

Our STN: BL 125613/0

May 24, 2017

Kamada Ltd.
Attention: Ms. Holli S. Vaughan
Biologics Consulting Group, Inc.
400 North Washington Street, Suite 100
Alexandria, VA 22314

Dear Ms. Vaughan:

Please refer to your Biologic License Application (BLA) submitted under section 351(A) of the Public Health Service Act for Rabies Immune Globulin (Human) [KEDRAB]

Attached are our meeting materials, including our agenda, for the Late-Cycle Meeting (LCM) scheduled for June 8, 2017 at 10 am

If you have any questions, please contact Dr. Jiahua Qian, at 240-402 8432.

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

ENCLOSURE:
Late-Cycle Meeting Materials

Late-Cycle Meeting Materials

Meeting Date and Time: 10 am, June 8, 2017
Meeting Location: 10903 New Hampshire Avenue
WO Bldg 32 Room 1211
Silver Spring, MD 20993
Application number: STN BL 125613/0
Applicant: Kamada Ltd
Product name: Rabies Immune Globulin (Human) [KEDRAB]
Proposed Indication: Passive, transient post-exposure prophylaxis of rabies infection, when given immediately after contact with a rabid or possibly rabid animal and in combination with rabies vaccine

INTRODUCTION

The purpose of a Late-Cycle Meeting (LCM) is to share information and to discuss any substantive review issues that we have identified to date, and our objectives for the remainder of the review. The application has not yet been fully reviewed by the signatory authorities, division directors, and application Chair. Therefore, the meeting will not address the final regulatory decision for the application. We are sharing this material to promote a collaborative and successful discussion at the meeting.

During the meeting, we may discuss additional information that could be submitted to address any identified issues. We may also discuss whether the submission of such information would be expected to trigger an extension of the PDUFA goal date if the review committee should decide, upon receipt of the information, to review it during the current review cycle.

Please note: if you submit any new information in response to the issues identified in this background package prior to this LCM, we may not be prepared to discuss that information at this meeting.

1. Discipline Review Letters

No Discipline Review letters have been issued to date.

2. Substantive Review Issues to be discussed during the LCM

For inspections: Inspections are complete. A final recommendation is pending at this time. However, please provide the time line for completion of the proposed (b) (4) media fill study. As (b) (4) will be used including the aseptic filling of the HRIG product, we recommend completion of the proposed media fill study at least 30 days before BLA 125613/0 action due date (8/29/2017).

3. Advisory Committee (AC) Meeting

An Advisory Committee meeting is not planned.

4. Risk Management Actions (e.g., REMS)

We have not identified any issues related to risk management. We do not believe that a risk management action (e.g., REMS) is needed at this time.

LCM AGENDA

1. Introductory Comments – 5 minutes (RPM/Chair)

Welcome, Introductions, Ground rules, Objectives of the meeting

2. Discussion of Substantive Review Issues – 15 minutes

3. Discussion of Minor Review Issues – 10 minutes

4. Additional Applicant Data – 10 minutes

5. Post-marketing Requirements/Post-marketing Commitments if necessary – 5 minutes

6. Applicant Questions – 10 minutes

7. Wrap-up and Action Items – 5 minutes

END