

SCHERING CORPORATION

2000 GALLOPING HILL ROAD



KENILWORTH, N.J. 07033

TELEPHONE: (908) 298-4000

May 3, 2000

5316 '00 MAY -5 PM 05

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20850

**SUBJECT: DOCKET NO. 00D-0087- COMMENTS ON FDA DRAFT
GUIDANCE FOR INDUSTRY: "IND MEETINGS FOR HUMAN
DRUGS AND BIOLOGICS CHEMISTRY, MANUFACTURING,
AND CONTROLS INFORMATION"**

Dear Sir/Madam:

Schering-Plough reviewed the published draft guideline "*IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information*" and has the following comments:

- Lines 78 through 85, Section II E, Focus of Meeting provides that in addition to the sponsor's issues the Agency may also wish to discuss relevant questions on safety issues or various scientific and/or regulatory aspects of the drug. It is unclear as to whether any of the referenced CMC guidances dictate the advance notice that the FDA should provide the sponsor of such additional items prior to the meeting. In order to be prepared to meaningfully discuss these other relevant questions/issues, we suggest the following wording be added as the third sentence: "If the Agency has additional items for discussion at the meeting, they will so notify the sponsor and provide the issues/questions at least 5 business days prior to the meeting."

If you have any questions regarding this submission, please feel free to contact Nicholas Pelliccione, Ph.D. at (908) 740-5680.

Sincerely,

Navi Chivukula / for

Nicholas J. Pelliccione, Ph.D.
Vice President, CMC
Worldwide Regulatory Affairs

C7

00D-0087

Attach the Airborne Express Shippers Label within the dotted lines.

AIRBORNE EXPRESS

IF DESTINATION IS OUTSIDE OF THE UNITED STATES: THESE COMMODITIES, TECHNOLOGY OR SOFTWARE WERE EXPORTED FROM THE UNITED STATES IN ACCORDANCE WITH THE EXPORT ADMINISTRATION REGULATIONS. DIVERSION CONTRARY TO U.S. LAW PROHIBITED.

SEARCHING LABORATORIES
REG AFFAIRS
2000 GALLOWING HILL RD
MENILWORTH NJ 07033
USA
RAVI C 908-740-5449

Origin
ELZ

These No.'s
MUST match
Shipment No.

4024764 214

4024764-214

Service



| | |
|----|---------------------------|
| TO | DOCKETS MANAGEMENT BRANCH |
| | ROOM 1061 |
| | 5630 FISHERS LANE — 1061 |
| | Rockville MD |
| | USA 20852 |

Seq. No. 5

Weight 1-L
Billing Ref.
Bill To

1 Pc

MLDA 4X ABH

Remember: Airborne Express cannot deliver without your airbill attached here.

United States Shipping

1. Complete applicable white sections of the U.S. Airbill. Sign and date the Airbill at the Sender's Signature line. Please press hard.
2. Peel off protective covering from back of Airbill.
3. Affix Airbill to envelope within dotted lines shown.
4. When using a Drop Box - follow special instructions on the Drop Box.

International Shipping

Includes Canada & Puerto Rico

Must be typed

1. Complete applicable white sections of the International Express Airbill. Sign and date the Airbill at the Sender's Signature line.
2. Place Airbill in plastic sleeve.
3. Peel off bottom portion from back of plastic sleeve. Do not seal top portion of the plastic sleeve to the envelope.
4. Affix bottom portion to envelope within the dotted lines shown. Airborne driver must sign Airbill before sealing.

Limitation on Contents

The maximum acceptable contents of a Letter Express is forty (40) 8-1/2 x 11 pages. If the gross weight of the contents, envelope and airbill exceeds 1/2 pound, the next higher rate will apply. Contents must be of a size and shape which fit the envelope and allow it to be securely sealed without damage. Cash or cash equivalent should not be shipped. Items of high intrinsic value should not be shipped in Letter Express packaging.

Limitations of Liability

Liability of Airborne Express is limited on Letter Express to \$100.00 U.S.D., unless a higher value is declared for carriage on our airbill. The maximum declared value on the Letter Express is \$500.00 U.S.D. Airborne Express shall not be liable in any event for special, incidental or consequential damages, including but not limited to loss of profits or income. Services are provided as defined in the current Airborne Express Service Guide (subject to change without notice). Copies are available upon request.

To reach your local CUSTOMER SERVICE CENTER Call 1-800-AIRBORNE (1-800-247-2676) U.S. only.

