



February 14, 2001

Dr. Lilia Talarico  
Director of the Division of GI and Coagulation Products  
FDA (HFD 180)  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Talarico:

As the medical director at the Cystic Fibrosis Foundation, it has been brought to my attention that some patients with cystic fibrosis (CF) are receiving the generic pancreatic products to the detriment of their health. Pharmacists are substituting the generic without the knowledge or consent of the patient or the physician. On behalf of the CF community, I ask the Food and Drug Administration take action to ensure that all generic enzymes are taken from the marketplace.

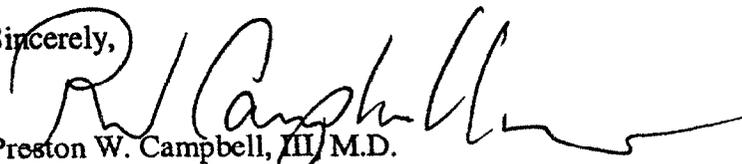
These products are "unapproved" according to the FDA's final rule, published on April 25, 1995, which declared that exocrine pancreatic insufficiency drug products, whether marketed on an OTC or prescription basis, are new drugs for which approved applications are required for marketing. Such applications require efficacy or bioequivalence studies.

Although these products provide symptomatic relief for patients with pancreatitis, they are life sustaining to patients with CF who require them at every meal throughout their lives. Accompanying this letter are examples of what has occurred to our patients because these substitutions were made. These adverse consequences were the result of the pharmacists substituting unapproved generic versions for brand name products. To summarize, there has been decreased fat absorption, as a result of the generics because they are not bioequivalent and could result in decreased weight gain, growth retardation, worsening lung disease and earlier death.

Again, we ask that the FDA take immediate and decisive action to prevent further harm to CF patients.

Thank you for considering our request and I hope to speak to you personally in the future.

Sincerely,

  
Preston W. Campbell, III, M.D.  
Executive Vice President for Medical Affairs

CC: Dr. Florence Houn  
Dr. Robert Meyer  
Mr. Don Hare  
Mr. Herb Gurstenzang