DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103780/S-5196

SUPPLEMENT APPROVAL
PLLR WAIVER DENIED
PLLR EXTENSION GRANTED

EMD Serono, Inc.
Attention: Lisa M. Hyde
Associate Director, Global Regulatory Medical Devices & Diagnostics
Global Regulatory Affairs & Quality Assurance
One Technology Place
Rockland, MA 02370

Dear Ms. Hyde:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 26, 2015, received November 27, 2015, and your amendments, submitted under section 351(a) of the Public Health Service Act for Rebif (interferon beta-1a) Injection.

This Prior Approval supplemental biologics application provides for the addition of a 2D barcode and near field communication (NFC) tag to the labeling of the Rebif Rebidose autoinjector, and for the use of the MSdialog System, which permits electronic documentation of medication injections when using the Rebif Rebidose autoinjector.

APPROVAL & LABELING

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 and with the minor editorial revisions listed below.

- MSdialog Mobile Application Instructions for Use (IFU): revise page 29, which is currently blank to state:

  CAUTION:
  Please be aware that recorded injections cannot be deleted.
  For assistance, you may contact your doctor or:
  MS LifeLines at
  1-877-447-3243

We also note and refer to your commitment to revise the MSdialog Mobile Application IFU, as described in our September 21, 2016, electronic communication, and as discussed with Drs. Marler, Ware and Lopez on September 27, 2016.

We based our review of the MSdialog Web Apps and their associated IFUs on our assessment of the low potential risk to patients posed by the Apps' features and functionality. You are advised that future modifications to the MSdialog Web Apps may require a regulatory submission and a more in-depth Agency review depending on what the modifications are. In determining the appropriate regulatory submission (if any) for such changes, you should consider the potential impact of the modifications on the safety and effectiveness of the modified system, including the potential risk to patients posed by the modifications. For any modifications not addressed by the comparability protocol included in this application, please contact the Review Division for more information regarding the appropriate submission type.

PLLR WAIVER REQUEST

We also refer to your submission dated July 22, 2016, requesting a waiver, under 21 CFR 201.58, of the requirements on content and format of labeling described at 21 CFR 201.56 and 201.57. Specifically, you are requesting a waiver of the Pregnancy and Lactation Labeling Rule (PLLR) requirements for this supplement.

We have reviewed your request and have determined that a waiver is not justified. However, we are granting an extension of the date for compliance with the labeling requirements until June 30, 2018, or with submission of another efficacy supplement, whichever is sooner.

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, text for the patient 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.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on November 27, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 103789/S-5196**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with final printed labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Nahleen Lopez, Regulatory Project Manager, at (240) 402-2659.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Deputy 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/

ERIC P BASTINGS
09/27/2016