DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125293/60

SUPPLEMENT APPROVAL
REMS MODIFICATION APPROVAL

Savient Pharmaceuticals, Inc.
400 Crossing Boulevard, 3rd Floor
Bridgewater, NJ 08807

Attention: Elizabeth Yamashita
Group Vice President, Regulatory Affairs

Dear Ms. Yamashita:

Please refer to your Supplemental Biologics License Application (sBLA), dated April 10, 2013, submitted under section 351(a) of the Public Health Service Act for Krystexxa (pegloticase).

We acknowledge receipt of your amendments dated April 22, May 31, July 31, September 20, and October 03, 2013.

This Prior Approval supplemental biologics application provides for proposed modification to the approved risk evaluation and mitigation strategy (REMS) to highlight for healthcare professionals information on the contraindication of use in patients with G6PD deficiency, candidates for G6PD testing, and patient risk for anaphylaxis and infusion reactions. This supplement is in response to our February 19, 2013, REMS Modification Notification letter.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Krystexxa (pegloticase) was originally approved on September 14, 2010, and a REMS modification was approved on October 10, 2010, (and last modified April 16, 2012). The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of modification to the communication plan as follows:

- Revision of the communication plan materials to highlight information on contraindications of Krystexxa (pegloticase) use, candidates for G6PD testing, and patients at a higher risk of anaphylaxis and infusion reactions;

- Dissemination of journal information piece for an additional year; and

- Distribution of the Dear Health Care Provider (DHCP) / Dear Infusion Site Medical Personnel (DISMP) letters for two additional years.

Your proposed modified REMS, submitted on October 03, 2013, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on September 14, 2010.

There are no changes to the REMS assessment plan described in our September 14, 2010 letter.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

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 the 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 125293 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 125293 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125293
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125293
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 Leila P. Hann, Regulatory Project Manager, at (301) 796-3367.

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:
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
10/10/2013