



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

We previously notified you of some drug products containing carbinoxamine that did not meet the definition of a covered outpatient drug. Since then, the FDA has determined that the following additional active NDC containing carbinoxamine is also 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 71 Fed. Reg. 33462 (June 9, 2006). 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 if it was 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 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
58177-0924	HYDRO-TUSSIN CBX 16 OZ.