FDA" encompasses the entire regulatory framework and activities surrounding the approval, use, and monitoring of medications and feed additives used in animals in the United States, ensuring both the health of animals and the safety of the human food supply.

Download

- <https://animaldrugsatfda.fda.gov/adafda/views/#/search>
- Data store in animaldrugsatfda

ls '../animaldrugsatfda'

```
In [1]: import sys
        sys.path.append('.')
        import os
        os.getcwd()
```

Out[1]: 'D:\\PharmApp\\notebook'

```
In [2]: sys.executable
```

Out[2]: 'D:\\PharmApp\\Python312\\python.exe'

```
In [66]: import numpy as np
         import pandas as pd
         import warnings
         warnings.simplefilter(action='ignore', category=FutureWarning)
```

Download

- Downlaod to folder '../animaldrugsatfda'

Load Animal Drugs Data

\LicensesbySiteName.xls
 \LicensesByState.xls
 \Section11ByTradeName.xls
 \Section12byApplicationNumber.xls
 \Section3PatentInformation.xls
 \Section4ExclusivityPeriods.xls
 \Section5NoticeofHearing.xls
 \Section6VoluntaryWithdrawal.xls
 \Section7SuitabilityPetition.xls

```
In [22]: columns={'Application Number': 'Application_Number', 'Trade Name': 'Trade_Name',
               'Sponsor Name': 'Sponsor_Name', 'Green Book': 'Green_Book', 'Publication Date': 'Publication_Date',
               'Date Withdrawn': 'Date_Withdrawn', 'Sponsor When Withdrawn': 'Sponsor_When_Withdrawn', 'Site Name': 'Site_Name',
               'License No.': 'License_No.', 'Zip Code': 'Zip_Code'}
```

```
In [23]: ApplicationNumber = pd.read_excel('../animaldrugsatfda/Section12byApplicationNumber.xls')
ApplicationNumber = ApplicationNumber.rename(columns=columns)
# ApplicationNumber.head(3)
ApplicationNumber
```

Out[23]:

	Application_Number	Trade_Name	Sponsor_Name
0	004-536	Somnopentyl Injection	Intervet, Inc.
1	005-236	Sulfodene® Medication for Dogs	Farnam Companies, Inc.
2	005-633	Protomone Thyroactive Casein	Agri-Tech, Inc.
3	006-084	Sulmet® Drinking Water Solution, 12.5%	Huvepharma EOOD
4	006-103	Follutein Veterinary	Zoetis Inc.
...
1612	200-788	MoxiSolv™ Injection	Bimeda Animal Health Limited
1613	200-793	PropofolVet Multidose	Parnell Technologies Pty. Ltd.
1614	200-795	CARPROFEN Soft Chewable Tablets	Felix Pharmaceuticals Pvt. Ltd.
1615	200-803	PAQFLOR™	Phibro Animal Health Corp.
1616	200-805	MEL™ 500	Virbac AH, Inc.

1617 rows × 3 columns

ApplicationNumber.iloc[:,1]ApplicationNumber.indexApplicationNumber = ApplicationNumber.drop("Trade_Name")

```
In [24]: PatentInformation = pd.read_excel('../animaldrugsatfda/Section3PatentInformation.xls')
PatentInformation = PatentInformation.rename(columns=columns)
# PatentInformation.head(3)
PatentInformation
```

Out[24]:

	Application_Number	Trade_Name	Patent	Expiration
0	098-431	TYLAN™ 20, TYLAN™ 40	1111111	12/08/2016
1	141-025	Cattlyst®	9149456	06/15/2029
2	141-026	Program™ Suspension	5776982	07/07/2015
3	141-033	Antisedan®	4933359	05/14/2007
4	141-033	Antisedan®	4689339	08/06/2010
...
394	141-590	MGA® and Experior™ and Rumensin™	11864567	10/10/2035
395	141-590	MGA® and Experior™ and Rumensin™	11344047	05/05/2037
396	141-591	MGA® and Experior™ and Rumensin™ and Tylan™	6730792	04/20/2025
397	141-591	MGA® and Experior™ and Rumensin™ and Tylan™	11344047	05/05/2037
398	141-591	MGA® and Experior™ and Rumensin™ and Tylan™	11864567	10/10/2035

