DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 206028

ANDA APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Limited
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202
Attention: Sudhir Kaushal
Director, Regulatory Affairs

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Memantine Hydrochloride Extended-Release Capsules, 7 mg, 14 mg, 21 mg, and 28 mg.

Reference is made to your amendments dated July 2, July 22, December 1, December 12, and December 16, 2014; February 16, April 28, and October 23, 2015; January 21, January 29, and February 10, 2016.

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 Office of Bioequivalence has determined your Memantine Hydrochloride Extended-Release Capsules, 7 mg, 14 mg, 21 mg and 28 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Namenda XR Capsules, 7 mg, 14 mg, 21 mg, and 28 mg of Forest Laboratories Inc. (Forest).

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:

USP Apparatus	I (basket)
Medium	pH 1.2 buffer (simulated gastric fluid without enzyme)
Volume	900 mL
Rotational Speed	100 rpm
Temperature	37 ± 0.5ºC
Specifications	1 hr: (b) (4) %; 4 hrs: (b) (4) %; 8 hrs: (b) (4) %; 12 hrs: NLT (b) (4) %

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if 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 reference listed drug (RLD) upon which you have based your ANDA, Forest's Namenda XR Capsules, 7 mg, 14 mg, 21 mg and 28 mg., is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,168,209 (the '209 patent)	May 22, 2026
8,173,708 (the '708 patent)	May 22, 2026
8,283,379 (the '379 patent)	May 22, 2026
8,329,752 (the '752 patent)	May 22, 2026
8,362,085 (the '085 patent)	May 22, 2026
8,598,233 (the '233 patent)	May 22, 2026 (28 mg only)
8,039,009 (the '009 patent)	September 24, 2029

With respect to each of these patents[1], your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Extended-Release Capsules, 7 mg, 14 mg, 21 mg, and 28 mg, under this ANDA. You have notified the agency that Lupin Limited (Lupin) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and litigation for infringement of the '009, '209, '708, '379, '752, '085, and '233 patents was brought against Lupin within the statutory 45-day period in the United States District Court for the District of Delaware [Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. v. Lupin Limited, Lupin Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Anchen Pharmaceuticals, Inc., Amerigen Pharmaceuticals, Inc., and Amerigen Pharmaceuticals Ltd., Civil Action No. 1:14-cv-01058-UNA]. You have further notified the Agency that the case was dismissed.

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.

[1] The agency notes that the '233 patent was listed in the Orange Book after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

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 1st 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,

{See appended electronic signature page}

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

Carol Holquist

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