

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
76th Meeting of the Cellular, Tissue, and Gene Therapies
Advisory Committee (CTGTAC)
October 31, 2023
Discussion Question**

Committee Discussion Question:

Please discuss the Applicant's off-target analysis (e.g., in silico and cellular methods) and provide recommendations for additional studies, if needed, to assess the risk of off-target editing for exa-cel.