DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022430/S-002

SUPPLEMENT APPROVAL

Ferring Pharmaceuticals Inc.
Attention: John B. Berryman, M.S.
Senior Director Regulatory Affairs
4 Gatehall Drive, 3rd floor
Parsippany, NJ 07054

Dear Mr. Berryman:

Please refer to your Supplemental New Drug Application (sNDA) dated December 2, 2010, and received December 3, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LYSTEDA (tranexamic acid) tablets 650 mg.

We acknowledge receipt of your amendments dated December 15, 2010, and March 29, 2011.

This supplemental new drug application proposes changes to the WARNING AND PRECAUTIONS section of Physician Labeling and to Patient Labeling. These changes are related to the risk of thromboembolic events, particularly the risk in women who are obese or smoke cigarettes and are using both LYSTEDA and a hormonal contraceptive. New language also states that LYSTEDA should not be used in women taking more than the approved dose of a hormonal contraceptive.

Other changes include:

- Addition of "ligneous conjunctivitis" to Highlights (WARNING AND PRECAUTIONS)
- Rearranging and formatting changes to the WARNING AND PRECAUTIONS section of Physician Labeling to include several topics under the general header of 5.1 Thromboembolic Risk
- Placing "ligneous conjunctivitis" in a separate section in the WARNING AND PRECAUTIONS section of Physician Labeling
- Other formatting and editorial changes

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 with the minor editorial revisions listed below:

- Changed "RECENT CHANGES" to "RECENT MAJOR CHANGES" in HIGHLIGHTS section.
- Revision date changed to April 2011.

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 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 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 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

SCOTT E MONROE
04/06/2011