OPTUMInsight™

131 Morristown Road
Basking Ridge, NJ 07920
T 866-722-6734
F 866-863-0243
www.optum.com

March 3, 2014

Mitchell V. Mathis, MD
CAPT, USPHS
Director (Acting),
Division of Psychiatry Products
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

ATTN: Hiren D. Patel, Pharm.D., M.S., RAC,
Senior Regulatory Health Project Manager

Dear Dr. Mathis:

RE: NDA 022331/ S-001/S-002/S-013; Seq. 0079
Kapvay® (clonidine hydrochloride) extended-release tablets,
0.1 mg and 0.2 mg
Response to PREA Non Compliance letter
Required Postmarketing Correspondence: Deferral Extension Requested

Reference is made to NDA 022331 for Kapvay® (clonidine hydrochloride) 0.1 mg and 0.2 mg Extended Release Tablets, which was approved on September 28, 2010 for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy (S-001) or as adjunctive therapy to stimulant medications (S-002). Reference is also made to the postmarketing study commitment 1676-2 outlined in the approval letter to Shionogi Pharma, Inc. (Shionogi Inc.) for a juvenile animal study of clonidine in combination with a stimulant, as communicated in the pre-NDA meeting of March 9, 2009 with Addrenex Pharmaceuticals, Inc., the original NDA holder as stated below:

1676-2 Juvenile animal study:

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

Final Protocol Submission:	10/31/2011
Study Initiation:	01/30/2012
Final Report Submission:	04/30/2013

In order to fulfill this postmarketing requirement (PMR 1676-2), on April 29, 2013 Shionogi Inc. submitted the following final study report dated February 19, 2013 (Seq. 0069):

(b) (4)

The Agency notified Concordia Pharmaceuticals, Inc. ("Concordia") in an e-mail dated May 10, 2013, that PMR 1676-2 was recoded to a prior approval supplement (PAS), S-013. Updated labeling was provided to the Agency on May 17, 2013 (Seq. 0072). Subsequently, the Agency issued a Notice of Non-Compliance with PREA letter on January 16, 2014.

The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 contains a provision to allow FDA to grant an extension for deferred studies conducted under PREA. The purpose of this submission is to request a deferral extension to PMR 1676-2 in order that Concordia may conduct the required juvenile animal study of clonidine in combination with a stimulant.

At the request of, and as US Agent for, Concordia, we request an extension for the following dates for PMR 1676-2:

Final Protocol Submission:	April 30, 2014
Study Initiation:	May 30, 2014
Final Report Submission:	April 30, 2015

This submission is being submitted electronically via the FDA ESG. All files were checked and verified to be free of viruses with Symantec Endpoint Protection to 12.1.2015.2015 (updated on Thursday, February 27, 2014 r2).

If there are any questions about the enclosed information, please do not hesitate to contact me at 973-348-1514, by e-mail at sheila.ehrenberg@optum.com or by fax at 866-863-0243.

Sincerely,

for

Sheila Ehrenberg
Regulatory Specialist
Strategic Regulatory Services

cc: John AR McCleery, CPA, CA
Concordia Pharmaceuticals Inc.