



TITLE:

District Implementation of Drug (Human and Animal)
Registrations

ORIGINAL EFFECTIVE DATE:
7/6/15

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1. Purpose/Scope

This document provides additional instructions to support the procedures for managing human and animal drug registrations as listed in FMD 92, to be followed by ALL district offices, Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO) in monitoring and processing registrations from Center for Drug Evaluations and Research (CDER) and Center for Veterinary Medicine (CVM) and updating FACTS FMS (Field Management Services).

2. Responsibility

It is the responsibility of the District OEI Coordinator, District Drug Monitor, Drug Registration Coordinator or designee to manage drug registrations in accordance with this work instruction.

District includes both domestic and foreign areas.

Note: The document refers to District Registration Monitor throughout, but is referring to the above statement.

3. Background

The Generic Drug User Fee Amendments of 2012 (GDUFA) requires that human generic drug facilities, and certain sites and organizations identified in a generic drug submission, provide identification information annually to FDA (self-identification). This information assists in constructing an accurate inventory of facilities, sites and organizations



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involved in the manufacture of generic drugs, setting annual facility fee amounts, and targeting inspections. GDUFA establishes application fees (for ANDAs, prior approval supplements (PASs) to ANDAs, and drug master files (DMFs)), annual facility fees.

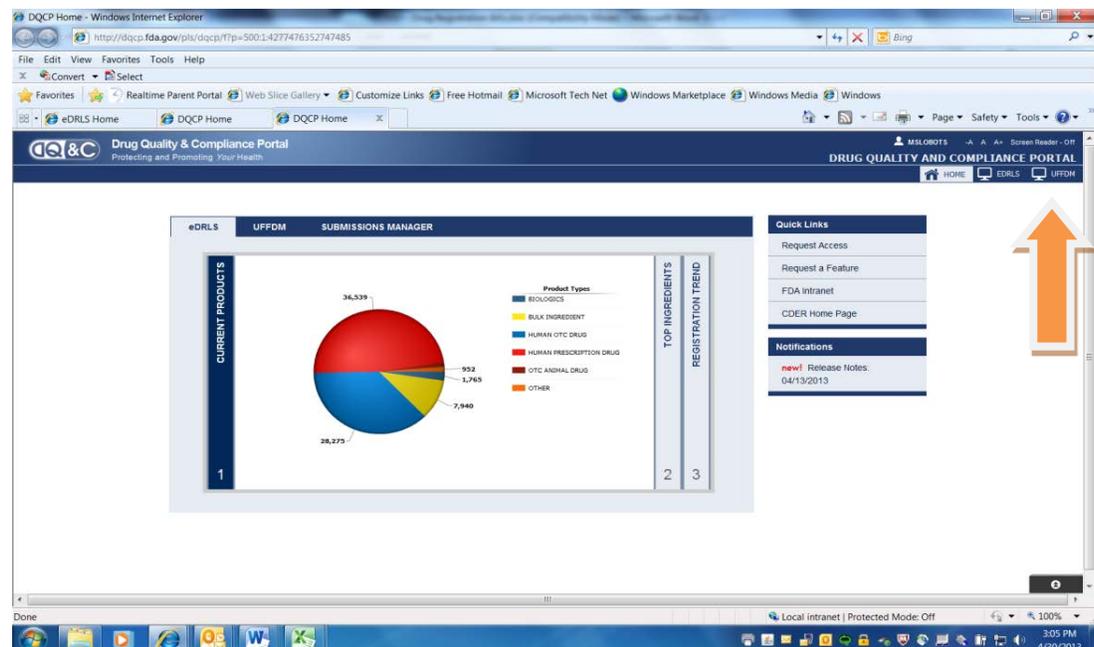
Although most facilities that are required to self-identify are also required to pay an annual facility user fee, certain types of generic facilities, sites and organizations are not required to pay the annual facility user fee. These include facilities, sites and organizations that solely manufacture positron emission tomography (PET) drugs; clinical bioequivalence or bioavailability study sites; in vitro bioequivalence testing or bioanalytical testing sites; API/FDF analytical testing sites; and repackagers.

CDER and CVM: The registration number is the nine digit DUNS number assigned by DUN and Bradstreet. The FEI number is an optional data element included with registration. Firms are encouraged to include it with their registration submission if they know it, but it is not required.

4. Procedure

4.1 Human Registration Data Download from CDER

Step 1: Go to “Inside FDA”, “CDER”, scroll to the bottom of the page and “Electronic Drug Registration and Listing System”



For the most current and official copy, check QMiS.

