

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

January 27, 2010

MEDICAID DRUG REBATE PROGRAM

Release No. 154



For State Medicaid Directors



CLARIFICATION ON POSTMARK DATE FOR WEB INVOICES

Recently, we have received questions from States that have decided to use a secured web site as the method of providing manufacturers their quarterly rebate invoices as to what constitutes a postmark date. Under section II(b) of the Medicaid Drug Rebate Agreement, it is stated that "the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at minimum, information on the number of units paid, by NDC." Therefore, we expect that when using electronic invoicing via email, States include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC. In this case, we view the postmark date as the date on which the email is sent. Please note that the date an email is sent with a link to an invoice web site does not qualify as a postmark date. If States choose to direct manufacturers to an invoice web site via a link in the email, then States need to include the invoice itself within the body of the email to a manufacturer or, at minimum, information on the number of units paid by NDC.

BANKRUPTCY FILINGS BY LABELER CODES: 66346 PEDIAMED, 67336 TEAMM, AND 67707 OSCIENT

Labeler code 66346, Pediamed Pharmaceuticals, Inc.; labeler code 67336, Teamm Pharmaceuticals, Inc.; and labeler code 67707, Oscient Pharmaceuticals, Corp., filed bankruptcy petitions under Chapter 11 of the U.S. Bankruptcy Code in the Bankruptcy Court.

Labeler code 66346, Pediamed Pharmaceuticals, Inc., was terminated on 10/1/07 and labeler code 67336, Teamm Pharmaceutical Inc., was terminated on 10/1/09. Labeler code 67707, Oscient Pharmaceuticals, Corp. remains active in the MDR program.

Until a labeler is terminated from the program, its drugs continue to be eligible for payment under the MDRP. Labelers that have filed for bankruptcy may voluntarily terminate from the program or be terminated from the program by CMS. However, filing for bankruptcy does not result in automatic termination from the program. If a labeler is terminated from the program following a filing for bankruptcy, we will notify states of the termination by email. In general, when labelers file for bankruptcy, states are expected to protect Medicaid interests related to any rebate payments owed from the affected labelers.

COVERAGE OF NON-COVERED OUTPATIENT DRUGS UNDER OTHER AREAS OF MEDICAID

When it comes to CMS' attention that a labeler has incorrectly submitted an NDC as a covered outpatient drug as defined in section 1927(k) of the Social Security Act (the Act) for purposes of the MDRP, CMS sends notice to states that these products are no longer eligible for coverage as a covered outpatient drug. Please note that while these products are not eligible for coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan. Please note that notice of non-coverage of these products as covered outpatient drugs does not necessarily exclude them from appropriate coverage elsewhere in the Medicaid program.

NEW REBATE AGREEMENTS

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

Labeler Name: PHARMAFORCE, INC.

Optional Effective Date: 10/28/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 40042

Labeler Name: EDENBRIDGE PHARMACEUTICALS LLC

Optional Effective Date: 12/16/2009 Mandatory Effective Date: 04/01/2010 Labeler Code: 42799

Labeler Name: EPIC PHARMA LLC

Optional Effective Date: 01/26/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 42806

Labeler Name: RHODES PHARMACEUTICALS L.P.

Optional Effective Date: 12/02/2009 Mandatory Effective Date: 04/01/2010 Labeler Code: 42858

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Labeler Name: EURAND PHARMACEUTICALS, INC.

Optional Effective Date: 10/19/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 42865

Labeler Name: CODADOSE INCORPORATED

Optional Effective Date: 01/15/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 43378

Labeler Name: ZARS PHARMA, INC.

Optional Effective Date: 10/22/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 43469

Labeler Name: SANCILIO & COMPANY, INC.

Optional Effective Date: 01/26/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 44946

Labeler Name: MANCHESTER PHARMACEUTICALS, INC.

Optional Effective Date: 01/14/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 45043

Labeler Name: ACTAVIS INC.
Optional Effective Date: 10/15/2009
Mandatory Effective Date: 01/01/2010
Labeler Code: 45963

Labeler Name: PALADIN LABS (USA), INC.

Optional Effective Date: 10/23/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 46129

Labeler Name: ACTAVIS KADIAN LLC

Optional Effective Date: 09/30/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 46987

Labeler Name: SUN PHARMA GLOBAL FZE

Optional Effective Date: 12/30/2009 Mandatory Effective Date: 04/01/2010 Labeler Code: 47335

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Labeler Name: FERA PHARMACEUTICALS, LLC

Optional Effective Date: 12/23/2009 Mandatory Effective Date: 04/01/2010 Labeler Code: 48102

Labeler Name: ALLOS THERAPEUTICS INC.

Optional Effective Date: 10/28/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 48818

Labeler Name: CARACO PHARMA INC.

Optional Effective Date: 01/04/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 49708

Labeler Name: VALEANT/DOW/DESCARTES ACQUISITION CORP.

Optional Effective Date: 01/19/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 59987

Labeler Name: VISTA PHARMACEUTICALS, INC.

