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APPLICATION NUMBER:

209311Orig1s000

APPROVAL LETTER



NDA 209311

NDA APPROVAL

Ironshore Pharmaceuticals & Development, Inc.
c/o Baker Botts L.L.P.
Attention: Margaret Sampson
US Agent
98 San Jancinto Boulevard, Suite 1500
Austin, TX 78701

Dear Ms. Sampson:

Please refer to your New Drug Application (NDA) dated September 30, 2016, received September 30, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jornay PM (methylphenidate hydrochloride) extended-release 20 mg, 40 mg, 60 mg, 80 mg, and 100 mg capsules.

We also refer to our approval letter dated August 8, 2018 which contained the following error:

We are waiving the pediatric studies requirement for ages 12 to 17 years because safety and efficacy from 6 to 12 years of age can be generalized to adolescent patients without the need for any additional clinical data.

The use of the partial waiver language was incorrect since we used an extrapolation of data in pediatric patients ages 12 to 17. Therefore, this sentence has been removed from the letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 8, 2018, the date of the original approval letter.

We acknowledge receipt of your amendment dated June 8, 2018, which constituted a complete response to our July 28, 2017, action letter.

This new drug application provides for the use of Jornay PM (methylphenidate hydrochloride) extended-release capsules for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

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

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 prescribing information and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 209311.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages 0 to less than 4 years because necessary studies are impossible or highly impracticable. This is because the diagnostic criteria and assessment measures for determining efficacy for the treatment of ADHD in children less than 4 years old are not well defined and studies in this age group are a challenge regarding patient safety and study validity. Pharmaceutical treatment in this age group is uncommon and non-medication interventions are preferred treatment for behavioral disorders such as ADHD in very young children (e.g., less than 4 years of age).

We are deferring submission of your pediatric study for ages 4 to less than 6 years for this application because this product is ready for approval for use in pediatric patients 6 to 17 years old, and the studies in patients 4 to less than 6 years have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

3546-1 A Phase 3, 3-Week, Double-blind, Randomized, Placebo-controlled, Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of Evening-dosed Jornay PM (methylphenidate hydrochloride) extended-release in Children Aged 4 to 5 With Attention Deficit Hyperactivity Disorder (ADHD).

Final Protocol Submission: 11/30/2018
Study/Trial Completion: 02/28/2020
Final Report Submission: 08/31/2020

Submit the protocol to your IND 118074, with a cross-reference letter to this NDA.

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

This product is appropriately labeled for use in ages 6 to 17 years for this indication. Therefore, no additional pediatric studies are needed in this pediatric group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the prescribing information, Medication Guide, and patient PI (as applicable) to:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft

Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the prescribing information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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>.

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 Hiren Patel, Regulatory Project Manager Team Leader, at (301) 796-2087.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
Content of Labeling
Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MITCHELL V Mathis
08/08/2018