DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 6, 2018

CDR Yon Yu, Pharm.D.
Associate Director for Regulatory Affairs
Office of the Director
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS E-51
Atlanta, GA 30329-4027

Re: EUA27/Serial #004—Request for Amendment to Allow Rafa-Planned Manufacturing Changes
Product Name: Rafa Atropine Auto-Injector
Dated: December 6, 2017 (Serial #004)
Received: December 7, 2017 (Serial #004)

Dear Dr. Yu:

This letter is to notify you that your request for a change to the Rafa-planned manufacturing process specified below for the authorized Rafa Atropine Auto-Injector (0.5 mg, 1 mg, and 2 mg) under the April 11, 2017, EUA has been granted.

Upon review, we concur that the additional data submitted by CDC support implementation of Item 6 of the proposed Rafa-planned manufacturing process changes (Serial #004).

By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the April 11, 2017, letter authorizing the emergency use of the Rafa Atropine Auto-Injector.

Sincerely,

{See appended electronic signature page}

Billy Dunn, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILLIAM H Dunn
03/06/2018