

## APPENDIX A

Initial REMS Approval: 10/2010

### NDA 022432 and NDA 008372

## H.P. ACTHAR<sup>®</sup> GEL (Repository Corticotropin Injection)

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### Risk Evaluation and Mitigation Strategy

#### I. Goals

The goal of the REMS is to inform parents or caregivers of patients taking H.P. Acthar Gel for the treatment of infantile spasms of the serious risks, including adrenal insufficiency, infections, and blood pressure elevation.

#### II. REMS Elements

##### A. Medication Guide

Questcor Pharmaceuticals, Inc. will ensure that a Medication Guide is dispensed with each H.P. Acthar Gel prescription and in accordance with 21 CFR 208.24.

##### B. Timetable for Submission of Assessments of the REMS

Questcor will submit REMS Assessments to the FDA 18 months, 3 years, and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Questcor will submit each assessment so that it will be received by the FDA on or before the due date.

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RUSSELL G KATZ  
10/15/2010