



MAY 11 1993

6325 Security Boulevard  
Baltimore, MD 21207



**MEDICAID DRUG REBATE PROGRAM**

**Release Number 29**

**\* \* \* IMMEDIATE ATTENTION REQUIRED \* \* \***

**NOTE TO: All State Medicaid Directors**

**DRUG LABELER TERMINATIONS**

The following terminations are being enforced due to the drug labelers not submitting timely pricing data; the termination date for each of these labelers is July 1, 1993 which is 60 days from the date of the termination notice sent to each labeler. Each labeler was advised, in writing, of its responsibilities for submitting pricing data and for paying rebates.

- Genetco, Incorporated (Labeler Code 00302);
- Landry Pharmaceuticals, Inc. (Labeler Code 00538);
- Columbia Drug Company, Inc. (Labeler Code 11735);
- Connaught Laboratories (Labeler Codes 11793 and 49281);
- Mass Public Health (Labeler Code 14362);
- Drug Guild (Labeler Code 26032);
- Carolina Medical Products (Labeler Code 46287);
- Pasteur Merieux (Labeler Code 50361);
- Quad Pharmaceuticals (Labeler Code 51309);
- Harber Pharmaceuticals, Inc. (Labeler Code 51432);
- Elan Pharmaceutical Research Corporation (Labeler Code 52472);
- Infinity Pharmaceuticals, Inc. (Labeler Code 58154);

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Baron Pharmaceuticals (Labeler Code 58570);

American Generics, Inc. (Labeler Code 58634);

Coral Pharmaceuticals, Inc. (Labeler Code 58729).

The following terminations are voluntary and are effective on July 1, 1993:

Clinical Pharmaceuticals, Inc. (Labeler Code 55081);

Pioneer Pharmaceuticals, Inc. (Labeler Code 60104).

#### DRUG LABELER DELETION

An erroneous, additional labeler code, #35802, for the Almay Corporation (Labeler Code 00311) was detected on the 4-92 pricing tape. It has been deleted from the HCFA data base and is not part of the rebate program. Our thanks to the South Carolina State Medicaid agency for spotting this incorrect labeler code.

#### NEW LABELER CODES

The following drug companies signed rebate agreements which are effective on July 1, 1993. Contact information is attached.

Arcola Laboratories (Labeler Code 00070);

Freeda Vitamins, Incorporated (Labeler Code 10432);

Advanced Nutritional Technology, Inc. (Labeler Code 10888);

Aid-Pack USA (Labeler Code 38206);

Ram Laboratories (Labeler Code 49729);

Creighton Products Corporation (Labeler Code 50752);

L. Perrigo Company (Labeler Code 58948);

Athena Neurosciences, Inc. (Labeler Code 59075);

Dapat, Inc. (Labeler Code 59154);

Atley Pharmaceuticals, Inc. (Labeler Code 59702);

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Bio-Pharm, Incorporated (Labeler Code 59741);

Greenstone Limited (Labeler Code 59762);

Apothecon, Inc. (Labeler Code 59772);

ESI Pharma, Incorporated (Labeler Code 59911).

NOTE: ESI Pharma requests that all rebate invoices be sent to their financial contact.

REINSTATED LABELER CODE

Concord Laboratories (Labeler Code 20254) has furnished all missing pricing data and will be rejoining the rebate program effective July 1, 1993.

DRUG LABELER INFORMATION CHANGES (Contact information attached)

Hoffman-LaRoche, Inc. (Labeler Code 00004) - change to technical contact;

Stuart Pharmaceuticals (Labeler Code 00038) - change to all contacts;

Hoechst-Roussel Pharmaceuticals, Inc. (Labeler Code 00039) - change to financial and technical contacts;

DuPont Pharmaceuticals (Labeler Codes 00056, 00094 & 00590) - change to technical contact;

Schering-Plough Corporation (Labeler Codes 00085 & 00369) - change to technical and financial contacts;

Mission Pharmacal (Labeler Code 00178) - change to financial contact;

Upsher-Smith Laboratories, Inc. (Labeler Code 00245) - change to technical contact;

Geriatric Pharmaceutical Corporation (Labeler Code 00249) - change to technical contact;

Mayrand Pharmaceuticals, Inc. (Labeler Code 00259) - change of address for all contacts;

Laser Incorporated (Labeler Code 00277) - change of address for all contacts;

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Tap Pharmaceuticals, Incorporated (Labeler Code 00300) - change to technical contact;

