

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
202667Orig1s000

OTHER ACTION LETTER(s)



NDA 202667

COMPLETE RESPONSE

Merck Sharp & Dohme Corp.
Attention: Chitkala Kalidas, PhD
Director, Worldwide Regulatory Affairs
126 E. Lincoln Avenue
P.O. Box 2000, Mail Drop RY33-204
Rahway, NJ 07065-0900

Dear Dr. Kalidas:

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, May 18, and 27, June 14 August 4 (2), August 30, September 9, September 23, and October 12, 2011.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

- Per 21 CFR 314.125 (a)(8) , the drug product's proposed labeling does not comply with the requirements for labels and labeling in part 201. Specifically, we recommend that you submit draft labeling which is consistent with the package insert, patient package insert, carton and container labeling attached to this letter.
- In addition, there is ambiguity in the terminology of the drug product specifications. To correct this ambiguity, as part of the drug product specifications, please revise the test currently identified as "Any unspecified Degradate" to read "Any unspecified impurity."

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application. A resubmission must fully

address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

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

24 pages of draft labeling have been withheld in full as B(4)
CCI/TS immediately following this page

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

/s/

RENATA ALBRECHT
12/16/2011