399 rows × 4 columns

```
In [25]: ExclusivityPeriods = pd.read_excel('../animaldrugsatfda/Section4ExclusivityPeriods.xls')
ExclusivityPeriods = ExclusivityPeriods.rename(columns=columns)
ExclusivityPeriods.head(3)
```

Out[25]:

	Application_Number	Trade_Name	Period	Expiration	Green_Book
0	012-491	Tylan™ 10, Tylan™ 40, Tylan™ 100, Tylan™ 100 CAL	3 years	11/07/2009	January 2007
1	013-076	Tylan Soluble™	3 years	07/30/2017	August 2014
2	034-267	Gentocin® Durafilm®	3 years	11/10/2017	December 2014

In [26]:

```
NoticeofHearing = pd.read_excel('../animaldrugsatfda/Section5NoticeofHearing.xls')
NoticeofHearing = NoticeofHearing.rename(columns=columns)
NoticeofHearing.head(3)
```

Out[26]:

	Application_Number	Trade_Name	Sponsor_Name	Publication_Date
0	009-252	Fumidil B	Mid-Continent Agrimarketing, Inc.	03/07/2013
1	031-971	Cuprate	Walco International, Inc.	01/08/2020
2	034-601	Synchro-Mate®	G.D. Searle LLC, Pharmacia Corp.	03/07/2013

In [27]:

```
VoluntaryWithdrawal = pd.read_excel('../animaldrugsatfda/Section6VoluntaryWithdrawal.xls')
VoluntaryWithdrawal = VoluntaryWithdrawal.rename(columns=columns)
VoluntaryWithdrawal.head(3)
```

Out[27]:

	Application_Number	Date_Withdrawn	Ingredients	Sponsor_When_Withdrawn
0	005-414	01/06/2014	Roxarsone	Zoetis Inc.
1	006-019	01/06/2014	Roxarsone	Zoetis Inc.
2	006-032	12/22/1995	Diphenylhydantoin Sodium	Parke-Davis Div. Warner-Lambert Co.

In [28]:

```
SuitabilityPetition = pd.read_excel('../animaldrugsatfda/Section7SuitabilityPetition.xls')
SuitabilityPetition = SuitabilityPetition.rename(columns=columns)
SuitabilityPetition.head(3)
```

Out[28]:

	Number	Petitioner	Description	Action	Date
0	89P-0191/CP1	Fermenta Animal Health Co.	Request to substitute sulfathiazole for sulfam...	Denied	07/13/1989
1	89P-0191/PRC1	Fermenta Animal Health Co.	Request to reconsider proposal to substitute s...	Denied	12/06/1989
2	89P-0446/CP1	Boehringer Ingelheim Vetmedica, Inc.	Request to differ the dosage form and strength...	Approved	12/29/1989

In [31]:

```
LicensesbySiteName = pd.read_excel('../animaldrugsatfda/LicensesbySiteName.xls')
LicensesbySiteName = LicensesbySiteName.rename(columns=columns)
LicensesbySiteName.head(3)
```

Out[31]:

	Site_Name	License_No.	Address	City	State	Zip_Code	CountryProvince
0	1256 Cattle Co.	500-745	26795 Highway 34	Wray	CO	80758	United States
1	4M Feeders - Yard #3	501-425	2955 Road 30	Stratton	CO	80836	United States
2	4M Feeders, North	500-756	2955 Road 30	Stratton	CO	80836	United States

In [32]:

```
LicensesByState = pd.read_excel('../animaldrugsatfda/LicensesByState.xls')
LicensesByState = LicensesByState.rename(columns=columns)
LicensesByState.head(3)
```

Out[32]:

	Site_Name	License_No.	Address	City	State	Zip_Code	CountryProvince
0	Tyson Foods, Inc.	501-011	1100 Railroad Ave	Albertville	AL	35951-3425	United States
1	Koch Farms of Gadsden	501-663	1051 Burgess Road	Attalla	AL	35954	United States
2	Tyson Foods, Inc.	500-563	200 Carnes Chapel Rd.	Attalla	AL	35954-7710	United States

In [34]:

```
TradeName = pd.read_excel('../animaldrugsatfda/Section11ByTradeName.xls')
TradeName = TradeName.rename(columns=columns)
TradeName.head(3)
```

Out[34]:

	Application_Number	Trade_Name	Sponsor_Name
0	006-677	20% Sulfaquinoxaline Sodium Solution	Huvepharma EOOD
1	007-087	25 % S.Q.® Soluble	Huvepharma EOOD
2	141-255	35% PEROX-AID®	Syndel USA

Merge all file in 1 file csv

```
In [44]: df = ApplicationNumber
df2 = PatentInformation
cols_to_use = df2.columns.difference(df.columns)
dfNew = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
# dfNew
```

```
In [45]: df = LicensesbySiteName
df2 = TradeName
cols_to_use = df2.columns.difference(df.columns)
dfNew2 = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
# dfNew2
```

```
In [46]: df = VoluntaryWithdrawal
df2 = SuitabilityPetition
cols_to_use = df2.columns.difference(df.columns)
dfNew1 = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
# dfNew1
```

```
In [47]: df = dfNew
df2 = dfNew1
cols_to_use = df2.columns.difference(df.columns)
dfNew3 = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
# dfNew3
```

```
In [48]: df = dfNew3
df2 = dfNew2
cols_to_use = df2.columns.difference(df.columns)
dfNew4 = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
# dfNew4
```

```
In [64]: df = dfNew4
df2 = LicensesByState
cols_to_use = df2.columns.difference(df.columns)
animal_drugs_fda_full = pd.merge(df, df2[cols_to_use], left_index=True, right_index=True, how='outer')
animal_drugs_fda_full.sample(5)
```

Out[64]:

	Application_Number	Trade_Name	Sponsor_Name	Expiration	Patent	Action	Date	Date_Withdrawn	Description	Indication
	527	104-493	Filaribits® Chewable Tablets	Zoetis Inc.	NaN	NaN	NaN	NaN	02/12/1998	NaN
	1257	200-283	Vetro-Max®	Fougera Pharmaceuticals, Inc.	NaN	NaN	NaN	NaN	NaN	NaN
	280	047-033	S.E.Z. C-R Oblets 15 Gm	Zoetis Inc.	01/17/2030	8383659	Filed	06/02/2014	05/03/2023	The petitioner requested to file an ANADA for ...
	89	012-965	Tylan™ 200 Injection, Tylan™ 50 Injection	Elanco US Inc.	03/04/2025	8859554	Approved	08/15/2000	07/15/1996	Request permission to file an ANADA for a gene...
	885	141-176	Baytril® Otic	Elanco US Inc.	NaN	NaN	NaN	NaN	NaN	NaN

```
In [55]: animal_drugs_fda_full.to_csv('../animaldrugsatfda/animal_drugs_fda_full.csv')
```

df.info()df.columns

Search name drug

```
In [57]: animal_drugs_fda_full = pd.read_csv('../animaldrugsatfda/animal_drugs_fda_full.csv')
```

```
In [58]: # search df
def search_df(df: pd.DataFrame, substring: str, case: bool = False) -> pd.DataFrame:
    mask = np.column_stack([df[col].astype(str).str.contains(substring.lower(), case=case, na=False) for col in df])
    return df.loc[mask.any(axis=1)]
```

```
In [67]: # ingredient = 'Hexanediol'
key_search = str(input("Enter drug name: ")) # PENTAVITIN
print(f'Your key search is {key_search}')
df_search = search_df(animal_drugs_fda_full, key_search)
from pandasgui import show
show(df_search)
```

Your key search is Vetro-Max

Out[67]: <pandasgui.gui.PandasGui at 0x256427b0440>

```
In [76]: def sv(key_search):
# key_search = str(input("Enter drug name: ")) # Vetro-Max
print(f'Your key search is {key_search}')
df_search = search_df(animal_drugs_fda_full, key_search)
# df_search
print(df_search)
```

```
In [77]: sv('Vetro-Max')
```

Your key search is Vetro-Max

	Application_Number	Trade_Name	Sponsor_Name	Expiration	\
1257	200-283	Vetro-Max®	Fougera Pharmaceuticals, Inc.		NaN

	Patent	Action	Date	Date_Withdrawn	Description	Ingredients	Number	\
1257	NaN	NaN	NaN	NaN	NaN	NaN	NaN	

	Petitioner	Sponsor_When_Withdrawn	Address	City	Country	Province	\
1257	NaN		NaN	NaN	NaN		NaN

	License_No.	Site_Name	State	Zip_Code
1257	NaN	NaN	NaN	NaN

```
In [81]: def svi():
key_search = str(input("Enter drug name: ")) # Vetro-Max
print(f'Your key search is {key_search}')
df_search = search_df(animal_drugs_fda_full, key_search)
# df_search
print(df_search)
```

```
In [92]: svi()
```

Your key search is Zoetis Inc.

