



Office of Orphan Products Development (HF-35)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

August 20, 2003

Bohdan Hugel  
US Agent for Now Pharm AG  
3250 Glase Road  
Danielsville, PA 18038

Re: Designation Request # 03-1693

Dear Mr. Hugel:

Reference is made to your request, submitted on behalf of Now Pharm AG, for orphan-drug designation dated February 27, 2003, of 5,5',5"-[phosphinothiolyldiylne-tris(imino-2,1-ethanediyl)] tris[5-methylchelidoninium] trihydroxide hexahydrochloride for the treatment of pancreatic cancer. Reference is also made to our acknowledgement letter dated April 8, 2003.

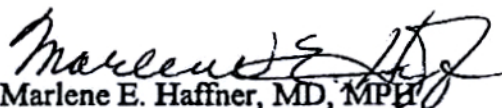
Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bb), your request for orphan drug designation of 5,5',5"-[phosphinothiolyldiylne-tris(imino-2,1-ethanediyl)] tris[5-methylchelidoninium] trihydroxide hexahydrochloride for the treatment of pancreatic cancer is granted.

Please note that it is the active moiety of the drug and not its formulation that is designated. Please also note that if the above product receives marketing approval for an indication broader than what is designated, it may not be entitled to exclusive marketing rights under section 527 (21 U.S.C. § 360cc). Therefore, prior to final marketing approval, we request that you compare the product's designated orphan indication with the proposed marketing indication, and submit additional information to amend the orphan-drug designation if warranted.

Please submit to the Office of Orphan Products Development a brief progress report of drug development within 14 months after this date and annually thereafter until marketing approval (see 21 C.F.R. § 316.30). Finally, please notify this Office within 30 days of a marketing application submission for the product's designated use.

If you need further assistance in the clinical development of your product, please feel free to contact John J. McCormick, MD, at (301) 827-3666. Please refer to this letter as official notification and congratulations on obtaining your orphan-drug designation.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Marlene E. Haffner". The signature is fluid and cursive, with a large, stylized initial "M" and "H".

Marlene E. Haffner, MD, MPH  
Rear Admiral, United States Public Health Service  
Director, Office of Orphan Products Development