



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: July 6, 2023

TO: Matthew Klinker, PhD, Chair
Upendra Mahat, MD, Clinical Reviewer
Adriane Fisher, MPH, MBA, RPM

FROM: Peter Lenahan, DC, PhD, MPH, Senior Regulatory Reviewer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Chief BMB

THROUGH: Carrie M. Mampilly, MPH, Director DIS

SUBJECT: Bioresearch Monitoring Final Review Memo
BLA: STN 125706/0
PRODUCT: Remestemcel-L, Allogeneic Mesenchymal Stem Cells,
Cultured ex vivo, (b) (4)
Allogenic Bone Marrow
SPONSOR: Mesoblast, Inc.

Four Bioresearch Monitoring (BIMO) Clinical Investigator (CI) inspections were performed between June 2020 and August 2020 of the pivotal studies, MSB-GVHD-001 and MSB-GVHD-002 at clinical sites: 301; 302; 304; and 323. In view of this previous inspectional history, the review committee decided that additional BIMO inspections are not warranted for this resubmission.

Should you have any questions or comments about the contents of this memo or any aspect of bioresearch monitoring, please contact me at (973) 331-4947.

Peter Lenahan, DC, PhD, MPH
Regulatory Officer

DISTRIBUTION:

Electronic Copy

EDR Upload to Application Folder BLA 125706/0

Matthew Klinker, PhD, Chair
Upendra Mahat, MD, Clinical Reviewer
Adriane Fisher, MPH, MBA, RPM
Carrie M. Mampilly, MPH
Dennis T. Cato
Char-Dell Edwards for Chron file
CBER BIMO Notification