



Purdue Pharma L.P.

One Stamford Forum
Stamford, CT 06901-3431
(203) 588 8000
Fax (203) 588 8850
www.purduepharma.com

4332

07 09 26

July 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0237

Dear Sir or Madam:

On behalf of Purdue Pharma L. P. (PPLP), we have reviewed *International Conference on Harmonisation: Draft Guidance on Q1E Evaluation of Stability Data; Availability*, and agree with your proposal. We have no comments other than it will be a very useful guidance; particularly with respect to clearer guidelines on using stability data to propose retest periods and shelf life.

Sincerely,

Suzett L. Perry
Sr. Regulatory CMC Associate
Regulatory Affairs

02D-0237

C2

From: JUDITH B. SANTOS (203)588-8045
PURDUE PHARMA LP/Regulatory Affairs
ONE STAMFORD FORUM, 8th Floor
201 TRESSER BLVD
STAMFORD, CT, 06901

REVENUE BARCODE



To: Dockets Management Branch (301)827-6860
FOOD AND DRUG ADMINISTRATION
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD, 20852

SHIP DATE: 30JUL02
WEIGHT: 1 LBS

Ref: 2700



DELIVERY ADDRESS BARCODE(FEDEX-EDR)

TRK # 7920 7878 4948 FORM 0201

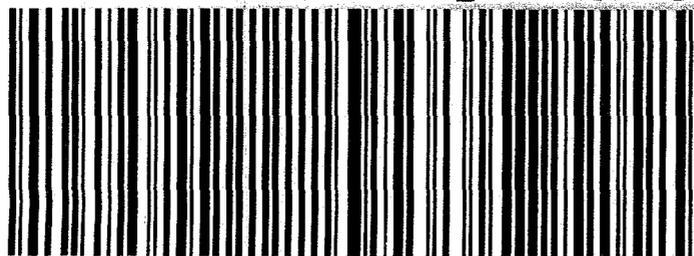
FedEx PRIORITY OVERNIGHT
IAD

20852-MD-US

ZM GAIA

WED
A2

Deliver by:
31JUL02



Shipping Label

Schedule Courier

Find a Dropoff Location

Shipping History

Shipment Complete

Cancel Shipment

Edit Shipment Information

1. Use the "Print" feature from your browser to send this page to your laser printer.
2. Fold the printed page along the horizontal line.
3. Place label in air waybill pouch and affix it to your shipment so that the barcode portion of the label can be read and sc

Shipment Details

To print a copy of the shipment information for your records, please click "Shipment Details".

Shipment Details

Ship a New Package

Ship Inside U.S.

Ship Outside U.S.

Ship to Same Recipient

Use of this system constitutes your agreement to the service conditions in the current FedEx service Guide, available upon request. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide.