

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244 -1850

DATE: April 13, 2009

MEDICAID DRUG REBATE PROGRAM

Release No. 151



For State Medicaid Directors



<u>DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETING –Week of</u> <u>June 22, 2009, IN DENVER, CO</u>

The 2009 National DRP Meeting will be held the week of June 22 at the CMS Denver Regional Office (RO), located at 1600 Broadway, Suite 700, Denver, Colorado 80202. This meeting is a continuation of the highly successful National DRP Meetings that have been previously held in both Baltimore and Denver. Due to limited conference room availability at the RO, we are only able to accommodate the participation of three labelers. We are in the process of sending out invitations at this time. Once we have the labeler commitment, this information will be posted on our web site at: http://www.cms.hhs.gov/MedicaidDrugRebateDispR/05_DRPMeetings.asp#TopOfPage.

In order to ensure that the labelers have an adequate number of states in attendance to conduct productive and successful face to face meetings, states that are interested in attending these meetings should register as soon as possible and no later than Friday, June 5. Prior planning by all parties is absolutely imperative to the success of these meetings; therefore, you may register by completing the registration information below and emailing it to <u>DRP@cms.hhs.gov</u>.

Registration Information: please indicate the name, phone number, and email of each person attending and whether they will be attending the entire three days (Tuesday, Wednesday, and Thursday) or for just part of the week by specifying which days.

Regarding the hotel, participants of last years meeting found accommodations at the Sheraton Denver Hotel located at 1550 Court Place, phone: 303-893-3333. If you are unable to secure your own reservations and need assistance, send an email to <u>DRP@cms.hhs.gov</u> and we will try to assist you.

If you have any questions, please contact Sue Gaston, DRP Team Lead at (410) 786-6918, <u>Susan.gaston@cms.hhs.gov</u> or Diane Dunstan, RO Team Lead at (303) 844-7040, <u>Diane.dunstan@cms.hhs.gov</u>.

BANKRUPTCY FILINGS BY LABELER CODES 67204 VINDEX AND LABELER 66813 ATHLON

We have recently become aware that two labelers that will be terminated on 4/1/09 have filed for bankruptcy. Vindex Pharmaceuticals, Inc., labeler code 67204, and Athlon Pharmaceuticals, Inc., labeler code 66813, filed bankruptcy petitions under Chapter 7 of the U.S. Bankruptcy Code in the Bankruptcy Court.

As has been stated in previous releases, when labelers file for bankruptcy, states are expected to protect Medicaid interests related to any rebate payments owed from the affected labelers.

PHYSICIAN-ADMINISTERED DRUGS TOP 20 MULTIPLE SOURCE DRUGS UPDATE

In accordance with section 1927(a)(7)(B) of the Social Security Act, we are updating the list of the 20 multiple-source, physician-administered drugs with the highest Medicaid dollar volume. States must collect National Drug Code (NDC) information on these drugs in order to secure manufacturer rebates. The law allows us to modify the current list to reflect changes in such volume.

The Secretary's list of the top 20 multiple source physician-administered drugs are ranked in order of highest cost and volume in the Medicaid program and may be updated year to year. The list provides the Healthcare Common Procedure Coding System (HCPCS) codes with corresponding NDCs, labeler drug names, labeler names and package sizes for each listed drug.

We realize that most States require the use of NDCs for all multiple-source drugs and that this update will accordingly have no effect on those programs. For any States still using the top 20 list however, we recommend they use this updated version of the top 20 multiple source drugs list effective the first day of the month more than 30 days after the date of the State Medicaid Release publication. The top 20 multiple source drugs list can be found at the following CMS website: http://www.cms.hhs.gov/Reimbursement/15 PhysicianAdministeredDrugs.asp.

NEW REBATE AGREEMENTS

The following are new labelers to the Medicaid Drug Rebate Program.

Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Generamedix, Inc. Labeler Code 10139	04/01/2009	12/09/2008
Seton Pharmaceuticals, LLC Labeler Code 13925	04/01/2009	11/18/2008
Neurosci, Inc. Labeler Code 14565	01/01/2009	10/08/2008
Centurion Labs, LLC, Labeler Code 23359	01/01/2009	10/27/2008
Aceto Pharma Corp. Labeler Code 25356	04/01/2009	12/18/2008
Capital Pharmaceutical, LLC Labeler Code 29978	07/01/2009	03/25/2009
Patrin Pharma, Inc Labeler Code 39328	07/01/2009	02/23/2009
Sun Pharma Global, Inc. Labeler Code 41616	01/01/2009	10/27/2008
Iroka Pharmaceuticals Labeler Code 42211	04/01/2009	01/27/2009
LEV Pharmaceuticals Labeler Code 42227	01/01/2009	01/01/2009
Prostrakan, Inc. Labeler Code 42747	04/01/2009	12/24/2008
Bay Pharma, Inc. Labeler Code 42769	10/01/2008	10/01/2008
Sirion Therapeutics, Inc. Labeler Code 42826	01/01/2009	10/08/2008
Marathon Pharmaceuticals, LLC Labeler Code 42998	04/01/2009	12/02/2008

