DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125277/65

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Dyax Corp.
55 Network Drive
Burlington, MA 01803

Attention: Nicole D'Auteuil
Vice President, Regulatory

Dear Ms. D'Auteuil:

Please refer to your Supplemental Biologics License Application (sBLA), dated March 15, 2013, received March 19, 2013, submitted under section 351 of the Public Health Service Act for Kalbitor (ecallantide).

This supplemental new drug application proposes to eliminate the requirement for the approved Kalbitor (ecallantide) REMS. 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 April 24, 2012. The REMS consists of communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA eliminate the requirement for a REMS for Kalbitor (ecallantide).

As we stated in our March 5, 2013, correspondence, because your November 30, 2012, REMS assessment demonstrated that the communication plan has been completed and met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Kalbitor (ecallantide) is no longer required.

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 Wayne Amchin, Senior Regulatory Health Project Manager for Safety, at (301) 796-0421.

Sincerely,

{See appended electronic signature page}

Sally M. 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

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
04/10/2013