DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 19, 2019

Aparna Dagar Ph.D., RAC
Director, Regulatory Affairs
Fresenius Kabi USA, LLC.
Three Corporate Drive
Lake Zurich, Illinois 60047

Sent via email to: Aparna.Dagar@fresenius-kabi.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA make a determination that Ketamine Hydrochloride Injection, 100 mg/10 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL) is suitable for submission as an ANDA was received by this office on 09/18/2019.

It was assigned docket number FDA-2019-P-4386. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.09.19 15:03:19 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)