DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 12911/S-033

APPROVAL LETTER

HRA Pharma
Attention: Richard Lowenthal, MS, MBA
Regulatory Representative
8195 Run of the Knolls Court
San Diego, CA 92127

Dear Mr. Lowenthal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 6, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metopirone® (metyrapone) Capsule.

We acknowledge receipt of your amendment dated August 21, 2013.

This "Prior Approval" supplemental new drug application provides for change of ink and imprint of Metyrapone 250mg soft gelatin capsules.

This supplemental new drug application provides for revisions to the labeling for Metopirone® (metyrapone) Capsule.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

We have completed our review of this supplemental new drug application as amended. This supplement is approved, for use as recommended in the enclosed, agreed-upon package insert and container labeling text.

If you have any questions, call Priyanka Kumar, Regulatory Project Manager, at (240) 402-3722.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
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/

RAMESH RAGHAVACHARI
09/05/2013