DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ESTELA RAYCHAUDHURI, PRESIDENT,
INBIOS INTERNATIONAL, INC.
562 1ST AVE. S. SUITE 600
SEATTLE, WA 98104

March 27, 2017

Re: EUA160013/A001
Trade/Device Name: ZIKV Detect IgM Capture ELISA
Dated: January 27, 2017
Received: January 31, 2017

Dear Ms. Raychaudhuri:

This is to notify you that your request to modify the Instructions for Use labeling for the ZIKV Detect IgM Capture ELISA to improve the overall clarity of the procedural steps involved in the ZIKV Detect IgM Capture ELISA and to modify the Fact Sheets authorized with the ZIKV Detect IgM Capture ELISA to combine the Fact Sheet for Patients and the Fact Sheet for Pregnant Women into one Fact Sheet for Patients and to include updated language to align with the latest CDC Zika Laboratory Guidance, implemented in November 2016, have been granted. By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the ZIKV Detect IgM Capture ELISA issued August 17, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure