



Our STN: BL125757/0

**MID-CYCLE COMMUNICATION
AGENDA**

DECEMBER 14, 2022

Seres Therapeutics, Inc.
Attention: Ann Kurowski
200 Sidney St.
Cambridge, MA 02139

Dear Ms. Kurowski:

Based on the progress of the review, we do not have any substantive review issues to discuss at this time. If you do not have any questions, additional data, or analyses to discuss for this application, the Mid-Cycle meeting may be cancelled upon your request. Please inform us in writing within two business days if you would like to cancel this meeting. If not, please identify your topics for discussion at the Mid-Cycle meeting.

Please include a reference to STN 125757/0 in your future submissions related to Fecal Microbiota Spores.

If you have any questions, please contact Christina Houck by email at Christina.Houck@fda.hhs.gov.

Sincerely,

Loris McVittie, Ph.D.
Deputy Director-Regulatory
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application Type and Number: BL STN 125757/0
Product Name: SER-109: Fecal Microbiota Spores
Proposed Indication for Use: To prevent the recurrence of *Clostridioides difficile* infection in adults with recurrent CDI (rCDI)
Applicant: Seres Therapeutics, Inc.
Meeting Date & Time: December 19, 2022, 1:00 PM-2:30 PM
Committee Chair: Girish Ramachandran
RPM: Christina Houck

Agenda:

1. Any significant issues/major deficiencies identified by the Review Committee to date.

As discussed in our telecon of November 28, 2022, your potency assay for release testing of your (b) (4) Drug Product is not adequately validated, and you need an adequately validated potency assay for approval of your BLA. As noted during this telecon, you must conduct additional validation studies to address the issues communicated to you in our November 18, 2022, Information Request. Your responses to our requests and timely submission of adequate additional data will determine whether these issues can be resolved to allow for approval of the BLA by the intended Action Due Date.

2. Information regarding major safety concerns.

No major safety concerns identified to date.

3. Preliminary Review Committee thinking regarding a.) risk management, b) the potential need for any post-marketing requirement(s) (PMRs), and c.) the ability of adverse event reporting and CBER's Sentinel Program to provide sufficient information about product risk.

At this time, a REMS is not anticipated for this product. A determination has not yet been reached about the need for any PMR or PMC.

4. Any information requests sent, and responses not received.

Date	IR Summary
11/30/2022	IR regarding validation data for a specific indicator microorganism, lot number(s), and need clarification on a chart displayed in transfer report. Response from Applicant expected by December 21, 2022. Response requested by December 21, 2022

5/12/2022	IR regarding (b) (4) assay, (b) (4) Assay, stool donor screening tests and list of manufacturer(s). Response requested by December 19, 2022.
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5. Any new information requests to be communicated.

CMC information request regarding (b) (4) Assay.

Clinical information request regarding an update on the two ongoing cases of UTIs and the completeness of the culture test carried out.

6. Proposed date for the Late-Cycle Meeting and the Late-Cycle Meeting Materials:

The LCM between you and the Review Committee is currently scheduled for February 22, 2023, at 1 p.m. We intend to send the LCM meeting materials to you approximately 10 days in advance of the LCM.

7. Updates regarding plans for the AC meeting, if appropriate.

N/A

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates, and notification of intent to inspect manufacturing facilities.

- Labeling Comments: we intend to send our labeling comments no later than March 27, 2023.
- Action Due Date: we intend to take action on this application no later than April 26, 2023.