CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-810

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 50-810

InSite Vision, Inc.
Attn: Ronald H. Carlson, Ph.D.
Vice President, Regulatory Affairs and Quality
965 Atlantic Avenue
Alameda, CA 94501

Dear Dr. Carlson:

Please refer to your new drug application (NDA) dated June 28, 2006, received June 28, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Azasite (azithromycin ophthalmic solution) 1%. This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 28, August 30, September 12, October 25, November 7, and 15, 2006, and January 22, February 14, and 27, March 23, and 26, April 2, 13, 17, and 19, 2007.

This new drug application provides for the use of Azasite (azithromycin ophthalmic solution) 1% for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G, *Haemophilus influenzae, Staphylococcus aureus, Streptococcus mitis group, Streptococcus pneumoniae.*

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 submitted April 19, 2007.

The final printed labeling (FPL) must be identical to enclosed agreed labeling text for the package insert, and immediate carton and container labels dated April 19, 2007. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL format, as described at http://fda.gov/oc/datacouncil.spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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-Infective and Ophthalmology Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Draft Labeling

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

/s/

Janice Soreth
4/27/2007 04:25:52 PM