DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 207407

ANDA APPROVAL

Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave.
Carmel, NY 10512
Attention: Katy Rudnick
Manager, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL.

Reference is also made to your amendments dated October 3, 2014; September 3, 2015; and April 8, April 12, October 7, December 8, and December 19, 2016.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Kaletra Oral Solution of AbbVie Inc. (AbbVie).

The RLD upon which you have based your ANDA, AbbVie's Kaletra Oral Solution, 80 mg/20 mg per mL, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,911,214 (the '214 patent) and 8,501,219 (the '219 patent) are scheduled to expire on May 28, 2022 (with pediatric exclusivity added) and November 28, 2021, respectively.

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL, under this ANDA. You have notified the agency that Silarx Pharmaceuticals, Inc. (Silarx) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Silarx within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Silarx was the first ANDA applicant for Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Silarx may be eligible for 180 days of generic drug exclusivity for Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL. This exclusivity, which is provided for under section

505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Silarx failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failed to obtain tentative approval). The agency is not, however, making a formal determination at this time of Silarx's eligibility for 180-day generic drug exclusivity. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Silarx begins commercial marketing of Lopinavir and Ritonavir Oral Solution USP, 80 mg/20 mg per mL, or (b) at any time prior to the expiration of the '214 and '219 patents if Silarx has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not

met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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