



Our STN: BL 125589/0

BLA FILING NOTIFICATION

Imugen, Inc.
Attention: Mr. Victor Berardi
315 Norwood Park South
Norwood, MA 02062

Dear Mr. Berardi:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated May 12, 2015 for Babesia microti Arrayed Fluorescence Immunoassay to determine its acceptability for filing. Under 21 CFR 601.2(a), we have filed your application today. The review goal date is November 11, 2015. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

While conducting our filing review, we identified potential review issues and will be communicating them to you on or before July 24, 2015.

If you have any questions, please contact the Regulatory Project Manager, Alisha Miller, at 240-402-8421.

Sincerely,

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