DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103780/5121

SUPPLEMENT APPROVAL

EMD Serono, Inc.
Attention: Todd G. Brill
Associated Director, US Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Mr. Brill:

Please refer to the supplement to your biologics license application, dated September 16, 2009, received September 17, 2009, submitted under section 351 of the Public Health Service Act for Rebif (interferon beta-1a) Injection.

We also refer to our January 15, 2010, Complete Response letter, and our June 29, 2010, Acknowledge Incomplete Response letter, in response to your May 14, 2010, submission providing a response to the deficiencies identified in the January 15, 2010, action letter. We also refer to our August 9, 2011, Discipline Review letter providing feedback to your clarifying questions about your proposed Human Factors testing plan for your Rebif Rebidose autoinjector.

Finally, we acknowledge receipt of your amendments dated August 21, 2012, October 3, 2012, October 17, 2012, October 19, 2012, October 16, 2012, November 30, 2012, December 4, 2012, December 12, 2012, and December 21, 2012.

The August 21, 2012, submission constituted a Complete Response to our January 15, 2010, action letter.

This "Prior Approval" supplemental biologics application proposes the use of a new Combination Product, Rebif Rebidose, a single-use autoinjector.

We have completed our review of this supplemental application, as amended. It is 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 and 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.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes 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.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 21, 2012, submission containing final printed carton and container labels.

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 Hamet Touré, PharmD MPH, Regulatory Project Manager at (301) 796- 7534.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
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
12/21/2012