

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-430

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 022430

NDA APPROVAL

Xanodyne Pharmaceuticals, Inc.
Attention: Sabrina Girty, Esq.
One Riverfront Place
Newport, KY 41071-4563

Dear Ms. Girty:

Please refer to your new drug application (NDA) dated and received January 30, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lysteda (tranexamic acid) tablets.

We acknowledge receipt of your submissions dated March 2, 6, 13, 20, 25, and 31, April 14, 24, and 30, May 18, June 4, 18, 23, and 30, September 4, 11, 15, 28, and 30, October 21, 27, and 30, November 2, 5, 6, 10, and 13, 2009.

This new drug application provides for the use of Lysteda (tranexamic acid) tablets for the treatment of cyclic heavy menstrual bleeding.

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 agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling. For administrative purposes, please designate this submission "SPL for approved NDA 022430."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your September 15, 2009, submission containing final printed carton and container labels.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

We are waiving the pediatric study requirement for ages 0 to 11 years because tranexamic acid is indicated for women with cyclic heavy menstrual bleeding and is not indicated for use in pre-menarcheal children.

We are deferring submission of your pediatric study for ages 12 to 17 years until March 31, 2012, because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1554-1 Deferred pediatric study under PREA for the assessment of the pharmacokinetics of tranexamic acid in healthy pediatric patients, ages 12 to 17 years, with heavy menstrual bleeding.

Protocol Submission Date:	February 28, 2010
Study Start Date:	September 30, 2010
Final Report Submission Date:	March 31, 2012

Submit the final study report to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated **“Required Pediatric Assessments.”**

POSTMARKETING COMMITMENT

We remind you of your postmarketing study commitment in your submission dated October 21, 2009. This commitment is listed below.

1554-2 Conduct a pharmacoepidemiologic study based on drug use information to assess the patterns of concomitant use of Lysteda and hormonal contraception, including assessment of the ages of women using both products as compared to women using Lysteda alone.

Final Protocol Submission:	January 30, 2010
Study Completion Date:	July 30, 2012
Final Report Submission:	January 30, 2013

Submit the final protocol to your IND for this product with a cross-reference letter to this NDA. Submit the final report and the interim study report, following collection of the first year of data, to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of your commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and the number of patients entered into the study. All submissions, including supplements, relating to this postmarketing study commitment should be prominently labeled **“Postmarketing Study Commitment Protocol,” “Postmarketing**

Study Commitment Final Report,” or “Postmarketing Study Commitment Correspondence.”

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials and the package insert at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

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

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22430

ORIG-1

XANODYNE
PHARMACEUTICS
INC

Lysteda

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

11/13/2009