DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103471\5063, 5067, 5079, 5088, 5120, 5124, 5136, and 5138

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Vicki Chen
Associate Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Chen:

Please refer to your Supplemental Biologics License Applications, dated January 19, 2005, received January 20, 2005, February 11, 2005, received February 14, 2005, November 2, 2005, received November 3, 2005, September 15, 2006, received September 18, 2006, November 5, 2007, received November 6, 2007, April 4, 2008, received April 7, 2008, February 13, 2009, received February 13, 2009, and June 16, 2009, received June 17, 2009, submitted under section 351 of the Public Health Service Act for Betaseron (Interferon beta-1b).

We acknowledge receipt of your amendments dated February 10, 2005, April 15, 2005, May 31, 2005, July 27, 2005, September 12, 2005, September 13, 2005, October 25, 2005, January 22, 2008, April 8, 2009, December 18, 2009, April 4, 2011, March 30, 2012, September 7, 2012, October 10, 2012, and October 26, 2012.

The September 12, 2005, and September 13, 2005, submissions constituted complete responses to our July 22, 2005, action letter for supplements 5063 and 5067.

Supplements 5067 and 5138 are Prior Approval Supplemental Biologics License applications providing for the removal of ten adverse events from the package insert based on post-marketing experience and the creation of a package insert in Physicians Labeling Rule (PLR) format.

Supplements 5063, 5079, 5088, 5120, 5124, and 5136 are “Changes Being Effected” Supplemental Biologics License Applications. They propose the following changes:

5063	Addition of three warnings (Hepato-biliary disorders, Nervous system disorders and Cardiac disorders) in the package insert, based on clinical trials data and post marketing experience

5079	Addition of the terms “psychotic symptoms” in the “Adverse Reactions” section of the package insert
5088	Addition of the terms “anorexia” and “weight decrease” in the “Adverse Reactions” section of the package insert
5120	Revision of storage conditions in the medication guide
5124	Addition of eleven adverse events in the “Postmarketing Experience” section of the package insert
5136	Updates to the package insert and medication guide, including revised pregnancy registry information and inspection of vials for cracks or damage.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert, Medication Guide and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 103471/5138**.”

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call LCDR Hamet Touré, PharmD MPH, Regulatory Project Manager, at (301) 796-7534.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
12/11/2012