



NDA 19777/S-074

SUPPLEMENT APPROVAL

Alvogen Malta Operations Ltd.
c/o Alvogen Pine Brook LLC
Attention: Patricia Jaworski, US Agent
Vice President, Regulatory Affairs
10 Bloomfield Avenue, Building B
Pine Brook, NJ 07058

Dear Ms. Jaworski:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 20, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zestril® (lisinopril) Tablets 2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg.

We also refer to your amendment submitted and received January 14, 2016.

This Prior Approval supplemental new drug application proposes the following changes to the Prescribing Information:

1. In section 12 CLINICAL PHARMACOLOGY, Subsection 12.3 Pharmacokinetics, Subheading *Pediatric Patients*, the following sentence was inserted at the end of the paragraph:
“In a multicenter, open-label pharmacokinetic study of daily oral lisinopril in 22 pediatric hypertensive patients with stable kidney transplant (ages 7-17 years; estimated glomerular filtration rate > 30 mL/min/1.73 m²), dose normalized exposures were in the range reported previously in children without a kidney transplant.”
2. Section 8 was revised to comply with the Pregnancy and Lactation Labeling Rule.
3. Minor formatting and editorial changes were made throughout the prescribing information (revision date, new ownership, label ID).

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact Sabry Soukehal, Regulatory Health Project Manager, at (240) 402-6187.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Agreed-upon labeling text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
04/21/2016