

Center for Medicaid, CHIP, and Survey & Certification

April 29, 2010

TO: Drug Rebate Technical Contacts

FROM: Medicaid Drug Rebate Program

SUBJECT: Deleted Products--Immediate Action Required

The FDA has determined that the following active Exocrine Pancreatic Insufficiency 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. 69 Fed. Reg. 23410 and 72 Fed. Reg. 60860 (April 28, 2004 and October 26, 2007). According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs 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, the following Exocrine Pancreatic Insufficiency 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 the NDCs if they were dispensed prior to the date of this notice. In addition, states should be aware that the second quarter 2010 tape to states will be the last quarterly tape that will include the 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 (FFP) will be available for these drugs after the date of this notice for purposes of the Medicaid Drug Rebate Program. As a reminder, while these products are not eligible for Medicaid coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan.

NDC	Product Name
00032-1205	CREON5CAPSULES
00032-1210	CREON10CAPSULES
00032-1220	CREON20CAPSULES
00091-4175	KUTRASE CAPSULES RX
10267-2737	PANCRELIPASE 8,000 TABLETS
39822-9045	PANCRELIPASE 4,500
39822-9100	PANCRELIPASE 10,000
39822-9160	PANCRELIPASE 16,000
39822-9200	PANCRELIPASE 20,000
58177-0028	PANGESTYME MT 16 CAPSULES

58177-0029	PANGESTYME CN 10 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0030	PANGESTYME CN 20 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0031	PANGESTYME EC CAPSULES
58177-0048	PANGESTYME UL 12 CAPSULES
58177-0049	PANGESTYME UL 18 CAPSULES
58177-0050	PANGESTYME UL 20 CAPSULES
58177-0416	PLARETASE
58914-0002	ULTRASE MT 12
58914-0004	ULTRASE MT 20
58914-0018	ULTRASE MT18
58914-0045	ULTRASE MS 4
58914-0111	VIKASE
58914-0115	VIKASE 8OZ POWDER
58914-0116	VIKASE 16000
59767-0001	PANCRECARB MS-8
59767-0002	PANCRECARB MS-4
59767-0003	PANCRECARB MS-16