DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125293/S-086

SUPPLEMENT APPROVAL

Crealta Pharmaceuticals LLC
c/o Horizon Pharma Rheumatology LLC
150 S. Saunders Road, Suite 400
Lake Forest, Il 60045

Attention: Jeffrey W. Sherman, MD, FACP
Chief Medical Officer and Executive Vice President Research & Development

Dear Dr. Sherman:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received March 4, 2016, submitted under section 351(a) of the Public Health Service Act for Krystexxa (pegloticase) Injection, 8 mg.

We also refer to our REMS Modification Notification letter dated February 5, 2016.

This prior approval supplemental biologics application provides for proposed modification to the approved risk evaluation and mitigation strategy (REMS) and proposes to eliminate the requirement for the approved REMS for Krystexxa (pegloticase).

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 Krystexxa (pegloticase) was originally approved on September 14, 2010, and the most recent REMS modification was approved on July 30, 2015. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modification:

- Removal of the communication plan from the REMS

Because the communication plan has been completed and the most recent assessment, submitted to the Agency on September 14, 2015, demonstrates that the communication plan has 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, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Krystexxa (pegloticase).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
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
04/11/2016