

Our STN: BL 125588

RESUBMISSION ACKNOWLEDGEMENT

Imugen, Inc.
Attention: Wolfgang Pieken, Ph.D.
315 Norwood Park South
Norwood, MA 02062

Dear Dr. Pieken:

We have received your December 12, 2016, resubmission to your biologics license application for *Babesia microti* Nucleic Acid Test on December 14, 2016.

The resubmission contains additional clinical, pre-clinical, process/product, CMC, quality systems, instruments and software, facility, equipment, and labeling information that you submitted in response to our September 29, 2015, complete response letter.

We consider this a complete response to our action letter. Therefore, the goal date is June 15, 2017.

If you have any questions, please contact me, the Regulatory Project Manager, at (240) 402-8444.

Sincerely,

Iliana Valencia
Chief, Regulatory Project Management Staff
Office of Blood Research and Review
Center for Biologics Evaluation and Research