



Center for Medicaid and State Operations

August 27, 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 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 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, these NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are therefore 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 third 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.

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
00095-0130	ANAPLEX HD COUGH SYRUP
00131-5129	CODIMAL DH SYRUP
00131-5134	CODICLEAR DH SYRUP
00225-0420	KWELCOF
00472-0077	HYCOSIN EXPECTORANT
00472-0958	DETUSSIN LIQUID
00485-0052	ED TLC LIQUID
00485-0053	ED TUSS HC LIQUID
00485-0055	ED A HIST LIQUID
00603-1111	CODITUSS DH (AF) SYR
00603-1283	H-C TUSSIVE-NR SYR 2.5-5-1MG/5ML

NDC	Product Name
00603-1284	HC TUSSIVE SYRUP
00603-1285	H-C TUSSIVE D SYR
00603-1625	QUINDAL-HD 2MG-7.5MG-2MG/5ML SYR
00603-1636	QUINTEX HC SF DF AF
00603-1799	TUSSICLEAR DH SYRUP 3.5MG-100MG/5ML
00603-1853	VI-Q-TUSS LIQ
00682-0420	MARCOF EXPECTORANT (REVISED FORMULA)
10914-0820	HC 3.5 MG / GUAI 300 MG SYRUP
10914-0830	HC 2.5 MG / PE 5 MG / DBROM 1 MG SYRUP
10914-0980	HYDROCODONE BITARTRATE 3.5 MG/GUAIFENESIN 100 MG SYRUP
12830-0715	M-CLEAR
12830-0733	M-END REFORMULATED
12830-0742	M-CLEAR JR
12830-0752	M-END MAX
14629-0302	LEVAL 5.0
16477-0956	DONATUSSIN DC SYRUP
23589-0008	ENDAL HD SYRUP
50991-0322	POLY-TUSSIN XP (NEW FORMULA)
50991-0603	POLY-TUSSIN HD
50991-0707	POLY-TUSSIN (NEW FORMULA)
50991-0714	POLY HIST HC
50991-0727	POLY-TUSSIN SYRUP (REVISED FORMULA)
50991-0925	POLY-TUSSIN XP (EXPECTORANT)
52604-0200	ENDAGEN-HD
52604-0300	VANEX-HD
58177-0877	HISTINEX HC
58177-0881	CIII HYDROCODONE BITARTRATE/GUAIFENSIN
58177-0883	HISTINEX PV
58177-0890	CIII HYDRO-TUSSIN HD
58177-0915	HYDRO-TUSSIN HC SYRUP (CIII)
58177-0916	HYDRO-TUSSIN XP
58605-0534	MAXI-TUSS HCX
58809-0442	PHENA-HC
58809-0929	VANACON
59702-0799	ATUSS HS
59702-0813	ATUSS HD CAPSULES
59702-0814	ATUSS HX CAPSULES
63481-0235	HYCOTUSS
64376-0035	PHENYLEPHRINE HD (CIII)
64661-0040	J-TAN D HC
65224-0610	Z-COF HCX
66594-0111	PRO-RED
66594-0222	PRO-CLEAR
66813-0545	ENTEX HC

NDC	Product Name
66813-0933	DYNEX HD
66813-0940	BROVEX HC
66813-0980	SYMTAN
66813-0982	SYMTAN A
66992-0250	VAZOTUSS HC
66993-0222	BROMPLEX HD SYRUP 30/2/1.7MG
67204-0320	ZYMINE LIQUID
67204-0390	ZYMINE HC LIQUID
67537-0940	BROMPHENIRAMINE/HYDROCODONE/PSE LIQUID
68025-0032	ZOTEX HC
68032-0165	HYDROCODONE BITARTRATE 4.5MG POTASSIUM GUAIACOLSULFONATE 300MG
68032-0167	HYDROCODONE BITARTRATE 5MG PHENYLEPHRINE HYDROCHLORIDE 5MG
68047-0131	ENDACOF-HC
68047-0132	ENDACOF-XP
68047-0133	ENDACOF-PLUS
68047-0135	ENDACOF-TAB
68047-0171	EXECOF-XP
68047-0182	EXETUSS-HC
68047-0190	DROTUSS
68047-0191	DROTUSS-CP
68047-0200	HYDROFED
68047-0220	EXECLEAR
68047-0260	PHENDACOF-HC
68047-0261	PHENDACOF-PLUS
68308-0134	D-TANN HC SUSPENSION
68308-0310	NAZARIN HC LIQUID
68453-0129	CODIMAL DH SYRUP CIII
68453-0134	CODICLEAR DH SYRUP
68453-0140	CODICLEAR DH SYRUP CIII
68453-0145	CODIMAL DH
68453-0860	HISTUSSIN HC SYRUP CIII