



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35  
Public Health Service  
Food and Drug Administration

11/9/00

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

November 7, 2000

Ref: 2001-DAL-WL-02

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Richard L. Caruso, Owner  
Hydrokinetic Contact Lens Laboratory  
6600 Hornwood Drive, Suite 6620  
Houston, Texas 77074

Dear Mr. Caruso:

During an inspection of your firm located in Houston, Texas on July 11, 13, and 17, 2000, our investigator determined that your firm manufactures, dispenses, and distributes the NewView2 Progressive Addition Contact Lenses (e.g., the 'RGP' and 'Soft' contact lenses).

Under a United States Federal Law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps to protect the public health by ensuring that new medical devices are shown to be both safe and effective or substantially equivalent to other devices already marketed in this country.

Our investigator determined that your firm, a lens finishing laboratory, manufactures the rigid gas permeable (RGP) multifocal contact lenses made from the Super Gas Permeable (SGP II™) lens blank material manufactured by [REDACTED]. Our records revealed that the SGP II™ lens blank material was approved under PMA [REDACTED] on [REDACTED] for single vision and multifocal configurations and is intended for daily wear and that [REDACTED] is the original PMA holder.

Information and records you provided to our investigator during the inspection do not show that your firm has obtained marketing clearance for the NewView2 RGP Progressive Addition Contact Lens. FDA based its findings upon the facts that your firm:

- is not currently certified as a finishing lab for [REDACTED]
- designed its own lens specifications using a special manufacturing process called [REDACTED] or [REDACTED] to change the original design of the [REDACTED] PMA approved version SGP II™ contact lens and admitted to the FDA investigator that your firm did not know if its multifocal RGP lens was equivalent to the [REDACTED] contact lens;
- could not provide documentation of authorization from [REDACTED] for the lens design;
- purchases the same SGP lens material from [REDACTED] who also is not approved as a lens finishing laboratory for [REDACTED]

Regarding your firm's use of another lens blank material ([REDACTED]) to manufacture the RGP multifocal contact lenses, our records revealed that the [REDACTED] lens material was cleared for single vision only under [REDACTED] in 1995. Your firm indicated to our investigator that your firm [REDACTED] this material for multifocal lenses in [REDACTED] and that you would work with the original PMA holder ([REDACTED]) so that it can obtain marketing clearance of the lens design your firm offers. We wish to remind you that your firm's promotional claims should be limited to the approved indications in [REDACTED] or in the new application.

Our investigator also determined that your firm manufactures soft contact lenses from the [REDACTED] material, which is provided by [REDACTED], for dispensing to patients seen at your firm. Similarly, FDA believes that your firm has not obtained marketing clearance for the NewView2 'Soft' Progressive Addition Contact Lens. FDA based its findings upon the following facts:

- the [REDACTED] soft contact lens is not cleared for multifocal vision or for sale in the United States;
- your firm has not received approval or authorization from [REDACTED] for your lens design.

Your firm should not be distributing or promoting these unapproved devices.

For your information, FDA issued a memorandum, dated May 9, 1985, and a revised guidance document, dated August 11, 1998, to RGP lens manufacturers regarding procedures for adding lens finishing laboratories. Your firm can obtain these documents through the Internet at <http://www.fda.gov>.

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FDA considers your firm's activities as a finishing laboratory to be an extension of the manufacturing process for RGP contact lenses. Finishing laboratories are not authorized to manufacture lens designs that are beyond the PMA or 510(k) holder's cleared specifications and intended uses.

If your finishing laboratory offers lens designs for sale that are not authorized in the marketing clearance of the RGP lens blank manufacturer's PMA or 510(k), there are two options for obtaining the appropriate clearance from FDA. The first is to work with the RGP lens blank manufacturer so that they can obtain a marketing clearance of the lens designs your lab offers. The second is for your lab to obtain its own marketing clearance for its unique designs.

With regard to the Quality System Regulation conformance, our investigator also determined that your firm had not documented manufacturing process instructions, maintained lot traceability records, performed and documented internal self-audits for Quality System Regulation conformance.

Your firm, as an independent finishing laboratory, is responsible for complying with those parts of the device manufacturing practice requirements, as set forth in the Quality System Regulation for medical devices, which apply to the manufacturing operations that the finishing laboratory performs for the PMA holder.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law might result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

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Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Mr. Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell  
Dallas District Director