DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18415/S-026

SUPPLEMENT APPROVAL

DAVA Pharmaceuticals, Inc.
Attention: Susan F. Hamet
Vice President, Regulatory Affairs
Parker Plaza
400 Kelby Street, 10th Fl
Fort Lee, NJ 07024

Dear Ms. Hamet:

Please refer to your Supplemental New Drug Application (sNDA) dated October 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Furosemide Tablets, 20 mg, 40 mg, and 80 mg.

We acknowledge receipt of your amendments dated October 9, 2006, February 23, 2007, and December 12, 2011

The December 12, 2011 submission constituted a complete response to our August 7, 2006, action letter.

This "Changes Being Effected" supplemental new drug application provides for container and package insert updates.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter. We understand that you have not manufactured this product since 2007. You have agreed to update the labeling to incorporate the most recent updates to the RLD prior to resuming manufacturing.

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 call Alexis Childers, Sr. Regulatory Project Manager at (301) 796-0442.

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

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
10/01/2014