



DEPARTMENT OF HEALTH & HUMAN SERVICES

g 4097d
Public Health Service

Via Federal Express

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

June 3, 2003

William Colone
President and CEO
ENDOMED, INC.
1022 S. 51st Street, Suite 1
Phoenix, Arizona 85044

Dear Mr. Colone:

The purpose of this Warning Letter is to inform you of objectionable conditions found during a Food and Drug Administration (FDA) inspection at your facility and to request a written response.

On February 3-5, 2003, Dr. Sandra Shire and Charles Larson, investigators from FDA's Los Angeles District Office, conducted the inspection. The purpose of the inspection was to determine whether your activities as a sponsor of investigational studies with significant risk devices, intended for use in the treatment of aortic aneurysms, complied with applicable FDA regulations. These implants are considered devices as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 USC 321(h)].

FDA investigators conducted this inspection under a program designed, in part, to ensure that data and information contained in applications for Investigational Device Exemptions (IDEs) are scientifically valid and accurate. Another objective of this program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

At the close of the inspection, the FDA investigators issued a Form FDA-483, "Inspectional Observations," and discussed the findings with you. The deviations listed below are not intended to be an all-inclusive list of violations observed at your facility. As a sponsor of investigational studies, it is your responsibility to ensure that devices you ship and investigations you sponsor comply with applicable FDA regulations. The following violation was observed:

You distributed significant risk devices without an FDA approved IDE or premarket approval application. Consequently, these devices are adulterated under section 501(f)(1)(A) of the Act.

The current inspection revealed that from 1998-2002 you manufactured and distributed approximately [REDACTED] unapproved significant risk devices. These unapproved devices, [REDACTED] were implanted into patients without the knowledge or approval of the FDA, without proper IRB oversight, and, in most cases, without the patient knowing that the devices were unapproved and investigational.

FDA is aware that EndoMed holds an approved IDE for [REDACTED]. However, EndoMed does not have an approved IDE for [REDACTED]. While the design of [REDACTED] may be similar, use in the thoracic aorta constitutes a different indication for use and requires a separate IDE.

FDA considers the continued distribution and use of these adulterated devices to be knowingly violating the Food, Drug, and Cosmetic Act. Therefore, you must immediately stop shipment of the [REDACTED] and retrieve any of these devices still in distribution.

We acknowledge receipt of your written response, dated February 6, 2003, to Ms. Doreen Kezer. In that response you stated, "Endomed voluntarily self-complied prior to the inspection by collecting all unused devices previously distributed to [REDACTED] and will continue to make every effort possible to maintain the highest level of compliance in the future."

FDA considers your activities to be serious violations of the law. Continuation of these activities may result in FDA taking regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, civil money penalties, or criminal prosecution.

Please respond to this letter in writing within 15 days. Your response should include distribution information for all [REDACTED] and any other unapproved devices. This information should include the following: the name, address and phone number of practitioners and institutions receiving the devices; the dates of shipment; and the names of the patients in which the devices were implanted and their clinical outcomes. If patients received additional unapproved devices during subsequent surgeries, this information should also be provided.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850. Attention: Doreen Kezer, MSN, Consumer Safety Officer.

Page 3 EndoMed, Inc.

A copy of this Warning Letter was sent to the Food and Drug Administration's Los Angeles District Office, 19900 MacArthur Blvd. Suite 300, Irvine, CA 92612. We request that a copy of your response also be sent to that office.

Please direct all questions concerning this matter to Ms. Kezer at (301)594-4720, ext. 131.

Sincerely yours,

Michael E. Maccarelli
for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Cc: PURGED COPIES
Kristine Borrow, Ph.D
Director of Division of Compliance Oversight
Department of Health and Human Services
Office of Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

[REDACTED]