



NDA 21278/S-017  
NDA 21802/S-026

**SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation  
Attention: Susan Kummerer, M.S.  
Global Program Regulatory Director  
Drug Regulatory Affairs  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Ms. Kummerer:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for Focalin (dexamethylphenidate) 2.5mg, 5mg, and 10mg tablets (NDA 21278) and Focalin XR (Dexamethylphenidate Hydrochloride) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg & 40mg extended-release tablets:

Reference is also made to an Agency letter dated August 27, 2013, informing you that the Agency identified cases suggestive of an association between the use of stimulants used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and increased erections or priapism during routine monitoring of our FDA Adverse Event Reporting System (FAERS) and the biomedical literature and requesting revisions to your product labeling.

These supplemental new drug applications propose the following revisions to product labeling.

1. The addition of a new subsection under **Warnings** entitled **Priapism**.
2. Revisions to the **Adverse Reactions** section to include "libido changes" & "priapism".
3. The addition of a subsection entitled Priapism under the **Information for Patients** section.
4. Revisions to the Medication Guide relating to priapism.

We have completed our review of these supplemental applications. They are 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, and Medication Guide), 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).

### **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, email Shin-Ye Sandy Chang, Regulatory Project Manager, at [juliette.toure@fda.hhs.gov](mailto:juliette.toure@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, M.D.  
CAPT, USPHS  
Director (acting)  
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  
12/12/2013