**August 1, 2002**

**MEDICAID DRUG REBATE PROGRAM** **RELEASE #117**

# For State Medicaid Directors

## CONFUSION WITH EON LABS (LABELER 00185) PRODUCT

We were contacted by a state with a concern about Eon Labs reusing an NDC for a new product where the old product had not, as yet, been reported as terminated. The NDC is 00185-0111-01. The "old" product is SMX-TMP SS (bactrium) and the labeler wants to use this NDC for their generic version of Ritalin – AMPHETAMINE SALT COMBO. Eon has been submitting pricing for SMX-TMP SS up to and including q1/2002.

After some investigation, we found out that 1) EON did stop producing this drug (SMX-TMP SS) in 1993, but failed to submit a termination date and 2) they kept submitting pricing, based on the last quarter of sales (from 1993). In checking our utilization history submitted by the states, we found that this drug has had no state utilization activity since 1994. Because the FDA rules state that an NDC may be used for a new product after the old product (under this NDC) has been terminated for more than 5 years, EON is within its right to submit new product and pricing data for (their generic version of) Ritalin using this old NDC (0111-01).

## NOVARTIS ROUNDING *ALL* URAs BACK TO 1991

Due to differences between Novartis URAs and CMS', Novartis attempted to realign their URAs to match ours. They changed each AMP/BP (back to 1991 for ***ALL*** of their labeler codes) **FROM** itself **TO** itself so that our system would recalculate ALL URAs and create PPA records that would be reported to the states, changing the URA only by rounding to the 4$^{th}$ place and filling positions 5 and 6 with zeros; but not changing the actual URA.

When changes are sent to CMS (pricing or baseline), the system examines each field, replacing those (fields) on history with those from the change record that contain a different value. Because Novartis changed a price back to itself, it, in effect, made no change, thus, no PPAs were generated and sent out and agreement of URA values between Novartis and CMS was not accomplished. If any state is having a problem with the action taken by Novartis, please contact Vince Powell on (410) 786-3314.

## NEW ADDRESS FOR DRUG POLICY QUESTIONS

Effective immediately, we are discontinuing the drugrebatepolicy@cms.hhs.gov e-mail box for policy questions on the Medicaid drug program. CMSO recently established a Pharmacy Team (referred to as the PharmT), comprising seven drug policy analysts and co-directed by Larry Reed and Deirdre Duzor. If you have a policy question, please address it to the PharmT lead analyst for your state, as shown on the attached chart.

## NEW INTERNET WEB SITE ADDRESS FOR DRUG REBATE

The new web site address for the Medicaid Drug Rebate Program is www.cms.hhs.gov/medicaid/drugs/drughmpg.asp.

## DISPUTE RESOLUTION PROGRAM (DRP) NATIONAL MEETINGS

We are pleased to announce that the next National DRP meetings will be held September 24 - September 26 in Denver. These meetings are a continuation of the highly successful meetings held in Denver since 1998. Nearly $1 billion in formerly disputed rebates have been resolved through the DRP and these meetings have been cited by many states and manufacturers as essential to the resolution of outstanding rebate disputes.

While these meetings are open to all states and manufacturers, we strongly encourage those with significant amounts in dispute to attend. Since it is unclear at this time because of budget and resource limitations as to whether we will be conducting other DRP meetings beyond these, it is profoundly important that you take advantage of the opportunity to attend these meetings in September. Further, we are requesting that, if possible, states plan on arriving in Denver in time to attend a “States-only” meeting with the DRP Team Tuesday morning September 24th. We will provide details on that meeting later.

Historically, our September DRP meetings have been the most heavily attended of all our national meetings. Due to CMS travel limitations, we have been forced to constrict this session; therefore, we may not be able to accommodate all states and manufacturers that wish to attend the September meeting.

As in the past, prior planning is absolutely imperative to the success of these meetings so we are requesting that you PROMPTLY complete the attached registration form and return it as instructed to Diane Dunstan, the National DRP Regional Office (RO) Coordinator. Whenever possible, priority scheduling will be afforded those who respond first. We will ensure that we provide adequate DRP staff to conduct the meetings based on your timely responses. Equally important, you should begin planning now in order to obtain satisfactory accommodations in Denver.

Please feel free to contact any of the RO DRP Team members for any dispute-related issue and they will coordinate with Diane, the RO lead in Denver. Of course, you may contact Tami Bruce, the DRP Central Office (CO) Coordinator or Mike Keogh, the DRP Team Leader, on any rebate dispute matter. Tami may be reached at (410) 786-1519 or and Mike at (410) 786-5910 or . If you have any specific questions regarding the National DRP meeting in Denver, please contact Diane Dunstan at (303) 844-7040 or ddunstan@cms.hhs.gov.

**NEW LABELERS**

| Labeler Name/Labeler Code | Mandatory Coverage Date | Optional Coverage Date |
|---|---|---|
| Trisenox (Labeler Code 60553) | 10/01/2002 | 06/10/2002 |
| United Therapeutics Corporation (Labeler Code 66302) | 10/01/2002 | 06/19/2002 |
| Novavax, Inc. (Labeler Code 66500) | 10/01/2002 | 06/20/2002 |
| MSP Marketing Services (c) LLC (Labeler Code 66582) | 10/01/2002 | 07/29/2002 |
| Pharmelle, LLC (Labeler Code 66663) | 10/01/2002 | 07/15/2002 |
| VistaPharm, Inc. (Labeler Code 66689) | 10/01/2002 | 07/17/2002 |
| Parenta Pharmaceuticals, Inc. (Labeler Code 66758) | 10/01/2002 | 05/14/2002 |
| Wraser Pharmaceuticals (Labeler Code 66992) | 10/01/2002 | 07/03/2002 |
| Prasco Laboratories (Labeler Code 66993) | 10/01/2002 | 06/05/2002 |
| Colorado Biolabs, Inc. (Labeler Code 67181) | 10/01/2002 | 06/06/2002 |
| For Ever Young Products, Inc. (Labeler Code 67197) | 10/01/2002 | 07/16/2002 |
| Pharmion Corporation (Labeler Code 67211) | 10/01/2002 | 07/23/2002 |

Contact information for the new labelers is attached for your convenience.

**TERMINATED LABELERS**

The following labeler code is being terminated effective October 1, 2002:

Zoetica Pharmaceutical Corporation (Labeler Code 64909).

The following labeler codes are being voluntarily terminated effective October 1, 2002:

Syntex Laboratories, Inc. (Labeler Code 00033);
Perrigo Company (Labeler Code 00113);
Center Laboratories (Labeler Code 00268);
ParMed Pharmaceuticals, Inc. (Labeler Code 00349).
Pfizer Pharmaceuticals Group (Labeler Code 00710);
Luitpold Pharmaceuticals (Labeler Code 10797);
Pharmaceutical Ventures, LTD (Labeler Code 50057);
Qualitest Pharmaceuticals, Inc. (Labeler Code 52446);
Praxis Biologics (Labeler Code 53124);
Vintage Pharmaceuticals, LLC (Labeler Code 53404);
SmithKline Beecham Corporation (Labeler Code 57294);
InSource, Inc. (Labeler Code 58441;
Peters Laboratories, Inc. (Labeler Code 58728; and
EM Pharma (Labeler Code 63254).

**OTHER ATTACHMENT**

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period February 26, 2001, is attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations

4 Attachments
cc:
All State Drug Rebate Technical Contacts
All Regional Administrators