

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217766Orig1s000

OTHER ACTION LETTERS



NDA 217766

TENTATIVE APPROVAL

Long Grove Pharmaceuticals, LLC (A Capstone Development Services Company)
Attention: Parthrajsinh Jadeja
Senior Manager, Regulatory Affairs
9450 W. Bryn Mawr Ave., Suite 200
Rosemont, IL 60018

Dear Parthrajsinh Jadeja:

Please refer to your new drug application (NDA) dated and received June 30, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Vasopressin in Sodium Chloride injection.

This NDA proposes the use of Vasopressin in Sodium Chloride injection to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information, carton and container labeling). This tentative approval determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Your application contains certifications to patents under section 505(b)(2)(A)(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, this drug product under this application ("paragraph IV certification"). Section 505(c)(3)(C) of the FD&C Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the FD&C Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of 45 days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the FD&C Act. However, because the 45-day period described in section 505(c)(3)(C) of the FD&C Act has not yet expired, final approval cannot be granted at this time.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **“REQUEST FOR FINAL APPROVAL”**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved, and cannot be legally marketed and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* (April 2016)¹, guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* (December 2020), and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)²

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² <https://www.fda.gov/media/151712/download>

If you have any questions, contact Quynh Nguyen, PharmD, RAC-US, Regulatory Project Manager, at (301) 796-0510.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, MD, PhD
Director
Division of Cardiology and Nephrology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
 - Prescribing Information
 - Carton and Container Labeling

13 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NORMAN L STOCKBRIDGE
04/30/2024 12:55:14 PM