

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-670

APPROVAL LETTER(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-670

DORC International, B.V.
c/o Dutch Ophthalmic USA, Inc.
Attention: Fran Carlton, Operations Manager
One Little River Road
P.O. Box 968
Kingston, New Hampshire 03848

Dear Ms. Carleton:

Please refer to your new drug application (NDA) dated October 24, 2003, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VisionBlue (trypan blue ophthalmic solution), 0.06%.

We acknowledge receipt of your submissions dated June 11, July 12, August 13 and 27, October 14, November 19, 24 and 30, and December 6, 9, 10 and 13, 2004. The June 11, 2004, submission constituted a complete response to our April 17, 2004, action letter.

This new drug application provides for the use of VisionBlue (trypan blue ophthalmic solution) as an aid in ophthalmic surgery by staining the anterior capsule of the lens.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, immediate container (syringe), and carton labels submitted December 6, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format - Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces are submitted electronically, the labeling does not need to be submitted in paper.

Please submit an electronic version of the FPL as soon as it is available, but no more than 30 days after it is printed, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

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 www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Lori Gorski, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca C. Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure