DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

October 24, 2008

**MEDICAID DRUG REBATE PROGRAM** **Release No. 150**


# For State Medicaid Directors

## IMPACT OF FDA NEW DRUG DETERMINATIONS ON THE MEDICAID DRUG REBATE PROGRAM (MDRP)

The FDA periodically issues Federal Register (FR) notices to announce certain FDA-related actions, such as the final determination that a drug is a new drug within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act. Drugs subject to such final new drug determinations generally require FDA approval by the date of the FDA action (i.e., the date of the FR notice) in order to legally remain on the market.

In accordance with section 1927(k)(2) of the Social Security Act, those drugs that have been subject to a final new drug determination by the FDA that they are "new drugs" and for which the labeler has not received required FDA approval do not meet the definition of a covered outpatient drug. Therefore, when a final new drug determination is made, we expect that affected labelers will notify CMS to update information submitted pursuant to section 1927. Labelers may send an email to CMS (mdroperations@cms.hhs.gov), including "Request for Deletion of Non-Rebate-Eligible NDC(s)" in the subject line and cite the appropriate FDA-issued FR notice in support of the requested deletion in the body of the email.

When either the labeler or CMS has determined that an NDC is not a covered outpatient drug, CMS will work with labelers and states to ensure that all parties are promptly notified in situations where the NDC may no longer be eligible for Federal Financial Participation under section 1927.

Please note that the national rebate agreement provides that labelers submit a list of all of those NDCs that meet the definition of a covered outpatient drug. As a result, labelers that submit false information regarding drugs that do not meet the definition of a covered outpatient drug may be subject to civil monetary penalties, termination and/or other Federal agency action.

**AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS AND BEST PRICE (BP) – KING PHARMACEUTICALS, INC.**

As a result of modifications in its methodology for the calculation of AMP and Best Price, King Pharmaceuticals, Inc. has revised AMPs and Best Price for first quarter 2003 through second quarter 2005, and will recover overpayments from states for excessive rebates during those quarters.

In many cases the recalculation resulted in significant overpayments to the states. King will recoup overpayments on a State-by-State basis from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. King indicated that it will contact each State representative to inform them of this action and has expressed a willingness to work with individual states to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meantime, states should continue to invoice King for current quarters as usual.

If you have any questions on this particular issue, please contact Kim Howell at 410-786-6762 or kimberly.howell@cms.hhs.gov.

**AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS – MORTON GROVE, INC.**

As a result of modifications in its methodology for the calculation of AMP, Morton Grove Pharmaceuticals, Inc. has revised AMPs for second quarter 2003 through first quarter 2006, and will recover overpayments from states for excessive rebates during those quarters.

In many cases the recalculation resulted in significant overpayments to the states. Morton Grove will recoup overpayments on a State-by-State basis from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. Morton Grove indicated that it will contact each State representative to inform them of this action and has expressed a willingness to work with individual states to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meantime, states should continue to invoice Morton Grove for current quarters as usual.

If you have any questions on this particular issue, please contact Kim Howell at 410-786-6762 or kimberly.howell@cms.hhs.gov.

**AVERAGE MANUFACTURER PRICE (AMP) RECALCULATIONS – BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

As a result of modifications in its methodology for the calculation of AMP, Boehringer Ingelheim Pharmaceuticals, Inc. has revised AMPs for first quarter 1991 through third quarter 2000, and will recover overpayments from states for excessive rebates during those quarters.

In many cases the recalculation resulted in significant overpayments to the states. Boehringer Ingelheim will recoup overpayments on a State-by-State basis from current and subsequent quarterly rebates (if necessary) until the overpayments have been recovered. Boehringer Ingelheim indicated that it will contact each State representative to inform them of this action and has expressed a willingness to work with individual states to recover the overpayments over several quarters, if necessary, to minimize financial hardship. In the meantime, states should continue to invoice Boehringer Ingelheim for current quarters as usual.

If you have any questions on this particular issue, please contact Kim Howell at 410-786-6762 or kimberly.howell@cms.hhs.gov.

**NEW REBATE AGREEMENTS**

The following are new labelers to the Medicaid Drug Rebate Program. Their contact information is attached:

| Labeler Name/Labeler Code | Mandatory Coverage Date | Optional Coverage Date |
|---|---|---|
| VERUS<br>Labeler Code 13436 | 01/01/2009 | 09/12/2008 |
| APACE PACKAGING LLC<br>Labeler Code 15338 | 01/01/2009 | 09/25/2009 |
| PROBACTIVE BIOTECH, INC.<br>Labeler Code 23110 | 10/01/2008 | 06/17/2008 |
| EKR THERAPEUTICS, INC.<br>Labeler Code 24477 | 10/01/2008 | 06/27/2008 |
| ARISTOS PHARMACEUTICALS, INC.<br>Labeler Code 24486 | 10/01/2008 | 06/09/2008 |
| SAGENT PHARMACEUTICALS, INC.<br>Labeler Code 25021 | 01/01/2009 | 08/06/2008 |
| MEDICURE<br>Labeler Code 25208 | 10/01/2008 | 05/15/2008 |
| ANESIVA<br>Labeler Code 28000 | 01/01/2009 | 09/23/2008 |
| UNICHEM PHARMACEUTICALS, INC.<br>Labeler Code 29300 | 01/01/2009 | 08/25/2008 |
| BROOKSTONE PHARMACEUTICALS, LLC<br>Labeler Code 42192 | 09/30/08 | 01/01/09 |

