



**U.S. FOOD & DRUG**  
ADMINISTRATION

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## Memorandum

**DATE:** November 4, 2025

**TO:** Eden Chane, RPM, CBER/OTAT/DRPM  
Wen (Aaron) Seeto, Ph.D., Committee Chair, CBER/OTAT/DCGT  
Ying Geng, M.D., Ph.D Clinical Reviewer, CBER/OTAT/DCEPT  
Mike Singer, M.D., Ph.D Clinical Reviewer, CBER/OTAT/DCEPT

**FROM:** Benjamin S. Cyge, Ph.D.  
Consumer Safety Officer  
APLB/DCM/OCBQ

**THROUGH:** Lisa L. Stockbridge, Ph.D.  
Branch Chief  
APLB/DCM/OCBQ

**SUBJECT: AVANCE (processed nerve allograft – ainr)**  
**BLA: 125816/0**  
Sponsor: AxoGen Corporation

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## Background

The sponsor submitted:

☒ New Approval  
☐ Changes Being Effectuated (CBE) supplement  
☐ Prior Approval Supplement (PAS)  
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)  
☐ Patient Package Insert (PPI)  
☒ Package and/or container labels  
☐ Other

Submission Date: September 5, 2025

PDUFA Action Date: December 5, 2025

**APLB Comments/Recommendations**

On September 5, 2024, AxoGen Corporation submitted their Biologics License Application (BLA 125816) for AVANCE. AVANCE is an acellular nerve scaffold indicated for the treatment of adult and pediatric patients with sensory nerve discontinuity, or mixed and motor nerve discontinuity.

The AVANCE Review Team iteratively negotiated revisions to the Prescribing Information (PI), package, and container labeling through communications with the applicant.

APLB reviewed the revised PI, package, and container labels. The following comments are from a promotional and comprehension perspective.

**FULL PRESCRIBING INFORMATION****ADVERSE REACTIONS**

Include a list of the most frequently occurring adverse reactions, along with the criteria used to determine inclusion (e.g., incidence rate greater than x%). Ensure this statement is consistent with the ADVERSE REACTIONS section in the HIGHLIGHTS.

**PACKAGE AND CONTAINER LABELS**

APLB has no comments on the revised package and container labels.

If you have any questions regarding this review, please contact Benjamin S. Cyge, Consumer Safety Officer at (301) 796-4212.

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