Zeneca Pharmaceuticals (Labeler Code 00310) - all contacts change;

Mallinckrodt Specialty Chemicals Company (Labeler Code 00406) - change to financial and technical contacts;

Lyphomed Division of Fujisawa (Labeler Code 00469) - change to technical contact;

Lannett Company, Inc. (Labeler Code 00527) - change to technical contact;

Barr Laboratories, Inc. (Labeler Code 00555) - change to technical contact;

Baker Norton Pharmaceuticals, Inc. (Labeler Codes 00575, 11414 & 52891) - change of address for all contacts;

Fisons Corporation (Labeler Code 00585) - change to technical contact;

Kabi Pharmacia, Inc. (Labeler Code 00601) - all contacts change;

Vanguard Labs, Inc. (Labeler Code 00615) - address change for all contacts;

Gensia Laboratories, Inc. (Labeler Code 00703) - change to technical contact;

Logen Pharmaceutical, Inc. (Labeler Code 00820) - change to financial and technical contacts;

Baxter Hyland Division (Labeler Codes 00944 & 47679) - change to technical contact;

Derma Sciences, Incorporated (Labeler Code 25382) - change to technical contact;

Good Health (Labeler Code 33261) - change to financial and technical contacts;

Dr. Rose, Inc. (Labeler Code 42037) - change to technical contact;

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Roberts-Hauck Pharmaceuticals, Inc. (Labeler Code 43797) - change to technical contact;

Bolan Pharmaceutical, Inc. (Labeler Code 44437) - address change for all contacts;

Genentech, Incorporated (Labeler Code 50242) - all contacts changed;

Janssen Pharmaceutica, Inc. (Labeler Code 50458) - change to technical contact;

UDL Laboratories, Inc. (Labeler Code 51079) - change to technical contact;

Dura Pharmaceuticals, Inc. (Labeler Code 51479) - all contacts changed;

Watson Laboratories, Inc. (Labeler Code 52544) - change to financial and technical contacts;

Roberts Laboratories, Inc. (Labeler Codes 54092 & 59441) - change to technical contact;

MOVA Pharmaceutical Corporation (Labeler Code 55370) - change to technical contact;

Fujisawa Pharm. Co. Div. of Fujisawa (Labeler Code 57317) - change to technical contact;

MGI Pharma, Inc. (Labeler Code 58063) - change to financial and technical contacts;

Baker Cummins Dermatologicals, Inc. (Labeler Code 58174) - address change for all contacts;

Nutraceutical Laboratories, Inc. (Labeler Code 58916) - change to financial and technical contacts;

Stratus Pharmaceuticals, Inc. (Labeler Code 58980) - change to technical contact.

**Note:** Stiefel Laboratories which has two labeler codes (00145 for Stiefel Labs and 59366 for Glades Pharmaceuticals) requests that all requests for rebates be sent to their financial contact.

CONTACT CHANGE CLARIFICATION

In release 28, we attached a technical contact change for Baxter Healthcare Corporation (Labeler Code 00338) but incorrectly highlighted the change as belonging to Baxter Labeler Code 47679. The contact change was for labeler code 00338.

DRUG LABELER RELEASE NUMBER 7

Attached is a copy of Release Number 7 that we recently sent to each drug labeler. The main topics in that note concerned the best price exclusions, manufacturers' data reporting requirements, a revised and condensed list of unit types to be implemented later this year and the explanation of the Remittance Advice Report (RAR). Please refer to the manufacturers' letter for detailed explanations of these topics. Below, we have provided a brief summary of the main issues involved.

- o Best Price Exclusions - We clarified for manufacturers which prices charged to a Public Health Service covered entity should be excluded from the calculation of Best Price.
- o Data Reporting Requirements - We reminded manufacturers of their obligation to provide timely information on Average Manufacturer Price (AMP) and Best Price (BP) to HCFA and the potential penalties manufacturers risk for non-compliance.
- o Revised Unit Types - We have revised the number of valid unit types from 18 to 8. These changes include the addition of EACH (EA). Please refer to the list we included in the manufacturers' letter for a description of the revised unit types. As indicated in the letter, we will send to each manufacturer a listing of the revised unit types for its drugs with the corresponding AMP and BP. Manufacturers will notify HCFA of any necessary corrections. We plan to implement the revised unit types later this year.
- o Remittance Advice Report (RAR) - We included in the letter to manufacturers instructions for the completion of the RAR. Although the use of the RAR is not mandatory until the publication of regulations concerning the Medicaid drug rebate program, we are encouraging manufacturers to begin using the RAR now.