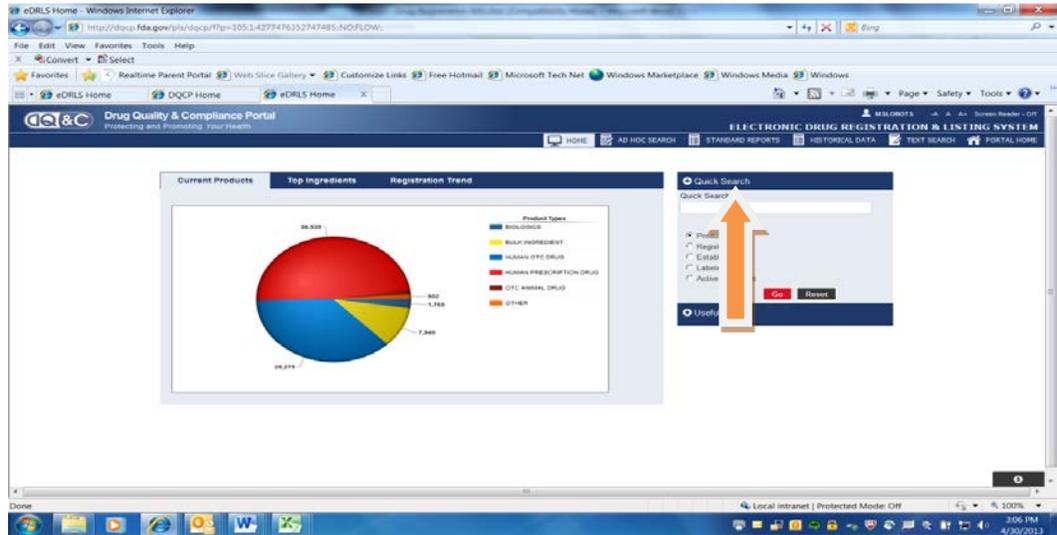


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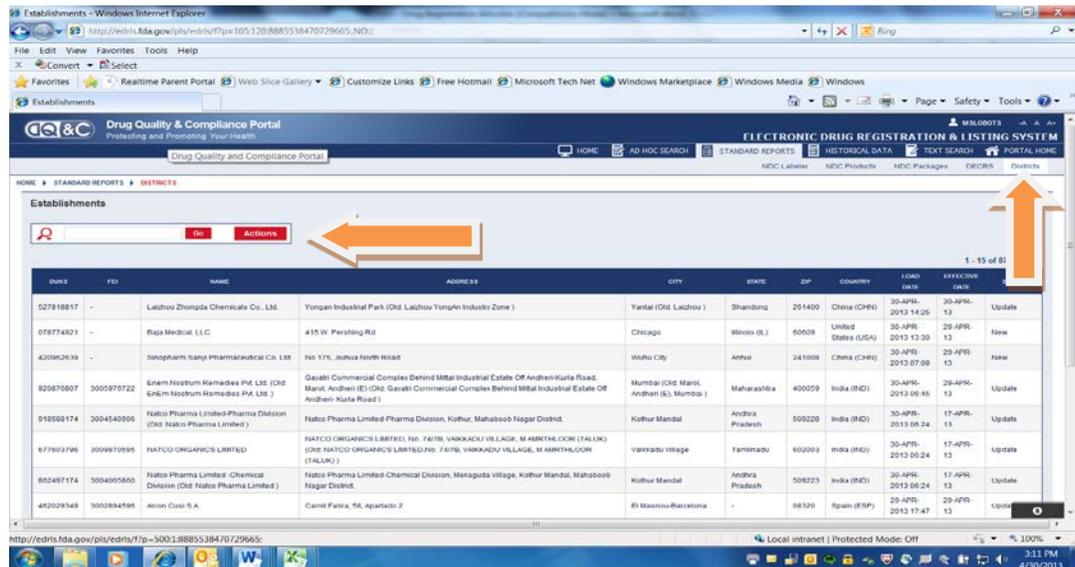
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Step 2: Select “Standard Reports” from the tool bar.



Step 3: Select the “Districts” tab. A list of establishments will populate the screen. Immediately above the list is a red rectangle with the word “Actions” within.



Step 4: Click on “Actions:” and a drop down menu will appear. Select the “Filter” option and a filter dialogue box will appear.



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The screenshot shows the 'ELECTRONIC DRUG REGISTRATION & LISTING SYSTEM' interface. A table of establishments is displayed with columns for DUNS, FEI, NAME, ADDRESS, CITY, STATE, ZIP, COUNTRY, LOAD DATE, EFFECTIVE DATE, and STATUS. A filter menu is open over the 'Filter' column header, showing options like 'Filter', 'Rows Per Page', 'Format', 'Flashback', 'Save Report', 'Reset', and 'Help'. An orange arrow points to the 'Filter' option in the menu.

DUNS	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	EFFECTIVE DATE	STATUS
527818817	-	Laihou Zhongda Chem	... Park (Old Laihou Yongle Industry Zone)	Yantai (Old Laihou)	Shandong	261400	China (CHN)	30-APR-2013 14:25	20-APR-2013	Update
078774821	-	Baja Medical, LLC	...	Chicago	Illinois (IL)	60609	United States (USA)	30-APR-2013 13:30	20-APR-2013	New
420952639	-	Singpharm Sanyl Pharm	... South Road	Wuhu City	Anhui	241008	China (CHN)	30-APR-2013 07:08	20-APR-2013	New
920876807	3005975722	Enem Nostrum Remed	... Industrial Estate Off Andheri-Kurla Road	Mumbai (Old Marol Andheri (E), Mumbai)	Maharashtra	400059	India (IND)	30-APR-2013 06:45	20-APR-2013	Update
918588174	3004540809	Natco Pharma Limited	... (Old Natco Pharma Limited)	Kothur Mandal	Andhra Pradesh	509226	India (IND)	30-APR-2013 06:24	17-APR-2013	Update
677603796	3009870595	NATCO ORGANICS LIM	... (TALUK)	Vaikaduvillage	Tamilnadu	602003	India (IND)	30-APR-2013 06:24	17-APR-2013	Update
862487174	3004056860	Natco Pharma Limited -Chemical Division (Old Natco Pharma Limited)	... Nagar District.	Kothur Mandal	Andhra Pradesh	509223	India (IND)	30-APR-2013 06:24	17-APR-2013	Update
462029349	3002894596	Alcon Cusi S.A.	... Apartado 2	El Masnou-Barcelona	-	08320	Spain (ESP)	20-APR-2013 17:47	13	Update

Step 5: Filter first by “Country” and click “Apply” and then second by “State Name” and click “Apply”.

Hint: if you filter by State and instead of “equal to” you filter by “in”, you can select multiple states. Include additional filters for status to build multi-filtered reports. (See examples)

The screenshot shows the 'Filter' dialog box in the system. The 'Filter Type' is set to 'Column'. The 'Column' is 'STATE' and the 'Operator' is '='. The 'Expression' field contains 'New Jersey'. A yellow arrow points to the 'Apply' button.

DUNS	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	EFFECTIVE DATE	STATUS
689893264	3008993334	China Chemical & Pharmaceutical Co., Ltd Taiwan Plant	No. 39, Gongye Rd	Guantian Dist., Taiwan City	-	72042	Taiwan, Province Of China (CHN)	09-MAY-2014 10:32	09-MAY-2014 10:31	No Change
378413153	3006527915	LALURIUS LABS PRIVATE LIMITED	Plot No. D51, IOP Knowledge Park, Sharnangpet Mandal, Turkapally	Hydrabad	Andhra Pradesh	500078	India (IND)	09-MAY-2014 10:31	09-MAY-2014 10:31	Change
650757774	3007083664 (Old)	LALURIUS LABS PRIVATE LIMITED	Plot No. 18, Jawaharal Nehru Pharma City, Panawada	Visakhapatnam	Andhra Pradesh	531021	India (IND)	09-MAY-2014 10:31	09-MAY-2014 10:31	Update
815075687	3007083664	LALURIUS LABS PRIVATE LIMITED	Plot No. 21, Jawaharal Nehru Pharma City, Panawada	Visakhapatnam	Andhra Pradesh	531021	India (IND)	09-MAY-2014 10:31	09-MAY-2014 10:31	Hi Ch



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Step 6: The returned data is sorted by “Load Date”, which is the date the registration data was received, with the most current information first. Data goes back to inspection of electronic registration in 2009.

A report can be generated that will automatically run weekly or monthly that will come in an email format. (See 4.2)

ID#	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	STATUS
19432363	-	Gannett Warehousing Corp.	1000 Fort Carteret Rd.	Carteret	New Jersey (NJ)	07008	United States (USA)	08-MAY-2014 16:31	New
91555888	2248991	COMPLETE ANALYSIS LABORATORIES INC	1259 ROUTE 46 STE 4	PARLIPPANAY	New Jersey (NJ)	07054	United States (USA)	08-MAY-2014 12:01	No Change
97846793	-	Surety Labs, a division of Substantia International	6 Passat Court	Atlantide	New Jersey (NJ)	07401	United States (USA)	08-MAY-2014 06:19	De-Registered
968119730	3003792057	Amneal Pharmaceuticals, LLC	209 McLean Boulevard	Paterson	New Jersey (NJ)	07604	United States (USA)	08-MAY-2014 06:16	No Change
06046946	300826118	Kaishu Pharma, LLC	1 New England Avenue	Placetaway	New Jersey (NJ)	08854	United States (USA)	08-MAY-2014 06:16	Dropped
99999194	3009269762	Amneal Pharmaceuticals, LLC	1 Murray Road	East Hanover	New Jersey (NJ)	07738	United States (USA)	08-MAY-2014 06:16	No Change
95342455	3008851605	Amneal Pharmaceuticals, LLC	1 New England Avenue	Placetaway	New Jersey (NJ)	08854	United States (USA)	08-MAY-2014 06:16	No Change
96390078	3004488497	Amneal Pharmaceuticals, LLC	131 Chambers Brook Road	Branchburg	New Jersey (NJ)	08876	United States (USA)	08-MAY-2014 06:16	No Change
03584820	2222743080	Color Technologies Inc.	263 Ryan Street	South Plainfield	New Jersey (NJ)	07080	United States (USA)	08-MAY-2014 16:48	New
02079819	2249919	Micromedex Laboratories Div. of Pharmax Group, Inc.	185 B Industrial Parkway	Branchburg	New Jersey (NJ)	08876	United States (USA)	08-MAY-2014 12:31	No Change
90738970	-	IPAK, INC	301 Grove Road	West Deptford	New Jersey (NJ)	08080	United States (USA)	08-MAY-2014 10:45	New
91018594	2215048	Merck Sharp & Dohme Corp.	2000 Gallopings Hill Road	Kentworth	New Jersey (NJ)	07033	United States (USA)	08-MAY-2014 06:16	No Change
03913882	2211256	Merck Sharp & Dohme Corp.	1011 Morris Avenue	Union	New Jersey (NJ)	07083	United States (USA)	08-MAY-2014 06:16	No Change
02311428	2211553	Advaia Eliabath LLC	200 Elmora Ave	Eliabath	New Jersey (NJ)	07202	United States (USA)	08-MAY-2014 06:16	No Change
01766526	3008917204	ARMAI, LLC	47 Brunerwick Ave	Edison	New Jersey (NJ)	08817	United States (USA)	08-MAY-2014 06:16	No Change

Step 7: Download the data using the above reference “Actions” pull down menu

ID#	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	STATUS
19432363	-	Gannett Warehousing Corp.	1000 Fort Carteret Rd.	Carteret	New Jersey (NJ)	07008	United States (USA)	08-MAY-2014 16:31	New
91555888	2248991	COMPLETE ANALYSIS LABORATORIES INC	1259 ROUTE 46 STE 4	PARLIPPANAY	New Jersey (NJ)	07054	United States (USA)	08-MAY-2014 12:01	No Change
97846793	-	Surety Labs, a division of Substantia International	6 Passat Court	Atlantide	New Jersey (NJ)	07401	United States (USA)	08-MAY-2014 06:19	De-Registered
968119730	3003792057	Amneal Pharmaceuticals, LLC	209 McLean Boulevard	Paterson	New Jersey (NJ)	07604	United States (USA)	08-MAY-2014 06:16	No Change
06046946	300826118	Kaishu Pharma, LLC	1 New England Avenue	Placetaway	New Jersey (NJ)	08854	United States (USA)	08-MAY-2014 06:16	Dropped
99999194	3009269762	Amneal Pharmaceuticals, LLC	1 Murray Road	East Hanover	New Jersey (NJ)	07738	United States (USA)	08-MAY-2014 06:16	No Change
95342455	3008851605	Amneal Pharmaceuticals, LLC	1 New England Avenue	Placetaway	New Jersey (NJ)	08854	United States (USA)	08-MAY-2014 06:16	No Change
96390078	3004488497	Amneal Pharmaceuticals, LLC	131 Chambers Brook Road	Branchburg	New Jersey (NJ)	08876	United States (USA)	08-MAY-2014 06:16	No Change
03584820	2222743080	Color Technologies Inc.	263 Ryan Street	South Plainfield	New Jersey (NJ)	07080	United States (USA)	08-MAY-2014 16:48	New
02079819	2249919	Micromedex Laboratories Div. of Pharmax Group, Inc.	185 B Industrial Parkway	Branchburg	New Jersey (NJ)	08876	United States (USA)	08-MAY-2014 12:31	No Change
90738970	-	IPAK, INC	301 Grove Road	West Deptford	New Jersey (NJ)	08080	United States (USA)	08-MAY-2014 10:45	New
91018594	2215048	Merck Sharp & Dohme Corp.	2000 Gallopings Hill Road	Kentworth	New Jersey (NJ)	07033	United States (USA)	08-MAY-2014 06:16	No Change
03913882	2211256	Merck Sharp & Dohme Corp.	1011 Morris Avenue	Union	New Jersey (NJ)	07083	United States (USA)	08-MAY-2014 06:16	No Change
02311428	2211553	Advaia Eliabath LLC	200 Elmora Ave	Eliabath	New Jersey (NJ)	07202	United States (USA)	08-MAY-2014 06:16	No Change
01766526	3008917204	ARMAI, LLC	47 Brunerwick Ave	Edison	New Jersey (NJ)	08817	United States (USA)	08-MAY-2014 06:16	No Change

For the most current and official copy, check QMiS.