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|---|---|---|
| EMMAUS MEDICAL, INC<br>Labeler Code 42457 | 01/01/2009 | 08/12/2008 |
| ALMUS PHARMACEUTICALS USA LLC<br>Labeler Code 42688 | 01/01/2009 | 09/05/2008 |
| PIERRE FABRE MEDICAMENT<br>Labeler Code 64370 | 10/01/2008 | 05/14/2008 |
| CHAIN DRUG CONSORTIUM, LLC<br>Labeler Code 68016 | 10/01/2008 | 07/29/2008 |

**REINSTATED REBATE AGREEMENTS**

| | | |
|---|---|---|
| MEDISCA, INC.<br>Labeler Code 38779 | 01/01/2009 | 08/15/2008 |

**TERMINATED REBATE AGREEMENTS**

| Labeler Name | Labeler Code |
|---|---|
| **Effective 10/01/2008:** | |
| NEXUS PHARMACEUTICALS, INC. | 14789 |
| ADVANCE PHARMACEUTICALS, INC. | 17714 |
| MARTEC USA, LLC | 52555 |
| COATS ALOE INTERNATIONAL, INC. | 58826 |
| DARTMOUTH PHARMACEUTICALS, INC. | 58869 |
| ALTAIRE PHARMACEUTICALS, INC. | 59390 |
| ADVENT PHARMACEUTICALS, INC. | 60242 |
| THE MEDICINES COMPANY | 65293 |
| AERO PHARMACEUTICALS, INC. | 66440 |
| CURA PHARMACEUTICAL CO., INC. | 66860 |
| **Effective 01/01/2009:** | |
| PURDUE FREDERICK COMPANY | 00034 |
| STAR PHARMACEUTICALS, INC. | 00076 |
| WATSON PHARMA INC. | 00364 |
| CHEMRICH LABORATORIES INC. | 10235 |
| GRIFOLS BIOLOGICALS, INC. | 49669 |
| GENERAMED, INC. | 52569 |
| CARRINGTON LABORATORIES, INC. | 53303 |
| WATSON PHARMA INC. | 62022 |
| VERACITY PHARMACEUTICALS, INC. | 67887 |
| CAROLINA PHARMACEUTICALS, INC. | 68249 |
| KVD PHARMA, INC | 68716 |

## VOLUNTARILY TERMINATED LABELERS

*Note: This labeler's termination date was made retroactive to 04/01/2008:
UNICO HOLDINGS, INC. 59640

**Effective 01/01/2009:**

CARDINAL HEALTH SINGAPORE 42115

## CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGES

The following products were reported by the labeler as DESI code 2 (safe and effective or non-DESI drug). The FDA has determined that the drugs are DESI code 5 (less than effective/IRS drug).

**11/11/1975, DESI 3265**

68308 0830 DIACETAZONE CAPSULES

**09/25/1981, DESI 10367**

00185 5174 NITROGLYCERIN SLOCAPS CAPSULES SUSTAINED RELEASE 2.5 MG
00185 1235 NITROGLYCERIN SLOCAPS CAPSULES SUSTAINED RELEASE 6.5 MG
00185 1217 NITROGLYCERIN SLOCAPS CAPSULES SUSTAINED RELEASE 9 MG
58177 0004 NITROGLYCERIN 2.5 MG EXTENDED RELEASE CAPSULES
58177 0005 NITROGLYCERIN 6.5 MG EXTENDED RELEASE CAPSULES
58177 0006 NITROGLYCERIN 9.0 MG EXTENDED RELEASE CAPSULES
58177 0323 NITROQUICK SUBLINGUAL TABLETS 0.3 MG
58177 0324 NITROQUICK SUBLINGUAL TABLETS 0.4 MG
58177 0325 NITROQUICK SUBLINGUAL TABLETS 0.6 MG

The following product was reported by the labeler as DESI code 5 (less than effective/IRS drug). The FDA has determined that the drug is a DESI code 2 (safe and effective or non-DESI drug).

52152 0060 URSODIOL

## NON-DRUG DELETIONS FROM MDR

00245 0022 AMLACTINXL
00245 0023 AMLACTIN 12% COSMETIC LOTION
00245 0024 AMLACTIN 12% COSMETIC CREAM
00182 4048 GLUCOSAMINE SULFATE CAPSULES 500MG 60
00182 4095 GLUCOSAMINE/CHONDROITIN CAPSULES 120
00536 3111 GLUCOSAMINE/CHONDROITIN/MSM
00615 1388 GLUCOSAMINE SULFATE 500MG
00677 1652 GLUCPSAMINE CHONDROTIN CAP 60
24385 0062 CENTURY VITAMIN (MULTIVITAMIN/MULTIMINERAL)
24385 0127 CENTURY FOR SENIORS (MULTIVITAMINS/MINERALS)
24385 0258 GLUCOSAMINE CHONDROITIN