Optional Effective Date: 10/27/2009 Mandatory Effective Date: 01/01/2010 Labeler Code: 61971

REINSTATED LABELERS

Labeler Name: CENTURION LABS, LLC

Optional Effective Date: 01/06/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 23359

Labeler Name: THE MEDICINES COMPANY

Optional Effective Date: 01/05/2010 Mandatory Effective Date: 04/01/2010 Labeler Code: 65293

Labeler Name: CURA PHARMACEUTICAL CO., INC.

Optional Effective Date: 12/17/2009 Mandatory Effective Date: 04/01/2010 Labeler Code: 66860

TERMINATED LABELERS

Effective 01/01/2010:

<u>Labeler Name</u> <u>Labeler Code</u>

Blansett Pharmacal Co., Inc. 51674

VOLUNTARILY TERMINATED LABELERS

Effective 01/01/2010:

Labeler Name Labeler Code

Aceto Pharma Corp. 25356 Multi-Pak Packaging 66789

NON-DRUG DELETIONS FROM MDR

The states were previously notified that the following products do not meet the definition of a covered outpatient drug and are not rebate eligible. Therefore, they are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs.

Please note that while these products are not eligible for coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan. Notice of non-coverage of these products as covered outpatient drugs does not necessarily exclude them from appropriate coverage elsewhere in the Medicaid program.

NDC Product Name

00536-0004	ORALYTE SOLUTION UNFLAVORED
00536-0935	ORALYTE SOLUTION-FRUIT FLAVORED
00536-0936	ORALYTE SOLUTION-BUBBLE GUM
00536-1385	ORALYTE SOL-GRAPE 33 OZ
00536-1395	ORAL FREE POPS 1.2OZ 16
24338-0620	XYLAREX3
24385-0003	GENTIAN VIOLET 1%
24385-0010	MENTHOL LOZENGES
24385-0038	ROSEWATER & GLYCERIN
24385-0041	COUGH DROPS CHERRY
24385-0042	COUGH DROPS HONEY-LEMON
24385-0043	COUGH DROPS MENTHOL
24385-0045	SORE THROAT BENZOCAINE LOZENGES
24385-0051	GNP SORE THROAT LOZ MENTHOL
24385-0057	MENTHOL COUGH DROPS SUGAR FREE
24385-0084	GNP CHILD CHEW ANIMAL SHAPE W/IRON

