Dear Ms. DeFeo:

Please refer to your supplemental new drug application dated April 16, 2009, received April 16, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Crestor (rosuvastatin calcium) Tablets.

We acknowledge receipt of your submissions dated May 6, June 16, 24, 29, and 30, July 2, August 4, 6, and 12, September 1 and 18, and October 15 (email), 2009.

This supplemental new drug application provides for the addition of an indication for the treatment of heterozygous familial hypercholesterolemia in adolescent boys and postmenarchal girls, ages 10 to 17 years, with a recommended dosing range of 5 to 20 mg once daily. This supplement responds to our Written Request of March 7, 2006.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at [http://www.fda.gov/oc/datacouncil/spl.html](http://www.fda.gov/oc/datacouncil/spl.html) that is identical to the enclosed labeling (text for the package insert and patient package insert submitted October 15, 2009, by email.) Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 21366/S-017.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of
administration are required to contain an assessment of the safety and effectiveness of the
product for the claimed indication(s) in pediatric patients unless this requirement is waived,
deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for ages 10 to 17 years for this
application. We are waiving the pediatric study requirement for ages 0 to 9 years.

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional
labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the
proposed materials in draft or mock-up form with annotated references, and the package insert(s)
to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the
package insert(s), at the time of initial dissemination or publication, accompanied by a Form
FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For
more information about submission of promotional materials to the Division of Drug Marketing,
Advertising, and Communications (DDMAC), see [http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm).

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product
(i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of
the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**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, 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 (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure
Content of Labeling
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<td>CRESTOR(ROSUVASTATIN CALCIUM) 10/20/40/80</td>
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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
10/15/2009