

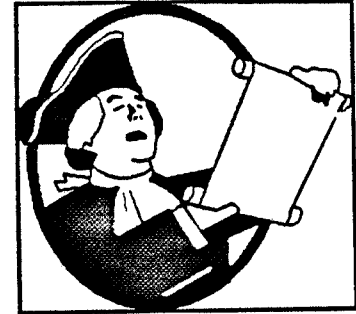
6325 Security Boulevard  
Baltimore, MD 21207

NOV 24 1992

**MEDICAID DRUG REBATE PROGRAM**

Release No. 26

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



NOTE TO: All State Medicaid Directors

**LESS THAN EFFECTIVE/IDENTICAL, RELATED OR SIMILAR (LTE/IRS) DRUGS**

As you are aware, the pricing tape for the third quarter of 1992 contains the final version of DESI Code indicators to be used to identify LTE/IRS drugs. There was a coordinated eight week effort by both federal personnel and State volunteers to contact every drug labeler that had assigned a "5" or "6" to a drug product not on the Food and Drug Administration (FDA) LTE/IRS list. Additionally, HCFA sent to each drug labeler a complete listing of its drug products identified by NDC, DESI Code and drug name with the instruction to verify each drug product's DESI Code value and to send corrections to HCFA by October 31, 1992. Many corrections were received by us and entered into the HCFA data base.

**DIPYRIDAMOLE ISSUE:** Per a Department of Health and Human Services Appeal Board decision reached in October, all dipyridamole, regardless of manufacturer, is deemed to be effective. We have changed the DESI Code Indicator field to a "2" for all NDCs which show dipyridamole in the drug name. As the FDA intends to appeal that decision, there may be a reversal on this drug at a future point in time.

Since the DESI Code values can be changed on a quarterly basis by drug labelers, the HCFA ADP system was modified to monitor changes to the DESI Code Indicator field to ensure that all NDCs marked as LTE by the FDA are unchanged. It would be prudent for State personnel to ensure that their ADP systems check the DESI Code Indicator field each quarter for changes.

The DESI Code values contained on the third quarter pricing tape are effective for the quarter beginning January 1, 1993. Likewise, the DESI Code values on subsequent quarterly pricing tapes will always be effective on the first day of the next quarter after the quarter in which the pricing tape is received. (e.g. Qtr 92-4 file received during February 1993 - DESI Code indicators are effective for quarter 93-2 which begins on April 1, 1993.)

MEDICAL SUPPLIES AND DEVICES

The FDA has begun identifying products that should be classified as devices and supplies rather than medications. As you know, devices and supplies may be covered by Medicaid at State option and, if covered, are eligible for FFP. However, devices and supplies are excluded from the drug rebate program. The following products are classified as supplies or devices and, therefore, should not be invoiced for rebates:

<u>NDC</u>	<u>PRODUCT NAME</u>	<u>COMPANY</u>
00005-2720-25	PPD TINE TEST 25X1 TEST	LEDERLE
00005-2720-28	PPD TINE TEST 100X1 TEST	LEDERLE
00005-2722-25	TUBERCULIN TINE, OLD 25X1 TEST	LEDERLE
00005-2722-28	TUBERCULIN TINE, OLD 100X1 TEST	LEDERLE
00005-2722-34	TUBERCULIN TINE, OLD 250X1 TEST	LEDERLE
00028-5567-01	BRETHANCER (SPACER-INHALER)	GEIGY
00058-0709-50	SCHIRMER TEAR TEST STRIPS	IOLAB

Additionally, four States are invoicing the E.R. Squibb & Sons Company for NDCs 00003-1877-10, 00003-1877-11 and 00003-1877-15 which identify a bandage called DuoDerm. This product is classified as a medical device by the FDA. Accordingly, Duoderm has never been reported to HCFA by the labeler as a drug product and should not be invoiced.

We will share this information with you as we receive it from the FDA.

VACCINE BEING DELETED

The following NDC has been identified as a vaccine, has been deleted from the HCFA data base and should be deleted from your files:

<u>NDC</u>	<u>Name</u>
00118-9945-12	Mixed Vespid Maintenance Kit

NEW LABELER CODES

The following drug companies signed rebate agreements which are effective on January 1, 1993:

Good Health (Labeler Code 33261) - contact information is attached.

Foxmeyer Drug Company (Labeler Code 52297) - contact information is attached.

Ion Labs, Incorporated (Labeler Code 55532) - contact information is attached. NOTE: THIS LABELER IS NOT TO BE CONFUSED WITH ION LABORATORIES, INCORPORATED (LABELER CODE 11808) LOCATED IN FORT WORTH, TEXAS.

Geri-Care Pharmaceuticals Corporation (Labeler Code 57896) - contact information is attached.

Professional Pharmacy Packaging (Labeler Code 58469) - contact information is attached.

Wilcole Pharmaceuticals, Incorporated (Labeler Code 58918) - contact information is attached.

Horus Therapeutics (Labeler Code 59229) - contact information is attached.

Glades Pharmaceuticals (Labeler Code 59366) - contact information is attached.

Pharmakraft, Incorporated (Labeler Code 59516) - contact information is attached.

West Point Pharma (Labeler Code 59591) - contact information is attached.

DRUG LABELER TERMINATIONS

Effective December 21, 1992:

Uni-Gen, Incorporated (Labeler Code 51203).

