DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 8 2000

TRANSMITTED BY FACSIMILE

Jeannie-Marie Skinner
Manager, Regulatory Submissions
Ciba Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097-1556

RE: **NDA 21-214**
Rescula (unoprostone isopropyl ophthalmic solution), 0.15%
MACMIS # 9281

Dear Ms. Skinner:

This letter is in reference to Ciba Vision Corporation's (Ciba Vision) promotional campaign for Rescula. We specifically refer to your press release posted on the Ciba Vision World Wide Web (WWW) site[1]. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the press release and has concluded that it is false or misleading under the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Our specific objections follow:

Omission of Material Fact

The press release is misleading because it fails to present material facts related to the approved indication for Rescula. Specifically, you fail to disclose that Rescula is a second-line therapy for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The approved product labeling (PI) states that Rescula should only be used in patients who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication. Your omission of these material facts suggests that Rescula may be used as first line treatment when such is not the case.

Failure to Provide Adequate Risk Information

This promotional labeling is misleading because it fails to present important risk information. Specifically, although you have presented the most common adverse

1. www.CibaVision.com September 5, 2000 FDA Approves RESCULA®, A New Docosanoid Compound For Glaucoma Marketed By CIBA Vision

events associated with the use of the drug, you failed to present the bolded warning that Rescula has been reported to cause changes to pigmented tissue, and that these changes may be permanent.

Failure to Submit Promotional Materials

Sponsors are required, as part of the post-marketing requirements for new drug applications, to submit specimens of labeling or advertising at the time of initial dissemination of the labeling and at the time of the initial publication of the advertisement to FDA via Form FDA 2253. We have no record that you submitted this press release.

Failure to Provide Full Prescribing Information

Under section 502 of the Act, sponsors are required to provide full prescribing information with promotional labeling. We note that this press release on your WWW site does not have full prescribing information or a link to readily access this important information.

Requested Actions

In order to address these objections, we request that you immediately cease the dissemination of this violative promotional material and all similar promotional materials that contain the same or similar messages.

You should respond in writing to us regarding this issue by September 22, 2000. Your response should include Ciba Vision's intent to comply with the above request, the date that it ceased disseminating this and any other violative promotional materials with the same or similar violations, and a list of the discontinued 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-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 9281 and NDA 21-214.

Sincerely,

/S/

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

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Press Releases

FDA Approves RESCULA®, A New Docosanoid Compound For Glaucoma Marketed By CIBA Vision

8/3/00

As Options For Treating Glaucoma Expand, RESCULA Gives Doctors Prescribing Versatility To Safely Build Therapies At Any Stage Of The Disease

ATLANTA, GEORGIA— CIBA Vision, the eye care unit of Novartis, announced today that the U.S. Food and Drug Administration (FDA) has approved RESCULA® (unoprostone isopropyl ophthalmic solution) 0.15%, a new synthetic docosanoid compound for the treatment of open-angle glaucoma or ocular hypertension*.

RESCULA differs from other anti-glaucoma drugs in that it is the only available ocular therapy containing a docosanoid. RESCULA consistently and safely lowers intraocular pressure (IOP) when used as either a monotherapy or in combination with other drugs, and IOP reduction is maintained at a constant level throughout the day. In clinical studies RESCULA shows no loss of efficacy over 12 months.

"With this approval, we are now able to provide doctors with a major new building block in glaucoma treatment," said Dan Myers, president of CIBA Vision's North American Ophthalmics group. "Research shows that unlike non-cardioselective beta blockers, RESCULA safely lowers intraocular pressure without affecting cardiovascular or pulmonary function."

The most common ocular adverse events with RESCULA (occurring in 10-25% of patients during clinical studies) were burning/stinging, burning and stinging upon instillation, dry eyes, itching, increased length of eyelashes and injection(redness).

Patients will use RESCULA, in the form of eye drops, twice a day. It rapidly penetrates the cornea, achieving maximum effects in as soon as 24 hours.

** "It's very exciting and important that we have as many different options as possible, including RESCULA, in the medical treatment of glaucoma," said Tom Mundorf, MD, a glaucoma specialist in Charlotte, N.C. "We're learning in preliminary research that many of these medicines, in addition to lowering pressure in the eye, may one day prove to have other additional benefits to the health of the eye."

FDA approval of RESCULA was based upon clinical studies in which more than 1,100 patients were studied for up to 12 months at more than 50 study sites in the US, Canada, Europe and Israel.

RESCULA at a 0.12% concentration is currently marketed in more than 25 countries globally. It has been licensed from Ueno Fine Chemicals Industry, Ltd. and R-Tech

Ueno, Ltd. of Japan, where more than 500,000 patients have been treated over the last six years. Glaucoma is an eye disease affecting an estimated 4 million people in the US and 5 million in Europe, and is one of the leading causes of preventable blindness.

About Docosanoids
Docosanoids are lipids with 22-carbon atoms. Naturally occurring docosanoids are derived from docosahexaenoic acid. Numerous published reports (in both human and animal studies) have shown that docosahexaenoic acid is essential in the development and functioning of the retina.

About Glaucoma
Glaucoma is one of the leading causes of blindness in the US. As many as 30 different types of the disease exist. Although the clinical features of glaucoma are reasonably understood, the pathogenesis of optic nerve damage remains unclear. Elevated IOP remains a well-accepted and important risk factor in the development of the disease; however, current understandings require definitions that are multi-factorial or multi-dimensional.

In the early stages of the disease, glaucoma usually has no noticeable symptoms. Loss of vision occurs in the late stages of the disease. However, through early detection and continuing treatment, glaucoma usually can be controlled and blindness prevented.

Patients with any type of glaucoma therapy sometimes get worse. As a result, treatments may need to be changed. It is important for patients to visit their eye care professionals regularly.

Background on CIBA Vision
With worldwide headquarters in Atlanta, Georgia, USA, CIBA Vision is a global leader in research development and manufacturing of optical and ophthalmic products and services, including contact lenses, lens care products, ophthalmic surgical products and ophthalmic pharmaceuticals. CIBA Vision products are available in more than 70 countries. For more information, you are invited to visit the CIBA Vision Web site at

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