FDA U.S. FOOD & DRUG ADMINISTRATION

NDA 022430

TRANSFER OF NDA OWNERSHIP

Amring Pharmaceuticals Inc.
c/o Freyr INC
Attention: Hiteshri Choksi
150 College Road West, Suite 102
Princeton, New Jersey 08540, USA

Dear Mr. Choksi:

We acknowledge the December 10, 2020, correspondence notifying the Food and Drug Administration of the change of ownership of the following new drug application (NDA):

Name of Drug Product:	Lysteda (tranexamic acid)
NDA Number:	022430
Name of New Applicant:	Amring Pharmaceuticals Inc.
Name of Previous Applicant:	Ferring Pharmaceuticals Inc.

Your correspondence provided the information necessary to effect this change, and we have revised our records to indicate Amring Pharmaceuticals Inc. as the applicant of record for this application.

DRUG MASTER FILE LETTER OF AUTHORIZATION

If your NDA references any Drug Master Files (DMF) we request that you notify your suppliers and contractors who have DMFs referenced by your NDA of the change so that they can submit a new letter of authorization (LOA) to their Drug Master File(s) and send you a copy of the new LOAs. Please submit these copies of the LOAs to this NDA.

REPORTING REQUIREMENTS

All changes to the information in the NDA from that described by the original owner, such as manufacturing facilities and controls, must be reported to us prior to implementation. However, changes in the name of the manufacturer, packer, or distributor in the drug product's label or labeling may be reported in the next annual report. Refer to the guidance for industry *Changes to an Approved NDA or ANDA* for information on reporting requirements.

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/

MARIA R WASILIK
01/13/2021 03:54:14 PM

MARGARET M KOBER
01/13/2021 04:19:28 PM
Chief, Project Management Staff

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 21 CFR 314.81. In addition, you are responsible for any correspondence outstanding as of the effective date of the transfer.

Please cite the NDA number listed above at the top of the first page of all submissions to this application.

If you have any questions, call Maria Wasilik, Regulatory Project Manager at 301-796-0567.

Sincerely,

{See appended electronic signature page}

Margaret Kober, R.Ph., M.P.A.
Chief, Project Management Staff
Urology, Obstetrics, and Gynecology
Division of Regulatory Operations for Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine
Office of Regulatory Operations
Center for Drug Evaluation and Research

cc: Ferring Pharmaceuticals Inc.
Attention: Kevin Wyckoff
Director, US Regulatory Affairs
100 Interpace Parkway
Parsippany, NJ 07054