DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125277/50

SUPPLEMENT APPROVAL

Dyax Corp.
55 Network Drive
Burlington, MA 01803

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

Dear Ms. D'Auteuil:

Please refer to your Supplemental Biologics License Application (sBLA), dated March 28, 2012, received March 28, 2012, submitted under section 351 of the Public Health Service Act for Kalbitor (ecallantide) Injection.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 28, 2012.

This Prior Approval supplement to your biologics license application provides for modifications to update the REMS and the appended Dear Healthcare Provider (DCHP) letter with a change of address for Dyax Corp. as well as a change of signatory on the DHCP letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Kalbitor (ecallantide) was originally approved on December 1, 2009, and a REMS modification was approved on August 17, 2011. The REMS consists of communication plan, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of an update to the REMS and the appended DCHP letter with a change of address for Dyax Corp. as well as a change of signatory on the letter.

Your proposed modified REMS, submitted on March 28, 2012, 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 August 17, 2011, 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.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

BLA 125277 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

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,

{See appended electronic signature page}

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

ENCLOSURE(S):
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
04/24/2012