Medimedtriks Pharmaceuticals, Inc. Labeler Code 43538	04/01/2009	12/30/2008
Slate Pharmaceuticals, Inc. Labeler Code 43773	04/01/2009	11/05/2008
Biocomp Pharma, Inc. Labeler Code 44523	04/01/2009	01/20/2009
McKesson Corp. – Rx Pak Division Labeler Code 65084	04/01/2009	12/10/2008
Biovitrum AB Labeler Code 66658	04/01/2009	12/15/2008
Bioniche Pharma Labeler Code 67457	07/01/2009	02/05/2009
Spectrum Pharmaceuticals, Inc. Labeler Code 68152	01/01/2009	10/30/2008
Legacy Pharmaceutical Packaging, LLC Labeler Code 68645	01/01/2009	10/30/2008

REINSTATED REBATE AGREEMENTS

Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Weeks & Leo Co., Inc. Labeler Code 11383	07/01/2009	02/23/2009
Generamed, Inc. Labeler Code 52569	07/01/2009	02/26/2009
Magna Pharmaceuticals, Inc. Labeler Code 58407	07/01/2009	03/11/2009
World Gen, LLC Labeler Code 66814	04/01/2009	01/26/2009

Contact information for new and reinstated labelers is attached for your convenience.

TERMINATED REBATE AGREEMENTS

<u>Labeler Name</u>	<u>Labeler Code</u>
TIRE 4 04/04/2000	

Effective 04/01/2009:

3
3
5
3
1
1
7
1

Effective 07/01/2009:

Idenix Pharmaceuticals	24108
Presutti Laboratories, Inc.	66378
Apothecon	62269

VOLUNTARILY TERMINATED LABELERS

<u>Labeler Name</u>	<u>Labeler Code</u>
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Effective 04/01/2009:

Anesiva, Inc	28000
Almus Pharmaceuticals, USA LLC	42688

Effective 07/01/2009:

WE Pharmaceuticals, Inc.	59196
Ligand Pharmaceuticals, Inc.	64365
Genta	66657

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGES

The following products have undergone several changes in DESI Code. The FDA has reversed a previous decision which changed the DESI Code to 5 (less than effective/IRS drug for all indications). The FDA has indicated that the correct code is DESI 2 (no determination made). The states were previously notified of these DESI Code changes on December 11, 2008.

00677-1900	CARBETA	20/DUENIV	15/CIIAIE	100 I O DT
(1/1/1) / / - 1 9 (1/1)	CANDEIA	ZU/FDENI	L)/UUAIF	100 LOFI

14629-0473 ZINX COUGH KIT

28595-0602 ALLRES G

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51991-0083 CARBETAPLEX LIQUID
55566-8101 PROSED DS
58177-0324 NITROQUICK .4MGS 100'S SUBLINGUAL TABLETS
58177-0323 NITROQUICK .3MG SUBLINGUAL TABLETS
58177-0325 NITROQUICK .4MGS 4X25'S SUBLINGUAL TABLETS
58809-0303 CARBA-XP
58809-0536 CARBATUSS
58809-0707 CARBATUSS-CL
60258-0425 PULMARI-GP SYRUP
64376-0537 PHENCARB GG SYRUP
66992-0120 BETAVENT SYRUP
67204-0210 ORATUSS LIQUID
67336-0188 RESPI-TANN G
68032-0176 CARBETAPENTANE CITRATE 20 PHENYLEPHRINE HCI 15 GUAFINESIN 100
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On December 11, 2008, we notified you of changes to DESI Codes for particular drugs. Per the FDA, two of the drugs on that notification are once again subject to DESI Code changes. Please update your records to change the DESI Code from 2 to 5 for:

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10914-0960 GUAFENESIN 600 MG/CARBETAPENTANE CITRATE 60 MG. 58809-0615 CARBATAB-12
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The following product was reported by the labeler as a DESI code 2 (no determination made); although, the FDA has determined that this class of drugs is less than effective, or a DESI code 5 (DESI Notice 8076, dated 12/09/75, FR 57379).

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16781-0113 EXACTACAIN
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The following product was reported by the labeler as a DESI code 3 (drug under review (no NOOH issued)); although, the FDA has determined that this class of drugs is less than effective, or a DESI code 5 (DESI Notice 8656, dated 7/1/1988, 53 FR 25013).

