

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**21-366/S-016**

***Trade Name:*** Crestor

***Generic Name:*** Rosuvastatin calcium

***Sponsor:*** AstraZeneca Pharmaceuticals, LP

***Approval Date:*** February 8, 2010

***Indications:*** For the primary prevention of cardiovascular disease, based on the results of Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER).

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*APPLICATION NUMBER:*  
**21-366/S-016**

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*APPLICATION NUMBER:*

**21-366/S-016**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 21366/S-016

**SUPPLEMENT APPROVAL**

AstraZeneca Pharmaceuticals LP  
US Agent for IPR Pharmaceuticals, Inc.  
Attention: Pat DeFeo, MS  
1800 Concord Pike, P. O. Box 8355  
Wilmington, DE 19803-8355

Dear Ms. DeFeo:

Please refer to your supplemental new drug application dated April 7, 2009, received April 8, 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 1, 11(2), and 21, July 1 and 31, August 5, 20, and 24, September 1, 11(2), and 14, October 2, 13, 19, and 30, November 13 and 23, and December 1, 4, 9, 10, 11(2), and 21, 2009, and January 11, 15, 19, 21, and 29 (email), 2010.

This supplemental new drug application provides for a new indication for CRESTOR for the primary prevention of cardiovascular disease, based on the results of Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER).

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> that is identical to the enclosed labeling (text for the package insert and patient package insert submitted January 29, 2010, by email). For administrative purposes, please designate this submission, "SPL for approved NDA 21366/S-016.

**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 are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. This is because the indication is for an adult-related condition.

### **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>.

### **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).

We request that for a period of two years, you submit additional safety reporting as semi-annual Periodic Safety Update Reports (PSUR). We request that in those PSURs you provide analyses

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of all clinical trial and post-marketing reports of diabetes mellitus or diabetes-related adverse events, alteration in neurocognition, and serious gastrointestinal events.

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

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-21366

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SUPPL-16

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IPR  
PHARMACEUTICA  
LS INC

-----  
CRESTOR(ROSUVASTATIN  
CALCIUM)10/20/40/80

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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.**  
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/s/

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ERIC C COLMAN  
02/08/2010