



Our STN: BL 103780/5062

**JUN 30 2005**

Serono, Inc.  
Attention: Pamela Williamson Joyce, RAC  
Vice President, Regulatory Affairs and Quality Assurance  
One Technology Place  
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Your request to supplement your biologics license application for Interferon Beta-1a to revise the package insert to include information on a patient's ability to mount an appropriate immune response to the influenza vaccine has been approved.

This fulfills your commitment:

“To conduct a study in 100 patients to evaluate the immunosuppressive effects of chronic Rebif treatment. The finalized protocol will be submitted to CBER by January 2003. Patient enrollment will be completed by December 2003, data collection completed by March 2004, and the final report with SAS datasets and applicable revised draft labeling will be submitted to CBER by June 2004.”

as stated in commitment #4 of the March 7, 2002 approval letter for STN # 103780/0.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (<http://www.fda.gov/cder/pmc/default.htm>). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see <http://www.fda.gov/cber/gdlns/post040401.htm>) for further information.

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).

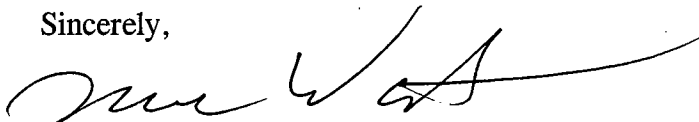
Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the address for submissions. Effective Oct 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room  
Center for Drug Evaluation and Research  
Food and Drug Administration

12229 Wilkins Avenue  
Rockville, Maryland 20852

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Marc K. Walton', with a long horizontal flourish extending to the right.

Marc K. Walton, M.D., Ph.D.  
Director  
Division of Therapeutic Biological Internal Medicine  
Products  
Office of Drug Evaluation VI  
Center for Drug Evaluation and Research

Cc: Package Insert (PI) 6.7.05

**CONCURRENCE PAGE**

Letter Type: LETTER: Approval (AP)  
LETTER: Fulfillment of PMC (FPC)

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: HFD- 108/W. Bryan  
HFD-108/E. Unger  
HFD-108/M. Walton  
HFD-109/K.Schneider  
HFD-109/E.Dye  
HFD-109/C.Michaloski  
HFD-106/K. Weiss  
HFD-106/G. Jones  
HFM-110/RIMS/R. Eastep  
HFD-400/ODS M. Dempsey  
HFD-006/Exec sec P. Guinn  
HFD-013/FOI D.Taub  
HFD-013/FOI H. Brubaker  
HFD-240/OTCOM/ B. Poole  
HFD-230/OTCOM/CDER WebMaster  
HFD-001/B. Duvall-Miller (if PMC commitments)  
HFD-42/DDMAC/M. Kiester  
HFD-410/ODS/DSRCS/ Karen Young  
HFM-570 C. Lee (if clinical PMC commitments)  
HFD-328/TFRB Blue File/Mike Smedley  
HFD-410/CDER Medwatch Safety Labeling HFD-430/ODS/DDRE (hard copy)  
DRMP BLA file (hard copy)

History: Michaloski: 6.6.05; 6.9.05

File Name: (S:Michaloski\letters\103780.5062Fluvacc.Supplement.doc)

Office	Name/Signature	Date
DRMP	C. Michaloski	6-9-05
DRMP	Schneider	6-9-05
DRMP	Winters for Dye	6-9-05
OTB/MP	Winters	6/30/05
DRMP	Kelly Lawrence	7/5/05