# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**22-278**

## OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-278

D.O.R.C. International, b.v.
c/o Dutch Ophthalmic USA
Attention: Fran Carleton
General Manager
One Little River Road
Kingston, NH 03484

Dear Ms. Carleton:

Please refer to your new drug application (NDA) dated October 1, 2007, received October 4, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for MembraneBlue (trypan blue ophthalmic solution) 0.15%.

We acknowledge receipt of your submissions dated November 15 and 23, and December 6, 2007, and January 30, April 14, and June 10 and 25, 2008.

We completed our review of this application, as amended, and it is approvable.

During a recent inspection of a manufacturing facility for this application, the facility was found to be out of compliance with current good manufacturing practice regulations in parts 210 and 211. Our field investigator conveyed deficiencies to the facility's representatives. Satisfactory resolution of these deficiencies and compliance with the current good manufacturing practice regulations is required before this application may be approved.

We will continue to work with you on the proposed labeling.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

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

If you have any questions, call Michael Puglisi, Project Manager, at (301) 796-0791.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/
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Wiley Chambers
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