42192-0107	HYDROCORTISONE ACETATE 2.5% PRAMOXINE HCL 1%
42192-0109	HYDROCORTISONE ACETATE 1% PRAMOXINE HCL 1% CREAM

The following product was reported by the labeler as a DESI code 2 (no determination made), although the FDA has determined that this class of drugs is less than effective, or a DESI code 5 (DESI Notice 7661, dated 4/14/2003, 68 FR 17953).

53746-0077	EEMT 0.625MG/1.25 TABLETS
53746-0078	EE/MT TABS 1.25MG/2.5MG
65162-0877	EE/MT 0.625MG/1.25 TABLETS
65162-0878	EE/MT TABS 1.25MG/2.5MG

NON-DRUG DELETIONS FROM MDR

The FDA has determined that the following active NDCs are dietary supplements; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, subsequently, no longer eligible for inclusion in the rebate program. The states were previously notified of these non-drug deletions in November and December 2008.

00182-1381	FER-GEN-SOL LIQUID DROPS 7.MG/0.3ML
00259-0291	NU-IRON 150 CAPSULES
00536-0710	FER IRON DROPS
10267-1994	IRON-FOLIC 500 TABLETS
24385-0528	FERROUS SULFATE SLOW
49348-0008	SM MAGNESIUM 250 MG. 100 CT.
49348-0050	SM SOYA LECITHIN 1200 MG. SOFTGEL 100 CT.
49348-0053	SM L-LYSINE 500MG. TABLETS 100 CT.
49348-0055	SM POTASSIUM GLUCONATE 90MG. TABLETS 100 CT.
49348-0080	SM VITAMIN C 250 MG. TABLET 100 CT.
49348-0083	SM VITAMIN C 500 MG. TABLET 500 CT.
49348-0095	SM STRESS FORMULA + ZINC AND B COMPLEX TABLET 60 CT.
49348-0098	SM VITAMIN E 200 IU SOFTGEL 100CT.
49348-0099	SM VITAMIN E 400 IU SOFTGELS 100'S
49348-0100	SM VITAMIN E 1000 IU SOFTGEL 100 CT.
49348-0101	SM MULTIPLE VITAMIN ESSENTIAL TABLET 250 CT.
49348-0102	SM MULTIPLE VITAMIN + IRON TABLET 100 CT.
49348-0103	SM COMPLETE TABLETS 300 CT.
49348-0110	SM CALCIUM 600 WITH D TABLETS 60 CT.
49348-0132	SM FISH OIL 1000 MG. SOFTGEL 60 CT.
49348-0139	SM CALCIUM 600 + MINERALS TABLET 60 CT.
49348-0141	SM ZINC 50MG. TABLET 100 CT.
49348-0168	SM JOHN'S WORT 300MG. CAPLET 50 CT.
49348-0172	SM SAW PALMETTO SOFTGEL 50 CT.
49348-0178	SM SELENIUM 200MCG. TABLET 100 CT.
49348-0180	IRON B/PAK 325MG
49348-0233	SM CALCIUM 600 TABLET 60 CT.
49348-0236	SM MULTIPLE VITAMIN WOMEN'S TABLET 100 CT.
49348-0238	SM CALCIUM MAGNESIUM ZINC COATED TABLETS 100 CT.
49348-0258	SM VITAMIN E WATER SOLUBLE 400 IU SOFTGEL 100 CT.
49348-0260	SM THERAPEUTIC-M CAPLET 100 + 30
49348-0304	SM CALCIUM 600 WITH D TABLETS 300 CT
49348-0321	SM BALANCED B-100 TABLET 50 CT.
49348-0322	SM BALANCED B-50 TABLET 50 CT.
49348-0324	SM CALCIUM CITRATE + D CAPLET 150 CT.
49348-0327	SM VITAMIN C NATURAL W/ROSE HIPS 1000MG. 100 CT.
49348-0328	SM VITAMIN E 400 IU SOFTGEL 300 CT.
49348-0331	SM ECHINACEA 125 MG. CAPLET 90 CT.
49348-0332	SM ECHINACEA + GOLDENSEAL CAPLET 50 CT.
49348-0334	SM CRANBERRY CAPLET 90 CT.
49348-0335	SM COMPLETE SENIOR FORMULA TABLETS 100 CT.