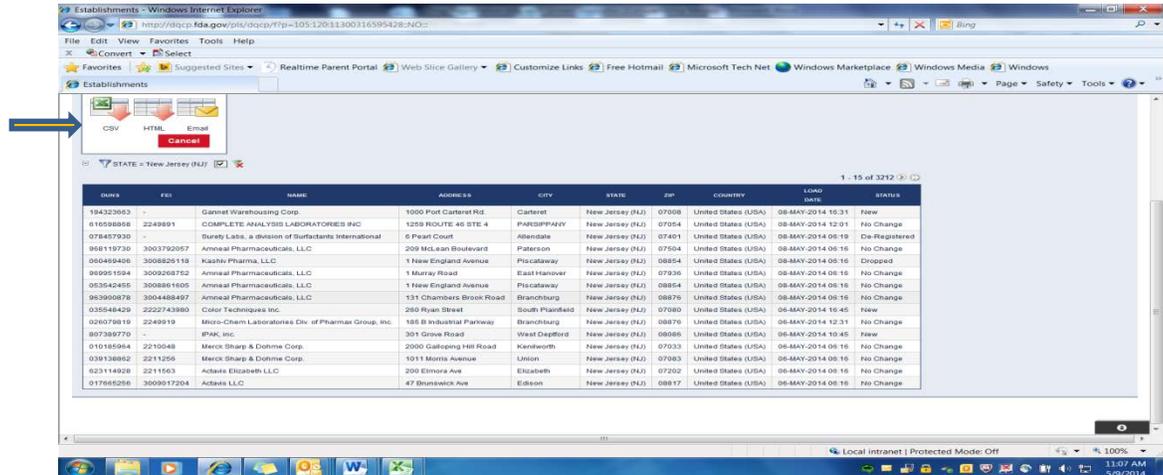


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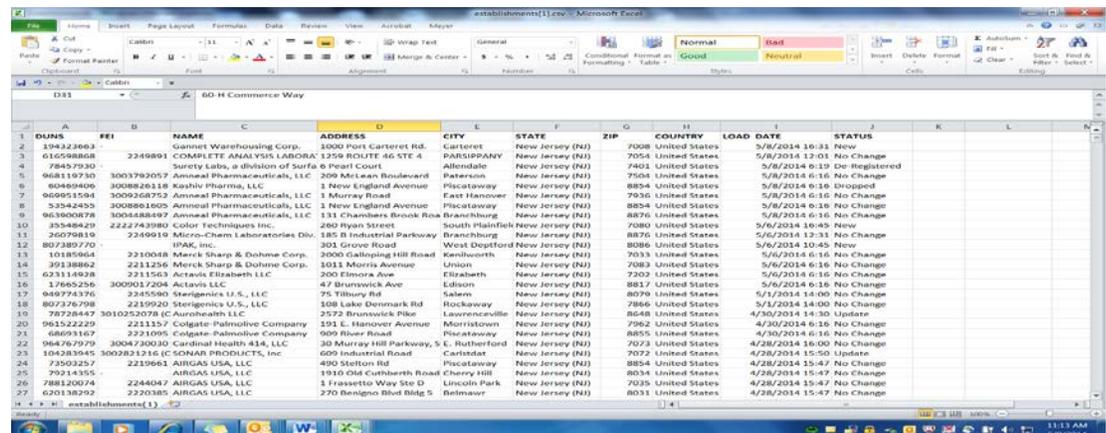
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Step 8: Choose the Excel (csv) option.



Step 9: Review the data for firm status (see Section 5 for definitions)

Example A: This is an example of the spreadsheet



Example B: Here is what the data would look like (line breaks added).



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FEI	NAME	LOAD DATE	ADDRESS	CITY	STATE	ZIP	COUNTRY	STATUS	PMS Update
	A & G Pharmaceuticals, Inc.	1/22/2013 12:21	3030 W. Commodore Blvd	Jackson	New Jersey (NJ)	8527	United States (USA)	New	
2221310	A G L Welding Supply Co Inc	10/2/2013 6:17	600 US Highway 46	Clifton	New Jersey (NJ)	7013	United States (USA)	No Change	
2221310	A G L Welding Supply Co Inc	7/24/2012 9:53	600 US Highway 46 (Old- 6 Clifton		New Jersey (NJ)	07013	United States (USA)	Update	
3004007943	A. P. Deauville, LLC	6/2/2010 14:29	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	New	
3004007943	A. P. Deauville, LLC	1/3/2011 9:16	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	1/8/2011 6:11	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	1/11/2011 12:43	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	1/3/2012 11:04	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	11/29/2012 13:06	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	1/2/2013 8:11	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	
3004007943	A. P. Deauville, LLC	10/23/2013 12:31	594 Jersey Avenue, Unit C	New Brunswick	New Jersey (NJ)	8901	United States (USA)	No Change	Yes
2246707	AAA Pharmaceutical, Inc.	5/20/2010 16:14	157 160 West Jefferson St	Paulsboro	New Jersey (NJ)	8066	United States (USA)	New	
2246707	AAA Pharmaceutical, Inc.	2/16/2012 6:07	157 160 West Jefferson St	Paulsboro	New Jersey (NJ)	8066	United States (USA)	No Change	
2246707	AAA Pharmaceutical, Inc.	3/12/2012 6:07	157 160 West Jefferson St	Paulsboro	New Jersey (NJ)	8066	United States (USA)	No Change	
2246707	AAA Pharmaceutical, Inc.	3/21/2014 14:00	157 160 West Jefferson St	Paulsboro	New Jersey (NJ)	8066	United States (USA)	Update	Yes
3010027650	AAA Pharmaceutical, Inc.	3/12/2012 6:07	681 Main Street	Lumberton	New Jersey (NJ)	8048	United States (USA)	New	
3010027650	AAA Pharmaceutical, Inc.	3/21/2014 14:00	681 Main Street	Lumberton	New Jersey (NJ)	8048	United States (USA)	Update	Yes
2210008	AAI/Pharma Analytical Servis	2/21/2012 6:08	105 Fieldcrest Avenue	Edison	New Jersey (NJ)	8837	United States (USA)	New	
2210008	AAI/Pharma Analytical Servis	1/2/2013 17:11	105 Fieldcrest Avenue	Edison	New Jersey (NJ)	8837	United States (USA)	Update	
2210008	AAI/Pharma Analytical Servis	1/7/2014 8:45	105 Fieldcrest Avenue	Edison	New Jersey (NJ)	8837	United States (USA)	Update	Yes
	Abon Pharmaceuticals, LLC	2/5/2010 8:30	140 Legrand Avenue	Northvale	New Jersey (NJ)	7647	United States (USA)	New	

Example C: This report is filtered for “Status” = “New” and will help find new registrants.

FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	STATUS	
194323963	Gannet Warehousing Corp.	1000 Port Carteret Rd.	Carteret	New Jersey (NJ)	07008	United States (USA)	08-08-2014 19:21	New	
030548429	2222743980	Color Techniques Inc.	200 Ryan Street	South Plainfield	New Jersey (NJ)	07080	United States (USA)	05-08-2014 15:45	New
307260710	FWK, INC.	301 Grove Road	West Dryfield	New Jersey (NJ)	30068	United States (USA)	05-08-2014 10:45	New	
024829238	SMS/HA LIR, INC.	140 Commerce Rd	Carteret	New Jersey (NJ)	07072	United States (USA)	16-APR-2014 07:04	New	
078229447	AuroraHealth LLC	2572 Brunswick Pike	Lancasterville	New Jersey (NJ)	08848	United States (USA)	14-APR-2014 14:01	New	
078046444	Health Science Funding, LLC	55 Madison Avenue, 4th Floor	Montclair	New Jersey (NJ)	07060	United States (USA)	03-APR-2014 16:31	New	
078463813	3009262636	Scireuro Pharma Inc	11 Sheppard Drive, Unit 120	Monmouth Junction	New Jersey (NJ)	08852	United States (USA)	25-MAR-2014 06:17	New
705159372	Bayer HealthCare LLC	35 Columbia Rd	Montclair	New Jersey (NJ)	07060	United States (USA)	04-MAR-2014 17:15	New	
132213001	3001238603	Air Products and Chemicals, Inc.	405 Route 33	Manlapan	New Jersey (NJ)	07725	United States (USA)	25-FEB-2014 14:15	New
078871474	Beady-FIL, LLC	170 Circle One Rd	Piscataway	New Jersey (NJ)	08854	United States (USA)	24-FEB-2014 09:30	New	
078214355	ARGAD USA, LLC	1910 Old Cuthbert Road	Cherry Hill	New Jersey (NJ)	08034	United States (USA)	20-JAN-2014 10:30	New	

Example D: This report is filtered for “Status” = “Out of Business” and tells which firms declared themselves out of business and could impact work planning for drug inspections.

Note: Remember that some firms set original registration information to OOB and then re-enter it. This list could give you wrong information.



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The screenshot shows the 'Drug Quality & Compliance Portal' interface. The 'Establishments' section is active, displaying a table of facilities in New Jersey. The table includes columns for ODS, FEI, NAME, ADDRESS, CITY, STATE, ZIP, COUNTRY, LOAD DATE, and STATUS. The data is filtered for New Jersey (NJ) and shows various pharmaceutical and chemical companies.

ODS	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	STATUS
07804844	-	Health Science Funding, LLC	25 Madison Avenue, 4th Floor	Manhattan	New Jersey (NJ)	07790	United States (USA)	07-APR-2014 17:31	Out of Business
02302410	3009305304	Salsu Pharma LLC	11 DEERPATH DR STE 120	MORRISVILLE	New Jersey (NJ)	08852	United States (USA)	17-MAR-2014 05:18	Out of Business
023114628	22711063	Actavis Elizabeth LLC	200 Simons Avenue	Elizabeth	New Jersey (NJ)	07207	United States (USA)	23-OCT-2013 16:45	Out of Business
017050250	3009017204	Actavis Inc.	47 Brunswick Ave	Edison	New Jersey (NJ)	08817	United States (USA)	23-DEC-2013 15:45	Out of Business
078791488	3003892222	Rand Group, LLC db/a Menasha Rand Group	112 Truman Drive	Edison	New Jersey (NJ)	08817	United States (USA)	09-DEC-2013 16:02	Out of Business
097243193	-	Promptcare	51 Terminal Ave suite A	Clark	New Jersey (NJ)	07066	United States (USA)	15-OCT-2013 13:00	Out of Business
902567263	2243311	Fride Solvents and Chemical Co. of NJ, Inc	35 Mileed Way	Avenel	New Jersey (NJ)	07007	United States (USA)	01-OCT-2013 15:45	Out of Business
026040458	3003895222	Rand Diversified Companies, LLC	112 Truman Drive	Edison	New Jersey (NJ)	08817	United States (USA)	15-APR-2013 10:15	Out of Business
021283733	3000551493	Bun Pharmaceutical Industries, Inc.	270 Prospect Plains Road	Cranbury	New Jersey (NJ)	08512	United States (USA)	11-APR-2013 13:01	Out of Business
047766841	1000122078	C.O.P.D. Services Inc	166 East Ninth Avenue	Runnemede	New Jersey (NJ)	08078	United States (USA)	02-APR-2013 17:01	Out of Business

4.2 Animal Drug Registration Download

Generate a report within the eDRLS system to identify those facilities that have self-identified as animal drug manufacturers.

Note: the self-identification “Operation Qualifiers” are voluntary at this time. Some firms may choose not to self-identify and therefore will only be found using the query described in step 4.1

- Step 1: Sign into DQCP (<http://dqcp.fda.gov>)
- Step 2: Click on the “eDRLS” tab
- Step 3: Click on “Ad Hoc Search”
- Step 4: Click on “Est/Reg”
- Step 5: Click on “Actions” then “Select Columns”



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The screenshot shows the 'Drug Quality & Compliance Portal' interface. The main heading is 'Establishment Registration Search'. Below the search bar, a table displays search results with columns for EST DUNS, FEI NUMBER, OPERATION QUALIFIERS, BUSINESS OPERATIONS, and REG DUNS. A 'Select Columns' dropdown menu is open, showing options like Filter, Rows Per Page, Format, Flashback, Save Report, Reset, Help, Download, and Subscription.

EST DUNS	FEI NUMBER	OPERATION QUALIFIERS	BUSINESS OPERATIONS	REG DUNS
370219289	3004694391	-	API MANUFACTURE	370219289
138258764	2031643	-	MANUFACTURE; RELABEL; REPACK	138258764
119086580	3003529219	-	ANALYSIS	119086580
946369055	3002323428	-	LABEL; MANUFACTURE; PACK	946369055
916182660	3003908605	-	ANALYSIS; API MANUFACTURE	916182660
808672120	-	-	LABEL	808672120
116743084	1036352	-	MANUFACTURE; REPACK	116743084
125330188	1000526423	-	ANALYSIS	116743084

Step 6: Move over “Operation Qualifiers” to the “Display on Screen” section. You can also remove “FMLS FEI NUMBER”, if you don’t need it, to make space for the new column and then click “Apply.”

The screenshot shows the 'Select Columns' dialog box. It has two lists: 'Do Not Display' and 'Display in Report'. The 'Display in Report' list has 'OPERATION QUALIFIERS' selected. There are 'Cancel' and 'Apply' buttons at the bottom.