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|---|---|---|
| 24385 | 0260 | CENTURY ADVANTAGE MULTI-VITAMINS |
| 24385 | 0381 | GLUCOSAMINE CHONDROITIN 750MG/600MG |
| 24385 | 0457 | GLUCOSAMINE SULFATE 750 MG |
| 24385 | 0672 | MSM WITH GLUCOSAMINE 1000/1500 MG |
| 24385 | 0703 | GNP GLUCOSAMINE CHONDROITIN W/HYALURONIC ACID |
| 24385 | 0950 | GLUCOSAMINE 500 MG |
| 24385 | 0956 | GLUCOSAMINE CHONDROITIN 1500/1200 MG |
| 49348 | 0083 | VITAMIN C 500 MC |
| 49348 | 0218 | GLUCOSAMINE 500MG |
| 49348 | 0404 | MSM W/GLUCOSAMINE COMPLEX |
| 49348 | 0421 | GLUCOSAMINE & CHOND |
| 49348 | 0501 | GLUCOSAMINE & CHONDROITIN REG STR |
| 49348 | 0513 | GLUCOSAMINE & CHONDROITIN TRIPLE STR. |
| 49348 | 0565 | GLUCOSAMINE SULFATE 750MG |
| 49348 | 0747 | GLUCOSAMINE WITH CALCIUM & D |
| 49348 | 0748 | GLUCOSAMINE TABLETS 1500MG |
| 49348 | 0749 | GLUCOSAM+MSM TABLETS 750MG |
| 51552 | 0541 | CHONDROITIN SULFATE SODIUM SALT |
| 51552 | 0544 | GLUCOSAMINE-D HYDROCHLORIDE |
| 51552 | 0592 | GLUCOSAMINE SULFATE |
| 51552 | 0951 | ACETYL-D-GLUCOSAMINE (N) |
| 51991 | 0031 | GLUCOSAMINE 500MG / CHONDROITIN 400 |
| 68032 | 0344 | NICOTINAMIDE ZCF |

**NEW DRUG DETERMINATIONS--DELETIONS FROM MDR**

The states were previously notified of the FDA's determination that the following product is a Post-62 Unapproved Drug Product for which FDA requires approval. As a result, this NDC does not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and is, therefore, no longer eligible for inclusion in the rebate program. It is being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs and should be deleted from state Medicaid Drug Rebate systems:

| | | |
|---|---|---|
| 16881 | 0300 | AURALGAN OTIC SOLUTION |

The states were previously notified of the FDA's determination that the following NDCs have been subject of a final determination by the FDA that they are new drugs 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 as set forth in 71 Fed. Reg. 33462 (June 9, 2006). As a result, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, therefore, no longer eligible for inclusion in the rebate program. They are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs and should be deleted from state Medicaid Drug Rebate systems:

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|---|---|
| 00182-1199 | CARDEC 4/60MG TABLETS |
| 00472-0727 | CARDEC-S SYRUP |
| 00472-0731 | CARDEC-DM SYRUP |
| 00472-0733 | CARDEC-DM DROPS |
| 10914-0920 | CARBINOXAMINE MALEATE 2 MG IR / 8 MB ER |
| 10914-0925 | CARBINOXAMINE MALEATE / TANNATE 2 MG. / 6 MG. SUSPENSION |

55654-0028 CARBODEX DM DROPS
58177-0924 HYDRO-TUSSIN CBX 16 OZ.

The states were previously notified of the FDA's determination that the following NDCs have been subject of a final determination by the FDA that they are new drugs 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 as set forth in 21 CFR 310.502(a)(14). 72 Fed. Reg. 29517 (May 29, 2007). As a result, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, therefore, no longer eligible for inclusion in the rebate program. They are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs and should be deleted from state Medicaid Drug Rebate systems:

00095 0067 PNEUMOTUSSIN 2.5 COUGH SYRUP
00131 2055 GUAIMAX-D TABLETS
00182 1042 GUAIFENESIN/DM TABLETS 600MG/30MG 100
00551 0189 GUA-SR TABLETS
00603 5543 Q-BID LA 250
00642 0421 TUSSO-HC
00642 0645 TUSSO-DMR
00677 1487 GUAIFENESIN 600MG/PSEUDOEPHEDRINE 60MG TAB 100
10914 0100 GUAIFENESIN 900 MG; PHENYLEPHRINE HYDROCHLORIDE 25 MG
10914 0200 GUAIFENESIN 1200MG; PHENYLEPHRINE HYDROCHLORIDE 25MG
10914 0300 PHENYLEPHRINE HCL 15 MG; GUAIFENESIN 600 MG
10914 0970 GUAIFENESIN 1200 MG./DEXTROMETHORPHAN HBR 20 MG
14629 0203 EXTENDRYL HC
14629 0204 EXTENDRYL G
51674 0124 PROLEX D TABLETS
51674 0126 PROLEX PD
51674 0127 PROSET D TABLETS
51991 0426 MINTEX DM
51991 0428 GUIAFEN PE TABLETS
51991 0429 GUIAFEN DM TABLETS
51991 0461 GUIAFEN II DM
52152 0139 AMIBID DM TABS (100)
52152 0246 GUAIF. & DEXTROMETHORPHAN ER TABS
53489 0424 GUAIFENESIN 600MG/PSEUDOEPHEDRINE 120MG LONG ACTING
53489 0425 GUAIFENESIN 600MG/PSEUDOEPHEDRINE 60MG LONG ACTING
57664 0222 MIRAPHEN PSE (GUIAFENESIN/PSEUDOEPHEDRINE 600/120 MG)
57664 0317 MIRAPHEN PE (GUAIFENESIN/PHENYLEPHRINE 300/20 MG)
57664 0355 GUAIFENESIN/DEXTROMETHORPHAN 600/30MG
58177 0078 PHENAVENT CAPS
58177 0079 PHENAVENT PED
58177 0095 PHENAVET LA CAPS 30's
58177 0444 PHENAVENT D 100's
58605 0530 ALLFEN DM
58605 0613 ALLFEN
58605 0621 ALLFEN DM
58605 0630 ALLFEN DM
58605 0713 ALLFEN C
58605 0721 ALLFEN CX