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49348-0336
           SM GARLIC CONCENTRATED 150 MG. TABLETS 100 CT.
49348-0381
           SM GINKGO BILOBA CAPLETS 60 MG. 50 CT.
49348-0384
           SM COD LIVER OIL CAP 100 CT.
49348-0385
           SM VITAMIN C NATURAL W/ROSE HIPS 500MG. 100 CT.
49348-0388
           SM VITAMIN C CHEWABLE ORANGE 500MG. TABLET 100 CT.
49348-0390
           SM VITAMIN C 1000MG. TABLET 100 CT.
49348-0391
           SM SUPER B COMPLEX + C CAPLET 100 CT.
49348-0392
           SM VITAMIN B-12 100 MCG. TABLET 100 CT.
49348-0394
           SM VITAMIN B-6 100MG. TABLET 100 CT.
49348-0410
           SM VITAMIN E NATURAL 400 IU SOFTGEL 100 CT.
           SM CALCIUM CHEWS, SOFT MILK CHOCOLATE 60 CT.
49348-0463
           SM VITAMIN C MIXED BERRY FLAVORED 500MG 100 CT.
49348-0466
49348-0467
           SM COMPLETE PREMIUM VITAMIN TABLETS 75 CT.
49348-0549
           SM OPTI-VITAMINS TABLETS 60 CT.
           SM FLAX OIL 1000 MG. SOFTGELS 100 CT.
49348-0566
49348-0605
           SM COENZYME Q-10 100 MG. 30 CT.
           IRON TABLETS, SLOW RELEASE
49348-0607
           SM DAILY DIET SUPPORT TABLETS 100 CT.
49348-0608
49348-0613
           SM CORAL CALCIUM 1000 MG. TABLETS 120 CT.
49348-0614
           SM NUTRI-DRINK CHOCOLATE 8 FL OZ.
49348-0615
           SM NUTRI-DRINK VANILLA 8 FL OZ.
49348-0620
           SM NUTRI-DRINK + CHOCOLATE 8 OZ.
49348-0621
           SM NUTRI-DRINK + VANILLA 8 OZ.
49348-0651
           SM FISH OIL ENTERIC COATED SOFTGEL 60 CT.
49348-0666
           SM ANIMAL SHAPES COMPLETE CHEWABLE TABLETS 100 CT.
49348-0667
           SM CRAN MAX CAPSULES 60 CT.
           SM OMEGA-3 FISH OIL SUPER POTENCY SOFTGEL 60 CT.
49348-0670
49348-0746
           SM GREEN TEA COMPLEX 60 CT.
49348-0821
           SM VITAMIN B-12 500 MCG. TABLET 100 CT.
49348-0825
           SM FOLIC ACID 400 MCG. TABLET 250 CT.
49348-0826
           SM CHROMIUM PICOLINATE 200MCG. TABLETS 100 CT.
49348-0180
           SM IRON TABLETS 325MG. 100 CT.
           PRENATAL MULTIPLE VITAMIN + MINERAL 100 COUNT
49348-0556
49348-0407
           SM VITAMIN B-12 TIME RELEASE 1000MCG TABLETS 60 CT.
49348-0607
           SM IRON TABLETS, SLOW RELEASE TABLETS 60 CT.
           FERROUS SULFATE SOLUTION DROPS
50383-0630
           FERROUS SULFATE ELIXIR
50383-0778
51645-0760
           FERROUS SULFATE 325MG TABLETS FC (GREEN)
68308-0910
           IRON CHEWS
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The states were previously notified of these non-drug deletions in March 2009.

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    51991-0014 MELATONIN 3 MG TABLETS
    51991-0022 DHEA 25 MG TABLETS
    51991-0081 MAGNESIUM OXIDE
    51991-0215 ELLIS TONIC
    51991-0182 FERROCITE PLUS TABLETS
    51991-0198 FERREX 150 FORTE CAPSULES
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51991-0682 FERROCITE PLUS CAPSULES 51991-0798 FERREX 150 FORTE PLUS CAPSULES

The following device products do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act. The states were previously notified of these product deletions on March 18, 2009. The device products that are no longer rebate-eligible are as follows:

68712-0007 BIONECT CREAM 68712-0008 BIONECT GEL 68712-0009 BIONECT SPRAY

NEW DRUG DETERMINATIONS--DELETIONS FROM MDR

The FDA has determined that the following active Quinine NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, subject to enforcement action, and that the drugs cannot be marketed without appropriate FDA approval as set forth in a December 15, 2006 Federal Register Notice (71 Fed. Reg. 75557). According to the FDA, these products do not have approved New Drug Applications; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, subsequently, no longer eligible for inclusion in the rebate program. The states were previously notified of these product deletions on December 11, 2008.

NDC	Product Name
00172-3001	QUININE SULFATE
00172-4171	QUININE SULFATE CAPSULES USP 200MG
00172-4172	QUININE SULFATE CAPSULES USP 325MG
00591-0716	QUININE SULFATE 325MG

The FDA has determined that the following active NDC is an unapproved new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. February 8, 2008 (73 Fed. Reg. 7565). According to the FDA, this product does not have an approved New Drug Application; therefore, the NDC does not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and is, subsequently, no longer eligible for inclusion in the rebate program. The states were previously notified of this product deletion on November 25, 2008.

