DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-664/S-010

ISTA Pharmaceuticals, Inc.
Attn: Paul Nowacki
Director, Regulatory Affairs
15295 Alton Parkway
Irvine, CA 92618

Dear Mr. Nowacki:

Please refer to your supplemental new drug application dated December 8, 2008, received December 9, 2008, submitted under section of theFederal Food, Drug, and Cosmetic Act for Xibrom (bromfenac ophthalmic solution) 0.09%.

This supplemental new drug application provides for the labeling change to reflect the recent compounding change of supplement (S-008) from purified water, USP, to water for injection, USP.

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

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://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate these submissions "**SPL for approved supplement NDA 21-664/S-010**." Approval of this submission by FDA is not required before the labeling is used.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-664/S-010**." Approval of this submission by FDA is not required before the labeling is used.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and to the text for the patient instruction leaflet, and immediate container and carton labels submitted December 8, 2008.

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 inserts 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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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}

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

Enclosure:

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

/s/

Wiley Chambers

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