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|---|---|---|
| 58869 | 0411 | TOURO DM |
| 58869 | 0441 | TOURO CC |
| 58869 | 0445 | TOURO CC-LD |
| 58869 | 0581 | TOURO HC |
| 58869 | 0635 | TOURO LA-LD |
| 58869 | 0636 | TOURO LA |
| 59196 | 0112 | SYMPAK COUGH/COLD BP |
| 59196 | 0120 | SYMPAK DM |
| 59243 | 0011 | RU TUSS 800 TABS |
| 59243 | 0012 | RU-TUSS 800 DM TABLETS |
| 59243 | 0017 | RU TUSS JR. TABS |
| 59310 | 0120 | MUCO-FEN 1200 |
| 59702 | 0191 | SUDEX TABLETS |
| 60258 | 0252 | GFN 1200/DM 20/PE 40 TABLETS |
| 60258 | 0256 | GANIDIN NR LIQUID |
| 60258 | 0263 | GFN 1200/DM 60 TABLETS |
| 60258 | 0264 | GFN 600/PSE60/DM30 TABLETS |
| 60258 | 0266 | GFN/PSE TABLETS |
| 60258 | 0267 | GFN 1000/DM60 TABLETS |
| 60258 | 0269 | GFN 600/PHENYLEPHRINE 20 MG TABS |
| 60258 | 0274 | GFN 600/PHENYLEPHRINE 40 |
| 60258 | 0275 | GUAIFENESIN 400 MG TABLETS |
| 60258 | 0277 | G/P 1200/75 |
| 60258 | 0284 | GFN 1200/PHENYLEPHRINE 40 |
| 60575 | 0078 | RESPA DM |
| 60575 | 0087 | RESPA 1 ST |
| 60575 | 0457 | TRIKOF-D |
| 60575 | 0786 | RESPA BR |
| 60575 | 0787 | RESPA-PE |
| 62022 | 0132 | ENTEX PSE CAPSULES |
| 62022 | 0333 | ENTEX LA CAPSULES |
| 62022 | 0334 | ENTEX ER |
| 62037 | 0827 | GENERIC ENTEX LA 30/400 MG |
| 63717 | 0240 | XPECT-AT TABLETS |
| 63717 | 0241 | XPECT PE TABLETS |
| 63717 | 0705 | XPECT HC |
| 64125 | 0126 | GUAIFENESIN & DEXTROMETHARPHEN HBR 1200/60 MG TABLETS |
| 64376 | 0033 | PSEUDO GG TR TABS |
| 64376 | 0539 | GUAIPHEN PD TR TAB |
| 64376 | 0540 | GUAIPHEN D TR TAB |
| 64376 | 0541 | GUAIPHEN D 1200 TR TAB |
| 64543 | 0140 | LIQUIBID D 1200 |
| 64543 | 0150 | LIQUIBID D BIPHASIC TAB |
| 64543 | 0240 | LIQUIBID D 1200 BIPHASIC 90’S |
| 64543 | 0246 | LIQUIBID PD BIPHASIC TAB |
| 66813 | 0036 | DYNEX LA |
| 66813 | 0525 | ENTEX PSE |
| 66813 | 0535 | ENTEX LA |
| 66869 | 0316 | DURADEX FORTE |
| 66869 | 0614 | DURAPHEN DM |

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|---|---|---|
| 66869 | 0616 | DURADEX |
| 66869 | 0626 | DURAMAX TABS |
| 66869 | 0669 | DURAPHEN 1000 |
| 66869 | 0715 | DURAPHEN II DM |
| 66869 | 0805 | DURAPHEN FORTE |
| 66869 | 0822 | DURAPHEN II |
| 66870 | 0012 | AMBIFED-G |
| 66870 | 0015 | AMBIFED-G DM |
| 66870 | 0115 | AMBI 45/800 |
| 66870 | 0116 | AMBI 45/800/30 |
| 66870 | 0118 | AMBI 80/700 |
| 66870 | 0119 | AMBI 80/700/40 |
| 66870 | 0120 | AMBI 1000/55 |
| 66870 | 0121 | AMBI 60/580 |
| 66870 | 0122 | AMBI 60/580/30 |
| 66870 | 0218 | AMBI 80/780 |
| 66870 | 0219 | AMBI 80/780/40 |
| 66870 | 0713 | 05/01/1000 |
| 66870 | 0912 | AMBI 60/1000 |
| 66870 | 0915 | AMBI 60/1000/30 |
| 66870 | 0919 | AMBI 40/1000 |
| 66870 | 0920 | AMBI 40/1000/60 |
| 66993 | 0312 | GUAIFENESIN DM TABLETS 1000/60 MG |
| 66993 | 0325 | GUAIFENESIN/PHENYLEPHRINE TABS |
| 66993 | 0326 | PHENYLEPHRINE/GUAIFENESIN TABS |
| 66993 | 0327 | GUAIFENESIN/PHENYLEPHRINE HCL |
| 66993 | 0328 | PHENYLEPHRINE/GUAIFENESIN TABS |
| 66993 | 0332 | PSE HCI/GUAIFENESIN TABLETS 120/1200 MG |
| 67204 | 0064 | SITREX TABLETS |
| 67204 | 0076 | SITREX TABLETS 20/1200 |
| 67204 | 0273 | ORATUSS 12 TABLETS |
| 68025 | 0002 | ZOTEX LA CAPLETS |
| 68025 | 0005 | ZOTEX GP CAPLETS |
| 68025 | 0018 | ZOTEX LAX CAPLETS |
| 68025 | 0020 | ZOTEX GPX CAPLETS |
| 68025 | 0023 | ZOTEX DMX |
| 68032 | 0133 | GUAPHEN FORTE 1200 MG |
| 68032 | 0134 | GUAPHEN II DM 800 MG |
| 68032 | 0164 | PHENYLEPHRINE HCI 20MG GUAIFENESIN 600MG LA |
| 68032 | 0180 | GUAIFENESIN AND PHENYLEPHRINE HCL |
| 68032 | 0183 | DEXTROMETH HBR 60 MG, PSEUDO 90 MG |
| 68032 | 0184 | PSEUDO HCL 90 MG, GUAIF 800 MG |
| 68032 | 0185 | PSEUDOEPHEDRINE HCL 60 MG GUAIFENESIN 500 MG SR |
| 68032 | 0186 | PSEUDO HCL 45 GUAIFENESIN 800 DEXTROMETHORPHAN HBR 300 LA |
| 68032 | 0187 | PSEUDOEPHEDRINE HCL 45 MG GUAIFENESIN 800 MG LA |
| 68084 | 0115 | GUAIFENSIN W/D-METHORPHARN HBR TAB 1200-60MG |
| 68047 | 0180 | EXETUSS |
| 68047 | 0181 | EXETUSS-GP |
| 68047 | 0183 | GP EXETUSS-DM |
| 68453 | 0550 | DURATUSS CS TABLETS |

The states were previously notified of the FDA's determination that the following NDCs have been subject of a final determination by the FDA that they are new drugs 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 as set forth in 21 CFR 310.502(a)(14). 72 Fed. Reg. 55780 (October 1, 2007). As a result, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are, therefore, no longer eligible for inclusion in the rebate program. They are being deleted from the Medicaid Drug Rebate master file of covered outpatient drugs and should be deleted from state Medicaid Drug Rebate systems:

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|---|---|
| 00095-0130 | ANAPLEX HD COUGH SYRUP |
| 00131-5129 | CODIMAL DH SYRUP |
| 00131-5134 | CODICLEAR DH SYRUP |
| 00225-0420 | KWELCOF |
| 00472-0077 | HYCOSIN EXPECTORANT |
| 00472-0958 | DETUSSIN LIQUID |
| 00485-0052 | ED TLC LIQUID |
| 00485-0053 | ED TUSS HC LIQUID |
| 00603-1111 | CODITUSS DH (AF) SYR |
| 00603-1283 | H-C TUSSIVE-NR SYR 2.5-5-1MG/5ML |
| 00603-1284 | HC TUSSIVE SYRUP |
| 00603-1285 | H-C TUSSIVE D SYR |
| 00603-1625 | QUINDAL-HD 2MG-7.5MG-2MG/5ML SYR |
| 00603-1636 | QUINTEX HC SF DF AF |
| 00603-1799 | TUSSICLEAR DH SYRUP 3.5MG-100MG/5ML |
| 00603-1853 | VI-Q-TUSS LIQ |
| 00682-0420 | MARCOF EXPECTORANT (REVISED FORMULA) |
| 10914-0820 | HC 3.5 MG / GUAI 300 MG SYRUP |
| 10914-0830 | HC 2.5 MG / PE 5 MG / DBROM 1 MG SYRUP |
| 10914-0980 | HYDROCODONE BITARTRATE 3.5 MG/GUAIFENESIN 100 MG SYRUP |
| 12830-0715 | M-CLEAR |
| 12830-0733 | M-END REFORMULATED |
| 12830-0742 | M-CLEAR JR |
| 12830-0752 | M-END MAX |
| 14629-0302 | LEVAL 5.0 |
| 16477-0956 | DONATUSSIN DC SYRUP |
| 23589-0008 | ENDAL HD SYRUP |
| 50991-0322 | POLY-TUSSIN XP (NEW FORMULA) |
| 50991-0603 | POLY-TUSSIN HD |
| 50991-0707 | POLY-TUSSIN (NEW FORMULA) |
| 50991-0714 | POLY HIST HC |
| 50991-0727 | POLY-TUSSIN SYRUP (REVISED FORMULA) |
| 50991-0925 | POLY-TUSSIN XP (EXPECTORANT) |
| 52604-0200 | ENDAGEN-HD |
| 52604-0300 | VANEX-HD |
| 58177-0877 | HISTINEX HC |
| 58177-0881 | CIII HYDROCODONE BITARTRATE/GUAIFENSIN |
| 58177-0883 | HISTINEX PV |
| 58177-0890 | CIII HYDRO-TUSSIN HD |
| 58177-0915 | HYDRO-TUSSIN HC SYRUP (CIII) |
| 58177-0916 | HYDRO-TUSSIN XP |

| | |
|---|---|
| 58605-0534 | MAXI-TUSS HCX |
| 58809-0442 | PHENA-HC |
| 58809-0929 | VANACON |
| 59702-0799 | ATUSS HS |
| 59702-0813 | ATUSS HD CAPSULES |
| 59702-0814 | ATUSS HX CAPSULES |
| 63481-0235 | HYCOTUSS |
| 64376-0035 | PHENYLEPHRINE HD (CIII) |
| 64661-0040 | J-TAN D HC |
| 65224-0610 | Z-COF HCX |
| 66594-0111 | PRO-RED |
| 66594-0222 | PRO-CLEAR |
| 66813-0545 | ENTEX HC |
| 66813-0933 | DYNEX HD |
| 66813-0940 | BROVEX HC |
| 66813-0980 | SYMTAN |
| 66813-0982 | SYMTAN A |
| 66992-0250 | VAZOTUSS HC |
| 66993-0222 | BROMPLEX HD SYRUP 30/2/1.7MG |
| 67204-0320 | ZYMINE LIQUID |
| 67204-0390 | ZYMINE HC LIQUID |
| 67537-0940 | BROMPHENIRAMINE/HYDROCODONE/PSE LIQUID |
| 68025-0032 | ZOTEX HC |
| 68032-0165 | HYDROCODONE BITARTRATE 4.5MG POTASSIUM GUAIACOLSULFONATE 300MG |
| 68032-0167 | HYDROCODONE BITARTRATE 5MG PHENYLEPHRINE HYDROCHLORIDE 5MG |
| 68047-0131 | ENDACOF-HC |
| 68047-0132 | ENDACOF-XP |
| 68047-0133 | ENDACOF-PLUS |
| 68047-0135 | ENDACOF-TAB |
| 68047-0171 | EXECOF-XP |
| 68047-0182 | EXETUSS-HC |
| 68047-0190 | DROTUSS |
| 68047-0191 | DROTUSS-CP |
| 68047-0200 | HYDROFED |
| 68047-0220 | EXECLEAR |
| 68047-0260 | PHENDACOF-HC |
| 68047-0261 | PHENDACOF-PLUS |
| 68308-0134 | D-TANN HC SUSPENSION |
| 68308-0310 | NAZARIN HC LIQUID |
| 68453-0129 | CODIMAL DH SYRUP CIII |
| 68453-0134 | CODICLEAR DH SYRUP |
| 68453-0140 | CODICLEAR DH SYRUP CIII |
| 68453-0145 | CODIMAL DH |
| 68453-0860 | HISTUSSIN HC SYRUP CIII |

**T-BILL AUCTION RATES**

A copy of the current listing of the Treasury Bill auction rates beginning January 07, 2008 is attached. Please note that the Treasury Department has changed the name of this listing from 91-Day to 13-Week.

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

Karen S. Raschke /s/ for

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

cc:
State Drug Rebate Technical Contacts
Regional Administrators

# US T-Bill Auction Results

**Weekly 13-Week Treasury Bill Auction Rates**

| Date of Auction | Investment Rate |
|---|---|
| 01-07-08 | 3.259 |
| 01-14-08 | 3.156 |
| 01-21-08 | 2.424 |
| 01-28-08 | 2.388 |
| 02-04-08 | 2.280 |
| 02-11-08 | 2.301 |
| 02-18-08 | 2.249 |
| 02-25-08 | 2.208 |
| 03-03-08 | 1.823 |
| 03-10-08 | 1.445 |
| 03-17-08 | 1.118 |
| 03-24-08 | 1.220 |
| 03-31-08 | 1.465 |
| 04-07-08 | 1.476 |
| 04-14-08 | 1.078 |
| 04-21-08 | 1.343 |
| 04-28-08 | 1.445 |
| 05-05-08 | 1.639 |
| 05-12-08 | 1.833 |
| 05-19-08 | 1.890 |
| 05-26-08 | 1.905 |
| 06-02-08 | 1.854 |
| 06-09-08 | 1.885 |
| 06-16-08 | 2.089 |
| 06-23-08 | 1.890 |
| 06-30-08 | 1.936 |
| 07-07-08 | 1.900 |
| 07-14-08 | 1.639 |
| 07-21-08 | 1.547 |
| 07-28-08 | 1.726 |
| 08-04-08 | 1.741 |
| 08-11-08 | 1.905 |
| 08-18-08 | 1.885 |
| 08-25-08 | 1.741 |
| 09-01-08 | 1.716 |
| 09-08-08 | 1.721 |
| 09-15-08 | 1.067 |
| 09-22-08 | 1.445 |
| 09-29-08 | 1.100 |
| 10-06-08 | 0.467 |
| 10-13-08 | 0.508 |
| 10-20-08 | 1.271 |

## MDRI Detailed Manufacturer Contact Information Date Range: 05/05/2008 to 01/01/2009

**Labeler Name:** VERUS **Effective Date:** 09/12/2008

**NDC:** 13436 **Transmission Option:** 1 **Termination Date:**

**Legal Information**
TOI WILSON
SCIELE PHARMA, INC.
5 CONCOURSE PARKWAY
SUITE 1800
ATLANTA, GA 30328
(678) 341-1449

**Invoice Information**
JENNIFER CROSSWELL
SCIELE PHARMA, INC.
5 CONCOURSE PARKWAY
ATLANTA, GA 30328
(678) 341-1421

**Technical Information**
JENNIFER CROSSWELL
SCIELE PHARMA, INC.
5 CONCOURSE PARKWAY
ATLANTA, GA 30328
(678) 341-1421

**Labeler Name:** APACE KY LLC DBA APACE PACKAGING, LLC **Effective Date:** 09/25/2008

**NDC:** 15338 **Transmission Option:** 1 **Termination Date:**

**Legal Information**
STEVE RICHARDSON
APACE KY LLC
12954 FOUNTAIN RUN ROAD
P.O. BOX 190
FOUNTAIN RUN, KY 42133
(270) 434-2722 x204

