



**Arent Fox Kintner Plotkin & Kahn, PLLC**  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339  
Phone 202/857-6000  
Fax 202/857-6395  
www.arentfox.com

April 29, 2002

**Peter S. Reichertz**  
202/857-6378  
reicherp@arentfox.com

**VIA FEDERAL EXPRESS**

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

Re: Citizen Petition Requesting That FDA Withdraw Approval of Intramuscular Indication for InFeD® Injectable Iron Dextran  
Docket 97P-0324/CPI

Dear Mr. Pendleton:

This letter is in response to your inquiry of Friday April 26, 2002, as to whether Luitpold Pharmaceuticals, Inc., requests that the Agency issue a decision on Luitpold's above-referenced 1997 Citizen Petition which requests that FDA withdraw approval of intramuscular indication for InFeD® brand of iron dextran injection. As it has already been five years since the date of submission of the Citizen Petition, Luitpold requests that FDA act immediately upon its petition and issue a decision without delay.

Sincerely,

Peter S. Reichertz

cc: Dockets Management Branch  
(in triplicate)

97P-0324

LET 2



**Arent Fox**

ATTORNEYS AT LAW

**Arent Fox Kintner Plotkin & Kahn, PLLC**

1050 Connecticut Avenue, NW

Washington, DC 20036-5339

ORIGIN ID: JPNA (202) 857-6264  
REICHERTZ  
ARENT F KINTNER PLOTKIN KAHN  
1050 CONNECTICUT AVE NW

SHIP DATE: 29APR02  
SYSTEM #0696447 / CAFE2084  
ACTUAL WGT: 1 LBS MAN-WGT  
ACCOUNT #: 020007273

WASHINGTON, DC 20036

**FedEx**



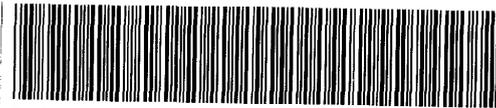
FedEx Revenue Barcode

TO:

DOCKETS MANAGEMENT BRANCH  
FOOD & DRUG ADMINISTRATION  
5630 FISHERS LANE

ROCKVILLE, MD 20857

REF: 0160-015579-00006-REICHERTZ-FOOD/DRUG-



Delivery Address Barcode (FedEx-EDR)

**PRIORITY OVERNIGHT**

TRK#

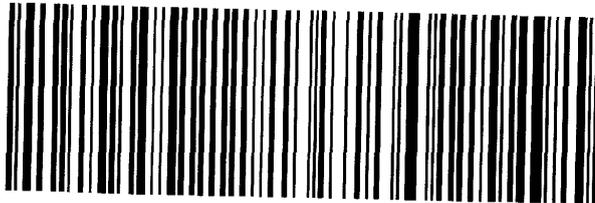
**6169 0878 6201** FORM 0201

TUE  
Deliver by:  
30APR02  
AZ

20857 -MD-US

IAD  
**19 GAIA**

Part # 156148 NRT 9-02



Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20857

*In Time*®

