



NDA 21-640/S-002 & S-003

ISTA Pharmaceuticals, Inc.
Attention: Marvin J. Garrett
V.P. Regulatory Affairs, Quality & Compliance
15279 Alton Parkway, Suite 100
Irvine, California 92618

Dear Mr. Garrett:

Please refer to your supplemental new drug applications dated July 30, 2004, received August 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vitrase (hyaluronidase injection) ovine, 200 USP Units/mL.

We acknowledge receipt of your submissions dated September 17; October 19 and 29; and November 2, 5, 16, 17 and 29, 2004.

These supplemental new drug applications provide for an alternate dosage form (hyaluronidase injection) for the drug product and revised labeling.

We completed our review of these applications, as amended. These applications are 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, which was submitted November 29, 2004.

For future submissions, 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 with proposed revisions clearly indicated, preferably using the track changes feature. If formatted copies of all labeling pieces are submitted electronically, the labeling does not need to be submitted in paper.

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

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 this division and two copies of both the promotional materials and the package insert directly to:

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

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, HFD-410
FDA
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 Lori M. Gorski, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
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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