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 unapproved significant risk devices. These
unapproved devices, 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 . However, EndoMed does not have an
approved IDE for . While the design of 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 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-
compelled prior to the inspection by collecting all unused devices previously
distributed to , 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 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.
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. Macarelli

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

Cc: PURGED COPIES
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