DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 202514

NDA APPROVAL

Merck Sharp & Dohme Corp.
Attention: Chitkala Kalidas, Ph.D.
Director, Worldwide Regulatory Affairs
P.O. Box 2000, RY33-204
Rahway, New Jersey 07065-0900

Dear Dr. Kalidas:

Please refer to your New Drug Application (NDA) dated and received January 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZIOPTAN (tafluprost ophthalmic solution) 0.0015%.

We acknowledge receipt of your amendments dated:

January 7, 2011 (2)	January 10, 2011	January 14, 2011
January 20, 2011	February 9, 2011	February 17, 2011
February 28, 2011	March 23, 2011	March 29, 2011
April 4, 2011	April 6, 2011	April 28, 2011
April 29, 2011	May 6, 2011	May 11, 2011
May 24, 2011	June 8, 2011	June 9, 2011
June 10, 2011	June 13, 2011	June 30, 2011
July 5, 2011	July 6, 2011	July 11, 2011
July 26, 2011	August 1, 2011	August 4, 2011
August 10, 2011	August 12, 2011	August 22, 2011
September 2, 2011	September 6, 2011	September 13, 2011
September 27, 2011	October 13, 2011	October 26, 2011
October 27, 2011	November 2, 2011 (2)	November 3, 2011
November 7, 2011	December 6, 2011	December 7, 2011
January 13, 2012	January 23, 2012	

The January 13, 2012, submission constituted a complete response to our November 7, 2011, action letter.

This new drug application provides for the use of ZIOPTAN (tafluprost ophthalmic solution) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and patient package insert. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton, container and pouch labels that are identical to the enclosed carton, container and pouch labels submitted on November 4, 2011, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton, Container and Pouch Labels for approved NDA 202514**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an un-approved new drug.

Your application for ZIOPTAN was not referred to an FDA advisory committee because it is a member of the class of ophthalmic prostaglandin analogs with similar potential risks and benefits as other members in this class. The benefits and risks of using prostaglandin analogs to treat elevated intraocular pressure have been previously discussed at a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee on December 8, 1995, and the safety profile of tafluprost did not raise any new significant safety issues. The clinical study design was similar to other approved drugs in this class and we are not aware of any controversial issues that would benefit from further advisory committee discussion.

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 in-applicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable as there are too few children with this disease/condition to study.

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 to:

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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, 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 Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm.

POST-ACTION FEEDBACK MEETING

New molecular entities and new biologics qualify for a post-action feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Health Project Manager for this application.

If you have any questions, please call Constantine J. Markos, B.S., Pharm.D., R.Ph., Regulatory Health Project Manager, at (301) 796-3871.

Sincerely,

{See appended electronic signature page}

Edward M. Cox, M.D., M.P.H.
Director
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling (Package Insert and Patient Package Insert)
Carton, Container and Pouch Labels

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

/s/

EDWARD M COX
02/10/2012