DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 008372/S-045

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT

Questcor Pharmaceuticals, Inc.
Attention: Sian Bigora, PharmD
Vice President, Regulatory Affairs
6011 University Blvd, Ste 260
Ellicott City, MD 21043

Dear Dr. Bigora,

Please refer to your Supplemental New Drug Application (sNDA) dated April 14, 2012, received April 14, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for H.P. Acthar Gel (respository corticotropin injection).

We acknowledge receipt of your amendment dated April 25, 2012. We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 20, 2012.

This sNDA proposes to eliminate the requirement for the approved 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 H.P. Acthar Gel (respository corticotropin injection) was originally approved on October 15, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for H.P. Acthar Gel (respository corticotropin injection).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of H.P. Acthar Gel (respository corticotropin injection) outweigh its risks, and a REMS is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Stephanie Parncutt, PharmD, Regulatory Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
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/

RUSSELL G KATZ
07/05/2012