55390-0605 COLCHICINE INJECTION USP

The FDA has determined that the following active ergotamine tartrate NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, subject to enforcement action, and that the drugs cannot be marketed without appropriate FDA approval as set forth in a July 27, 1972 Federal Register Notice (37 Fed. Reg. 15032) and subsequent Warning Letters issued by the FDA on February 26, 2007. According to the FDA, these products do not have approved New Drug Applications; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k)

of the Social Security Act and are, subsequently, no longer eligible for inclusion in the rebate program. The states were previously notified of these product deletions on March 6, 2009.

00603-2423 BELLASPAS 00904-2548 BELLAMINE 52152-0115 BELLAMINE S TAB

UNAPPROVED DRUGS--DELETIONS FROM MDR

CMS has determined that the following unapproved drug products containing sodium hyaluronate do not appear to meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act (the Act). As a result, they are no longer eligible for inclusion in the Medicaid Drug Rebate Program. The states were previously notified of these deletions on April 2, 2009. The drug products that are no longer rebate eligible are as follows:

NDC	Product Name
50383-0293	SODIUM HYALURONATE LOTION 0.1%
60258-0025	SODIUM HYALURONATE 0.1%
63717-0034	HYLIRA .2% GEL
63717-0036	HYLIRA
68032-0238	SODIUM HYALURONATE 0.1% LOTION
68032-0348	SODIUM HYALURONATE 0.2% GEL

T-BILL AUCTION RATES

A copy of the current listing of the Treasury Bill auction rates beginning October 27, 2008, is attached. The rates may also be found on our MDRP website at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/ as well as the Department of Treasury's website at http://www.treasurydirect.gov/RI/OFBills; therefore, we will not be including these rates in the releases anymore.

Please direct your drug rebate data questions to <u>mdroperations@cms.hhs.gov</u> and your drug policy questions to the Division of Pharmacy at <u>DRARxPolicy@cms.hhs.gov</u>.

/s/

Edward C. Gendron Director Finance, Systems and Budget Group

Attachments:
T-Bill Rates
New Labeler Contact Information

cc: Regional Administrators

US T-Bill Auction Results
Weekly 13-Week Treasury Bill Auction Rates

Date of Auction	Investment Rate
10-27-08	0.915
11-03-08	0.538
11-10-08	0.360
11-17-08	0.152
11-24-08	0.152
12-01-08	0.051
12-08-08	0.005
12-15-08	0.051
12-22-08	0.041
12-29-08	0.051
01-05-09	0.152
01-12-09	0.122
01-19-09	0.142
01-26-09	0.152
02-02-09	0.274
02-09-09	0.345
02-16-09	0.330
02-23-09	0.304
03-02-09	0.284
03-09-09	0.243
03-16-09	0.254
03-23-09	0.228
03-30-09	0.198
04-06-09	0.203

NEW LABELER CONTACT INFORMATION

GENERAMEDIX INC. Labeler Name:

NDC: 10139

Legal Information **Invoice Information**

ROBIN SMITH HOKE CHRISTINE CANNON GENERAMEDIX INC. GENERAMEDIX INC. 150 ALLEN ROAD 150 ALLEN ROAD

LIBERTY CORNER, NJ 07938 LIBERTY CORNER, NJ 07938 (908) 504-1341 (908) 504-1341 (614) 460-1832

Labeler Name: WEEKS & LEO CO., INC.

NDC: 11383

Legal Information Invoice Information

SANJAY SRIVASTAVA WEEKS & LEO CO., INC. 4000 NW 100TH STREET

P.O. BOX 3570 DES MOINES, IA 50323

DES MOINES, IA 50323

(515) 276-1586 (515) 276-1586

Labeler Name: SETON PHARMACEUTICALS, LLC

NDC: 13925

Legal Information

ROBERT LINKIN, ESQ ROBERT LINKIN, ESQ. 215 BLAIR ROAD

AVENEL, NJ 07001-2026

(732) 596-6042

Labeler Name: NEUROSCI, INC.

NDC: 14565

Legal Information

KIRSHNA VISHNUPAD NEUROSCI, INC.

1458 CLEARBROOK DRIVE DAYTON, OH 45440 (937) 409-1466

NDC: 23359

Legal Information

JAY EDWARDS CENTURION LABS, LLC 4700 CALDWELL MILL RD BIRMINGHAM, AL 35243

(601) 720-0111

BRIAN A. COX

P.O. BOX 3570

WEEKS & LEO CO., INC.

