DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BLA 125029/80

MAR 2 2 2007

Eli Lilly and Company
Attention: Peter Morrow, M.Sc.
Manager, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Morrow:

Please refer to your supplemental biologics license application, submitted September 19, 2005, for Xigris [drotrecogin alfa (activated)]. This submission revises the following sections of the labeling and fulfills post-marketing commitment #15 identified in the November 21, 2001 approval letter.

CLINICAL PHARMACOLOGY section, **Special Populations**, *Pediatrics*, subsection
CLINICAL STUDIES section, **STUDY 3 (Pediatric Study)**, subsection
INDICATIONS AND USAGE section
PRECAUTIONS section, **Pediatric Use** subsection

We also acknowledge receipt of your additional correspondence to this supplement dated December 23, 2005, January 11, 2006, May 30, 2006, November 13, 2006, and January 25, 2007.

Postmarketing commitment #15 is as follows:

"To evaluate the efficacy and safety of Drotrecogin alfa (activated) in a study of approximately 500 pediatric patients with severe sepsis. The protocol will include appropriate neurological evaluation of patients to detect potential occult neurological events".

We have completed our review of this supplement and it has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding this postmarketing study on our Web site (http://www.fda.gov/cder/pmc/default.htm). Please refer to the February 2006 Guidance for Industry: Reports on the Status of Postmarketing Study Commitments - Implementation of Section 130 of the Food and Drug Administration

Modernization Act of 1997 (see http://www.fda.gov/cder/guidance/5569fnl.htm) for further information.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research