



Center for Medicaid and State Operations

August 14, 2008

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Products-Immediate Action Required

CMS previously notified you that many NDCs containing extended release guaifenesin should be deleted from your Medicaid Drug Rebate systems, effective immediately. In addition to the products included on those previous notifications, the FDA has also determined that the following active NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval as set forth in 21 CFR 310.502(a)(14). 72 Fed. Reg. 29517 (May 29, 2007). As a result, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are therefore no longer eligible for inclusion in the rebate program. **Consequently, these NDCs should be deleted from your state Medicaid Drug Rebate system as of the date of this notice.** The labelers of these products are responsible for paying rebates on any of these NDCs that were dispensed prior to the date of this notice. In addition, states should be aware that the third quarter 2008 tape to states will be the last quarterly tape that will include these NDCs in order to facilitate rebate billing for any utilization that occurred in good faith prior to the date of this notice. However, states are reminded that no Federal Financial Participation will be available for these drugs after the date of this notice.

Please note that this list does not include comparable NDCs with termination dates that are equal to a date earlier than the date of this notice. As the last lot shelf life date (i.e. termination date) for such NDCs has already passed, the products aren't being included here since states should have previously ceased payment of those NDCs as of those termination dates.

NDC	Product Name
59243-0011	RU TUSS 800 TABS
59243-0012	RU-TUSS 800 DM TABLETS
59243-0017	RU TUSS JR. TABS
66813-0036	DYNEX LA
67204-0273	ORATUSS 12 TABLETS
68047-0180	EXETUSS
68047-0181	EXETUSS-GP
68047-0183	EXE-TUSS-DM
68453-0550	DURATUSS CS TABLETS