

Peter S. Reichertz
202.408.9222
preichertz@sonnenschein.com

1301 K Street N.W.
Suite 600, East Tower
Washington, D.C. 20005
202.408.6400
202.408.6399 fax
www.sonnenschein.com

*Chicago
Kansas City
Los Angeles
New York
San Francisco
Short Hills, N.J.
St. Louis
Washington, D.C.
West Palm Beach*

3033 5 AUG 10 A9:46

August 9, 2005

VIA FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97P-0324/CP1
Citizen Petition Requesting That FDA Withdraw Approval of
Intramuscular Indication for InFeD® Injectable Iron Dextran

Dear Sir/Madam:

This letter confirms my telephone conversation of yesterday with Brian Pendleton, Regulatory Counsel, Center for Drug Evaluation and Research, indicating that our client Luitpold Pharmaceuticals, Inc., requests that FDA act on the above-referenced petition. It does not agree to withdraw it, and, for the reasons stated therein, including the complete lack of any data demonstrating that InFeD® (Iron Dextran Injection, USP) is safe for intramuscular injection, requests that the Agency respond to the Petition as required by 21 C.F.R. § 10.30.

Please note the change of address for counsel of record:

Peter S. Reichertz
Sonnenschein Nath & Rosenthal LLP
1301 K Street, N.W.
Suite 600, East Tower
Washington, DC 20005
202-408-9222 (phone)
202-408-6399 (fax)
preichertz@sonnenschein.com (e-mail)

97P-0324

LET 3

Division of Dockets Management (HFA-305)
August 9, 2005
Page 2

Should there be any questions, please contact the undersigned.

Respectfully submitted,

SONNENSCHN NATH & ROSENTHAL LLP

By:



Peter S. Reichertz

Filed in Triplicate

cc: Mr. Brian Pendleton, Esq.
Regulatory Counsel
U.S. Food and Drug Administration
Woodmont Office Complex 2
1451 Rockville Pike
Rockville, MD 20852