DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

APR - 6 1999

TRANSMITTED VIA FACSIMILE

Lawrence D. Mandt
Director, Regulatory and Medical Affairs
Ciba Vision, Inc.
11460 Johns Creek Parkway
Duluth, GA 30097

RE: **NDA 20-219**
Livostin 0.05% (levocabastine HCl) Ophthalmic Suspension
MACMIS # 7396

Dear Mr. Mandt:

This letter is in reference to Ciba Vision, Inc.'s (Ciba Vision) submissions, dated July 23, 1998, and March 19, 1999, of promotional materials under cover of Form FDA 2253 for Livostin. The submissions each included sales aids titled, "Stop the Attack with Livostin" (identified as 9826/080929) and "No Waiting" (identified as 9062/081120). We also refer to a sales aid identified as 8462/080995. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these sales aids and has concluded that they are false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Promotion of An Unapproved Dosing Regimen

As you know, promotional claims must be supported by adequate evidence. Further, they should not be inconsistent with the product's approved product labeling. The dosing instructions presented in the Dosing and Administration section of Livostin's approved product labeling states, "The usual dose is one drop instilled in affected eyes four times per day." However, in these sales aid, you claim that it is a "Patient's choice to DOSE AS NEEDED up to QID" and it is a "Patients' choice to dose as needed--Average dosage less than BID." Your promotion of a dosing as needed (PRN) dosing regimen for Livostin is inconsistent with the approved product labeling and constitutes an unapproved dosing regimen.

Comparison to Placebo

In the sales aids, you claim that Livostin has a "placebo-like safety profile," and a "safety profile comparable to placebo." In prior correspondence dated March 28,

1995, DDMAC notified you that, in clinical trials, Livostin was compared to a vehicle that contained the functional ingredients other than the active ingredient. Thus, we considered Ciba Vision's statement that Livostin had similar side-effects to placebo to be false or misleading. In your response to this letter, you agreed to use the term "Livostin-vehicle" in promotional materials when the describing the drug product minus levocabastine.

Promotion of Unapproved New Uses

In that same letter dated March 28,1995, we objected to your comparison of Livostin to other types of drug products with dissimilar indications such as mast cell stabilizers and non-steroidal anti-inflammatory drugs (NSAIDs). Mast cell stabilizers are indicated for vernal conjunctivitis, not seasonal allergic conjunctivitis like Livostin. And NSAIDs; such as Ciba Vision's product Voltaren, are indicated for post-op inflammation and photophobia. In the sales aid identified as 8462/080995, you claim that "unlike ocular NSAIDs and mast cell stabilizers, only Livostin provides comprehensive relief from all these common symptoms of eye allergy...." DDMAC continues to object to your comparison of Livostin to NSAIDs and mast cell stabilizers because they have dissimilar indications to Livostin, and by comparing Livostin to these drugs, you are promoting Livostin for unapproved uses.

Thus, DDMAC requests that Ciba Vision immediately cease the dissemination of these violative sales aids and any other violative promotional materials that promote Livostin for unapproved new uses, and misrepresent the safety profile of Livostin. Ciba Vision should respond to DDMAC regarding this violation by April 20, 1999, providing the date it ceased the dissemination of the promotional materials.

If you have any questions, please contact me by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Ciba Vision that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7396 and NDA 20-219.

Sincerely,

/S/

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications