

Information Request, July 25, 2013- Eloctate

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Our Reference: BL 125487/0

Biogen Idec Inc.
Attention: Ms. Debra Segal
July 24, 2013
Sent by email

Dear Ms. Segal:

We are reviewing your March 7, 2013 biologics license application (BLA) for Antihemophilic Factor (Recombinant), Fc Fusion protein. We are providing request for additional information to continue our review:

1. Please provide 8 vials/lot from one lot each of the following sizes: 250, 750, 1500 and 3000 IU/vial.

2. Please provide the following reagents for the –b(4)----- assay:

- –b(4)-----

- –b(4)-- -----

- –b(4)-- -----

3. Please provide the following reagents for the FVIII Chromogenic method:

- 5 vials of reference standard

- 5 vials of assay control
- Sample dilution buffer

4. Please provide the following reagents for the –b(4)----- assay:

- –b(4)-----
- –b(4)-----
- –b(4)-----

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request by August 8, 2013 referencing the date of this request.

Please ship the material to the address below:

Catherine Poole
Regulatory Coordinator
Division of Biological Standards and Quality Control (DBSQC)
OCBQ/CBER/FDA
NLRC Bldg. B Room 2411
5516 Nicholson Lane
Kensington, MD 20895
Office: 301-594-6272

The action due date for this file is March 8, 2014.

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh Pracht
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB