DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20852

January 8, 2019

Laurie Wojtko
Director, Sterile Injectable Pipeline & API
Pfizer Innovative Health Global Regulatory Affairs
Hopira, Inc.
275 North Field Drive, Bldg. H1
Lake Foret, IL 60045

Sent via email to: laurie.wojtko@pfizer.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration make a determination that Ketamine Hydrochloride Injection, 200 mg/2mL (100 mg/mL) is suitable for submission as an ANDA was received by this office on 1/3/2019.

It was assigned docket number FDA-2019-P-0114. 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,

Karen Kennard

Karen Kennard
Acting Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)