



January 28, 2008

MEDICAID DRUG REBATE PROGRAM**Release No. 148****For State Medicaid Directors****APPROVAL OF ORTHO-McNEIL PHARMACEUTICALS/HALDOL RECALCULATION**

Ortho-McNeil Pharmaceuticals (formerly McNeil Pharmaceuticals, labeler 00045) recalculated Base Date AMPs for Haldol Tablets and Concentrate. These recalculated Base Date AMPs will result in revised quarterly unit rebate amounts, which was included with 3rd quarter 2007 rebate data provided to the States. As a result, additional rebates may be due the states for first quarter 1994 through the current quarter. Ortho-McNeil intends to pay these additional rebates and applicable interest along with payment of 3rd quarter 2007 invoices. Ortho-McNeil indicated to CMS that they have previously manually calculated and paid rebates to states for earlier quarters (1991-1993) as a result of the Haldol recalculation. (See Medicaid Drug Rebate Program Releases 73 & 75 to State Medicaid Directors.)

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

NEW LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Nexus Pharmaceuticals, Inc. 14789	04/01/2008	11/13/2007
Northstar Rx, LLC 16714	04/01/2008	01/15/2008
Tiber Laboratories, LLC 23589	01/01/2008	08/22/2007
Arbor Pharmaceuticals, Inc. 24338	10/01/2007	08/01/2007
Aton Pharma, Inc. 25010	01/01/2008	10/22/2007
Camber Pharmaceuticals, Inc. 31722	01/01/2008	10/03/2007
JHP Pharmeceuticals, LLC 42023	04/01/2008	01/17/2008
Karalex Pharma, LLC 42043	04/01/2008	01/10/2008
Avanir Pharmaceuticals, Inc. 64597	01/01/2008	08/09/2007
Rare Disease Therapeutics, Inc. 66621	01/01/2008	09/10/2007
Harris Pharmaceutical, Inc. 67405	01/01/2008	09/06/2007
Ascend Laboratories 67877	04/01/2008	12/28/2007
Cephazone Pharma LLC 68330	01/01/2008	08/07/2007
Northstar Rx LLC 68820	01/01/2008	09/04/2007

REINSTATED LABELERS

<u>Labeler Name/Labeler Code</u>	<u>Mandatory Coverage Date</u>	<u>Optional Coverage Date</u>
Reddy's Pharmaceuticals, LLC 67857	01/01/2008	08/29/2007

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

TERMINATED LABELERS

The following labeler code is being terminated effective 10/01/2007:

F. Dohman (aka Healthcare America (HCA)) Labeler Code 64899

The following labeler codes are being terminated effective 01/01/2008:

Elan Pharmaceuticals, Inc. Labeler Code 00086

Stada Pharmaceuticals, Inc. Labeler Code 55370

Stada Pharmaceuticals, Inc. Labeler Code 64860

The following labeler codes are being terminated effective 04/01/2008:

Glaxosmithkline Labeler code 00108

Vintage Pharmaceuticals, Inc. Labeler code 00254

Teva Pharmaceuticals USA Labeler code 38245

Oncology Therapeutics Network Joint Vent. Labeler code 67817

NOTE: The termination of *Laser Pharmaceuticals, LLC*, Labeler Code 68134, effective October 1, 2007 has been rescinded.

VOLUNTARILY TERMINATED LABELERS

The following labelers have requested voluntary termination effective 01/01/2008:

FEI Products LLC Labeler Code 50907

Snuva Incorporated Labeler Code 58291

The following labeler has requested voluntary termination effective 04/01/2008:

Zila Pharmaceuticals, Inc.	Labeler Code 51284
Johnson & Johnson Health Care Systems	Labeler Code 00501
McNeil-PPC, Inc.	Labeler Code 08004
Johnson & Johnson Merck Consumer Pharmaceuticals Company	Labeler Code 16837
McNeil Consumer Healthcare	Labeler Code 50580
Personal Products Company	Labeler Code 62341

PRODUCT DELETIONS FROM MDR

As part of our continuing effort to remove non-rebate-eligible data from the Medicaid Drug Rebate (MDR) system, the following products have been deleted from the MDR master file of covered outpatient drugs:

