NDA 022430/S-009

SUPPLEMENT APPROVAL

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

Dear Mr. Wyckoff:

Please refer to your supplemental new drug application (sNDA) dated December 10, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lysteda (tranexamic acid).

This Prior Approval supplemental new drug application provides for the following change for Lysteda: Pregnancy and Lactation Labeling/PLLR Conversion with proposed changes to Section 8 USE IN SPECIFIC POPULATIONS of the full prescribing information.

APPROVAL & LABELING

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

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert), with the addition of any labeling changes in pending "Changes Being Effected" (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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

The SPL will be accessible from publicly available labeling repositories.

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 Maria Wasilik, Regulatory Project Manager, at 301-796-0567.

Sincerely,

{See appended electronic signature page}

Catherine Sewell, M.D., M.P.H.
Deputy Director for Safety
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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
12/04/2020 01:16:38 PM

CATHERINE A SEWELL
12/07/2020 09:00:21 AM