DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202093

Watson Laboratories, Inc.-Florida
Attention: Radha Goolabsingh
Manager, Regulatory Affairs
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 23, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tranexamic Acid Tablets, 650 mg.

Reference is made to your amendments dated February 18, April 26, July 22, August 3, October 6, October 21, and November 29, 2011; and February 6, 2012. We also acknowledge receipt of your correspondences dated May 24, July 11, October 12, and November 30, 2011, addressing the patent and exclusivity issues associated with this ANDA.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Lysteda Tablets 650 mg of Ferring Pharmaceuticals AS, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with

Therapeutic Equivalence Evaluations (the “Orange Book”), U.S. Patent Nos. 7,947,739 (the '739 patent) and 8,022,106 (the '106 patent) are both scheduled to expire on March 4, 2025.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tranexamic Acid Tablets, 650 mg, under this ANDA. You have notified the agency that Watson Laboratories, Inc.-Florida (Watson) complied with the requirements of section 505(j)(2)(B) of the Act. The ‘739 and ‘106 patents were not listed when you submitted your ANDA; litigation with respect to either of these patents will not give rise to a stay of approval under the Act.

However, we are unable to fully approve your ANDA at this time because of the RLD’s exclusivity (new dosage form) that has not yet expired. This exclusivity expires on November 13, 2012.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

To reactivate your ANDA prior to final approval, please submit a “MINOR AMENDMENT – FINAL APPROVAL REQUESTED” 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' cGMPs are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either “major” or “minor” changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the “Orange Book.”

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Frank J. Nice, Project Manager, at (240) 276-8555.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

ROBERT L WEST

02/16/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.