





SHORLA ONCOLOGY
THE HEART OF INNOVATION

 Shorla Oncology Inc.
245 Main St
2nd Floor
Cambridge
MA 02142
USA

 +1 617-225-4379

 info@shorlaoncology.com

 www.shorlaoncology.com

May 17th, 2023

To Whom It May Concern:

This email is to inform the Attorney General's Office for the State of Vermont that Shorla Oncology has been granted FDA Approval as of March 6th, 2023, for the following products:

- 81927-0111-01 - NELARABINE (NELARABINE) 250MG/50ML (5MG/ML) 1 x 50 ML VIAL, Single-Dose Vial
- 81927-0111-06 - NELARABINE (NELARABINE) 250MG/50ML (5MG/ML) 6 x 50 ML VIAL, Single-Dose Vial

Shorla made both products commercially available on May 16th, 2023. This product is a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. Please see attached FDA Approval letter.

Please contact us with any questions.

Sincerely,





ANDA 214809

ANDA APPROVAL

RegCon Solutions, LLC
U.S. Agent for Shorla Pharma Limited
10525 Vista Sorrento Parkway, Suite 100
San Diego, CA 92121
Attention: Lauren Ford
President

Dear Lauren Ford:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 11, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial.

Reference is also made to the complete response letter issued by this office on August 10, 2022, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Arranon Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial, of Novartis Pharmaceuticals Corporation.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated May 26, 2020.

We note that Shorla Pharma Limited (Shorla) was granted a Competitive Generic Therapy (CGT) designation for Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial. However, Shorla is not a “first approved applicant” for such CGT, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

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 and 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.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506l of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506l(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <https://www.fda.gov/media/128163/download>).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <https://www.fda.gov/media/73013/download>. Information and Instructions for completing the form can be found at <https://www.fda.gov/media/132152/download>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-ectd>.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions¹ with respect to self-identification of facilities and payment of annual facility fees. ANDAs that identify at least one facility that is referenced in an approved ANDA are subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st 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 or active pharmaceutical ingredients 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.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

CONTENT OF LABELING

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 <https://www.fda.gov/media/71211/download>. The SPL will be accessible via publicly available labeling repositories.

We remind you that you must continually monitor available labeling resources such as DRUGS@FDA for changes to your reference listed drug's labels and labeling and make any necessary revisions to your labels and labeling.

More information on post-approval labeling changes may be found in the guidance for industry titled "Changes to an Approved NDA or ANDA" at <https://www.fda.gov/media/71846/download>.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

¹ Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



Paul
Levine

Digitally signed by Paul Levine

Date: 3/03/2023 11:38:32AM

GUID: 56323ddc003554a87fad6698c2baa467