DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125277/32

SUPPLEMENT BLA APPROVAL
April 5, 2011

Dyax Corp.
300 Technology Square
Cambridge, MA 02139

Attention: Nicole D' Auteuil
Vice President, Regulatory Affairs & Operations

Dear Ms. D' Auteuil:

Please refer to your Supplemental Biologics License Application (sBLA), dated March 9, 2011, received March 10, 2011, submitted under section 351 of the Public Health Service Act for Kalbitor (ecallantide) Injection, and your risk evaluation and mitigation strategy (REMS) assessment dated March 9, 2011.

This Prior Approval supplement to your biologics license application provides for modifications to the approved REMS to update the name of the signatory of the Dear Healthcare Provider (DHCP) Letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Kalbitor (ecallantide) was originally approved on December 1, 2009. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of an update to the DHCP letter to change the name of the signatory.

Your proposed modified REMS, submitted on March 9, 2011, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on December 1, 2009.

There are no changes to the REMS assessment plan described in our December 1, 2009, letter.

We remind you that assessments of an approved REMS must also include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any

difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 601.70 and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

BLA 125277 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125277
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125277
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 796-1230.

Sincerely,

/ Sally Seymour /
Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
REMS
REMS Materials

Appears This Way On Original