



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125798/0

From: Salil K Ghosh, Ph.D., LAC/DBSQC/OCBQ/CBER

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

Sponsor: Neurotech Pharmaceuticals, Inc.

Subject: Review of Analytical Methods used for NT-501 (Implant containing allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor [rhCNTF] drug product (DP) Lot Release

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of NT-501 were reviewed by Simleen Kaur (LMIVTS), Jing Lin (LBVI), and Salil K Ghosh (LAC). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for NT-501 were found to be adequate for their intended use.