

Warning Letter

DEC 30 1999

Mr. Joseph Breger
Breger Vision
522 Clinton Stret, #801
Chicago, Illinois 60607

Dear Mr. Breger:

On September 2, 1998, a letter was forwarded to you regarding Breger Vision's sale of a rigid gas permeable bifocal lens called Z-10 Discover or Zebra lens. As you were advised at that time, contact lenses are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The law requires that manufacturers of medical devices obtain marketing clearance for their devices before they may offer them for sale.

In November 1998, our office received a letter from Mr. Daniel J. Manelli on your behalf stating that the Z-10 Discover lens is manufactured from buttons provided by suppliers that have FDA marketing clearance. However, we have yet to receive a response to our subsequent letter of November 12, 1998, asking that you provide information relative to your suppliers, and our records still indicate that no approval has been granted for a lens with the Z-10 Discover or Zebra trade name.

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 may 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.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct this problem. We also ask that you explain how you plan to

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prevent this from happening again. Please direct your response to the attention of Sharon Kalokerinos within the Dental, ENT and Ophthalmic Devices Branch (HFZ-331), at 2098 Gaither Road, Rockville, Maryland 20850.

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 device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for medical devices by contacting our Division of Small Manufacturers Assistance at 1-800 638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Sharon Kalokerinos at the above mentioned address.

Sincerely yours,


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

cc:
Daniel J. Manelli
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