DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022210/S-008

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Eurand Pharmaceuticals Limited
c/o Eurand Pharmaceuticals, Inc., U.S. Agent
Attention: Susan Thornton
Director, Regulatory Affairs
790 Township Line Road, Suite 250
Yardley, PA 19067

Dear Ms. Thornton:

Please refer to your Supplemental New Drug Application (sNDA) dated May 26, 2011, received May 27, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZENPEP (pancrelipase) Delayed-Release Capsules.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 14, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved ZENPEP (pancrelipase) REMS.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for ZENPEP (pancrelipase) was originally approved on August 27, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for ZENPEP (pancrelipase).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of ZENPEP (pancrelipase) outweigh its risks and a REMS for ZENPEP (pancrelipase) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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, call Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

JOYCE A KORVICK
06/10/2011