DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

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,

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	Tyson Medlock	11-2-05
OCPB/Div 5	[signature]	11-2-05
OODP	[signature]	11-2-05
OODP	[signature]	11-2-05
OAP/DAVP	Virginia L. Behr	11/2/05
OAP/DAVP	[signature]	11/2/05
OCPB/Div 5	Hong Zhao	11/2/05