The Medical Letter®

On Drugs and Therapeutics

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IN BRIEF

Pancreatic Enzyme Products

Pancreatic enzyme products (PEPs) have been used for decades to improve digestion in patients with insufficient pancreatic enzyme production, such as those with cystic fibrosis. All porcine-derived PEPs contain a mixture of amylases, lipases and proteases. Since use of PEPs preceded the Federal Food, Drug and Cosmetic Act of 1938, they have been marketed without formal FDA approval,[1] and major differences have been reported between the actual enzyme content in the product and the amount indicated on the label.[2] In 1991, the FDA announced that all manufacturers of PEPs would be required to submit a new drug application (NDA) for their products to remain on the market; the approval deadline for submitted NDAs was April 28, 2010. As of the deadline, only 3 PEP products had been approved by the FDA and are available commercially. Manufacturers of unapproved PEPs are no longer allowed to distribute their products. Patients taking an unapproved PEP will be required to switch to an FDA-approved product.

Table 1. FDA-Approved PEPs

Product	Cost[1]
Creon (Solvay)	$92.90
Pancreaze (Ortho-McNeil)	87.59[2]
Zenpep (Eurand)	78.89

1. Cost of 100 capsules of lowest available dosage form, according to *Red Book* 2010.
2. Cost according to a local retail chain pharmacy.

1. FDA. Exocrine pancreatic insufficiency drug products-submitting NDAs. April 2006. Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071651.pdf. Accessed January 31, 2011.
2. M Kraisinger et al. Clinical pharmacology of pancreatic enzymes in patients with cystic fibrosis and in vitro performance of microencapsulated formulations. J Clin Pharmacol 1994; 34:158.