



Our Reference: BL 125562/0

**LATE CYCLE MEETING
BACKGROUND PACKAGE**

Cangene Corporation
Attention: Ms. Allison Kennedy
155 Innovation Drive
Winnipeg
Manitoba R3T 5Y3
Canada

Dear Ms. Kennedy:

Please refer to your biologics license application (BLA), submitted under section 351(a) of the Public Health Service Act, for Anthrax Immune Globulin Intravenous (Human).

We also refer to the Late Cycle meeting (LCM) scheduled for January 27, 2015. Attached is our background package, to include a review status update and an agenda for the meeting.

If you have any questions, please contact Iliana Valencia at (240) 402-8444.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

ENCLOSURE:

Late Cycle Meeting Background Package

LATE CYCLE MEETING BACKGROUND PACKAGE

Meeting Date and Time: Tuesday, January 27, 2015; 1:30 p.m. - 3:00 p.m. EDT

Meeting Location: Teleconference

Application Number: STN 125562/0

Product Name: Anthrax Immune Globulin Intravenous (Human)

Indication: Treatment of adult and pediatric patients with toxemia associated with inhalational anthrax.

Applicant Name: Cangene Corporation

INTRODUCTION

The purpose of this Late Cycle meeting (LCM) is to share information, to discuss substantive review issues identified to date, and to communicate our objectives for the remainder of the review cycle. The application has not yet been fully reviewed by the signatory authority, division director or chairperson; therefore, the meeting will not address the final regulatory decision for the application. We are sharing this information to promote collaborative and successful discussion.

Please be advised that any new information submitted before the LCM that had not been requested by the Agency will not be addressed during the meeting. Furthermore, during the meeting, we may request the submission of additional information, as necessary, to address identified issues. Our planned review timelines for any requested additional information will be communicated to you during the meeting.

SUBSTANTIVE ISSUES TO BE DISCUSSED AT THE LATE CYCLE MEETING:

CHEMISTRY, MANUFACTURING AND CONTROLS

There are no substantive review issues at this time.

NON-CLINICAL PHARMACOLOGY / TOXICOLOGY

There are no substantive review issues at this time.

CLINICAL PHARMACOLOGY

There are no substantive review issues at this time.

CLINICAL

There are no substantive review issues at this time.

BIORESEARCH MONITORING

There are no substantive review issues at this time.

PHARMACOVIGILANCE

There are no substantive review issues at this time.

LABELING

- APLB will perform a secondary review of the proprietary name within 90 days of the Action Due Date.
- Recommendations to the Prescribing Information and the vial and carton labels will be provided as part of the labeling review.

ADVISORY COMMITTEE MEETING

Presentation of the BLA at the Blood Products Advisory Committee meeting is not planned.

REMS OR OTHER RISK MANAGEMENT ACTIONS

No issues were identified that would require a Risk Evaluation and Mitigation Strategy (REMS).

OUTSTANDING INFORMATION REQUESTS

There are no outstanding information requests at this time.

POSTMARKETING STUDIES NOT SUBJECT TO REPORTING REQUIREMENTS OF 21 CFR 601.70

1. Cangene commits to (b) (4) [REDACTED] This change will be submitted, with validation data, as a CBE-30 by March 25, 2016.
2. Cangene commits to (b) (4) [REDACTED] The validation report will be submitted to CBER as a CBE-30 by March 25, 2016.
3. Cangene commits to (b) (4) [REDACTED] will be submitted to CBER as a CBE-0 by March 25, 2016.

LCM AGENDA

1. Introductory Comments – 5 minutes (RPM/Chair)
Welcome, Introductions, Ground rules, Objectives of the Meeting
2. Discussion of Substantive Review Issues – 55 minutes
 - a. Other noted issues
 - b. Outstanding information requests
3. Post-marketing commitments and risk management – 10 minutes
4. Questions from Cangene – 10 minutes
5. Wrap up and Action Items – 10 minutes