



Center for Medicaid and State Operations

March 6, 2009

TO: Drug Rebate Technical Contacts
FROM: Medicaid Drug Rebate Program
SUBJECT: Deleted Products-Immediate Action Required

The FDA has determined that the following active ergotamine tartrate 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 July 27, 1972 Federal Register Notice (37 Fed. Reg. 15032) and subsequent Warning Letters issued by the FDA on February 26, 2007. 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 first quarter 2009 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
00603-2423	BELLASPAS TAB
00904-2548	BELLAMINE
52152-0115	BELLAMINE S TAB