



Our STN: BL 125589

**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* Arrayed Fluorescence Immunoassay on December 13, 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 14, 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