DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 203583

APPROVAL

Mallinckrodt, Inc.
675 McDonnell Blvd.
Hazelwood, MO 63042
Attention: Jessica Emerson
Sr. Regulatory Affairs Product Specialist

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 18, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Methylphenidate Hydrochloride Extended-release Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg.

Reference is also made to the complete response letter issued by this office on December 4, 2013, and to your amendments dated February 25, July 3, and July 8, 2014; and May 1 and May 19, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Methylphenidate Hydrochloride Extended-release Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Metadate CD Extended-release Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg, of UCB, Inc. (UCB).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Medium:	Apparatus I (Baskets)
Volume:	100 RPM
Apparatus:	0.001N HCl
Speed:	500 mL
Sampling times:	37° C $\pm$ 0.5° C

The test product should meet the following specifications:

1 hr: (b) (4)%
4 hrs: (b) (4)%
10 hrs: NLT (b) (4)%

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, UCB's Metadate CD, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,344,215 (the '215 patent) is scheduled to expire on October 27, 2020. The agency notes that the '215 patent is only listed for the 10 mg, 20 mg, 30 mg, and 40 mg strengths.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the '215 patent is invalid, unenforceable, or will not be infringed by your manufacture, use or sale of Methylphenidate Hydrochloride Extended-release Capsules, 10 mg, 20 mg, 30 mg, 40 mg, under this ANDA. You have notified the agency that Mallinckrodt, Inc. (Mallinckrodt) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Mallinckrodt for infringement of the '215 patent within the statutory 45-day period in the United States District Court for the District of Delaware [UCB, Inc. and UCB Manufacturing, Inc. v. Mallinckrodt, Inc., Civil Action No. 1:2012cv00463]. You have also notified the agency that the court determined that claims 1 and 2 of the patent are valid and enforceable. However, Mallinckrodt and UCB entered into a settlement agreement under which the agency is not precluded from granting full approval to your ANDA.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

Sincerely yours,

Carol A. Holquist -S

Digitally signed by Carol A. Holquist -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052464, cn=Carol A. Holquist -S
Date: 2015.09.29 08:52:29 -04'00'

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research