



Our STN: BL 103949/5077

**November 3, 2005**

Schering Corporation  
Attention: Rachael Steiner  
Regulatory Affairs Manager  
Global Regulatory Affairs  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

Dear Ms. Steiner:

Please refer to your supplemental biologics license application for Peginterferon alfa-2b dated December 23, 2003 and received on December 29, 2003. This supplement provides for revisions to the Drug Interactions section of the package insert based on a pharmacokinetic study and is approved, effective on the date of this letter.

This approval fulfills your commitment to evaluate the effects of single and multiple doses of Peginterferon alfa-2b on the disposition of drugs known to be metabolized by hepatic cytochrome P450 enzymes in patients diagnosed with chronic hepatitis C and compensated liver disease. This commitment was established as commitment number 2 in our January 19, 2001, approval letter.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

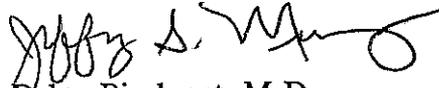
Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products.

Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Therapeutic Biological Products Document Room  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

Sincerely,

A handwritten signature in black ink, appearing to read "Debra S. Birnkrant", with a stylized flourish at the end.

Debra Birnkrant, M.D.

Director

Division of Antiviral Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research

**CONCURRENCE PAGE**

Letter Type: LETTER: Approval (AP)  
LETTER: Fulfillment of PMC (FPC) [ADD ONLY IF FULFILLING A  
PMC]

Summary Text: Clinical Supplmt. - Labeling Only  
**REVIEW COMPLETION REQUIRED BY: RIS**

**SS Data Check:**

- Place copy of Approval Ltr. with original signature concurrence page in Archival package behind the "Approval Materials" Tab after LAR (Licensing Action Recommendation).

**RIS Data Check:**

- Verify short summary - Ltr. & Submission screen should match.
- Check Letter for PMCs (if PMCs - add "PMCs - Approved With" special characteristic code.)
- Perform Review Completion Process
- Milestone: Confirm Approved Status

cc: Attached label is sent to everyone  
HFD-530/S. Proestel  
HFD-108/ A. Rajpal  
HFD-530/ K. Laessig  
HFD-108/ H. Zhao  
HFD-530/ J. Murray  
HFD-530/ D. Birnkrant  
HFM-110/RIMS/R. Eastep  
HFD-400/ODS M. Dempsey  
HFD-006/Exec sec P. Guinn  
HFD-013/FOI H. Brubaker  
HFD-240/OTCOM/ B. Poole  
HFD-230/OTCOM/CDER WebMaster  
HFD-001/B. Duvall-Miller (if PMC commitments)  
HFD-020/C. O'Leary (if PMC commitments)  
HFD-42/DDMAC/M. Kiester  
HFD-410/ODS/DSRCS/ Karen Young  
HFD-328/TFRB Blue File/Mike Smedley  
HFD-410/CDER Medwatch Safety Labeling HFD-430/ODS/DDRE (hard copy)

History:

File Name: V:DAVDP\TysonMedlock\103949.5077\110205.approval letter

Office	Name/Signature	Date
DAVP	<i>Tyson Medlock</i>	11-2-05
OCPB/div 5	<i>Paul [Signature]</i>	11-2-05
ODDP	<i>Mr [Signature]</i>	11-2-05
ODDP	<i>R. Mangella</i>	11-2-05
OAP/DAVP	Virginia L. Behr	11/2/05
OAP/DAVP	<i>[Signature]</i>	11/2/05
OCPB/div 5	<i>Hong Zhao</i>	11/2/05