DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-13-15
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification

June 30, 2010

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Products--Immediate Action Required

The FDA has determined that the following active NDCs are unapproved new drugs within the meaning of section 301(a) and (d) and Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d) and 355(a) and the drugs are misbranded in violation of Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1), subject to enforcement action, and cannot be marketed without appropriate FDA approval. According to the FDA, these products do not have approved applications; therefore, CMS has determined that 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, the following NDCs should be deleted from your state Medicaid Drug Rebate system as of the date of this notice.** The labeler of these products is responsible for paying rebates on any of the NDCs if they were dispensed prior to the date of this notice. In addition, states should be aware that the second quarter 2010 tape to states will be the last quarterly tape that will include the 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 (FFP) will be available for these drugs after the date of this notice for purposes of the Medicaid Drug Rebate Program. As a reminder, while these products are not eligible for Medicaid coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan.

NDC	Product Name
00603-1314	**HYOSCYAMINE SULFATE DROPS (15 ML)**
00603-1315	**HYOSCYAMINE SULFATE LIQUID (16 OZ)**
00603-5141	**PHENAZOPYRIDINE HC1 (O.1G) TABLETS**
00603-5142	**PHENAZOPYRIDINE HC1 (O.2G) TABLETS**