DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079161

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on August 13, 2007, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg.

Reference is made to your amendments dated November 13, and December 21, 2007; March 20, 2008; October 19, 2009; and January 28, January 29, March 9, March 17, and May 6, 2010.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Crestor Tablets of IPR Pharmaceuticals, Inc., is subject to periods of patent protection. The following patents with expiration dates (pediatric exclusivity extensions added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
6,316,460 (the '460 patent)	February 4, 2021
6,858,618 (the '618 patent)	June 17, 2022
7,030,152 (the ‘152 patent)	April 2, 2018
RE37314 (the '314 patent)	July 8, 2016

With respect to the '618 and ‘152 patents, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that these are method of use patents that do not claim any indication for which you are seeking approval.

With respect to the '460 and '314 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Mylan Pharmaceuticals, Inc. (Mylan) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You notified the agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '314 patent was brought against Mylan in the United States District Court for the District of Delaware [AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha v. Mylan Pharmaceutical, Inc., Civil Action No. 07-805] and in the United States District Court for the Northern District of West Virginia [AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha v. Mylan Pharmaceutical, Inc., Civil Action No. 1:07-cv-00177].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 8-year period provided for in sections 505(j)(5)(B)(iii), 505(j)(5)(F)(ii), and 505A(c)(1)(A)(i) of the Act,

   b. the date the court decides[1] that the ‘314 patent is invalid or not infringed (see sections

[1] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or

c. the ‘314 patent has expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your ANDA prior to final approval, please submit a “MINOR AMENDMENT – FINAL APPROVAL REQUESTED” 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either “major” or “minor” changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be

approved for marketing under section 505 of the Act, and will not be listed in the “Orange Book.”

For further information on the status of this application, or prior to submitting additional amendments, please contact Leigh Ann Bradford, Project Manager, at (240) 276-8453.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research