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 and State Operations

October 16, 2008

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Product-Immediate Action Required

We previously notified you of some drug products containing hydrocodone that did not meet the definition of a covered outpatient drug. Following is an additional NDC that the labeler added with their second quarter 2008 submission.

The FDA has determined that the following NDC is an unapproved new drug 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. 55780 (October 1, 2007). As a result, this NDC does not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and is therefore no longer eligible for inclusion in the rebate program. **Consequently, this NDC should be deleted from your state Medicaid Drug Rebate system as of the date of this notice.** The labeler of this product is responsible for paying rebates on this NDC that was 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 this NDC 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 this drug after the date of this notice.

NDC	**Product Name**
50383-0043	HYDROCODONE