DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22037/S-010

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Shire
Attention: Mary Beth Wigley
Regulatory Lead – ADHD/NA
Global Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Ms. Wigley:

Please refer to your Supplemental New Drug Application (sNDA) dated May 19, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Intuniv (guanfacine) extended-release 1 mg, 2 mg, 3 mg, and 4 mg tablets.

We acknowledge receipt of your amendments dated May 19, 2014, June 2, 2014, July 3, 2014, July 29, 2014, August 6, 2014, August 27, 2014, September 4, 2014, September 17, 2014, September 23, 2014, October 8, 2014, and November 4, 2014.

This "Prior Approval" supplemental new drug application proposes to update the labeling to reflect the results of two short-term, randomized, placebo-controlled studies evaluating the safety and efficacy of Intuniv in children and adolescents ages 6 to 17 with ADHD. Supplement 10 was undertaken in response to the following postmarketing requirement issued in the original approval letter dated September 2, 2009 and corrected (specified that patient ages to be studied are 13 to 17) in Agency correspondence dated September 15, 2009:

1538-2 Deferred pediatric study under PREA for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adolescent patients ages 13 to 17. An efficacy and safety study of guanfacine in adolescents.

APPROVAL, LABELING, & FULFILLMENT OF POSTMARKETING REQUIREMENT

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. We have also concluded that the above requirement was fulfilled.

We remind you that the following postmarketing requirement listed in the September 2, 2009 approval letter is still open:

1538-1 Deferred pediatric study under PREA for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17. A long-term maintenance study of efficacy and safety of guanfacine as monotherapy in children and adolescents.

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 and text for the patient 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric studies requirement for ages 6 to 17 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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, call Brendan Muoio, Regulatory Project Manager, at (240) 402-4518.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
CAPT, USPHS
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
11/19/2014