Do Not Display	Display in Report
SPL DOC	EST DUNS
ESTABLISHMENT ADDRESS	FEI NUMBER
ESTABLISHMENT CITY	OPERATION QUALIFIERS
ESTABLISHMENT STATE	ESTABLISHMENT NAME
ESTABLISHMENT COUNTRY	BUSINESS OPERATIONS
ESTABLISHMENT ZIP	REG DUNS
ESTABLISHMENT CONTACT EMAIL	REGISTRANT NAME
REGISTRANT CONTACT EMAIL	EFFECTIVE DATE
ESTABLISHMENT CONTACT NAME	

Step 7: Click on the magnifying glass to specify the column (next to the search box on the left) you want to search on which is “Operation Qualifiers”. Select “Operation Qualifiers” from the drop down list.

	<p align="center">WORK INSTRUCTION FDA OFFICE OF REGULATORY AFFAIRS</p>	<p align="center">DOCUMENT NUMBER OPRM-WI.001</p>	<p align="center">PAGE 10 OF 17</p>
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Drug Quality & Compliance Portal
Protecting and Promoting *Your Health*

HOME | AD HOC SEARCH | STANDARD

HOME > AD HOC SEARCH > ESTABLISHMENT REGISTRATION

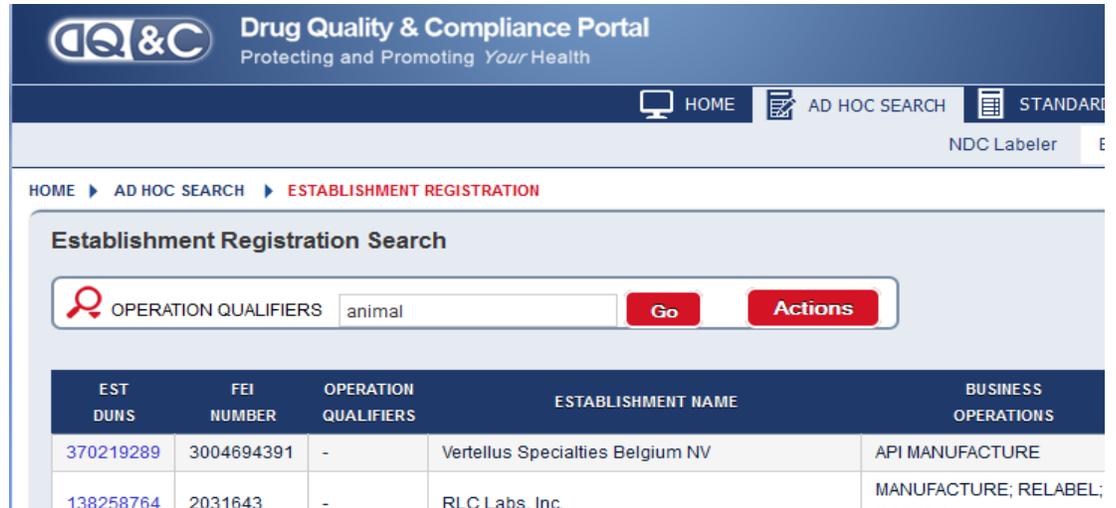
Establishment Registration Search

SEARCH BOX: [] [Go] [Actions]

OPERATION QUALIFIERS

EST DUNS	FEI NUMBER	OPERATION QUALIFIERS	ESTABLISHMENT NAME	BUSINESS OPERATIONS
			Vertellus Specialties Belgium NV	API MANUFACTURE
			RLC Labs, Inc.	MANUFACTURE; REPACK
			ALLIED ANALYTICAL LABORATORY SERVICES, INC.	ANALYSIS
			Atlas Operations Inc.	LABEL; MANUFACTURE
916182660	3003908605	-	MYLAN INDIA PRIVATE LIMITED	ANALYSIS; API MANUFACTURE
009670100			Micron Products Holdings, Inc.	LABEL

Step 8: Then in the search box enter “animal”



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Establishment Registration Search

SEARCH BOX: OPERATION QUALIFIERS [animal] [Go] [Actions]

EST DUNS	FEI NUMBER	OPERATION QUALIFIERS	ESTABLISHMENT NAME	BUSINESS OPERATIONS
370219289	3004694391	-	Vertellus Specialties Belgium NV	API MANUFACTURE
138258764	2031643	-	RLC Labs, Inc.	MANUFACTURE; RELABEL;

Step 9: Click “Go” in order to perform the search

4.3 Subscribing to a Report

Step 1: Subscribe to the report you have created and have it emailed at a particular frequency (daily, weekly, monthly, etc.) for the newly registered



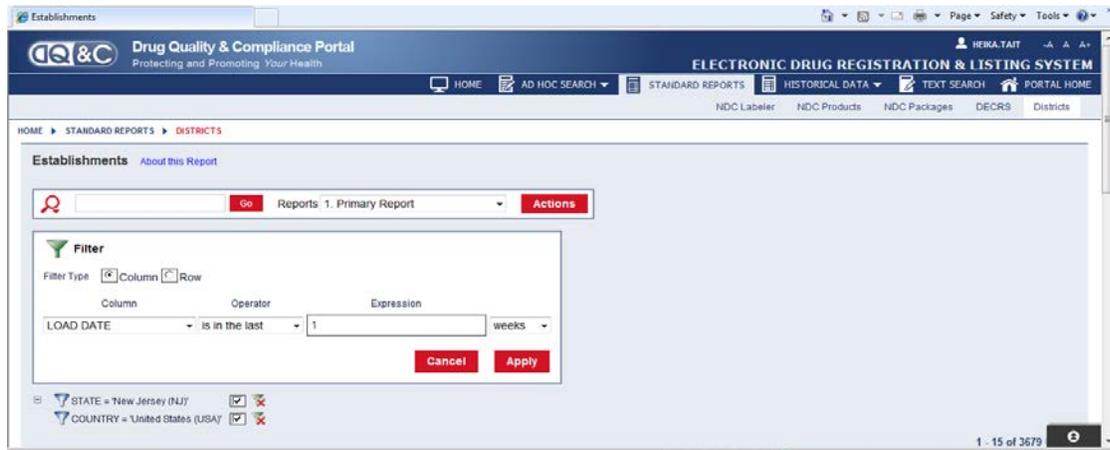
TITLE:

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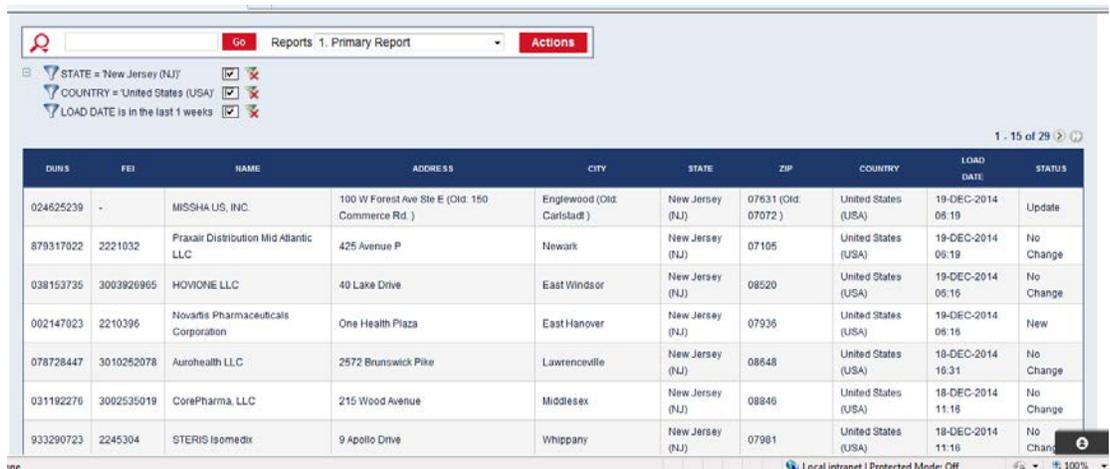
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or updated firms in your district. This report will only include firms that have made changes (new, update, dropped, etc.) since the time specified.

Step 2: Apply a load date to a report that you will save as a weekly/monthly registration report. Select Actions, Filter and Load Date. In this example, a load date of “is in the last” “1” “weeks” was selected. Now click “Apply”.



Step 3: Once you apply this field to your filter, it should reduce the number of firm’s returned to just those that have been entered in the system in the last one week.



Step 4: Save the report



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The screenshot shows the 'Save Report' dialog box. The 'Name' field contains 'NWJ-DO Registrations' and the 'Description' field contains 'Weekly Registration Report'. Below the fields are 'Cancel' and 'Apply' buttons. Underneath the dialog, there are filter options: 'STATE = New Jersey (NJ)', 'COUNTRY = United States (USA)', and 'LOAD DATE is in the last 1 weeks', each with a checked checkbox and a delete icon. The background shows a table with columns: DUNS, FEI, NAME, ADDRESS, CITY, STATE, ZIP, COUNTRY, LOAD DATE, and STATUS. The table contains three rows of data.

DUNS	FEI	NAME	ADDRESS	CITY	STATE	ZIP	COUNTRY	LOAD DATE	STATUS
024625239	-	MISSHA US, INC.	100 W Forest Ave Ste E (Old: 150 Commerce Rd.)	Englewood (Old: Carlstadt)	New Jersey (NJ)	07631 (Old: 07072)	United States (USA)	19-DEC-2014 06:19	Upd
879317022	2221032	Praxair Distribution Mid Atlantic LLC	425 Avenue P	Newark	New Jersey (NJ)	07105	United States (USA)	19-DEC-2014 06:19	No Char
038153735	3003926965	HOVIONE LLC	40 Lake Drive	East Windsor	New Jersey (NJ)	08520	United States (USA)	19-DEC-2014 06:16	No Char

Step 5: Create a Subscription. Go to Actions and at the bottom of the list of values is "Subscription". Click on "Subscription".

The screenshot shows the software interface with the 'Actions' menu open. The menu items are: Select Columns, Filter, Rows Per Page, Format, Flashback, Save Report, Reset, Help, Download, and Subscription. The 'Subscription' option is highlighted. The background shows the same table as in the previous screenshot, but with more rows visible. The 'Status' column shows 'Update', 'No Change', 'No Change', 'New', 'No Change', and 'No Change'.

Step 6: The following screen should appear. Change the frequency to weekly:

The screenshot shows the 'Add Subscription' dialog box. The 'Email Address' field is empty. The 'Subject' field contains 'NWJ-DO Registrations'. The 'Frequency' dropdown is set to 'Weekly'. The 'Starting From' field is '19-DEC-14' with a calendar icon, and the time is '01:05:00 AM'. The 'Ending' field is '- No End Date -' and the 'Day' dropdown is empty. There are 'Cancel' and 'Apply' buttons. Below the dialog, the filter options are visible: 'COUNTRY = United States (USA)', 'STATE = New Jersey (NJ)', and 'LOAD DATE is in the last 1 weeks', each with a checked checkbox and a delete icon. A blue arrow points to the 'Apply' button.



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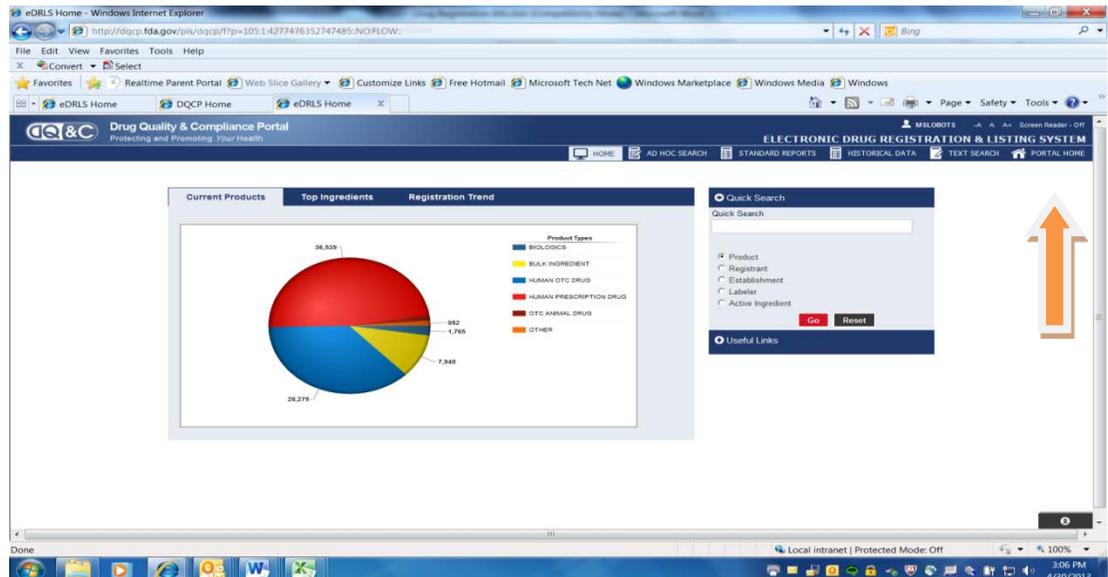
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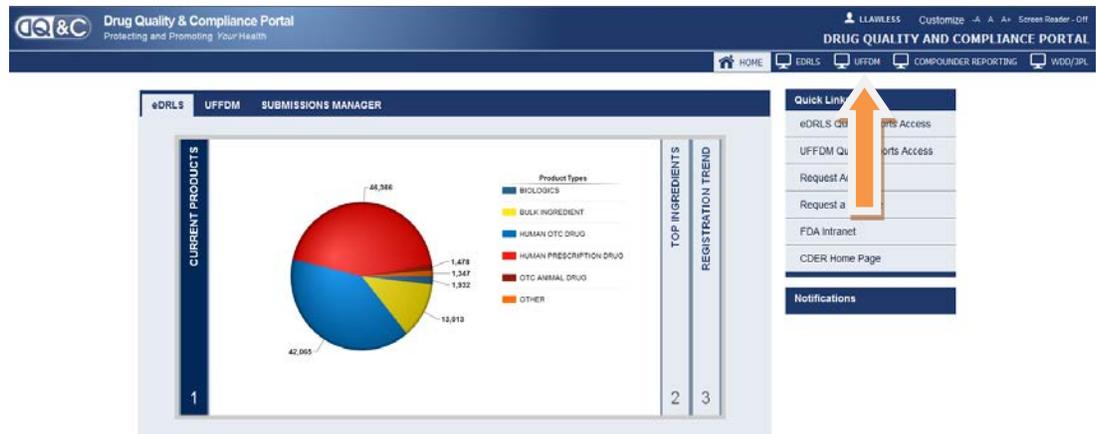
Step 7: Insert your own email address. The report that is sent to your e-mail will change dynamically depending upon the frequency you set so that you don't see the same facility in subsequent reports. Once you have done this, click "Apply" and you should begin receiving weekly registration reports.

