November 7, 2025

Peter Kim, M.D., Director
Division of Anti-Infectives
Office of Infectious Diseases
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Rockville, MD 20705-1266

DEFERRAL EXTENSION REQUESTED
RESPONSE TO PREA NON-COMPLIANCE LETTER

RE: NDA # 216755
LIKMEZ® (metronidazole) Oral Suspension, 500 mg/5 mL
Sequence 0076

IND # 132217
LIKMEZ® (metronidazole) Oral Suspension, 500 mg/5 mL
Sequence 0040

Dear Dr. Kim,

Reference is made to Saptalis Pharmaceuticals, LLC. (Saptalis; Sponsor) NDA for Likmez® (metronidazole) Oral Suspension, 500 mg/5 mL, approved on September 22, 2023.

This correspondence is submitted in response to the Notification of Non-Compliance with the Pediatric Research Equity Act (PREA), dated September 30, 2025. The notification pertains to Postmarketing Requirements (PMRs) 4502-2 and 4502-3 associated with the subject New Drug Application (NDA). The Sponsor acknowledges receipt of the notification and appreciates the FDA's continued guidance in fulfilling the obligations under PREA.

At this time, the Sponsor respectfully requests a deferral extension to (b) (4), for **PMR 4502-2** and **PMR 4502-3**, for completion of the remaining activities necessary to achieve full compliance. The deferral extension is requested for the following reasons:

- The Sponsor has been diligently coordinating with Subject Matter Experts (SMEs) and external collaborators to develop a comprehensive and scientifically robust response to fulfill the requirements of PMR 4502-2 and PMR 4502-3. Following receipt of the FDA's comments and recommendations on September 15, 2025, regarding the pharmacokinetic (PK) information and the preparation of separate reports for PMRs 4502-2 and 4502-3, originally submitted on June 30, 2025, the Sponsor has undertaken additional analyses and report revisions to ensure that all feedback is thoroughly and appropriately addressed.

The scope and complexity of these additional activities have required more time than initially anticipated to ensure the accuracy, completeness, and scientific rigor of the submission. Accordingly, the Sponsor intends to submit the finalized pediatric assessment for PMR 4502-2 and PMR 4502-3 (b) (4).

- The additional time under the deferral extension will allow the Sponsor to collaborate effectively with external partners to ensure the development of a comprehensive and scientifically sound response that fully addresses any subsequent FDA feedback to the planned (b) (4) submission.

In view of these considerations, Saptalis respectfully requests that the due date for PMR 4502-2 and PMR 4502-3 be extended to (b) (4) The Sponsor appreciates FDA's understanding and continued collaboration as these efforts are completed.

The Sponsor remains committed to meeting all applicable regulatory requirements under PREA and ensuring the timely completion and submission of pediatric study data to support the safe and effective use of the drug product in the pediatric population.

Should additionally details or a teleconference be required to discuss this request further, we are available at your convenience.

Thank you for your consideration.

Sincerely,

Hema Sam
Digitally signed by Hema Sam
Date: 2025.11.07 11:01:48
-05'00'

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PETER W KIM
09/30/2025 11:08:01 AM