Schein Pharmaceutical, Inc.
Eastern Distribution Center
Mt. Ebo Drive, South
Brewster, NY 10509

Tel. 914 278-3700

SCHEIN
PHARMACEUTICAL

2093 '99 OCT 27 A9:26

October 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Reference: Docket No. 99D-2635

Dear Sir/Madam,

Reference is made to the draft guidance for industry entitled "ANDAs: Blend Uniformity Analysis" issued on August 27, 1999. Schein Pharmaceutical, Inc. acknowledges that the Agency has requested that written comments on the draft guidance be submitted by October 26, 1999. Schein Pharmaceutical is in the process of preparing comments regarding the draft guidance, including an alternate proposal for blend uniformity analysis. Schein Pharmaceutical is hereby notifying the Agency that our comments will be submitted within two weeks.

Please contact the undersigned at (914) 278-3735 or by fax at (914) 278-3741 if you have any questions concerning this correspondence.

Sincerely,

Ann Mullarkey
Director, Regulatory Affairs
Schein Pharmaceutical, Inc.

99D-2635

LET 1

FedEx *USA Airbill* FedEx Tracking Number 809822669163

Form I.D. No. 0210 SPH22 **Recipient's Copy**

1 From

Date 10 Oct 99

Sender's Name Ann Mullarney Phone (914) 278-3735

Company SCHEIN PHARMACEUTICALS

Address MT EBO CORPORATE PARK RTE 22 Dept./Floor/Suite/Room

City BREWSTER State NY ZIP 10509

2 Your Internal Billing Reference Information 7007562 009 2132

3 To

Recipient's Name [illegible] Phone [illegible] (HFA-350)

Company [illegible]

Address [illegible] Dept./Floor/Suite/Room
(To "HOLD" at FedEx location, print FedEx address here)

☐ Check here if residence (Extra charge applies for FedEx Express Saver)

City [illegible] State [illegible] ZIP [illegible]

For HOLD at FedEx Location check here
☐ **Hold Weekday** (Not available with FedEx First Overnight)
☐ **Hold Saturday** (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

For WEEKEND Delivery check here (Extra Charge. Not available at all locations)
☐ **Saturday Delivery** (Available for FedEx Priority Overnight and FedEx 2Day only)
☐ **NEW Sunday Delivery** (Available for FedEx Priority Overnight only)

8 0 9 8 2 2 6 6 9 1 6 3

4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas

☐ FedEx Priority Overnight (Next business morning)
☑ FedEx Standard Overnight (Next business afternoon)
☐ FedEx First Overnight (Earliest next business morning delivery to select locations) **(Higher rates apply)**
☐ FedEx 2Day (Second business day)
☐ FedEx Express Saver (Third business day)
FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

☐ FedEx Overnight Freight (Next business day)
☐ FedEx 2Day Freight (Second business day)
☐ FedEx Express Saver Freight (Up to 3 business days)
(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging
☑ FedEx Letter (Declared value limit $500.)
☐ FedEx Pak
☐ FedEx Box
☐ FedEx Tube
☐ Other Pkg.

6 Special Handling (One box must be checked)

Does this shipment contain dangerous goods?*
☐ No
☐ Yes (As per attached Shipper's Declaration)
☐ Yes (Shipper's Declaration not required)
☐ Dry Ice — Dry Ice, 9, UN 1845 _____ x _____ kg.
☐ Cargo Aircraft Only

*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment
☐ Obtain Recipient FedEx Account No.

Bill to:
☑ Sender (Account No. in Section 1 will be billed)
☐ Recipient
☐ Third Party
☐ Credit Card
☐ Cash/Check
(Enter FedEx Account No. or Credit Card No. below)

Total Packages	Total Weight	Total Declared Value*	Total Charges
		$ .00	$

*When declaring a value higher than $100 per shipment, you pay an additional charge. See **SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY** section for further information.

Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

Questions?
Call 1·800·Go·FedEx® (800)463-3339

321

WCSL 1098
Rev. Date 7/98
Part #153023PS
©1994-98 FedEx
PRINTED IN U.S.A.

0077514219