4000 NW 100TH STREET

Technical Information CHRISTINE CANNON

GENERAMEDIX INC. 150 ALLEN ROAD

LIBERTY CORNER, NJ 07938

Technical Information

PATRICK NEIBERGALL WEEKS & LEO CO., INC. 4000 NW 100TH STREET

P.O. BOX 3570

DES MOINES, IA 50323

(515) 276-1586

Invoice Information Technical Information

BILL BARISH BILL BARISH SETON PHARMACEUTICALS, LLC SETON PHARMACEUTICALS. ATLANTIC CORPORATE CENTER ATLANTIC CORPORATE CTR

2317 HIGHWAY 34, SUITE 1E MANASQUAN, NJ 08736

(732) 292-2661 x125

Invoice Information

MATTHEW D. HARMON MASTERS PHARMACEUTICAL, INC.

CINCINNATI, OH 45240

11930 KEMPER SPRINGS DRIVE

(513) 354-2690 x1104

Technical Information

(732) 292-2661 x125

MATTHEW HARMON MASTERS PHARM, INC. 11930 KEMPER SPRINGS DR CINCINNATI, OH 45240

2317 HIGHWAY 34, SUITE 1E MANASQUAN, NJ 08736

(513) 354-2690 x1104

Labeler Name: CENTURION LABS, LLC

Invoice Information

DARRIN ABERNATHY CENTURION LABS, LLC 4700 CALDWELL MILL RD BIRMINGHAM, AL 35243

(205) 305-5625

Technical Information

JAY EDWARDS CENTURION LABS, LLC

4700 CALDWELL MILL RD BIRMINGHAM, AL 35243

(601) 720-0111

Labeler Name: ACETO PHARMA CORP.

NDC: 25356

Legal Information

STANLEY FISCHER FISCHER & BURSTEIN 98 CUTTERMILL ROAD GREAT NECK, NY 11021 (516) 829-1900

Labeler Name: CAPITAL PHARMACEUTICAL, LLC NDC: 29978

Legal Information

SEAN CRAWFORD CAPITAL PHARMACEUTICAL, LLC P.O. BOX 1901

POWELL, OH 43065 (614) 638-4622

NDC: 39328

Legal Information

JAY TRIVEDI PATRIN PHARMA, INC. 7817 BABB AVENUE P.O. BOX 1481 SKOKIE, IL 60077

(800) 936-3088 x704

Legal Information

ANAND SHAH CARACO PHARMACEUTICAL LABS, LTD 1150 ELIJAH MCCOY DR

NDC: 41616

DETROIT, MI 48202 (313) 556-4115

Legal Information VEENITA BLEZNAK

IROKO PHARMACEUTICALS LLC ONE CRESCENT DRIVE SUITE 400 NAVY YARD CORPORATE CENTER

PHILADELPHIA, PA 19112

(267) 546-3008

Invoice Information

PRIYANKA KASID ACETO PHARMA CORP. 1 HOLLOW LANE, SUITE 201 LAKE SUCCESS, NY 11042

(516) 627-6000 x552

Technical Information

PRIYANKA KASID ACETO PHARMA CORP. 1 HOLLOW LANE, SUITE 201 LAKE SUCCESS, NY 11042

(516) 627-6000 x552

THERESA CRAWFORD CAPITAL PHARMACEUTICAL, LLC

P.O. BOX 1901 POWELL, OH 43065 (614) 638-4622

Invoice Information

Labeler Name: PATRIN PHARMA, INC.

Invoice Information

JAY TRIVEDI PATRIN PHARMA, INC. 7817 BABB AVENUE P.O. BOX 1481 SKOKIE, IL 60077 (800) 936-3088 x704

ANAND SHAH

CARACO PHARMACEUTICAL LABS, LTD

1150 ELIJAH MCCOY DR DETROIT, MI 48202 (313) 556-4115

Invoice Information

Technical Information

THERESA CRAWFORD CAPITAL PHARM., LLC P.O. BOX 1901 POWELL, OH 43065 (614) 638-4622

Technical Information

JAY TRIVEDI PATRIN PHARMA, INC. **7817 BABB AVENUE** P.O. BOX 1481 SKOKIE, IL 60077 (800) 936-3088 x704

Technical Information

ANAND SHAH CARACO PHARM LABS, LTD 1150 ELIJAH MCCOY DR DETROIT, MI 48202 (313) 556-4115

Labeler Name: IROKO PHARMACEUTICALS LLC

Labeler Name: SUN PHARMA GLOBAL, INC.

NDC: 42211

Invoice Information

WALTER RAHN IROKO PHARMACEUTICALS LLC ONE CRESCENT DRIVE SUITE 400

NAVY YARD CORPORATE CENTER PHILADELPHIA, PA 19112

(267) 546-3035

Technical Information

WALTER RAHN IROKO PHARM., LLC ONE CRESCENT DRIVE SUITE 400 NAVY YARD CORP. CTR

PHILADELPHIA, PA 19112

(267) 546-3035

Labeler Name: LEV PHARMACEUTICALS

NDC: 42227

Legal Information

PETER WOLF VIRO PHARMA, INCORPORATED 730 STOCKTON DRIVE EXTON, PA 19341

(610) 321-6204

Labeler Name: PROSTRAKAN, INC.

NDC: 42747

Legal Information

MATTHEW D'AMBROSIO PROSTRAKAN, INC. 1430 US HIGHWAY 206 SUITE 110 BEDMINSTER, NJ 07921

(908) 234-1096

Labeler Name: BAY PHARMA, INC.

NDC: 42769

Legal Information

JANE WILLIAMS ANIP ACQUISITION COMPANY 7131 AMBASSADOR ROAD SUITE 150

WOODLAWN, MD 21244

(410) 281-9450

Labeler Name: SIRION THERAPEUTICS, INC.

NDC: 42826

Legal Information

DREY COLEMAN SIRION THERAPEUTICS, INC. 9314 EAST BROADWAY AVENUE

TAMPA, FL 33619 (813) 496-7325 x247

Labeler Name: MARATHON PHARMAEUTICALS, LLC

NDC: 42998

Legal Information

BEN HAAS LATHAM & WATKINS, LLP 555 ELEVENTH ST. NW WASHINGTON, DC 20004-1304

(202) 637-1084

Invoice Information

FRANK MULLERY VIRO PHARMA, INCORPORATED

730 STOCKTON DRIVE EXTON, PA 19341

Invoice Information

PHARMA METRICS, INC.

220 COMMERCE DRIVE

FT. WASHINGTON, PA 19034

DEBBIE MATTHIAS

SUITE 405

(215) 274-1316

(610) 321-2367

Technical Information

LYNNE MARTON LYNNE MARTON CONSULT

349 BURNING TREE COURT HALF MOON BAY, CA 94109

(650) 726-9544

Technical Information

SARAH MCINTYRE PROSTRAKAN, INC. 1430 US HIGHWAY 206

SUITE 110

BEDMINSTER, NJ 07921

ANIP ACQUISITION CO.

7131 AMBASSADOR ROAD

(908) 375-7909

PAM HAWSON

Invoice Information Technical Information

PAM HAWSON ANIP ACQUISITION COMPANY 7131 AMBASSADOR ROAD

SUITE 150

WOODLAWN, MD 21244

(410) 281-9450

SUITE 150 WOODLAWN, MD 21244 (410) 281-9450

Invoice Information KAREN AGAMA

COMPLIANCE IMPLEMENTATION SVS.

LLC

3005 CARRINGTON MILL BLVD

SUITE 580

MORRISVILLE, NC 27560

(919) 233-8348

Technical Information

MARIKA THIESSEN SIRION THERAPEUTICS 9314 EAST BROADWAY TAMPA, FL 33619 (813) 496-7325 x314

Invoice Information

LAURA CARLSON DDN

800WOODLAND PRIME

SUITE 200

MENOMONEE FALLS, WI 53051

(414) 434-4631

Technical Information

DAN PIERGIES

DDN

800 WOODLAND PRIME #200 MENOMONEE FALLS, WI 53051

(414) 434-4630

Labeler Name: MEDIMETRIKS PHARMACEUTICALS, INC.

NDC: 43538

Legal Information

DAVID ADDIS MEDIMETRIKS PHARMACEUTICALS, INC.

363 ROUTE 46 WEST FAIRFIELD, NJ 07004

(973) 882-7512 x569

Invoice Information

DAVID ADDIS MEDIMETRIKS PHARMACEUTICALS, INC.

363 ROUTE 46 WEST FAIRFIELD, NJ 07004

(973) 882-7512

Technical Information

DAVID ADDIS

MEDIMETRIKS PHARM, INC. 363 ROUTE 46 WEST FAIRFIELD, NJ 07004 (973) 882-7512 x569

Labeler Name: SLATE PHARMACEUTICALS, INC.

NDC: 43773

Legal Information

JOHN JAYE SLATE PHARMACEUTICALS, INC. 318 BLACKWELL STREET **SUITE 240** DURHAM, NC 27701 (704) 335-9872 x150

Invoice Information

TAYLOR CALDWELL SLATE PHARMACEUTICALS, INC. 318 BLACKWELL STREET SUITE 240 DURHAM, NC 27701

(919) 682-8800 x153

Technical Information

TAYLOR CALDWELL SLATE PHARM, INC. 318 BLACKWELL STREET SUITE 240 DURHAM, NC 27701 (919) 682-8800 x153

Labeler Name: BIOCOMP PHARMA, INC.

