



Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125816/0

From: M. Nahid Parvin, Ph.D., LBVI/DBSQC/OCBQ

Through: Maryna Eichelberger, Ph.D.
Division Director, DBSQC/OCBQ

Sponsor: Axogen Corporation (Axogen)

Subject: Suitability of lot-release test methods for Avance Nerve Graft drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of Avance Nerve Graft were reviewed by Hyesuk Kong (LMIVTS) and M. Nahid Parvin (LBVI). Their review memoranda are attached to this cover letter.

Conclusion:

The analytical methods and their validations/qualifications reviewed for Avance Nerve Graft were found to be adequate for their intended use.