4.4 Identify firms which should receive "GDF" identifier.

Step 1: Go to "Inside FDA", "CDER", scroll to the bottom of the page and "Electronic Drug Registration and Listing System". Click on "Portal home"



Step 2: Click on "UFFDM"





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Step 3: Click on “Facility”, then “Standard Reports”

Step 4: Click on “Actions” and then “Select Columns”

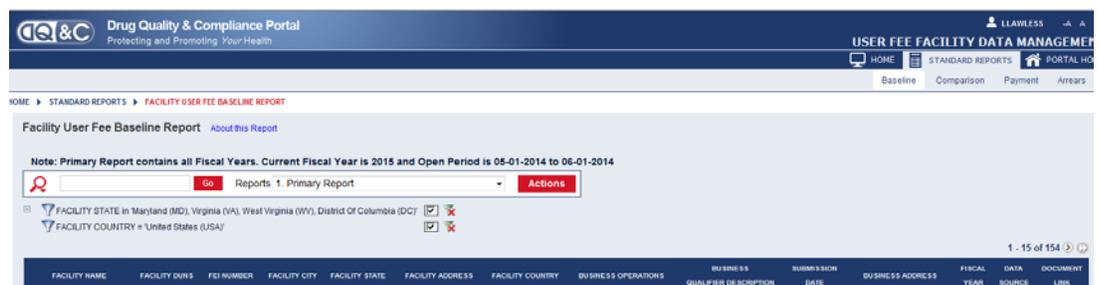
Step 5: Under “Do Not Display”, click on “Facility Address”, “Facility City”, and Facility State”. Click the buttons in the middle to move these categories to the right under “Display in Report”. This is important because ORA is interested in “Facility Address” and not “Business Address”. (Other changes can be made as desired). Use the up and down arrows on the list to change the order of the columns. Click on “Apply”.

 <p style="text-align: center;">WORK INSTRUCTION FDA OFFICE OF REGULATORY AFFAIRS</p>	<p style="text-align: center;">DOCUMENT NUMBER OPRM-WI.001</p>	<p style="text-align: center;">PAGE 15 OF 17</p>
<p>TITLE: District Implementation of Drug (Human and Animal) Registrations</p>		<p>ORIGINAL EFFECTIVE DATE: 7/6/15</p>



Step 6: Continue running the query by applying filters as described in 4.1.Steps 5-7, first filtering by “Country”, and then either individual states or all states within District boundaries.

- a. District Registration Monitors may also want to filter by “Current Fiscal Year”. If not, the export will include data from previous fiscal years.
- b. By running the query with all the current fiscal year and the previous fiscal year, the District Registration Monitor will be able to determine which firms have not self – identified during the current cycle and may delete the GDUFA identifier to FACTS/FMS.



4.5 Registration maintenance in FACTS

Step 1: At least annually, the District Registration Monitor will run ORADSS canned report “REG4_RegistrationforDrugs” for the district.

Step 2: Export the results to EXCEL (in .csv format), and sort by “Registration Date”.

Step 3: Review firms that do not have current registration information in FACTS/FMS.



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Step 4: The District Registration Monitor should follow up on these firms to determine if the firm is still involved in an FDA regulated activity and update FACTS/FMS as appropriate.

5. Glossary/ Definitions

- A. CDER: Center for Drug Evaluation and Research
- B. CVM: Center for Veterinary Medicine
- C. CFN: Central File Number
- D. eDRLS: Electronic Drug Registration and Listing System
- E. FEI: Field Establishment identifier
- F. FACTS: Field Accomplishment Tracking System
- G. GDUFA: Generic Drug User Fee Amendments
- H. OEI: Official Establishment Inventory
- I. UFFDM: User Fee Facility Data Management
- J. Status:
 - a. New: this is the first time a firm has registered using the electronic registration process. A firm may have been previously registered using the former paper-based system.
 - b. Update: the firm has performed an update of a previously filed electronic registration.
HINT: If a firm has multiple locations and updates the information on one location, all locations will be designated as "Updated".
 - c. Out of Business: the establishment ceases to exist as a business entity.
Note: There are some fields in eDRLS that once completed by the firm may not be changed. If a firm finds they entered a labeler code wrong or certain other information they have to set the firm to OOB and then re-create it. If you run across this, you should call the registrant and get the details to understand what process took place and whether the firm is really OOB.
 - d. De-registered: the firm is still viable but has ceased activities in those areas requiring registration.
 - e. Dropped: an expected annual update was not performed by a firm. The firm may have neglected to do the update, or could be out of business, or could have stopped handling items which require registration.



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6. Supporting Documents

- A. [FMD 92 "Agency Establishment Registration and Controls Procedure"](#)
 - B. [FMD 130 "OEI Development and Maintenance Procedure"](#)
-

7. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	7/2/15	LORI LAWLESS, NATIONAL OEI COORDINATOR	Kate Bent, Director OPRM

* - D: Draft, I: Initial, R: Revision, C: Cancel

8. Change History

Version	Change
1.0	Initial