DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

May 15, 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, #005, and #006—Requests for Amendments to Allow Rafa-Planned Manufacturing Changes and Response to FDA Request for Information Regarding Manufacturing Changes
Product Name: Rafa Atropine Auto-Injector
Dated: December 6, 2017 (Serial #004); March 12, 2018 (Serial #005); April 13, 2018 (Serial #006)
Received: December 7, 2017 (Serial #004); March 13, 2018 (Serial #005); April 16, 2018 (Serial #006)

Dear Dr. Yu:

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

Upon review, we concur that the additional data submitted by CDC support implementation of Item 1 (Serial #004) and Item 9 (Serial #005 and #006) of the proposed Rafa-planned manufacturing process changes.

By submitting these amendments 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
05/15/2018