DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103628/5129
BLA 103628/5177
BLA 103628/5224
BLA 103628/5194

SUPPLEMENT APPROVAL

Biogen Idec Inc
Attention: Nadine D. Cohen, PhD
Senior Vice President, Regulatory Affairs
14 Cambridge Center
Cambridge, MA
02142

Dear Dr. Cohen:

Please refer to your Supplemental Biologics License Applications (sBLA), dated and received November 30, 2006, dated and received August 31, 2010, dated and received June 22, 2011, dated and received April 19, 2012, submitted under section 351(a) of the Public Health Service Act for Avonex (interferon beta-1a).

We acknowledge receipt of your amendments dated April 19, 2011, June 17, 2011, December 9, 2011, March 29, 2013, April 25, 2013, March 29, 2013, May 23, 2013, September 4, 2013, and June 25, 2014.

Supplement 5129 is a Changes Being Effected labeling supplement proposing the addition of a sticker to the outside packaging to distinguish between luer lock and luer slip syringes. We note that you implemented the use of the sticker for a short period of time. However, you are no longer using the sticker. Supplement 5129 is superseded.

Supplement 5177 is a Changes Being Effected labeling supplement to update the patient instructions to help address an issue with syringe breakages.

Supplement 5194 is a Changes Being Effected labeling supplement proposing the inclusion of dry natural rubber latex labeling.

Supplement 5224 is a Prior Approval labeling supplement to update the lyophilized powder and pre-filled syringe instructions for use.

APPROVAL & LABELING

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 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 June 25, 2014, 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, Regulatory Project Manager, at (301) 796-7534.

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

ENCLOSURES:
Content of Labeling
Carton and Container 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
08/28/2014