At this time, the RAR is to be generated by the labelers and relates only to rebates paid rather than being used as both an invoice by the State and a remittance advice report by the manufacturer. However, it may become a turn-around document in the future.

**POLICY CLARIFICATION FOR THE CALCULATION OF INTEREST UNDER SECTION V(b) OF THE REBATE AGREEMENT**

The following is an overview of the interest provisions of the Medicaid Drug Rebate program. For purposes of section V(b) of the rebate agreement, the interest rate as specified in section 1903(d)(5) of the Act is used. The interest rate is based on the yield of the weekly 90-day Treasury bill auction rates. The investment yield is considered the bond equivalent rate or the true discount rate.

Auctions of 90-day Treasury bills are generally held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Tuesday. Information on the rates will be provided by HCFA to the manufacturers and State Medicaid Agencies periodically in the State Medicaid Director/Manufacturer letters to assure both parties are using the same interest rates in their calculations.

Interest is applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments. Interest will begin ← accruing on disputed or unpaid amounts 38 calendar days from the date the State mails the State utilization data, as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage meter stamp). Note that this is a revision to the policy described in our Release Number 15 to States. In that release, we specified that interest on unpaid amounts accrues beginning on the 31st day after the manufacturer receives utilization data from a State. We are now including 7 additional days to allow time for receipt by the manufacturer of the mailing.

This revised policy allows sufficient time for the mailing and receipt of the State utilization data while reducing costs previously associated with return receipt requests.

For documentation purposes, States must maintain a record of the date of mailing and manufacturers must maintain the envelope bearing the postmark from the State.

Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all quarters beginning January 1, 1991 and only stops accruing on the date the check is disbursed. We consider the date of disbursement to be the date the check is mailed by the manufacturer. Interest must be collected and may not be disregarded as part of the dispute resolution process by the State or manufacturer.

The interest calculation is based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. (For purposes of this calculation, include the rate for the entire week if the beginning and/or ending date fall within that week.) To calculate the interest rate to be applied to disputed rebate amounts, use the following formula:

1. Total the yield of each weekly auction of 90-day Treasury bills during the period for which interest will be charged.
2. Divide the total from Step 1 by the number of rates to determine the average interest rate.
3. Multiply the average interest rate from Step 2 by the unpaid rebate amount that is outstanding to obtain the amount of interest due.
4. Divide the amount of interest due from Step 3 by 365 days to obtain the daily amount of interest due.
5. Multiply the daily amount of interest due from Step 4 by the number of days that the unpaid rebate amount is outstanding to obtain the total interest due. Interest is applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments. The first day of interest starts on the 38th day after the State mails the State utilization data to the labeler(s), as evidenced by the postmark.

**Example:**

The State sends a manufacturer utilization data postmarked 01/25/93, resulting in rebates due totalling \$5,400 for the 4th quarter of 1992. Within 30 days after receipt of the data, the manufacturer pays \$4,400 of that amount and disputes the remaining \$1,000. Interest starts accruing on 3/4/93, which is the 38th day after the State mailed the data. Subsequently, the manufacturer decides that the State data are correct and pays the remaining \$1,000 by check mailed on 4/2/93.



In this example, interest is accrued for the period 3/4/93 through 4/1/93. The check from the manufacturer must include the principal of \$1,000 plus interest calculated as follows:

Obtain yield rates (bond equivalent rates) for period involved:

**AUCTION DATES AND YIELD RATES**

3/01/93	3.035%
3/08/93	3.043%
3/15/93	3.064%
3/22/93	3.003%
3/29/93	3.022%

- Step 1. Total the yield rates of each weekly auction of 90-day Treasury Bill.  
Total: 15.167%
- Step 2. Divide the total from Step 1 by the number of rates to determine the average interest rate.  
15.167% divided by 5 = 3.0334% Average Interest Rate.
- Step 3. Multiply average interest rate by amount of unpaid rebate.  $\$1,000 \times 3.0334\% = \$30.33$  Amount of Interest Due.
- Step 4. Divide the amount of interest due by 365 days to obtain the amount of interest due per day.  $\$30.33$  divided by 365 days =  $\$.08309$  = Amount of Interest Due Per Day.
- Step 5. Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding.  $\$.08309 \times 29$  days (3/4/93-4/1/93) =  $\$2.41$  Total Interest Due


**THEREFORE, THE AMOUNT OF THE CHECK SHOULD BE \$1,002.41.**

To reiterate, when a manufacturer pays the State for disputed rebate amounts or late rebate payments, the manufacturer must also pay all interest due. If a manufacturer fails to reimburse the State for the interest due, the interest calculations described above will apply to the unpaid balance. The unpaid interest will be treated as principal due, and interest will begin accruing as of the date the manufacturer paid the original disputed invoice amount. Interest will continue accruing on the unpaid balance of the principal for all quarters and stop accruing the date the check is mailed by the manufacturer.

