Dear Ms. Cantrell:

Please refer to your supplemental new drug application dated November 25, 2003, received
November 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for
BSS Plus (sterile intraocular irrigating solution), 500 mL and 250 mL.

These “Changes Being Effected in 30 days” supplemental new drug applications provide for changes
to the labeling and packaging for the drug product.

We completed our review of these applications. These applications are approved, effective on the date
of this letter, for use as recommended in the enclosed labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15
of the copies on heavy-weight paper or similar material. For administrative purposes, this submission
should be designated "FPL for approved supplement NDA 18-469/S-038 & S-039.” Approval of this
submission by FDA is not required before the labeling is used.

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

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/

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Wiley Chambers
5/25/04 11:40:05 AM