



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Rockville MD 20857

Warning Letter

JAN 25 2000

Mr. John Gibson
Specialty Tint
8442-84 Via Sonoma
La Jolla, California 92037

Dear Mr. Gibson:

On November 5, 1998, a letter was sent to you relative to your providing tinted contact lenses without having the necessary clearance from the U.S. Food and Drug Administration (FDA). In January 1999, you responded to that letter stating that you considered Specialty Tint to be exempt from FDA regulation because you 1) provide a service and do not manufacture products, 2) do not offer this service to the general public; and, 3) consider your devices to be custom devices.

FDA considers the tinting of contact lenses, including previously manufactured lenses, to be a manufacturing process, one that changes the device specifications and one that can effect the safety and efficacy of the lens. If, for example, a contact lens manufacturer produced finished lenses and used another firm for the sole purpose of tinting the finished lenses, the firm providing the tinting "service" would be considered an extension of the manufacturer, or a contract manufacturer. As such, the "service" firm is subject to the medical device requirements set forth in the Federal Food, Drug and Cosmetic Act. This includes requirements for marketing clearance as well as registration and listing and applicable good manufacturing practice (GMP) requirements set forth in the Quality System (QS) regulation.

You point out in your letter that the color additives you use are only those recognized as safe for use in contact lenses. FDA has no way of verifying that at this point because you have not obtained premarket clearance through the submission of a premarket notification which should contain this information, nor have we inspected your facility.

You are also of the opinion that your device qualifies as a custom device. FDA does not agree. While every model of lenses may not be generally available tinted, the lenses are in commercial distribution for dispensing by prescription, and the Agency has cleared 510(k)s for firms to perform the same type of service which you provide. The fact that a physician offers a certain lens in various colors and uses your "service" to fulfill that commitment does not make the lens a custom device. With regard to the fact that you do not take ownership of the lens, this would also apply in the scenario described above relative to the contract manufacturer.

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Therefore, because you do not have marketing clearance from FDA, the “service” you are providing is a violation of the law. As explained in our original letter, your product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act.

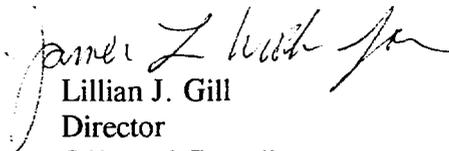
This violation may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction or assessing civil money penalties. Also, other Federal agencies are informed about warning letters we issue 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. Please direct your response to Sharon Kalokerinos, Dental, ENT and Ophthalmic Devices Branch (HFZ-331), 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 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 address.

Sincerely yours,



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