FDA U.S. FOOD & DRUG ADMINISTRATION

Kip Vought
Vice President, Global R&D
Scilex Pharmaceuticals, Inc.
27201 Puerta Real, Suite 235
Mission Viejo, CA 92691

Re: Docket No. FDA-2019-P-0417 JUN 28 2019

Dear Mr. Vought:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on December 31, 2018. Your petition requests that the Agency 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.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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