DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202100/S-005

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Lisha Cole, MSc, MBA
Director, US Regulatory Cluster Lead
Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Ms. Cole:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 6, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act Quillivant XR® (methylphenidate hydrochloride) for Extended Release Oral Suspension 25 mg per 5 mL.

This "Prior Approval" supplemental new drug application proposes revisions to the carton labeling for all strengths consistent with our December 18, 2014 letter.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on April 6, 2015, 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 *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/S-005**." 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.

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, contact Shin-Ye Sandy Chang, Regulatory Project Manager, at shinye.chang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D
CAPT, USPHS
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:
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/

MITCHELL V Mathis
07/13/2015