May 7, 2002

MEDICAID DRUG REBATE PROGRAM **RELEASE #115**

For State Medicaid Directors

FDA/MDRI PRODUCT MATCH

Last year, in state release #107, dated June 27, 2001 and labeler releases #51 and #52, dated June 27, 2001 and September 19, 2001, respectively, I told you about a new operations initiative where we would be matching the MDRI master file to the FDA drug file and removing those products and /or package sizes that were not reported to the FDA as required under the FDA Drug Listing act of 1972. We did an initial match in October, sent the results to each affected labeler, and gave them a 2 quarter lead time to report them to the FDA so they would stay on the MDRI master file as covered drugs.

This month after we "shut down" for the q1/2002 Unit Rebate Amount (URA) processing, we will again perform the FDA/MDRI match. A file of non-matches (i.e., NDCs on the MDRI but not on the FDA file) will be supplied to each state, with a cover letter explaining that these NDCs are being deleted from the MDRI master file and will not be carried or covered by the drug rebate program beginning July 1, 2002. It will be each state's responsibility to assure non-coverage of these NDCs. A listing of the deleted NDCs for each labeler code will be generated and sent to the affected labelers.

There have been several calls to the operations staff from labelers during the past month expressing their concern that their drug reports to the FDA may not have made it on the FDA listed/pending file before the March 31 cutoff. In order to assist in this area, we will be matching the (above mentioned) deleted NDCs to the FDA file after the **q2/2002** URA run, in mid-August. Those NDCs that missed the March 31 date, but are on the June 30

FDA file will be restored (including pricing history) to the MDRI master file. A report of these will be sent to each state and they will be instructed that these NDCs are to be restored and covered as of q4/2002, thus having their coverage terminated for only one quarter. Listings to affected labelers will also be provided.

Please contact a member of the drug rebate operations staff listed in section "O" of the operations guide with questions regarding this procedure.

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
SDA Laboratories, Inc. (Labeler Code 66424)	07/01/2002	04/15/2002
Xanodyne Pharmacal, Inc. (Labeler Code 66479)	07/01/2002	04/17/2002
Biocodex Incorporated (Labeler Code 66825)	07/01/2002	04/16/2002
ProEthic Laboratories, LLC (Labeler Code 66869)	07/01/2002	04/28/2002

REINSTATED LABELERS

Miza Pharmaceuticals USA, Inc. (Labeler Code 52238) and EMT-RX (Labeler Code 64054) have signed new rebate agreements and will be reinstated in the drug rebate program effective July 1, 2002.

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

TERMINATED LABELERS

The following labelers are being voluntarily terminated as of July 1, 2002:

3M Pharmaceuticals (Labeler Codes 21200 and 51131); and
PTS Labs (Labeler Code 65005).

OTHER ATTACHMENTS

A copy of the topic index and a 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.

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

3 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

May 7, 2002

TO: All State Technical Contacts
Medicaid Drug Rebate Program

In release no. 115 on page 2, paragraph 1, we incorrectly refer to drugs being reinstated as of q3/2002. The reinstatement quarter should read "q4/2002." Please pen/ink this change on your release. I apologize for any inconvenience this may have caused.

Vince Powell
Technical Director
CMS,CMSO, FSQG, DSS
Drug Rebate Program