RECEIPT OF STATE UTILIZATION DATA

Effective with this latest notice, we will begin attaching a copy of our internal State Tapes Status Report which we use to ascertain which States have submitted data and how many NDCs were included with each quarter's data transmission. We anticipate changing the format for this report in the near future when we add additional information showing when the State transmittal of data notice was received by HCFA.

Please continue to contact us for all other concerns by using the Drug Rebate hotline at (410) 966-3249.

  
Richard Blumenthal  
Rozann Abato  
Acting Director *for*  
Medicaid Bureau

3 Attachments

CC:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid

## STATE TAPES STATUS REPORT

5/10/93

STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92	ALL QTRS
AK	X	X	X	X	X	X	X	X	X
AL	X	X	X	X	X	R	X	X	
AR	X	X	X	X	X	X	X	X	X
CA	X	X	X	X	X	X	X		
CO	X	X	X	X	X	X	X	X	X
CT	X	X	X	X	X	X	X		
DC	X	X	X	X	X	X		X	
DE	X	X	X	X	X				
FL	X	X	X	X	X	X	X	X	X
GA	X	X	X	X	X	X	X	X	X
HI	X	X	X	X	X	X	X	X	X
IA	X	X	X	X	X	X	X	X	X
ID	X	X	X	X	X	X	X	X	X
IL	U	X	X	X	X	X	X		
IN	X	X	X	X	X	X	X	X	X
KS	X	X	X	R	X	X	X	X	
KY	X	X	X	X	X	X	X	X	X
LA	X	X	X		X	X	X	X	
MA	X	X	X	X	X	X	X		
MD	X	X		X	X	X	X	X	
ME	X	X	X	X	X	X	X	*X	*X
MI	X	X	X	X	X	X			
MN	X	X	X	X	X	X	X	X	X
MO	X	X	X	X	X	X	X	X	X
MS	U	X	X		X	X	X	X	
MT	X	X	X	R	X	X	X	X	
NC	X	X	X	X	X	X	X	X	X
ND	X	X	X	X	X	X	X	X	X
NE	X	X	X	X	X	X	X		X
NH	X	X	X	X	X	X		X	
NJ	X	X	X	X	X	X	X		
NM	U	U	X	X	X	X	X		
NV	R	X	X	X	X	X	X	X	
NY	X	X	X	X	X				
OH	X	X	X	X	X	X	X	X	X
OK	X	X	X	R	X	X	X	X	
OR	X	X	X	X	X	*X		*X	
PA	X	X	X	X	X				
RI	X	X	X	X	X	X	X	X	X
SC	X	X	X	X	X	X	X	X	X
SD	X	X	X	X	X	X	X	X	X
TN	X	X	X	X	X	X	X	X	X
TX	X	X	X	X		X	X	X	
UT	R	X	X	X	X	X			
VA	X	X	X	X	X	X			

**STATE TAPES STATUS REPORT**

STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92	ALL QTRS
VT	X	X	X	X	X	X	X	X	X
WA	X	X	X	X	X	X	X	X	X
WI	X	X	X	X	X	X	X	X	X
WV	X	X	X	X	X	X	X	X	X
WY	X	X	X	X	X	X	X	X	X
<b>TOTAL</b>	<b>47(45)</b>	<b>49(49)</b>	<b>49(49)</b>	<b>48(45)</b>	<b>49(49)</b>	<b>47(46)</b>	<b>41(41)</b>	<b>37(37)</b>	<b>26</b>

\* - Tapes received since last (4/26/93) Report.

X - Files processed; good data.

R - Files rejected and must be corrected.

U - State is unable to generate and submit tapes for this Quarter.

Totals shown in parentheses indicate number of usable tapes received.

