



Center for Medicaid and State Operations

December 11, 2008

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Products-Immediate Action Required

The FDA has determined that the following active Quinine 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 that the drugs cannot be marketed without appropriate FDA approval as set forth in a December 15, 2006 Federal Register Notice (71 Fed. Reg. 75557). According to the FDA, these products do not have approved New Drug Applications; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently 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 fourth 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 for purposes of the Medicaid Drug Rebate Program.

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
00172-3001	QUININE SULFATE
00172-4171	QUININE SULFATE CAPSULES USP 200MG
00172-4172	QUININE SULFATE CAPSULES USP 325MG
00591-0716	QUININE SULFATE 325MG