



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

March 7, 2005

Mr. Peter S. Reichertz, Esq.
Sonnenschein Nath & Rosenthal LLP
1301 K Street, N.W.
Suite 600 East Tower
Washington, D.C. 20005

Dear Mr. Reichertz:

Your petition to the Food and Drug Administration submitted on behalf of Luitpold Pharmaceuticals, Inc., to request that the Commissioner of Food and Drugs withhold approval of any Abbreviated New Drug Application (ANDA) or any application for any generic version or other pharmaceutical alternative of Venofer, was received by this office on 03/04/2005. It was assigned docket number 2005P-0095/CP 1 and it was filed on 03/04/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0095

ACK 1