	Application_Number	Trade_Name \
0	004-536	Somnopentyl Injection
1	005-236	Sulfodene® Medication for Dogs
3	006-084	Sulmet® Drinking Water Solution, 12.5%
4	006-103	Follutein Veterinary
5	006-281	Intrigel
...
1234	200-244	Tucoprim® Powder
1253	200-274	Lincomycin Injectable 30%
1316	200-367	Synovex® T120, Synovex® T40, Synovex® T80
1434	200-560	Actogain™ 45/Rumensin®/MGA®
1447	200-582	Loncor™ 300

	Sponsor_Name	Expiration	Patent	Action	Date \
0	Intervet, Inc.	12/08/2016	1111111	Denied	07/13/1989
1	Farnam Companies, Inc.	06/15/2029	9149456	Denied	12/06/1989
3	Huvepharma EOOD	05/14/2007	4933359	Approved	01/24/1990
4	Zoetis Inc.	08/06/2010	4689339	Approved	03/21/1990
5	Zoetis Inc.	07/07/2015	5776982	Denied	04/12/1990
...
1234	Zoetis Inc.	NaN	NaN	NaN	NaN
1253	Zoetis Inc.	NaN	NaN	NaN	NaN
1316	Zoetis Inc.	NaN	NaN	NaN	NaN
1434	Zoetis Inc.	NaN	NaN	NaN	NaN
1447	Zoetis Inc.	NaN	NaN	NaN	NaN

	Date_Withdrawn	Description \
0	01/06/2014	Request to substitute sulfathiazole for sulfam...
1	01/06/2014	Request to reconsider proposal to substitute s...
3	01/06/2014	Request to change dosage form in NADA 131-918 ...
4	07/15/1996	Request to change Nemex Tabs from two tablet s...
5	11/03/1994	Request to revoke approval of petition 89P-044...
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	Ingredients	Number \
0	Roxarsone	89P-0191/CP1
1	Roxarsone	89P-0191/PRC1
3	Roxarsone	89P-0509/CP1
4	Diethylcarbamazine Citrate	90P-0051/CP1
5	Butacaine Sulfate, Nitrofurazone	90P-0073/CP1
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	Petitioner \
0	Fermenta Animal Health Co.
1	Fermenta Animal Health Co.
3	Cheminex Laboratories, Inc.
4	Beecham Laboratories
5	A. L. Laboratories
...	...
1234	NaN
1253	NaN
1316	NaN
1434	NaN
1447	NaN

	Sponsor_When_Withdrawn	Address \
0	Zoetis Inc.	26795 Highway 34
1	Zoetis Inc.	2955 Road 30
3	Zoetis Inc.	2955 Road 30
4	Bayer HealthCare LLC, Animal Health Division	7500 Road KK
5	SmithKline Beecham Animal Health	100 Mill Street
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	City	Country	Province	License_No. \
0	Wray	United States		500-745
1	Stratton	United States		501-425
3	Stratton	United States		500-757
4	Idalia	United States		501-523
5	Ardmore	United States		500-855
...
1234	NaN	NaN		NaN

1253	NaN	NaN	NaN
1316	NaN	NaN	NaN
1434	NaN	NaN	NaN
1447	NaN	NaN	NaN

	Site_Name	State	Zip_Code
0	1256 Cattle Co.	CO	80758
1	4M Feeders - Yard #3	CO	80836
3	4M Feeders, South	CO	80836
4	5 Star Feedlots, Inc. dba Bonny Feeders	CO	80735
5	AC Nutrtn, LP dba Bluebonnet Feed	OK	73401
...
1234	NaN	NaN	NaN
1253	NaN	NaN	NaN
1316	NaN	NaN	NaN
1434	NaN	NaN	NaN
1447	NaN	NaN	NaN

[423 rows x 20 columns]

```
In [78]: def svpd(key_search):
        # key_search = str(input("Enter drug name: ")) # Vetro-Max
        print(f'Your key search is {key_search}')
        df_search = search_df(animal_drugs_fda_full, key_search)
        df_search
        print(df_search)
        from pandasgui import show
        show(df_search)

In [ ]: svpd('Elanco US Inc.')
```

```
In [ ]: svpd('Tevcodyne Injectable')
```

```
In [ ]: svpd('Baytril')
```

```
In [ ]: svpd('Vetro-Max')
```

```
In [93]: svpd('Zoetis Inc.')
```

PandasGUI INFO – pandasgui.gui – Opening PandasGUI

Your key search is Zoetis Inc.

