October 30, 2019

La Misha Fields
Electronic Submissions Gateway
U.S Food and Drug Administration
3WFN, Room 7C34
12225 Wilkins Avenue
Rockville, MD 20852
Office: (240) 402-5192

Re: Electronic Signature Certificate Statement (Non-Repudiation Letter)

Dear Ms. Fields,

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that SUNY Downstate Health Sciences University (also known as SUNY Health Science Center at Brooklyn and SUNY Downstate Medical Center), intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures.

Sincerely yours,

Heidi Aronin, MPA
Senior Vice President and Chief Administrative Officer
Additional original source document with hand-written signature to:
  U.S Food and Drug Administration
  Office of Regional Operations (HFC-100)
  5600 Fishers Lane
  Rockville, MD 20857

Electronic copy to FDA Electronic Submissions Gateway e-mail: ESGHelpDesk@fda.hhs.gov

CC: Renee Poncet
    Joseph Barabino
    Shoshana Milstein
    Clinton Brown, MD, FASN, FAHA, FNLA
    Kevin Nellis, MS, CIP