DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

January 24, 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 #003 and #004—Requests for Amendments to Allow Administration of Auto-Injector through Clothing and Rafa-Planned Manufacturing Changes
Product Name: Rafa Atropine Auto-Injector
Dated: October 23, 2017 (Serial #003) and December 6, 2017 (Serial #004)
Received: October 24, 2017 (Serial #003) and December 7, 2017 (Serial #004)

Dear Dr. Yu:

This letter is to notify you that your requests (1) to update the authorized EUA Fact Sheets for the authorized Rafa Atropine Auto-Injector under the April 11, 2017, EUA to clarify that the authorized product (0.5 mg, 1 mg, and 2 mg) may be administered through clothing and (2) for changes to certain Rafa-planned manufacturing processes specified below have been granted.

Upon review, we concur that the additional data that CDC submitted for EUA27 support the administration of the 0.5 mg, 1 mg, and 2 mg strengths of the Rafa Atropine Auto-Injector through clothing (Serial #003). We also concur with the related updates of the Fact Sheets for the authorized Rafa Atropine Auto-Injector to provide instructions on the administration of this product through clothing (Serial #003). In addition, we concur with Items 2-5 of the proposed Rafa-planned manufacturing process changes (Serial #004).

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

Enclosures:
Healthcare Provider and Patient/Caregiver Fact Sheets

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/s/

WILLIAM H Dunn
01/24/2018