DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 28, 2019

Kip Vought
Scilex Pharmaceuticals, Inc.
27201 Puerta Real, Suite 235
Mission Viejo, CA 92691

Sent via email to: kvought@scilexpharma.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner initiate all administrative and judicial action necessary to remove from the market, and to prevent the further marketing of lidocaine-containing drug products in patch, plaster, poultice, or comparable delivery systems that have not been approved pursuant to a new drug application or an abbreviated new drug application submitted under 21 U.S.C. § 355 and implementing regulations was received by this office on 12/31/2018.

It was assigned docket number FDA-2019-P-0417. 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 Bigby

Digitally signed by Dynna Bigby
Date: 2019.01.28 16:50:13 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)