DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid, CHIP and Survey & Certification

Disabled and Elderly Health Programs Group

October 4, 2011

TO: State Drug Rebate Technical Contacts

FROM: Larry Reed
Director, Division of Pharmacy

SUBJECT: Deleted Products--Immediate Action Required

On May 4, 2011, CMS provided you with a list of cough, cold and allergy NDCs that were no longer eligible for coverage under the Medicaid Drug Rebate Program. In addition to the products included on that initial notification, the FDA has also determined that the following NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act 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" (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 fourth 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 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
00642-0647	TUSSO-ZMR CAP
00642-0649	TUSSO-ZR SYRUP
23589-0002	HISTEX LIQUID
23589-0004	ACCUHIST DROPS
50383-0856	TANNATE 12D SUSPENSION

51991-0286	MINTUSS DR SYRUP
51991-0493	TRIPLEX DM LIQUID
51991-0537	QUARTUSS DM DROPS
51991-0597	GUIATEX PE SYRUP
64543-0085	NEW RESCON JR TABLETS
64543-0090	NEW RESCON MX
66992-0136	VAZOL-D LIQUID
66993-0534	R-TANNA TABLETS
66993-0537	R-TANNA S PEDIATRIC SUSP 5/4.5MG
68032-0211	RE DRYLEX SYRUP