	Application_Number	Trade_Name \
0	004-536	Somnopentyl Injection
1	005-236	Sulfodene® Medication for Dogs
3	006-084	Sulmet® Drinking Water Solution, 12.5%
4	006-103	Follutein Veterinary
5	006-281	Intrigel
...
1234	200-244	Tucoprim® Powder
1253	200-274	Lincomycin Injectable 30%
1316	200-367	Synovex® T120, Synovex® T40, Synovex® T80
1434	200-560	Actogain™ 45/Rumensin®/MGA®
1447	200-582	Loncor™ 300

	Sponsor_Name	Expiration	Patent	Action	Date \
0	Intervet, Inc.	12/08/2016	1111111	Denied	07/13/1989
1	Farnam Companies, Inc.	06/15/2029	9149456	Denied	12/06/1989
3	Huvepharma EOOD	05/14/2007	4933359	Approved	01/24/1990
4	Zoetis Inc.	08/06/2010	4689339	Approved	03/21/1990
5	Zoetis Inc.	07/07/2015	5776982	Denied	04/12/1990
...
1234	Zoetis Inc.	NaN	NaN	NaN	NaN
1253	Zoetis Inc.	NaN	NaN	NaN	NaN
1316	Zoetis Inc.	NaN	NaN	NaN	NaN
1434	Zoetis Inc.	NaN	NaN	NaN	NaN
1447	Zoetis Inc.	NaN	NaN	NaN	NaN

	Date_Withdrawn	Description \
0	01/06/2014	Request to substitute sulfathiazole for sulfam...
1	01/06/2014	Request to reconsider proposal to substitute s...
3	01/06/2014	Request to change dosage form in NADA 131-918 ...
4	07/15/1996	Request to change Nemex Tabs from two tablet s...
5	11/03/1994	Request to revoke approval of petition 89P-044...
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	Ingredients	Number \
0	Roxarsone	89P-0191/CP1
1	Roxarsone	89P-0191/PRC1
3	Roxarsone	89P-0509/CP1
4	Diethylcarbamazine Citrate	90P-0051/CP1
5	Butacaine Sulfate, Nitrofurazone	90P-0073/CP1
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	Petitioner \
0	Fermenta Animal Health Co.
1	Fermenta Animal Health Co.
3	Cheminex Laboratories, Inc.
4	Beecham Laboratories
5	A. L. Laboratories
...	...
1234	NaN
1253	NaN
1316	NaN
1434	NaN
1447	NaN

	Sponsor_When_Withdrawn	Address \
0	Zoetis Inc.	26795 Highway 34
1	Zoetis Inc.	2955 Road 30
3	Zoetis Inc.	2955 Road 30
4	Bayer HealthCare LLC, Animal Health Division	7500 Road KK
5	SmithKline Beecham Animal Health	100 Mill Street
...
1234	NaN	NaN
1253	NaN	NaN
1316	NaN	NaN
1434	NaN	NaN
1447	NaN	NaN

	City	Country	Province	License_No. \
0	Wray	United States		500-745
1	Stratton	United States		501-425
3	Stratton	United States		500-757
4	Idalia	United States		501-523
5	Ardmore	United States		500-855
...
1234	NaN	NaN		NaN

1253	NaN	NaN	NaN
1316	NaN	NaN	NaN
1434	NaN	NaN	NaN
1447	NaN	NaN	NaN

	Site_Name	State	Zip_Code
0	1256 Cattle Co.	CO	80758
1	4M Feeders - Yard #3	CO	80836
3	4M Feeders, South	CO	80836
4	5 Star Feedlots, Inc. dba Bonny Feeders	CO	80735
5	AC Nutrtn, LP dba Bluebonnet Feed	OK	73401
...
1234	NaN	NaN	NaN
1253	NaN	NaN	NaN
1316	NaN	NaN	NaN
1434	NaN	NaN	NaN
1447	NaN	NaN	NaN

[423 rows x 20 columns]

In []: