DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022331/S-013

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING REQUIREMENT

Concordia Pharmaceuticals, Inc.
Attention: Mandy Dorsey
Associate Director, U.S. Regulatory Affairs
OptumInsight Life Sciences, Inc.
131 Morristown Road
Basking Ridge, NJ 07920

Dear Ms. Cole:

Please refer to your Supplemental New Drug Application (sNDA) dated April 29, 2013, received April 29, 2013, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kapvay (clonidine hydrochloride) extended-release tablets, 0.1 mg and 0.2 mg.

We acknowledge receipt of your amendment dated August 28, 2015, which constituted a complete response to our December 5, 2013, action letter.

This Prior Approval supplemental new drug application proposes revisions to Section 8.4 (Use in Specific Populations-Pediatric use) and 13 (Nonclinical Pharmacology) based upon the results of your Postmarketing Requirement study report.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the

addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.
Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING REQUIREMENT

Your August 28, 2015, submission contained the final report for the following postmarketing requirement listed in the September 28, 2010, approval letter.

1676-2 In order to support safe use of clonidine in combination with stimulants in pediatric patients and to provide additional safety information for labeling, you must conduct a juvenile animal study of clonidine in combination with a stimulant as a postmarketing requirement (as communicated in the minutes of our 3/9/2009 meeting).

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes all of your postmarketing requirements acknowledged in our September 28, 2010, letter.

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 Hiren Patel, Regulatory Project Manager, at hiren.patel@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MITCHELL V Mathis
08/16/2016