



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

H7I-35
M2117.7

AUG 28 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Dr. Thad J. Overmyer
Micrylium Laboratories
1755 West University Drive, Suite 118
Phoenix (Tempe), Arizona 85281

Dear Dr. Overmyer:

This is to acknowledge receipt of your letter of July 4, 1998, wherein you state that you are not making anti-microbial claims for your device, Bio-2000, a dental waterline treatment. The issue, at this point, is not the claims that are being made for your device, but the fact that you do not have clearance from the U.S. Food and Drug Administration (FDA) to market Bio-2000. The law requires that manufacturers of medical devices obtain marketing clearance for their devices before they may offer them for sale.

In our letters of April 16 and June 12, you were advised that marketing Bio-2000 without clearance is a violation of the Federal Food, Drug, and Cosmetic Act (the Act). You have been asked to advise the agency how you intend to correct this violation of the Act, which you have failed to do. In legal terms, the device is adulterated under Section 501(f)(1)(B) and misbranded under 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 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 device, 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 received this letter what steps you are taking to correct the problem.

Page 2 - Dr. Thad J. Overmyer

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 manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (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 (301) 594-4613 ext. 139.

Sincerely yours,



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

cc:

Dr. Thad J. Overmyer
132 North Second Street
Danville, Kentucky