00074	0103	VI-DAYLIN DROPS MULTIVITAMIN
00074	0105	VI-DAYLIN ADC DRP ADC VITAMIN DROPS
00074	0116	VI-DAYLIN/IRON DRP MULTIVITAMIN WITH IRON
00074	0117	VI-DAYUIR ADC DR MULTIVITAMIN IRON ADC
00074	3606	VI-DAYLIN MULTIVITAMIN LIQUID
00074	4519	VI-DAYLIN CHEW MULTIVITAMIN SUPPLEMENT
00074	4520	VIDAY/IRON CHEW MULTIVITAMIN WITH IRON
00074	6992	VI-DAYLIN W/IRON MULTIVITAMIN WITH IRON
00904	0518	VITAMIN B-6
00904	0520	VITAMIN B-6
00904	2641	CERTA-VITE W/LUTEIN TABS
00904	5486	CERTA-VITE SENIOR W/LUTEIN TABS
00904	5493	CERTA-VITE PERFORMANCE TABLETS
49281	0880	BCG LIVE INTRAVESICAL
51645	0826	OYSTER SHELL CALCIUM 250+D TABS
51645	0827	OYSTER SHELL CALCIUM 500 TABS
51645	0828	OYSTER SHELL CALCIUM 500+D TABS
51645	0829	OYSTER SHELL CALCIUM 500+ D CHEWABLE TABS
00406	8050	LEUPROLIDE ACETATE
00406	8061	DESMOPRESSIN ACETATE
00406	8074	CALCITONIN (SALMON)

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

The following drug was reported by the labeler as DESI Code 2 (i.e., Safe and Effective or non-DESI drug). The FDA has determined that the drug is DESI Code 5 (i.e., Less-than-Effective/IRS Drug) (DESI FR Notice 6514, 02/09/1973). Please be aware that this drug is not rebate eligible.

51991-0513 Quartuss Syrup

The following drug was reported by the labeler as DESI Code 2 (i.e., Safe and Effective or non-DESI drug). The FDA has determined that the drug is DESI Code 5 (i.e., Less-than-Effective/IRS Drug) (FR Notice 20495, 05/06/1983). Please be aware that this drug is not rebate eligible.

68032-0256 Servira

The following products were reported by the labelers as DESI Code 5 (i.e., Less-than-Effective/IRS drug for all indications); however, the FDA has informed us that the drugs are DESI Code 2 (i.e., Safe and effective or non-DESI drug).

68462-0105	Ondansetron Hydrochloride Tablets 4mg 30's
68462-0106	Ondansetron Hydrochloride Tablets 8mg
68462-0162	Carvedilol Tablets 3.125 mg
68462-0163	Carvedilol Tablets 6.25 mg
68462-0164	Carvedilol Tablets 12.5 mg
68462-0165	Carvedilol Tablets 25 mg
68462-0178	Naproxen Sodium Tablets 275mg
68462-0179	Naproxen Sodium Tablets 550mg

STATE ROLE IN DESI PROCESS

Labelers that market new drugs during a rebate period should report the relevant product data, including DESI code, to CMS within thirty days from the end of the rebate period. Each quarter, CMS compiles the report of approximately 1,000 to 2,000 new NDCs to send to the FDA for their review and comment. As part of this review, the FDA ensures that the new NDCs reflect the correct DESI code. In those instances where the review determines that an incorrect DESI code was reported by the labeler, CMS notifies states via fax and the reporting labeler via letter of the error and correction. CMS subsequently publishes any DESI code corrections in a program release.

Prior to CMS's notification of DESI changes/errors to states, some State Medicaid Agency pharmacists have identified potential DESI errors and have notified CMS before the FDA's review has been completed. In many cases CMS is then able to confirm the DESI status with the FDA on an individual NDC basis and to subsequently alert states within twenty-four to forty-eight hours from the state's initial notification.

We appreciate state input on these DESI issues and encourage all states to continue notifying CMS when they are aware of or suspect other potential DESI corrections. In the interest of the Medicaid beneficiaries, CMS and states will continue to work closely to detect and correct DESI code errors as expeditiously as possible. Please send your DESI issues and concerns to the rebate operations email resource box, mdroperations@cms.hhs.gov.

CHANGE IN METHOD OF SENDING STATE NOTIFICATIONS

Future State Program Releases and other state notifications (e.g., new labeler agreements and NDC status changes/corrections) will be shared with states via email rather than mail or fax. Emails will be sent to each state's Technical Contact (TC). As a result, states should review their contact information (including the TC's email address) at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/07_StContactInfo.asp to ensure that it is correct. If you need to update your state contact information, please use the MDR Program State Agency Contact Form (form 368) located at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/15_ContactChangeForm.asp. All changes should be either emailed to MDROperations@cms.hhs.gov or faxed to 410-786-0390 as soon as possible. Although the method of sending these updates is changing, it is important for states to keep all contact information on the form 368 current (including fax numbers, mailing addresses, etc.).

OTHER ATTACHMENTS

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period May 1, 2006, is attached.

