



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFE-35

File
Purged

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675 Fax 781.279.1742

WARNING LETTER

NWE-04-99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 17, 1998

Jeffrey P. Gilbard, MD
President and CEO
Advanced Vision Research
7 Alfred Street, Suite 330
Woburn, MA 01801

Dear Dr. Gilbard:

On October 8, 9, and 21, 1998, Food and Drug Administration Investigator Constance DeSimone conducted an inspection at Advanced Vision Research, 7 Alfred Street, Suite 300, Woburn, MA 01801. Ms. DeSimone collected a sample of **TheraTears™ Lubricant Eye Drops** and its accompanying labeling.

The label for this product states that it "Contains: 0.25% sodium carboxymethylcellulose, sodium chloride, potassium chloride, sodium bicarbonate, calcium chloride, magnesium chloride, sodium phosphate, borate buffers, and purified water."

The labeling for **TheraTears™ Lubricant Eye Drops** states that, "TheraTears has the extra water needed to rehydrate the tear film and quench dryness of the eye, and the patented electrolyte balance that promotes natural healing and provides dry-eye relief ... Increased tear evaporation most commonly results from an inflammation within the eyelids themselves—a condition doctors call 'blepharitis' ... TheraTears creates the environment needed to promote natural healing and provide dry-eye relief."

In addition, the product is promoted on the internet which carries statements such as, "TheraTears is the first eye drop shown in pre-clinical studies not just to wet and lubricate the eye, but to restore conjunctival goblet cells."

The above claims make this product a drug—section 201(g) of the Federal, Food, Drug, and Cosmetic Act (the Act). Based on its intended uses, this product is subject to the final rule (Title 21 Code of Federal Regulations Part 349 (21 CFR 349) concerning OTC ophthalmic drug products. The final rule does not provide for inclusion of the claims cited. Consequently, as labeled and formulated, this product fails to meet all the requirements of the final OTC rule.

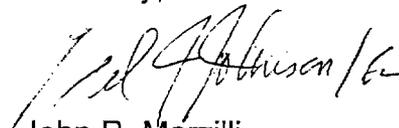
We do not have any evidence that scientific experts generally recognize these products as safe and effective for the labeled indications described above. Therefore, they are "new drugs" under section 201(p) of the Act, which may not be legally marketed in the United States without an approved new drug application (NDA) (section 505(a) of the Act). This product is also misbranded (section 502(f)(1) of the Act) because it does not bear adequate directions for its safe and effective use.

The above list of violations is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure that the drug products you distribute are in compliance with the Act and regulations promulgated under the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including a seizure and/or injunction, without further notice. Federal agencies are routinely advised of Warning Letters issued so that they may consider this information when awarding contracts.

Please notify this office in writing within fifteen (15) days of receipt of this letter and the specific steps you have taken to correct the violations described above. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

You should direct your reply to Mark Lookabaugh, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at 781.279.1675 ext. 118.

Sincerely,



John R. Marzilli
Director, New England District