



ANDA 202093

Watson Laboratories, Inc. - Florida  
Attention: Janet Vaughn  
Director, 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 also made to the tentative approval letter issued by this office on February 16, 2012, and to your amendments dated August 29, October 10, November 5, and November 26, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Tranexamic Acid Tablets, 650 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lysteda Tablets, 650 mg, of Ferring Pharmaceuticals AS (Ferring). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Ferring's Lysteda Tablets, 650 mg, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,947,739 (the '739 patent)	March 4, 2025
8,022,106 (the '106 patent)	March 4, 2025
8,273,795 (the '795 patent)	March 4, 2025

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is 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 agency notes that the '739, '106, and '795 patents were submitted to the agency after submission of your ANDA and therefore litigation, if any, with respect to it creates no statutory stay of approval.

With respect to 180-day generic drug exclusivity, we note that Watson was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the '739 patent. Therefore, with this approval, Watson is eligible for 180 days of generic drug exclusivity for Tranexamic Acid Tablets, 650 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed

launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

Gregory P. Geba, M.D., M.P.H.  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT L WEST

12/27/2012

Deputy Director, Office of Generic Drugs, for  
Gregory P. Geba, M.D., M.P.H.