



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

**To:** Administrative File: STN 125734/0

**From:** Pete Amin, CMC/Facilities Reviewer, OCBQ/DMPQ/MRB3,  
Prajakta A Varadkar (PV), Biological Reviewer, CBER/OCBQ/DMPQ

**Through:** CDR Donald Ertel, Branch Chief, OCBQ/DMPQ/MRB3

**CC:** Jie He, Team Lead, OCBQ/DMPQ/MRB3

**Applicant:** CellTrans Inc. License # 2213

**Product:** Donislecel (USAN) (indication- Brittle type I diabetes in adults)

**Facility:** CellTrans., Chicago USA 60612 (FEI 3019202665)

**Subject:** Addendum DMPQ Review memorandum for Biologics License Application filed per  
21 CFR 601.2 (Evaluation of CellTrans' response to the Complete Response (CR)  
Letter issued August 18, 2021)

**Action Due:** June 28, 2023

#### Signature Block

Reviewer/Title/Affiliation	Concurrence	Signature and Date
Pete Amin, DMPQ Reviewer CBER/OCBQ/DMPQ/MRB3	Concur	
CDR Donald Ertel, Branch Chief CBER/OCBQ/DMPQ/MRB3	Concur	
Carolyn Renshaw, Division Director CBER/OCBQ/DMPQ	Concur	

#### RECOMMENDATION

Based on review of the CR letter deficiency #1, approval of this BLA is recommended by providing all Office of Therapeutic Products (OTP) issues are resolved.

The response from CellTrans to the Complete Response Letter issued August 18, 2021 for deficiency #1 under DMPQ purview appears acceptable, therefore, the inspection results support the approval of BLASTN 125734/0.

### **SUMMARY (Timeline)**

- June 07 to 11, 2021: CBER performed a pre-license inspection at CellTrans Inc. Islet Manufacturing Facility (FEI: 3010872260) located within the University of Illinois Hospital (UIH), 1740 W. Taylor Street, C200, Chicago, IL 60612 in support the review of BLA 125734/0 submitted by CellTrans Inc. for licensure of the Purified islets of Langerhans for transplant known as Donislecel (USAN) or LANTIDRA (proposed proprietary name). At the conclusion of the inspection, a Form FDA-483 (12 observations) was issued.
- June 29, 2021: Primary DMPQ Review was completed by Timothy Martin, DMPQ. No recommendation was provided pending inspectional outcome.
- August 18, 2021: CBER issued a complete response letter (CR letter) to the BLA. The CR letter identified a total of nine deficiencies including one deficiency related to outstanding resolution of 483 observations.
- December 30, 2022: CellTrans submitted their response (amendment 45) to the deficiencies outlined in the Complete Response Letter dated August 18, 2021.
- May 19, 2023: CellTrans provided additional clarification to FDA Request for Information, dated May 10, 2023. (amendment 53).

In the CR letter response, CellTrans provided responses to all nine CR letter deficiencies. The CR letter deficiency #1 was related to the outstanding FDA-483 inspectional observation resolution. Please see a separate DMPQ FDA-483 response review memo by Pete Amin with detailed evaluation of all the corrective actions and preventive actions taken by CellTrans to address all FDA-483 inspectional observations issued during the June 2021 Pre-License Inspection (PLI).

### **REVIEW**

CR letter Deficiency #1: outstanding issues identified during the pre-license inspection (PLI) at the CellTrans Inc. manufacturing facility between June 7, 2021, to June 11, 2021, as detailed in Form FDA 483 issued to you on June 11, 2021, have yet to be resolved. Per your response dated June 28, 2021, (as per amendment 39) to the Form 483 Observations, change controls have been initiated; however, the data to confirm the adequacy of the changes have not been submitted. Please submit documentation with data that demonstrates that all outstanding inspectional issues identified during the PLI have been resolved.

**Reviewer Comment:** The Applicant has implemented corrective and preventive actions (CAPA) and addressed all the Form FDA- 483 inspectional observations. Follow-up of the CAPA is recommended to be inspected at the next FDA post approval inspection. Please refer to the separate DMPQ FDA-483 response review memo by Pete Amin with detailed evaluation of all the resolutions and CAPA implemented by CellTrans to address all FDA-483 inspectional observations. The review of the CR letter deficiencies #2 to 9 is deferred to OTP reviewer. Based on my review, found that the applicant has implemented CAPA to address all the Form FDA-483 inspectional observations and appears to be acceptable.