DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 008372/S-044

SUPPLEMENT APPROVAL

Questcor Pharmaceuticals, Inc.
Attention: Sian Bigora, Pharm.D.
Vice President, Regulatory Affairs
6011 University Boulevard
Suite 260
Ellicott City, MD 21043

Dear Dr. Bigora:

Please refer to your Supplemental New Drug Application (sNDA) dated May 3, 2011, received May 4, 2011, 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 October 21, 2014.

The October 21, 2014, submission constituted a complete response to our October 22, 2013, action letter.

This "Changes Being Effected" supplemental new drug application provides for the indication for the treatment of infantile spasms to be associated with the parent NDA number 008372, since the tracking NDA number 022432 will no longer be used.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 008372/S-044**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, contact Stephanie N. Parncutt, M.H.A., Regulatory Health Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

ERIC P BASTINGS
03/24/2015