## STATE DISPOSITION STATUS REPORT

5/10/93

STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92
AK	4252	4894	5232	5305	5329	5471	5407	5518
AL	6745	11899	13893	14932	15542		15355	15723
AR	14565	15852	15191	15171	14967	14470	14219	14663
CA	8142	11026	11500	11279	10871	10791	9207	
CO	7026	7837	9010	9019	9327	9909	10138	10382
CT	9278	8330	11074	11669	11683	12123	12022	
DC	5451	6214	6584	6556	7337	7316		6816
DE	5556	1716*	6800	7119	7410			
FL	19360	22136	21784	20985	21369	21295	21633	21289
GA	14603	17609	17781	18152	17741	17993	17345	16381
HI	7168	8000	1947*	8458	8331	8249	8451	8261
IA	14040	15171	15396	15562	15976	15617	15701	15007
ID	8155	8795	9038	8981	9434	9541	9091	9116
IL		1370*	21498	22514	22050	21431	21258	
IN	20237	22273	22506	23727	23526	23659	19742	19536
KS	9053	10514	11414		11870	12029	12190	12063
KY	12793	15926	16554	16898	17336	17539	17484	17624
LA	1785*	16659	15555		16013	15971	15699	15485
MA	11936	12639	3735*	13977	14243	13889	14690	
MD	13192	14291		14530	15995	14537	14671	14340
ME	8172	8416	8470	8830	9115	9046	9042	9021
MI	2305*	16257	16554	17069	17205	17335		
MN	12852	13491	13722	13891	13688	13927	13480	14050
MO	11955	17499	19716	20550	20304	21182	20678	20678
MS		5942	13878		15166	15808	15807	15805
MT	7477	8647	8811		9148	9316	9117	9133
NC	9866	10528	14705	15165	15658	15436	15814	15750
ND	6180	6743	6798	6854	7021	6980	6885	6658
NE	2347*	2505*	2510*	7460	7570	7333	7909	
NH	7740	7415	9509	9222	10626	9856		9792
NJ	14801	15849	17058	16807	16321	16806	15309	
NM			10471	10924	10869	10442	10206	
NV		7247	7039	7431	7635	7739	7609	7952
NY	17836	18723	20107	21445	21736			
OH	18484	20018	21435	21659	22213	21528	21517	21529
OK	10995	11583	12401		1969*	2070*	12791	13135
OR	10990	10392	9722	12089	11323	11717		12641
PA	20848	23048	22976	23746	23324			
RI	8231	9064	9247	9135	9605	9590	9388	9316
SC	12917	13856	14090	13859	13332	13363	13353	13447
SD	5317	6815	7577	7346	7517	7550	7508	6920
TN	15997	17348	18398	18663	19223	19095	18161	18367
TX	13653	14502	14713	14039		15420	15279	15255
UT		10539	10309	10517	10853	10904		
VA	17056	19116	18762	19347	18230	19154		

**STATE DISPOSITION STATUS REPORT****2**

<b>STATE</b>	<b>1/91</b>	<b>2/91</b>	<b>3/91</b>	<b>4/91</b>	<b>1/92</b>	<b>2/92</b>	<b>3/92</b>	<b>4/92</b>
<b>VT</b>	<b>6255</b>	<b>6860</b>	<b>7005</b>	<b>7259</b>	<b>7356</b>	<b>7395</b>	<b>7324</b>	<b>7353</b>
<b>WA</b>	<b>12197</b>	<b>12868</b>	<b>12852</b>	<b>12756</b>	<b>13714</b>		<b>13486</b>	<b>13691</b>
<b>WI</b>	<b>6024</b>	<b>15380</b>	<b>15994</b>	<b>15986</b>	<b>16161</b>	<b>16198</b>	<b>16244</b>	<b>16406</b>
<b>WV</b>	<b>1352*</b>	<b>9122</b>	<b>11244</b>	<b>11405</b>	<b>11568</b>	<b>11444</b>	<b>11920</b>	<b>10885</b>
<b>WY</b>	<b>5322</b>	<b>6404</b>	<b>6293</b>	<b>6621</b>	<b>5425</b>	<b>6075</b>	<b>6305</b>	<b>6223</b>
<b>TOTAL</b>	<b>45</b>	<b>49</b>	<b>49</b>	<b>45</b>	<b>49</b>	<b>45</b>	<b>41</b>	<b>37</b>

\* - Indicates States submitting less than 5000 records in a Quarter.  
Totals shown indicate number of States submitting usable tapes.