

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202100Orig1s000

Trade Name: **QUILLIVANT™ XR**

Generic Name: (methylphenidate hydrochloride)

Sponsor: NextWave Pharmaceuticals, Inc.

Approval Date: 09/27/2012

Indications: QUILLIVANT XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of QUILLIVANT XR was established in a 2-week, placebo-controlled trial in children aged 6-12 years with a diagnosis of ADHD. Accumulated efficacy data from other methylphenidate products were also considered.

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APPLICATION NUMBER:

224322Orig1s000

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APPROVAL LETTER



NDA 202100

NDA APPROVAL

NextWave Pharmaceuticals, Inc.
Attention: Michael Burdick
VP, Product Development
20450 Stevens Creek Blvd, Suite 150
Cupertino, CA 95014

Dear Mr. Burdick:

Please refer to your New Drug Application (NDA) dated July 29, 2010, received July 30, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for QUILLIVANT XR (methylphenidate hydrochloride) for Extended-Release Oral Suspension 25 mg per 5 mL.

We acknowledge receipt of your amendments dated March 30, 2012, April 17, 2012, May 7, 2012, and August 2, 2012.

The March 30, 2012, submission constituted a complete response to our August 30, 2011, action letter.

This new drug application provides for the use of QUILLIVANT XR (methylphenidate hydrochloride) for Extended-Release Oral Suspension for the treatment of Attention Deficit Hyperactivity Disorder.

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.

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(1)] 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, text for the patient package insert, Medication Guide). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON & CONTAINER LABELS

We acknowledge your September 25, 2012, submission containing final printed carton and container labels.

The following container sizes have been approved:

Bottles of 300 mg powder (to prepare 60 mL suspension)
Bottles of 600 mg powder (to prepare 120 mL suspension)
Bottles of 900 mg powder (to prepare 180 mL suspension)
Bottles of 1200 mg powder (to prepare 240 mL suspension)
Bottles of 1500 mg powder (to prepare 300 mL suspension)
Bottles of 1800 mg powder (to prepare 360 mL suspension)

Additionally, please note that only the container sizes that you have chosen to market are listed in the labeling.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on September 25, 2012, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 202100**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 are waiving the pediatric study requirement for ages 0 to 5 years because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group. The diagnostic criteria and assessment measures for determining efficacy for the treatment of ADHD in children less than 6 years old are not well defined

We note that you have fulfilled the pediatric study 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, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. 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, email Shin-Ye Sandy Chang, Regulatory Project Manager, at shinye.chang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

Carton and Container Labeling

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

/s/

THOMAS P LAUGHREN
09/27/2012