NDC: 44523

Legal Information

MARIO A. MACIAS MISSION PHARMACAL COMPANY 10999 IH 10 WEST SUITE 1000 SAN ANTONIO, TX 78230-1355 (210) 696-8400 x5253

Invoice Information

MARIO A. MACIAS MISSION PHARMACAL COMPANY 10999 IH 10 WEST SUITE 1000 SAN ANTONIO, TX 78230-1355 (210) 696-8400 x5253

Technical Information

MARIO A. MACIAS MISSION PHARMACAL CO. 10999 IH 10 WEST SUITE 1000 SAN ANTONIO, TX 78230-1355 (210) 696-8400 x5253

Labeler Name: GENERAMED, INC.

NDC: 52569

Legal Information

JOHN PHAIR GENERAMED, INC. 1180 LOMOND DRIVE EL DORADO HILLS, CA 95762

95762

(916) 207-7763

Invoice Information

JOHN PHAIR GENERAMED, INC. 1180 LOMOND DRIVE

EL DORADO HILLS, CA 95762

(916) 207-7763

Technical Information

JOHN PHAIR GENERAMED, INC. 1180 LOMOND DRIVE EL DORADO HILLS, CA

Labeler Name: MCKESSON CORP, RX PAK DIVISION

NDC: 65084

Legal Information

TIENNE LEE MCKESSON CORPORATION, RX PAK DIV

ONE POST STREET SAN FRANCISCO, CA 94104

(415)983-8863

Invoice Information

LAURA CARLSON DDN

800 WOODLAND PRIME, SUITE 200 MENOMONEE FALLS, WI 53051

(414) 434-4631

Technical Information

DAN PIERGIES DDN

(916) 207-7763

800 WOODLAND PRIME, STE 200 MENOMONEE FALLS, WI 38141

(414) 434-4630

Labeler Name: BIOVITRUM AB

NDC: 66658

Legal Information

JOSEPH W. METRO, ESQ. REED SMITH LLP 1301 K. STREET, NW SUITE 1100 EAST TOWER WASHINGTON, DC 20005

(202) 414-9200

Invoice Information

RONJIT SANDHU IMS HEALTH

11 WATERVIEW BOULEVARD PARSIPPANY, NJ 07054

(973) 394-2943

Technical Information

JILL PAGE **BIOVITRUM AB** 17 CAMELOT DRIVE BUDD LAKE, NJ 07828

(732) 522-3426

Labeler Name: WORLD GEN, LLC

NDC: 66814

Effective Date:

Termination Date:

04/01/2009

Legal Information

BOB GORDANELLA COWAN, LIEBOWITZ AND LATMAN, P.C. 1133 AVENUE OF THE AMERICAS NEW YORK, NY 10036-6799

(212) 790-9200

Invoice Information

Transmission Option: 2

DANIELA CASTELLITTO WORLD GEN. LLC 120 ROUTE 17 NORTH SUITE 127

PARAMUS, NJ 07652 (201) 857-8210

Technical Information

DANIELA CASTELLITTO WORLD GEN. LLC 120 ROUTE 17 NORTH

SUITE 127

PARAMUS, NJ 07652 (201) 857-8210

Labeler Name: BIONICHE PHARMA

NDC: 67457

Legal Information

KARA MAXWELL **BIONICHE PHARMA** 272 E. DEERPATH ROAD SUITE 304

LAKE FOREST, IL 60045

(847) 739-3249

Invoice Information

LAURA CARLSON DDN

800 WOODLAND PRIME

SUITE 200

MENOMONEE FALLS, WI 53051

(414) 434-4631

Technical Information

DAN PIERGIES

DDN

800 WOODLAND PRIME

SUITE 200

MENOMONEE FALLS, WI 53051

(414) 434-4630

Labeler Name: SPECTRUM PHARMACEUTICALS, INC.

NDC: 68152

Legal Information

SHYAM KUMARIA SPECTRUM PHARMACEUTICALS, INC. 157 TECHNOLOGY DRIVE

IRVINE, CA 92618

(949) 788-6700

Invoice Information

RANDALL PERRY SPECTRUM PHARMACEUTICALS, INC.

P.O. BOX 259

ACWORTH, GA 30101-0259

(770) 975-7337

Technical Information

RANDALL PERRY SPECTRUM PHARMALS, INC. P.O. BOX 259

ACWORTH, GA 30101-0259

(770) 975-7337

Labeler Name: LEGACY PHARMACEUTICAL

PACKAGING, LLC

NDC: 68645

Invoice Information

LAURA CARLSON

DDN

800 WOODLAND PRIME, SUITE 200 MENOMONEE FALLS, WI 53051

(414) 434-4631

Technical Information

DAN PIERGIES

DDN

800 WOODLAND PRIME, SUITE 200 MENOMONEE FALLS, WI 38141

(414) 434-4630

Legal Information

WAYNE WELBORN LEGACY PHARMACEUTICAL PACK. LLC 13480 LAKEFRONT DRIVE EARTH CITY, MO 63045

(314) 549-8057