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CHILDRENS CHEWABLE VITAMINS W/EXTRA C
24385-0089
          GNP CHILDRENS GUMMY ZOO CHEWS VITAMIN
24385-0090
24385-0096
          PEDIATRIC ELECTROLYTE
24385-0100
          PEDIATRIC ELECTROLYTE UNFLAVORED
          PEDIATRIC ELECTROLYTE BUBBLE GUM FLAVOR (8X32)
24385-0101
          PEDIATRIC ELECTROLYTE GRAPE
24385-0103
24385-0108
          VITAMIN B-1 100MG
          VITAMIN B-6 50 MG
24385-0112
24385-0115
          VITAMIN B-6 100 MG
24385-0117
          VITAMIN B-12 500 MCG
          GNP FISH OIL ENTERIC COATED 1200MG
24385-0122
24385-0128
          GNP ONE DAILY MULTI MEN'S 50+
24385-0132
          THERAPEUTIC M
          ONE DAILY MULTIVITAMINS
24385-0139
          ONE DAILY MULTIVITAMINS & IRON
24385-0148
24385-0158
          FABRIC STRIP ASSORTED SIZES
          GNP CENTURY ADULT MULTI CARDIO
24385-0162
24385-0180
          GNP SHEER
24385-0184
          LOTION FACE MOISTURIZING FOR SENSITIVE
24385-0186
          FACIAL MOISTURIZER
24385-0199
          DEEP CLEANSING WASH
24385-0208
          STRESS FORMULA & ZINC
24385-0211
          GNP CINNAMON 1000MG
24385-0214
          WITCH HAZEL
24385-0215
          GNP MEN'S PROSTATE HEALTH
          GNP PEDIATRIC ELECTROLYTE APPLE 4PK
24385-0216
24385-0219
          GNP COUGH DROP NATURAL HERB
24385-0246
          NASAL STRIPS MEDIUM/LARGE
          EYE WASH WITH CUP
24385-0252
24385-0257
           VITAMIN C 500 MG CHEWABLE
24385-0261
          GNP ONE DAILY MULTI WOMEN'S 50+
24385-0265
          CALCIUM 500
24385-0266
          CALCIUM 500 & D
24385-0269
          CALCIUM 600
24385-0273
          CALCIUM 600 & D
          GNP CHILD CHEW ANIMAL SHAPE
24385-0275
          CALCIUM MAGNESIUM & ZINC
24385-0277
24385-0279
          GNP COUGH DROP WILD CHERRY
          BETA CAROTENE 25000 IU
24385-0280
           VITAMIN A 8000 IU
24385-0281
24385-0284
          COD LIVER OIL
          FOLIC ACID 400 MCG
24385-0286
          VITAMIN B-50 BALANCED B-COMPLEX
24385-0288
24385-0290
          VITAMIN B-100 BALANCED B-COMPLEX T/R
24385-0292
          VITAMIN C 250 MG
          VITAMIN C 500 MG CHEWABLE
24385-0293
24385-0295
          VITAMIN C 500 MG ETS
24385-0297
          VITAMIN C 500 MG T/R
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24385-0298
           VITAMIN C 1000 MG
           GNP NATURAL FIBER POWDER SMOOTH TEXTURE 48 DOSE
24385-0299
24385-0306
           BORIC ACID POWDER
24385-0311
           VITAMIN C 500 MG W/ROSEHIPS ETS
           VITAMIN C 1000 MG W/ROSEHIPS T/R
24385-0312
           VITAMIN E 200 IU
24385-0314
24385-0318
           VITAMIN E 400 IU
24385-0319
           VITAMIN E 1000 IU
24385-0321
           VITAMIN E 400 IU
           GNP NASAL STRIP MEDIUM/LARGE CLEAR
24385-0327
24385-0335
           FISH OIL CONCENTRATE 1000 MG
24385-0336
           GARLIC OIL 3 MG NATURAL
24385-0345
           POTASSIUM GLUCONATE 99 MG
           ZINC GLUCONATE 50 MG
24385-0346
           GNP PEDIA STRIPS GRAPE
24385-0391
24385-0395
           COUGH DROPS VITAMIN C CITRUS
           GNP PREGNANCY TEST ONE STEP
24385-0474
24385-0478
           CALCIUM ANTACID TABLETS ASSORTED
24385-0485
           CALCIUM ANTACID TABLETS
           CO-Q-10, 100MG
24385-0508
24385-0513
           SUPER POTENCY FISH OIL
24385-0515
           CASTOR OIL O/T
24385-0516
           DAILY DIET
24385-0538
           ZINC CHERRY
24385-0539
           ZINC CITRUS
24385-0591
           CO Q 10 WITH FISH OIL
           CARB VANTAGE
24385-0592
24385-0593
           MERCUROCLEAR
           ULTRA STRENGHT CALCIUM ANTACID
24385-0595
24385-0641
           GINGKO BILOBA
24385-0648
           EVENING PRIMROSE OIL
24385-0655
           GNP VITAMIN D 1000IU
24385-0657
           ECHINACEA GOLDEN SEAL
24385-0662
           ECHINACEA
24385-0663
           CRANBERRY FRUIT
24385-0666
           VITAMIN E 400 IU
24385-0679
           ONE DAILY MULTI-VITAMINS
           ONE DAILY MULTI-VITAMINS - WOMEN'S
24385-0680
           VITAMIN E 1000 IU
24385-0681
           CALCIUM 600 MG W/VITAMIN D & MINERALS
24385-0787
24385-0790
           GNP CALCIUM 1200MG W/1000IU VIT D CHEWABLE
           OPTI-VITAMINS
24385-0809
           CALCIUM CITRATE + D 630 MG
24385-0898
24385-0900
           CALCIUM 600 + SOY
24385-0931
           CINNAMON OIL ARTIFICIAL
           PEPPERMINT SPIRITS
24385-0932
24385-0948
           GINSENG 100 MG
24385-0957
           GARLIC TAB HIGH POTENCY 400 MG
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24385-0958	GNP ZINC COLD REMEDY QUICK DISSOLVE TAB
24385-0967	MAGNESIUM
24385-0969	NIACIN T/R
24385-0971	SAW PALMETTO
24385-0973	EUCALYPTUS OIL
24385-0996	VITAMIN E 400 IU
24385-0999	VITAMIN B-12
24385-1007	SORE THROAT LOZ MENTHOL
37205-0220	PEDIATRIC ELECTROLYTE FRUIT
37205-0221	PEDIATRIC ELECTROLYTE GRPE
37205-0222	PEDIATRIC ELECTROLYTE UNFLAVOR
37205-0963	PED ELECTROLYTE FRZP
49348-0570	PEDIATRIC ELECTROLYTE, UNFLAVORED
49348-0571	PEDIATRIC ELECTROLYTE, FLAVORED
49348-0880	PEDIATRIC ELECTROLYTE, BUBBLE GUM FLAVORED
49614-0222	PEDIATRIC ELECTROLYTE FRUIT 1 LITER
49614-0223	PEDIATRIC ELECTROLYTE GRAPE 1 LITER
63868-0007	PEDIATRIC ELECTROLYTE GRAPE
63868-0261	PEDIATRIC ELECTROLYTE UNFLAVORED
63868-0606	PEDIATRIC ELECTROLYTE FRUIT FLAVORED

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The states were previously notified of the FDA's determination that the following NDCs that were reported by the labeler as DESI code 5 (less than effective/IRS drug for all indications) are DESI code 2 (no determination made). These drugs are eligible for Medicaid coverage and rebate billing.

NDC	Product Name
63717-0552	CORZALL LIQUID
63717-0553	CORZALL PLUS

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

cc:

Regional Administrators

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