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

December 14, 2022

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

Dear Mr. Vought:

This letter responds to your citizen petition received on December 31, 2018 (Petition), requesting that the Food and Drug Administration (FDA or the Agency) take the following actions with respect to unapproved, lidocaine-containing drug products in patch, plaster, poultice, and comparable delivery systems:

1. Initiate all administrative and judicial actions 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 ("NDA") or an abbreviated new drug application ("ANDA") submitted under 21 U.S.C. 355 and implementing regulations;

2. Strictly apply the provisions of 21 U.S.C. 355, 21 C.F.R. 330, and related regulatory decisions, which do not allow the marketing or distribution of lidocaine-containing patch dosage form drug products that were introduced into United States ("U.S.") commerce after the OTC drug review was initiated on May 11, 1972;

3. Finalize the Tentative Final Monograph for External Analgesic Drug Products for Over-the-Counter Human Use, as amended (the "TFM" or "External Analgesics TFM"), which expressly excludes lidocaine-containing products in patch dosage forms from its scope because of concerns about the safety and efficacy of these products;

4. Publish an immediately applicable enforcement policy guidance document that will apply until the final OTC External Analgesic Monograph is codified, and that affirms that lidocaine-containing drug products marketed in nonprescription patch dosage forms ("OTC lidocaine patches") and that are marketed without approved NDAs or ANDAs do not conform to the terms of the External Analgesics TFM, are outside the scope of any enforcement discretion that may exist pursuant to Compliance Policy Guide 450.200 or other relevant statements of enforcement discretion, and may be the subject of immediate enforcement action without further notice; and

5. Initiate and regularly review drug listing and other marketplace information to identify lidocaine-containing products in patch dosage forms and take appropriate administrative and judicial action to ensure their compliance with the Federal Food, Drug, and Cosmetic Act, implementing regulations, and findings pursuant to this Petition.

(Petition at 1-3). We have carefully considered your Petition. For the reasons described below, your Petition is denied.

While your Petition was pending with the Agency, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted,[1] adding section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) and changing certain aspects of the legal framework for nonprescription drug products marketed without an approved application. As a result of the enactment of section 505G, the process by which the Agency evaluates a request for an addition to or revision of an over-the-counter (OTC) monograph has changed. In particular, the addition of section 505G to the FD&C Act has changed the mechanism for establishing, amending, or withdrawing OTC monographs from a rulemaking process to an administrative order process.

Under section 505G(b) of the FD&C Act, FDA may, on its own initiative or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs is determined to be not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)) and generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). Under section 505G(b)(5) of the FD&C Act, a requestor seeking that the Secretary issue such an administrative order "shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary." According to section 744L(7) of the FD&C Act (21 U.S.C. 379j-71(7)), such a request is termed an *OTC monograph order request* (OMOR). A "requestor" is broadly defined in section 505G(q)(3) as "any person or group of persons marketing, manufacturing, processing, or developing a drug."

Because you are a *requestor*, as defined in section 505G(q)(3) of the FD&C Act and your Petition requests a type of relief that could be sought under an OMOR (see 505G(b)(5) of the FD&C Act), the citizen petition process is no longer the appropriate procedure for addressing your request, and your Petition is denied. Please note that information about the OMOR process is available on FDA's website[2] should you pursue that process for your request.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2022.12.14 10:02:19 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[1] Public Law No. 116-136, 134 Stat. 281 (March 27, 2020).

[2] See *OTC Drug Review Process | OTC Drug Monographs*, available at https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs; see also *Over-the-Counter (OTC) Drug Review | OTC Monograph Reform in the CARES Act*, available at https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor.