



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20852-1448

December 26, 2006

ZymoGenetics, Inc.  
Attention: Mr. Mark W Gauthier  
1201 Eastlake Avenue East  
Seattle, WA 98102

Dear Mr. Gauthier:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

**Our Submission Tracking Number (STN):** BL 125248/0

**Name of Biological Product:** Thrombin (Recombinant)

**Indication:** General adjunct to hemostasis

**Date of Application:** December 15, 2006

**Date of Receipt:** December 18, 2006

**Action Due Date:** October 18, 2007

**US License Number and Manufacturing Site:** 1758

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirements. We acknowledge receipt of your request for a waiver of pediatric studies for this application. Once the application has been filed we will notify you whether we have waived the pediatric study requirement for this application.

We request that you submit all future correspondence, supporting data, or labeling relating to this application in triplicate, citing the above STN number. Send all correspondence to the following address:

Jay Epstein, M.D.  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
Suite 200N  
1401 Rockville Pike  
Rockville, MD 20852-1448

Page 2 – Mr. Gauthier

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

If you have any questions, please contact the Regulatory Project Manager, Mark Shields, at (301) 827-6173.

Sincerely yours,

A solid black rectangular box redacting the signature of Mark A. Shields.

For  
Mark A. Shields  
Consumer Safety Officer  
Division of Blood Applications  
Office of Blood Research and Review  
Center for Biologics  
Evaluation and Research