

Telecon Script

Date: June 15, 2016

Product: *Babesia microti* Nuclei Acid Test (NAT)
Babesia microti Arrayed Fluorescence Immunoassay (AFIA)

Sponsor: Imugen, Inc.

STN: 125588, 125589

Topic: Response to Imugen regarding their request to (b) (4) the *Babesia* NAT and AFIA tests

This telephone conference is in response to (b) (6) request, on behalf of Imugen, Inc., “to discuss very briefly why the company believes the (b) (4) claim that the (b) (4) have been shown to reduce the incidence of disease transmission is a critical and clinically meaningful claim that extends beyond the stand-alone uses of the individual tests.”

FDA Teleconference Participants:

Sayah Nedjar
John (Peyton) Hobson
Babita Mahajan
Denise Zavagno
Hira Nakhasi
Robert Duncan
Iliana Valencia

Imugen Inc. (Imugen) teleconference Participants:

Victor Berardi, Imugen
Mary Ellen Hewins, Imugen
Bob Fortier, Imugen
Tony Fiore, Imugen
Katie Pomerantz, Imugen

(b) (6)

Summary of (b) (4) discussion:

Imugen presented a brief summary of the item for discussion. Imugen acknowledged that FDA and Imugen have held extensive discussions on the (b) (4) of the NAT and AFIA claim. Imugen reiterated its belief that it will be a service to the public health to

(b) (4) with a (b) (4) indication that will serve as a tool to interrupt disease transmission.

FDA reiterated that the (b) (4). And that the FDA does not support a (b) (4) claim. FDA stated that the (b) (4) of the NAT and AFIA tests is Imugen's business decision and would not be recognized in labeling by the FDA.

Imugen and the FDA discussed their positions several times without reaching an agreement.

To conclude, Denise Zavagno, general attorney, from OC indicated her agreement to OBRR's recommendation on not supporting a (b) (4) claim.

In addition, FDA raised concerns that Imugen has not reached out to us to discuss the items listed in the CR letters issued on September 29, 2015. FDA reminded Imugen of our wiliness to have an open dialogue for moving forward to achieving licensure for the two devices.

QC and Finalized:
Robert Duncan
Iliana Valencia