DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202172 **TENTATIVE APPROVAL**

Watson Laboratories, Inc.
Attention: Joyce Anne DelGaudio
Executive Director, Regulatory Affairs
360 Mount Kemble Ave.
Morristown, NJ 07962

Dear Ms. DelGaudio:

Please refer to your New Drug Application (NDA) dated July 15, 2010, received July 16, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Rosuvastatin Zinc 5, 10, 20, and 40 mg Tablets.

We acknowledge receipt of your amendments dated August 11, 13, and 19, October 4 and 27, and December 9, 2010, and January 26, April 1 (2), May 5, June 6, and July 22, 2011.

This NDA provides for the use of Rosuvastatin Zinc as an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia and as an adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as described above. This determination is based upon information available to the Agency at this time, [i.e., information in your application 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 any new information that may come to our attention.

The listed drug product upon which you rely for approval of your application is subject to a period of patent and/or exclusivity protection. Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications").

Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date

the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act. In addition, you have notified the Agency that the patent owner and approved application holder have initiated a patent infringement suit against you with respect to patent RE37,314 in the United States District Court for the District of Delaware (Case 1:99-mc-09999, filed October 26, 2010). Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or

   b. the date the court decides that the patent is invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or

   c. the listed patent has expired, and

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

If you wish to seek final approval of this application, submit an amendment two or six months prior to the expiration of the patents and/or exclusivity protection or prior to the date you believe that your NDA will be eligible for final approval, if appropriate. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any court decision, or settlement or licensing agreement, as appropriate. In your cover letter, clearly identify your amendment as "REQUEST FOR FINAL APPROVAL." In addition to a safety update, the amendment should also identify any changes in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data. If there are no changes, clearly so state in your cover letter. Any changes require our review before final approval and the goal date for the application will be set accordingly.

To facilitate review of your amendment, provide a highlighted or marked-up copy of the labeling that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should include annotations that support any proposed changes. We remind you of the need to remove any information related to indications that are protected by patents or exclusivity in the most updated version of the innovator's label.

Until we issue a final approval letter, this NDA is <u>not</u> deemed approved.

Please note that this drug product may not be marketed in the United States 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 501 of the Act and 21 U.S.C. 331(d).

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

If you have any questions, call Margaret Simoneau, M.S., R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

{See appended electronic signature page}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

ERIC C COLMAN
08/04/2011