

1/14/2008 Telecon - Seraclone Blood Grouping Reagent Anti-S (Monoclonal)

Memorandum

Date/Time: January 14, 2008 / 3:20 PM
CBER Najma Khan, CSO, DRB
Representatives: Valerie Coleman, CSO, DRB
Biotest' Representative: Pamela J. Vaughan
Subject: Discuss additional information required for submission.
To: File of STNs listed below

Submission Tracking Numbers	Product Proper Names
BL 125219/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal)
BL 125220/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal)
BL 125221/0	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)
BL 125224/0	Blood Grouping Reagent, Anti-M (Murine Monoclonal)
BL 125225/0	Blood Grouping Reagent, Anti-N (Murine Monoclonal)
BL 125230/0	Blood Grouping Reagent, Anti-K (Monoclonal)
BL 125232/0	Blood Grouping Reagent, Anti-k (Murine Monoclonal)
BL 125233/0	Blood Grouping Reagent, Anti-Le a (Murine Monoclonal)
BL 125213/0	Blood Grouping Reagent, Anti-P(Murine Monoclonal) 1

Submission Tracking Numbers	Product Proper Names
BL 125216/0	Blood Grouping Reagent, Anti-S (Monoclonal)
BL 125217/0	Blood Grouping Reagent, Anti-Jkb (Monoclonal)
BL 125222/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125223/0	Blood Grouping Reagent, Anti-D (Monoclonal Blend)
BL 125226/0	Blood Grouping Reagent, Anti-C (Monoclonal)
BL 125227/0	Blood Grouping Reagent, Anti-c ((Monoclonal)
BL 125228/0	Blood Grouping Reagent, Anti-E ((Monoclonal)
BL 125229/0	Blood Grouping Reagent, Anti-e ((Monoclonal)

Introduction: Biotest AG submitted the Biological License Applications (BLAs) for Blood Grouping Reagents.

Discussion: The italicized texts after the questions are the summary of the sponsor's response. The following issues were discussed:

1. Please provide the Blood Grouping Reagents lots to FDA and Lot Release Protocols to Joe Quander at APLB. During the review of response for CR letter, Attachment Q36, the following changes are recommended:

- Please replace STN to US license number in the CC column
- Reagent Lot number be more visible
- Please document results of bioburden testing. e.g. no growth.

Diagast promised to provide the recommended changes to the Lot Release Protocols and submit them to Joe Quander and me. She stated that she would find out the status of reagents from Biotest and respond by January 17, 2008.

2. Question 43 in the CR letter in Volume I, Investigational Plan, page 4 includes the liquid reagents list for the monoclonal antisera, Anti-M, Anti-N, Anti-k and Anti-P1, but does not include Anti-Lea. Furthermore, the introduction section contains detailed information for Monoclonal Rh and Kell antisera but not for Anti-Lea. The

response indicates that the results were omitted in error from the investigation plan and reagents were tested in the original trials and again in during the additional testing in 2007. However, the results were not included in the response. Please submit the results by January 17, 2008.

Diagast promised to submit the results of original testing and additional testing to FDA.

Agreements/Decisions/Action:

- Biotest will fax the response to FDA.

Prepared by Najma Khan on January 14, 2008