

Filing Letter - Eloctate

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our STN: BL 125487/0

Biogen Idec Inc.
Attention: Nadine D Cohen, PhD
14 Cambridge Center
Cambridge, MA 02142

Dear Dr. Cohen:

This letter is in regard to your biologics license application (BLA) submitted under section 351(a) of the Public Health Service Act.

We have completed an initial review of your application dated March 7, 2013 for Antihemophilic Factor (Recombinant), Fc Fusion Protein to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is March 8, 2014. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which include the timeframes for FDA internal milestone meetings. We plan to hold our internal mid-cycle review meeting on August 27, 2013. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

We will contact you regarding your proposed labeling no later than February 6, 2014. If post-marketing study commitments (506B) are required, we will contact you no later than February 6, 2014.

While conducting our filing review, we identified the following potential review issues:

Chemistry, Manufacturing and Controls

1. Control of your FVIII potency assay

- Please submit a study report containing the protocol for and results from complete method validation for the intended commercial potency assay.
- Please provide a report that summarizes all comparative testing between one stage and chromogenic assays performed during clinical development. Comparative testing results should include patient monitoring as well as product release.

2. Control of the ---b(4)----- chromatography step

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4. Control of raw materials

- Please provide representative, recent Certificates of Analysis for all raw materials.
- Please include an identity test as part of in-house receipt testing of all raw materials.
- Please be advised that any change in the supplier of a raw material requires notification to FDA.
- Please submit the in-house specification for all non-compendial raw materials.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our complete review. Issues may be added, deleted,

expanded upon, or modified as we review the application. If you respond to these issues during this review cycle, we may not consider your response before we take an action on your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Leigh Pracht, at (301) 827-6116.

Sincerely yours,

Iliana Valencia, MS
Chief, Regulatory Project
Management Branch
Office of Blood Research and Review
Center for Biologics
Evaluation and Research