This company appears to have gone out of business. Mail is sent back as undeliverable and the telephone number is no longer in service.

Effective January 1, 1993:

Bolar Pharmaceutical Company, Incorporated (Labeler Code 00725);

Spectrum Chemical Mfg. Corporation (Labeler Code 49452).

These are voluntary terminations. Personnel at these companies are aware that their companies remain responsible for paying rebates for prior calendar quarters.

DRUG LABELER INFORMATION CHANGES (Contact sheets attached.)

Reed and Carnrick (Labeler Code 00021) - change to technical contact.

The Purdue Frederick Company (Labeler Code 00034) - all contacts are changed.

William P. Poythress, Incorporated (Labeler Code 00095) - all contacts are changed.

West-Ward Pharmaceutical Corporation (Labeler Code 00143) - change to legal and financial contacts.

The Gray Pharmaceutical Company (Labeler Code 00152) - all contacts are changed.

Scherer Laboratories, Incorporated (Labeler Code 00274) - all addresses changed.

Schein Pharmaceutical, Incorporated (Labeler Code 00364) - all addresses changed.

Steris Laboratories, Incorporated (Labeler Code 00402) - all addresses changed.

Hall Laboratories, Incorporated (Labeler Code 00417) - change to legal and technical contacts.

American Regent Laboratories, Incorporated (Labeler Code 00517) - all addresses changed.

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

Danbury Pharmacal, Incorporated (Labeler Code 00591) - all addresses changed.

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Qualitest Products, Incorporated (Labeler Code 00603) - all addresses changed.

Cetus Oncology (Labeler Code 00702) - all addresses changed.

Major Pharmaceuticals, Incorporated (Labeler Code 00904) - all addresses changed.

Perry Medical Products (Labeler Code 11763) - change to legal and technical contacts.

Somerset Pharmaceuticals, Incorporated (Labeler Code 39506) - all addresses changed.

Royce Laboratories, Incorporated (Labeler Code 51875) - change to technical contact.

Cetus Oncology (Labeler Code 53905) - all addresses changed.

Stafford-Miller (Labeler Code 55372) - change to technical contact.

Esquire Pharmaceuticals, Incorporated (Labeler Code 55629) - all contacts are changed.

R-A Pharmaceuticals (Labeler Code 58743) - all addresses changed.

Otsuka America Pharmaceutical, Incorporated (Labeler Code 59148) - change to financial and technical contacts.

Pioneer Pharmaceuticals, Incorporated (Labeler Code 60104) - change to legal and technical contacts.

#### INFORMATION CORRECTIONS

On page 10 of Release Number 19 dated May 18, 1992, we identified MGI Pharma as labeler code 58062. That is incorrect! The correct labeler code for MGI Pharma is 58063. Our thanks to the personnel at Illinois Medicaid for spotting this problem.

In Release Number 23 dated August 11, 1992, we included contact change information about a number of labelers. Inadvertently, we failed to highlight changes in the body of that release to Parmed Pharmaceuticals, Incorporated (Labeler Code 00349) and Janssen Pharmaceutica, Incorporated (Labeler Code 50468). However, the sheets containing the change information were attached to Release 23. Our thanks to Wanda Morris, Georgia Medicaid, for bringing this oversight to our attention.

NATIONAL DRUG CODE (NDC) DELETIONS

The following NDCs should be deleted from your data bases:

<u>NDC</u>	<u>Name</u>	<u>Termination Date</u>
00008-0608-01	Codeine 30MG/MG Tubex	09/30/90
00008-0609-01	Codeine 60MG/ML Tubex	09/30/90
00046-0251-81	Anacin 3 - Codeine	04/30/89
00178-0232-01	Folicet	07/31/88
00603-4098-21	Indomethacin 50MG Cap	n/a
00603-4112-21	Isosorbide Sublingual 2.5MG Tab	n/a
00603-4199-21	Isosorbide Oral	n/a

INCORRECT INVOICING

Kabi Pharmacia (Labeler Code 00016) reports that there are States reporting the drug product, Cyklokapron (NDC 00016-0114-00), under their other labeler code 00601 and mailing their invoices to Kabi Pharmacia in Clayton, North Carolina instead of Kabi Pharmacia in Piscataway, New Jersey. Additionally, there are States reporting unit usage under both labeler codes and sending invoices to both locations. Eight States have been notified by Kabi Pharmacia. Please ensure that your State system is processing invoices correctly for this drug product.

FACSIMILE TELEPHONE NUMBERS FOR STATE CONTACT PERSONNEL

It was suggested that we get important information to State contact personnel as fast as we can by using facsimile transmissions. In order for this to occur, we need to know the facsimile telephone number where the technical and/or policy contact wishes to receive a facsimile transmission for drug rebate issues. (We assume this number to be different than the number used by the Medicaid director for facsimile transmissions.) If you wish to be included in this additional line of communication, please send your facsimile telephone number information to HCFA via mail or facsimile transmission at (410) 966-0390. We will attempt to get this new process in place by January 1, 1993.

QUARTERLY LABELER CONTACT FILE

At the request of several State technical contact personnel, we will begin sending the drug labeler contact file to you on diskette each calendar quarter. The next diskette will be sent to you on or about January 15, 1993.

Please continue to contact us by using the Drug Rebate Hotline number at (410) 966-3249.



Christine Nye  
Director  
Medicaid Bureau

*for*

8 Attachments

CC:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid