

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**202667Orig1s000**

***Trade Name:*** COSOPT® PF

***Generic Name:*** (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%

***Sponsor:*** Merck Sharp and Dohme Corp

***Approval Date:*** 02/01/2012

***Indications:*** COSOPT PF is a carbonic anhydrase inhibitor with a beta-adrenergic receptor blocking agent indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers.  
The IOP-lowering of COSOPT twice daily was slightly less than that seen with the concomitant administration of 0.5% timolol twice daily, and 2% dorzolamide three times daily.

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**APPROVAL LETTER**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 202667

**NDA APPROVAL**

Merck Sharp & Dohme Corp.  
Attention: Dori L. Glassner  
Director, Worldwide Regulatory Affairs  
P.O. Box 2000, RY33-204  
Rahway, NJ 07065

Dear Ms. Glassner:

Please refer to your New Drug Application (NDA) dated and received February 16, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COSOPT PF (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%.

We acknowledge receipt of your amendments dated:

March 15, 2011  
June 14, 2011  
September 9, 2011  
January 24, 2012

May 18, 2011  
August 4, 2011 (2)  
September 23, 2011

May 27, 2011  
August 30, 2011  
October 12, 2011

The January 24, 2012 submission constituted a complete response to our December 16, 2011, action letter.

This new drug application provides for the use of COSOPT PF (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%, for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers.

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, which is identical to the labeling submitted on January 24, 2012.

## **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 text for the 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 and container labels that are identical to the enclosed carton, container, and pouch labels submitted on January 24, 2012, 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 and Container Labels for approved NDA 202667.**” 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 unapproved new drug.

## **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.

Your application does not qualify for any of the criteria described above; Therefore, the PREA requirement is inapplicable.

## **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:

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).

If you have any questions, call Judit Milstein, Chief Project Management Staff (301) 796-0763.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, MD  
Director  
Division of Transplant and Ophthalmology  
Products  
Office of Antimicrobial Products  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling  
Carton, Container, and Pouch Labeling

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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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RENATA ALBRECHT  
02/01/2012