



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 31 2005

Food and Drug Administration
Rockville MD 20857

4423 5 SEP -6 P3:06

Richard Lawrence
Director of Research and Development
Luitpold Pharmaceuticals, Inc.
P.O. Box 9001
Shirley, New York 11967

Re: Docket No. 2005P-0095/CP1

Dear Mr. Lawrence:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated March 3, 2005. Your petition requests that the Food and Drug Administration withhold approval of any Abbreviated New Drug Application or any 505(b)(2) application for a generic version or other pharmaceutical alternative of Venofer (iron sucrose injection, USP) unless or until certain conditions are satisfied. You also request that FDA establish guidelines for approval of any such applications referencing Venofer (iron sucrose injection, USP).

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0095

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