Please remember to direct your drug rebate data questions to mdroperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

WEEKLY U.S. T-BILL INVESTMENT RATE

Weekly 91-day Treasury Bill Auction Rates

Date of Auction	Invest. Rate	Date of Auction	Invest. Rate	Date of Auction	Invest. Rate
05-01-06	4.807	12-04-06	4.999	07-02-07	4.930
05-08-06	4.864	12-11-06	4.926	07-09-07	4.956
05-15-06	4.864	12-18-06	4.952	07-16-07	4.982
05-22-06	4.828	12-25-06	5.004	07-23-07	5.029
05-30-06	4.843	01-01-07	5.062	07-30-07	4.966
06-05-06	4.833	01-08-07	5.072	08-06-07	4.909
06-12-06	4.926	01-15-07	5.108	08-13-07	4.763
06-19-06	4.958	01-22-07	5.129	08-20-07	2.919
06-26-06	5.036	01-29-07	5.145	08-27-07	4.732
07-03-06	5.088	02-05-07	5.145	09-03-07	4.472
07-10-06	5.056	02-12-07	5.160	09-10-07	3.901
07-17-06	5.098	02-19-07	5.171	09-17-07	4.160
07-24-06	5.108	02-26-07	5.185	09-24-07	3.922
08-07-06	5.124	03-05-07	5.112	10-01-07	3.942
08-14-06	5.114	03-12-07	5.112	10-08-07	4.030
08-21-06	5.109	03-19-07	5.075	10-15-07	4.300
08-28-06	5.093	03-25-07	5.070	10-22-07	4.004
09-04-06	4.984	04-02-07	5.055	10-29-07	4.025
09-11-06	4.947	04-09-07	5.023	11-05-07	3.642
09-18-06	4.942	04-16-07	5.008	11-12-07	3.518
09-25-06	4.895	04-23-07	4.976	11-19-07	3.476
10-02-06	4.890	04-30-07	4.924	11-26-07	3.254
10-09-06	4.978	05-07-07	4.898	12-03-07	3.104
10-16-06	5.072	05-14-07	4.867	12-10-07	3.073
10-23-06	5.124	05-21-07	4.914	12-17-07	3.073
10-30-06	5.108	05-28-07	4.919	12-24-07	3.363
11-06-06	5.088	06-04-07	4.846	12-31-07	3.394
11-13-06	5.088	06-11-07	4.773	01-07-08	3.259
11-20-06	5.071	06-18-07	4.617	01-14-08	3.156
11-27-06	5.036	06-25-07	4.820	01-21-08	2.424

MDRI Detailed Manufacturer Contact Information

Labeler Name: NEXUS PHARMACEUTICALS, INC.

Effective Date: 11/13/2007

NDC: 14789

Transmission Option: 2

Termination Date:

Legal Information

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Labeler Name: NORTHSTAR RX LLC

Effective Date: 01/15/2008

NDC: 16714

Transmission Option: 1

Termination Date:

Legal Information

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Labeler Name: TIBER LABORATORIES, LLC

Effective Date: 08/22/2007

NDC: 23589

Transmission Option: 2

Termination Date:

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Labeler Name: ARBOR PHARMACEUTICALS, INC.

Effective Date: 08/01/2007

NDC: 24338

Transmission Option: 2

Termination Date:

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Labeler Name: ATON PHARMA, INC.

Effective Date: 10/22/2007

NDC: 25010

Transmission Option: 2

Termination Date:

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Labeler Name: CAMBER PHARMACEUTICALS, INC.

Effective Date: 10/03/2007

NDC: 31722

Transmission Option: 2

Termination Date:

Legal Information

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Labeler Name: JHP PHARMACEUTICALS LLC

Effective Date: 01/17/2008

NDC: 42023

Transmission Option: 1

Termination Date:

Legal Information

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Labeler Name: KARALEX PHARMA, LLC

Effective Date: 01/10/2008

NDC: 42043

Transmission Option: 1

Termination Date:

Legal Information

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Labeler Name: AVANIR PHARMACEUTICALS, INC.

Effective Date: 08/09/2007

NDC: 64597

Transmission Option: 2

Termination Date:

Legal Information

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Labeler Name: RARE DISEASE THERAPEUTICS, INC.

Effective Date: 09/10/2007

NDC: 66621

Transmission Option: 2

Termination Date:

Legal Information

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Labeler Name: HARRIS PHARMACEUTICAL, INC.

Effective Date: 09/06/2007

NDC: 67405

Transmission Option: 1

Termination Date:

Legal Information

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Labeler Name: REDDY PHARMACEUTICALS, LLC

Effective Date: 01/01/2008

NDC: 67857

Transmission Option: 2

Termination Date:

Legal Information

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Labeler Name: ASCEND LABORATORIES, L.L.C.

Effective Date: 12/28/2007

NDC: 67877

Transmission Option: 1

Termination Date:

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Labeler Name: CEPHAZONE PHARMA LLC

Effective Date: 08/07/2007

NDC: 68330

Transmission Option: 2

Termination Date:

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Labeler Name: NORTHSTAR RX LLC

Effective Date: 09/04/2007

NDC: 68820

Transmission Option: 2

Termination Date:

Legal Information

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