**Invoice Information**
BRENDA MUTTER
APACE KY LLC
12954 FOUNTAIN RUN ROAD
P.O. BOX 190
FOUNTAIN RUN, KY 42133
(270) 434-2722 x201

**Technical Information**
STEVE RICHARDSON
APACE KY LLC
12954 FOUNTAIN RUN ROAD
P.O. BOX 190
FOUNTAIN RUN, KY 42133
(270) 434-2722 x204

**Labeler Name:** PROBACTIVE BIOTECH. INC. **Effective Date:** 06/17/2008

**NDC:** 23110 **Transmission Option:** 1 **Termination Date:**

**Legal Information**
JIMMY NGO
PROBACTIVE BIOTECH, INC.
11555 MONARCH STREET
SUITE B
GARDEN GROVE, CA 92841
(714) 903-1000 x222

**Invoice Information**
HIEU HUYNH
PROBACTIVE BIOTECH, INC.
11555 MONARCH STREET
SUITE B
GARDEN GROVE, CA 92841
(714) 903-1000 x223

**Technical Information**
DR. HENRY SMITH
PROBACTIVE BIOTECH, INC.
11555 MONARCH STREET
SUITE B
GARDEN GROVE, CA 92841
(714) 903-1000 x226

**Labeler Name:** EKR THERAPEUTICS, INC. **Effective Date:** 06/27/2008

**NDC:** 24477 **Transmission Option:** 1 **Termination Date:**

**Legal Information**
RICHARD DESIMONE
EKR THERAPEUTICS, INC.
1545 ROUTE 206 SOUTH
3D FLOOR
BEDMINSTER, NJ 07921
(877) 435-2524

**Invoice Information**
RANDALL PERRY
EKR THERAPEUTICS, INC.
PO BOX 259
ACWORTH, GA 30101-0259
(770) 975-7337

**Technical Information**
RANDALL PERRY
EKR THERAPEUTICS, INC.
PO BOX 259
ACWORTH, GA 30101-0259
(770) 975-7337

**Labeler Name:** ARISTOS PHARMACEUTICALS, INC. **Effective Date:** 06/09/2008

**NDC:** 24486 **Transmission Option:** 1 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| DAVE CLEMENT<br>SMITH ANDERSON, BLOUNT, DORSETT, PHARMACEUTICALS, INC.<br>MITCHEL<br>SUITE 255<br>2500 WACHOVIA CAPITOL CENTER<br>RALEIGH, NC 27602-2611<br>(919) 821-6754 | CHENYQUA BALDWIN<br>ARISTOS PHARMACEUTICALS, INC.<br><br>2000 REGENCY PARKWAY, SUITE 255<br><br>CARY, NC 27518-8511<br>(919) 678-6539 x6507 | CHENYQUA BALDWIN<br>ARISTOS<br><br>2000 REGENCY PARKWAY,<br><br>CARY, NC 27518-8511<br>(919) 678-6539 |

**Labeler Name:** SAGENT PHARMACEUTICALS, INC. **Effective Date:** 08/06/2008

**NDC:** 25021 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| MICHAEL LOGERFO<br>SAGENT PHARMACEUTICALS, INC.<br>LOGISTICS<br>1901 N. ROSELLE ROAD<br>SUITE 700<br>SCHAUMBURG, IL 60195<br>(847) 312-0511<br>53051-4483 | LINDSEY HUNKEL<br>DDN PHARMACEUTICAL LOGISTICS<br><br>W127 N7564 FLINT DRIVE<br>SUITE 200<br>800 WOODLAND PRIME<br>MENOMONEE FALLS, WI 53051-4483<br>(414) 434-4635 | DAN PIERGIES<br>DDN PHARMACEUTICAL<br><br>W127 N7564 FLINT DRIVE<br>SUITE 200<br>800 WOODLAND PRIME<br>MENOMONEE FALLS, WI<br>(414) 434-4630 |

**Labeler Name:** MEDICURE **Effective Date:** 05/15/2008

**NDC:** 25208 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| DEREK REIMER<br>MEDICURE<br>200 COTTONTAIL LANE<br>SOMERSET, NJ 08873<br>(732) 584-5231 | LYNNE MARTON<br>MEDICURE<br>349 BURNING TREE CT.<br>HALF MOON BAY, CA 94019<br>(650) 726-9544 | LYNNE MARTON<br>MEDICURE<br>349 BURNING TREE CT.<br>HALF MOON BAY, CA 94019<br>(650) 726-9544 |

**Labeler Name:** ANESIVA, INC. **Effective Date:** 09/23/2008

**NDC:** 28000 **Transmission Option:** 1 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| SPENCER CHEN<br>ANESIVA, INC.<br>650 GATEWAY BLVD.<br>SOUTH SAN FRANCISCO, CA 94080<br>94080<br>(650) 246-6873 | JOHN TRAN<br>ANESIVA, INC<br>650 GATEWAY BLVD.<br>SOUTH SAN FRANCISCO, CA 94080<br><br>(650) 246-6959 | JOHN TRAN<br>ANESIVA, INC<br>650 GATEWAY BLVD.<br>S SAN FRANCISCO, CA<br><br>(650) 246-6959 |

**Labeler Name:** UNICHEM PHARMACEUTICALS, INC. **Effective Date:** 08/25/2008

**NDC:** 29300 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| RAJEEV LAMBA<br>UNICHEM PHARMACEUTICALS, INC.<br>SHERBROOKE OFFICE CENTER<br>SUITE 301A<br>201 WEST PASSAIC STREET<br>ROCHELLE PARK, NJ 07662<br>(201) 226-0240 | LAURA CARLSON<br>DDN PHARMACEUTICAL LOGISTICS<br>SUITE 200<br>800 WOODLAND PRIME<br>MENOMONEE FALLS, WI 53051<br>(414) 434-4631 | DAN PIERGIES<br>DDN PHARMACEUTICAL<br>SUITE 200<br>800 WOODLAND PRIME<br>MENOMONEE FALLS, WI<br>(414) 434-4630 |

**Labeler Name:** MEDISCA, INC. **Effective Date:** 08/15/2008

**NDC:** 38779 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| DARIAN ZACCARDO<br>MEDISCA, INC.<br>661 ROUTE #3<br>UNIT C<br>PLATTSBURG, NY 12901<br>(800) 665-6334 | MARIANA VETRO<br>MEDISCA, INC.<br>661 ROUTE #3<br>UNIT C<br>PLATTSBURG, NY 12901<br>(800) 665-6334 x257 | MARIANA VETRO<br>MEDISCA, INC.<br>661 ROUTE #3<br>UNIT C<br>PLATTSBURG, NY 12901<br>(800) 665-6334 x257 |

**Labeler Name:** BROOKSTONE PHARMACEUTICALS, LLC **Effective Date:** 09/30/2008

**NDC:** 42192 **Transmission Option:** 3 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| ALLEN FIELDS<br>BROOKSTONE PHARMACEUTICALS, LLC<br>9005 WESTSIDE POARKWAY<br>ALPHARETTA, GA 30009<br>(817) 825-6637 | JEFF FAICH<br>DDN PHARMACEUTICAL LOGISTICS<br>800 WOODLAND PRIME<br>SUITE 200<br>MENOMONEE FALLS, WI 53051<br>(262) 509-2764 | SARIKA ARORA<br>BROOKSTONE<br>9005 WESTSIDE PARKWAY<br>ALPHARETTA, GA 30009<br>(678) 325-5189 |

**Labeler Name:** EMMAUS MEDICAL, INC. **Effective Date:** 08/12/2008

**NDC:** 42457 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| DANIEL R. KIMBELL<br>EMMAUS MEDICAL, INC.<br>20725 S. WESTERN AVE<br>SUITE 136<br>TORRANCE, CA 90501-1884<br>(310) 214-0065 x2004 | THOMAS HART<br>EMMAUS MEDICAL, INC.<br>20725 S. WESTERN AVE<br>SUITE 136<br>TORRANCE, CA 90501-1884<br>(310) 214-0065 x2015 | THOMAS HART<br>EMMAUS MEDICAL, INC.<br>20725 S.WESTERN AVE<br>SUITE 136<br>TORRANCE, CA 90501-1884<br>(310) 214-0065 x2015 |

**Labeler Name:** ALMUS PHARMACEUTICALS USA LLC **Effective Date:** 09/05/2008

**NDC:** 42688 **Transmission Option:** 1 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| ERIC CHRISTENSEN<br>CARDINAL HEALTH<br>7000 CARDINAL PLACE<br>DUBLIN, OH 43017<br>(614) 757-3555 | MARC CHESNES<br>CARDINAL HEALTH<br>7000 CARDINAL PLACE<br>DUBLIN, OH 43017<br>(614) 757-5302 | MARK PILKINGTON<br>CARDINAL HEALTH<br>7000 CARDINAL PLACE<br>DUBLIN, OH 43017<br>(614) 757-7896 |

**Labeler Name:** PIERRE FABRE MEDICAMENT **Effective Date:** 05/14/2008

**NDC:** 64370 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| CHRIS KELLY<br>PIERRE FABRE PHARMACEUTICALS<br>PHARMACEUTICALS<br>9 CAMPUS DRIVE<br>2ND FLOOR<br>PARSIPPANY, NJ 07054<br>(973) 898-1042 x170 | KIM DEWITT<br>PIERRE FABRE PHARMACEUTICALS<br><br>9 CAMPUS DRIVE<br>2ND FLOOR<br>PARSIPPANY, NJ 07054<br>(973) 898-1042 x104 | KIM DEWITT<br>PIERRE FABRE<br><br>9 CAMPUS DRIVE<br>2ND FLOOR<br>PARSIPPANY, NJ 07054<br>(973) 898-1042 x104 |

**Labeler Name:** CHAIN DRUG CONSORTIUM, LLC **Effective Date:** 07/29/2008

**NDC:** 68016 **Transmission Option:** 2 **Termination Date:**

| Legal Information | Invoice Information | Technical Information |
|---|---|---|
| LOU HELFRICH<br>CHAIN DRUG CONSORTIUM, LLC<br>LLC<br>1020 WILLIAM PITT WAY<br>SUITE 338<br>PITTSBURGH, PA 15238<br>(412) 828-2061 | LOU HELFRICH<br>CHAIN DRUG CONSORTIUM, LLC<br><br>1020 WILLIAM PITT WAY<br>SUITE 338<br>PITTSBURGH, PA 15238<br>(412) 828-2061 | LOU HELFRICH<br>CHAIN DRUG CONSORTIUM,<br><br>1020 WILLIAM PITT WAY<br>SUITE 338<br>PITTSBURGH, PA 15238<br>(412) 828-2061 |

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