



Center for Medicaid, CHIP and Survey & Certification

Disabled and Elderly Health Programs Group

May 4, 2011

TO: State Drug Rebate Technical Contacts

FROM: Larry Reed
Director, Division of Pharmacy

SUBJECT: Deleted Products--Immediate Action Required

In accordance with the notice published in the Federal Register titled, "Drugs for Human Use: Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough or Allergy; Enforcement Action Dates", the following active cold, cough and allergy NDCs qualify as unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, are subject to enforcement action, and should not be marketed without appropriate Food and Drug Administration (FDA) approval (76 Fed. Reg. 11794 (March 3, 2011)). Therefore, in accordance with the notice, we have determined that the NDCs listed below 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 unapproved oral cold, cough and allergy NDCs should be deleted from your State Medicaid Drug Rebate database as of the date of this notice.**

The labelers of these products are responsible for paying rebates on these NDCs for any State utilization that occurred prior to the date of this notice. In addition, States should be aware that the second quarter 2011 rebate file will be the last quarterly rebate file that will include these NDCs in order to facilitate rebate billing for such utilization.

Please note that the list below may not be an all-inclusive list of the products that are subject to this FDA enforcement action; therefore, we may remove additional oral cough, cold and allergy products at a later time as we are able to identify other NDCs to which this Federal Register Notice applies. Should you become aware of NDCs that you believe are subject to the FDA's Federal Register Notice on unapproved oral, cough, cold and allergy drug products, please send a list of those NDCs to our email resource box at mdroperations@cms.hhs.gov.

NDC	Product Name
00037-0655	RYNA 12 SUSP
00037-0673	RYNA-12 TITRATABLE TABLETS
00037-0692	TUSSI-12D TABS
00037-0693	TUSSI-12D SUSPENSION
00037-1708	RYNA-12X TABLETS

00037-4214	ORGANIDIN NR LIQUID
00037-4312	ORGANIDIN NR TABS
00037-6301	SINA-12X TABLETS
00095-0645	LODRANE 12 D TABLETS
00095-1200	LODRANE 24 EXTENDED RELEASE CAPSULES
00095-1290	LODRANE 24 D EXTENDED RELEASE CAPSULES
00185-1304	CPM 8MG/PSEUDO ER 120MG
00277-0160	DALLERGY TABLETS
00277-0182	DALLERGY CAPLETS
00277-0183	DALLERGY-JR CAPSULES
00485-0054	ED A-HIST TABS
00485-0055	ED A-HIST LIQUID
00485-0071	ED-A-HIST DM
00485-0072	ED-CHLOR-TAN
00485-0074	ED CHLORPED
00603-1066	CARDEC ORAL DROPS 1MG-3.5MG/1ML 30ML
00603-1068	CARDEC DM ORAL DROPS 1MG-3.5MG-3MG/1ML 30ML
00603-1069	CARDEC DM SYRUP 4MG-12.5MG-15MG
00603-1328	IOPHEN NR LIQUID LIQ
00603-1330	IOPHEN-DM NR LIQ
00603-4886	ORGAN-I-NR
00642-0645	TUSSO-DMR
10122-0650	ALLERX DOSEPACK
10122-0702	ALLERX D
10122-0704	ALLERX DOSEPACK DF
10122-0705	ALLERX DOSEPACK PE
11528-0115	TENAR PSE
11528-0120	TENAR DM
13811-0001	Z-DEX PEDIATRIC DROPS
13811-0002	Z-DEX SYRUP
13811-0003	Z-DEX 12D
15370-0006	RU-TUSS DM SYRUP
16477-0130	DONATUSSIN DM SUSPENSION
16477-0132	DONATUSSIN DM SYRUP
16477-0146	DALLERGY PSE TABLET
16477-0819	DALLERGY SYRUP
23359-0003	EXPECTUSS
23359-0011	DOXYTEX
23589-0011	VIRAVAN-P SUSPENSION
23589-0013	VIRAVAN-PDM
24839-0346	RYNEZE LIQUID
28595-0110	SERADEX LA 6-19 MG
28595-0602	ALLRES G
42192-0507	BP 8 COUGH SUSPENSION
50383-0871	CP DEC ORAL DROPS
50383-0873	CP DEC-DM ORAL DROPS
50991-0126	POLY HIST DM
50991-0320	POLY-TUSSIN DM
50991-0412	POLYTAN

50991-0607	ALA-HIST LQ
51991-0131	TRITAL DM LIQUID
51991-0145	COLFED A CAPSULES
51991-0211	DYNATUSS-EX SYRUP
51991-0513	QUARTUSS SYRUP
51991-0534	ALLERGY DN II TABLETS
51991-0591	DURADRYL CHEWABLE TABLETS
51991-0633	GUIADRINE DX LIQUID
54838-0123	GUAIFENESIN-NR LIQUID
54838-0124	GUAIFENESIN DM NR LIQUID
54838-0542	SILDEC PE SYRUP
54838-0544	SILDEC PE-DM SYRUP
58605-0274	BROVEX ADT SUSPENSION
58605-0277	BROVEX PD SUSPENSION
58605-0414	AMBIFED
58605-0415	AMBIFED DM
58809-0303	CARBA-XP
58809-0536	CARBATUSS
58809-0707	CARBATUSS-CL
60258-0220	DEHISTINE SYRUP
60258-0221	CHLOR-MES D LIQUID
60258-0238	CORFEN-DM
60258-0239	DECHLOR DM LIQUID
60258-0240	DE-CHLOR DR LIQUID
60258-0246	CHLORDEX GP
60258-0262	GANI-TUSS DM NR LIQUID
60258-0335	DYPHYLLINE-GG ELIXIR
60258-0371	DY-G LIQUID
60258-0395	NEUTRAHIST PEDIATRIC DROPS
60258-0414	CERON SYRUP
60258-0415	CERON DM SYRUP
60258-0425	PULMARI-GP SYRUP
60258-0426	SIMUC-DM ELIXER
60258-0429	BROMHIST PDX SYRUP
60258-0431	TUSDEC DM SYRUP
60258-0446	BROMHIST DM SYRUP
60258-0760	DIHYDRO-CP
60258-0761	DIHYDRO-GP
60258-0762	DIHYDRO-PE
60575-0619	RESPAHIST 2
63717-0290	NASOHIST DROPS
63717-0291	NASOHIST DM DROPS
63717-0552	CORZALL LIQUID
63717-0554	EXALL LIQUID
63717-0555	EXALL D LIQUID
64376-0530	PCM CHEWABLE TAB
64376-0537	PHENCARB GG SYRUP
64376-0543	BPM 6MG TAB
64376-0544	BPM PSEUDO 6/45MG TAB

64376-0546	PSEUDO CM NF TAB
64376-0707	P CHLOR GG DROPS
64376-0710	PDM GG SYRUP
64376-0711	DEX PC SYRUP
64376-0712	PSEUDO DM GG SYRUP
64376-0714	CPM PSE SYRUP
64376-0716	PSEUDOEPHEDRINE GG SYRUP
64376-0721	PSE BPM LIQUID
64376-0723	PEDIAHIST DM SYRUP
64376-0726	C PHEN DM DROPS
64376-0727	C PHEN DM SYRUP
64376-0728	C PHEN DROPS
64376-0729	C PHEN SYRUP
64376-0733	PSUEDO COUGH LIQUID
64376-0737	DEXPHEN M SOLN
64543-0091	RESCON MX
64543-0096	RESCON TABLETS
64661-0050	J-TAN D SR 100TB
66870-0030	MAXIPHEN ADT
66870-0701	TIME-HIST QD
66992-0146	LUSONAL LIQUID
66992-0230	VAZOBID
68013-0007	BROMPHENIRAMINE TANNATE CHEWABLE 12MG
68013-0014	VISRX DOSE PACK
68032-0191	REME TUSSIN DM
68032-0192	REME HIST DM
68032-0276	GUAIFENESIN 200MG/ PHENYLEPHRINE HYDORCHLORIDE 5 MG SYRUP
68032-0320	SONAHIST DM PEDIATRIC DROPS
68032-0324	BROMPHENIRAMINE MALEATE 1MG DROPS
68032-0325	BROMPHENIRAMINE MALEATE 1MG/PSEUDOEPHEDRINE 7.5 MG DROPS
68032-0326	SONAHIST PEDIATRIC DROPS
68032-0368	RE PHENYLEPHRINE 1.5 MG / GUAIFENESIN 20 MG DROPS
68047-0153	EXEFEN DMX
68047-0160	NOHIST
68047-0167	NOHIST-DMX
68047-0270	CORYZA-DM
68047-0330	SUDAHIST