



U.S. FOOD & DRUG
ADMINISTRATION

DATE: February 7, 2023

FROM: Char-Dell Edwards, BS, MT (ASCP), Consumer Safety Officer
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

TO: Christina Houck, BS, RPM
Joohee Lee, MD, Clinical
Girish Ramachandran, PhD, Committee Chair

SUBJECT: Bioresearch Monitoring Final Discipline Review
SPONSOR: Seres Therapeutics, Inc.
PRODUCT: SER-109 (Purified Microbiome Therapeutic, (b) (4))
BLA: STN 125757/0

FINAL SUMMARY STATEMENT:

Bioresearch Monitoring (BIMO) inspection assignments were issued for one foreign and three domestic Clinical Investigators (CI) who participated in the conduct of Protocol SERES-012. The inspections did not reveal substantive issues that impact the data submitted in this original Biologics License Application (BLA).

BACKGROUND:

One foreign and three domestic CI sites participating in the conduct of Protocol SERES-012 were identified for BIMO inspections. The BLA review committee concurred with the proposed sites. The sites were selected based upon sponsor-reported deaths, adverse events, geographic location, protocol deviations, number of subjects enrolled, and previous BIMO inspection histories.

The inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for CI. Information submitted in the original BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical study Protocol SERES-012.

PROTOCOL:

SERES-012: ECOSPOR III: A Phase 3 Multicenter, Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of SER-109 vs. Placebo to Reduce Recurrence of Clostridium difficile Infection (CDI) in Adults Who Have Received Antibacterial Drug Treatment for Recurrent CDI (RCDI). Approximately 188 subjects were enrolled under study SERES-012 at approximately 100 study centers in North America.

BIMO INSPECTIONS SUMMARY:

No significant BIMO inspectional findings were noted. The below table summarizes site information and outcomes from the BIMO inspections.

Site ID	Firm Name	Location	FDA Form 483 Issued	Final Classification
234	Val R. Hansen, MD	Bountiful, UT	No	No Action Indicated (NAI)
302	Paul P. Cook, MD	Greenville, NC	No	NAI
406	Thomas Louie, MD, FRCPC	Alberta, Canada	No	NAI
305	Bret A. Lashner, MD, MPH	Cleveland, OH	No	NAI

SPONSOR MONITORING ISSUES:

No significant sponsor or monitoring issues were identified during the above inspections.

FINANCIAL DISCLOSURE:

The CI CP directs the FDA investigator to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouse(s), and dependent children, as well as if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected clinical study sites.

ADMINISTRATIVE FOLLOW-UP:

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at (240) 402-8423.

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Consumer Safety Officer