



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M33291

Food and Drug Administration
Rockville MD 20857

Via Federal Express

JAN - 7 2000

WARNING LETTER

Ronald A. Schachar, M.D., Ph.D.
President and Chief Executive Officer
Presby Corp
5910 N Central Exway
Suite 1770
Dallas, Texas 75206

Dear Dr. Schachar:

The Food and Drug Administration (FDA) has reviewed Presby Corp's promotional materials pertaining to the Surgical Reversal of Presbyopia (SRP), and use of the Scleral Expansion Band (SEB). The SEB is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The SEB device is currently under investigation in the United States.

The SEB device does not yet have marketing clearance in the United States.

The promotional materials, copies of which are enclosed, include information distributed via the Internet at www.presbycorp.com. The Presby Corp web site contains many objectionable statements, and numerous promotion and advertising violations.

In addition to making performance claims, your firm represents the SEB product and its associated surgery for "scleral expansion" as safe and effective for the reversal of presbyopia. You state that the product and procedure offers advantages over other treatment options such as reading glasses, bifocals, and contact lenses.

The FDA considers as objectionable the following claims made by your firm for the unapproved SEB device:

- "Unlike laser and most types of refractive surgery, scleral expansion is a fully reversible procedure." (web site, www.presbycorp.com/bands.htm, last sentence under "Product and the Procedure").

- “Scleral Expansion provides the following benefits to patients: Long term corrected vision . . . Low Risk Procedure . . . Minimally invasive procedure . . . Reversible . . . ” (web site www.presbycorp.com/benefits.htm).
- “Packages of 50 with four devices in each package, are sold for \$25000 (US).” (web site www.herzig-eye.com/cutting_edge.html, accessed through your web site). This statement refers to the surgical reversal of presbyopia procedure and supplying doctors with the “patented” SEB device.
- “[T]here are no sight-complicating implications in this reversible procedure since only the white of the eye is touched.” (web site www.herzig-eye.com/cutting_edge.html, accessed through your web site).
- “The Surgical Reversal of Presbyopia (SRP) procedure is safer than laser and other types of optical surgery . . . ” (web site www.presbycorp.com/gen.htm).
- “Implants can be removed with no permanent damage.” (web site www.presbycorp.com/news.htm, WFAA-TV (ABC), Dallas/Ft. Worth).

In addition, your home page reveals that your company is training physicians in the United States on the clinical use of the device. The web sites accessed from your home page, “Surgical Seminar Schedule, Surgical Technique for the Restoration of Accommodation, Training Course,” (www.presbycorp.com/train.htm); and “Recent Updates on Scleral Expansion,” (<http://eye.med.uth.tmc.edu/rwyee/presby.htm>); describe the next training course(s), and give a step by step explanation of the “Current Surgical Procedure.”

The above-referenced items establish that your company is promoting the SEB for the surgical reversal of presbyopia despite the fact that the product has not received marketing clearance. Such promotion renders your SEB device adulterated within Section 501(i) of the Federal Food, Drug, and Cosmetic Act. Furthermore, the promotion and commercialization of an investigational device is prohibited under FDA regulations, Title 21, Code of Federal Regulations (21 CFR), Part 812.7.

A sponsor or investigator, or any person authorized to act on their behalf, is prohibited from promoting or test marketing an investigational device until the device is approved by the FDA for commercial distribution. No claims can be made explicitly or implicitly that the device is either safe or effective for the purposes for which it is being investigated, or that the device is in any way superior to other devices.

We consider your explicit surgical procedure training materials (<http://eye.med.uth.tmc.edu/rwyee/presby.htm>) as promotional and a form of test marketing of a device that has not been cleared for commercial distribution. Until devices have received FDA approval for specific indications, their use, including demonstration and teaching to persons not engaged in an approved IDE study, is regarded as commercialization of an investigational device.

In addition, your firm's web site, www.presbycorp.com/news.htm, contains four (4) news videos. The videos suggest that the device under study is safe and effective, an unproven claim. News videos may not be used by your firm as promotional tools or as an attempt to commercialize a product before approval or clearance.

Although the FDA encourages full exchange of scientific information concerning investigational devices, including dissemination of scientific findings through scientific/medical publications or conferences, safety and effectiveness conclusions and statements of a promotional nature are unacceptable. Information concerning investigational devices may be provided only for the purpose of soliciting clinical investigators and study subjects. Enclosed is a guidance document entitled, *Guidance for Industry and FDA Staff, Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects*, to assist you in this area.

This letter does not contain an all-inclusive list of deficiencies associated with your promotion of the SEB device. It is your responsibility to ensure that materials distributed within the United States are in conformance with each requirement of the Act and other applicable Federal regulations. For your information, promotional materials distributed via the Internet are subject to the same regulations and statutory requirements as materials distributed by other means.

Please notify this office, in writing, **within fifteen (15) working days of receipt of this letter**, of the specific actions you plan to take to correct the cited violations and other violations known to you. You should include all steps being taken to address violative information currently in the marketplace and actions to prevent similar violations in the future.

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Your response should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kathleen Swisher, R.N., J.D. Please direct all questions regarding this matter to Ms. Swisher at (301) 594-4720, extension 135.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures