DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203491/S-006

APPROVAL LETTER

Alcon Research, Ltd.
Attention: Paul Nitschmann, M.D.
Vice President, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Dr. Nitschmann:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2014, received March 14, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ilevro® (nepafenac ophthalmic suspension), 0.3%.

We acknowledge receipt of your amendments dated May 5 and June 11, 2014.

This Prior Approval supplemental new drug application provides for addition of an alternate fill size for Ilevro from a maximum of 1.7 mL in a 4 mL bottle to 3 mL in a 4 mL bottle.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Diana Willard, Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant 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/

WILEY A CHAMBERS
07/03/2014