

From: Maruna, Thomas  
Sent: Friday, February 27, 2015 5:04 PM  
To: Allison Kennedy (akennedy@ebsi.com)  
Cc: Fisher, Robert  
Subject: STN 125562/0 Anthrax Immune Globulin Intravenous (Human):  
Labeling  
Comments  
Attachments: aig-prescribing-information-word. Feb-9-2015.docx

Importance: High

Our Reference: BL 125562/0

Dear Ms. Kennedy:

We have reviewed your February 9, 2015 revised Package Insert (PI), and are providing our additional comments in the annotated PI for revision (attached).

Please note that the review of the labeling is ongoing, and additional comments may be provided at a later date. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

Please submit your revisions as an amendment to this file by Tuesday, March 3, 2015 referencing the date of this request. Your early response will be appreciated.

The action due date for this file is March 25, 2015.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP)CM  
Lieutenant, U.S. Public Health Service  
Senior Regulatory Management Officer  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
thomas.maruna@fda.hhs.gov  
O: (240) 402-8454  
www.usphs.gov

"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the

document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.