DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

May 23, 2017

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 #001 and #002—Request for Amendment of the Rafa Emergency Use Authorization (EUA) to Authorize 0.5 mg and 1 mg Strengths and to Revise the Authorized Fact Sheets and Labels
Product Name: Rafa Atropine Auto-Injector
Dated: April 19, 2017 (Serial #001) and April 20, 2017 (Serial #002)
Received: April 20, 2017 (Serial #001) and April 21, 2017 (Serial #002)

Dear Dr. Yu:

This letter is to notify you that your request for the Food and Drug Administration (FDA) to (1) authorize additional strengths (i.e., 0.5 mg and 1 mg) of the authorized Rafa Atropine Auto-Injector under the April 11, 2017, EUA and (2) update the authorized EUA Fact Sheets and carton and container labels for the authorized Rafa Atropine Auto-Injector to include information about the 0.5 mg and 1 mg strengths has been granted.

Upon review, we concur that the additional data that CDC submitted for EUA27 support the authorization of the 0.5 mg and 1 mg strengths, in addition to the 2 mg strength, such that all three of these strengths (i.e., 0.5 mg, 1 mg, and 2 mg) of the Rafa Atropine Auto-Injector are now authorized under the EUA. We also concur with the related updates of the Fact Sheets and labels for the authorized Rafa Atropine Auto-Injector that reflect the addition of the 0.5 mg and 1 mg strengths. 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,

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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
0.5 mg and 1 mg Carton and Container Labels