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May 1, 2007

VIA FACSIMILE AND REGULAR MAIL

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

**Re: Warning Letter
CBER-07-009
April 26, 2007**

Dear Ms. Malarkey:

I write on behalf of MedEnclosure LLC (“MedEnclosure”) in partial reply to the above-referenced correspondence for which you identified me as a recipient.

The letter signed by you “describes the results of Food and Drug Administration (“FDA”) inspections of and conversations” with various third parties. It appears that the content of your letter contains assumptions that are not based on fact or in law. Consequently, before MedEnclosure can reply in full, it will require further information from you, specifically the documentation associated with and supporting the “results” that you reference.

Until such documents are provided, MedEnclosure has directed that I advise you of the following:

1. At no time prior to the commencement of the clinical investigation described above did any representative of the FDA identify or document a basis for characterizing the MedClose™ Vascular Closure System (“VCS”) as a significant risk device.
2. The Independent Investigational Review Board (“IIRB”) that you identify did unanimously determine that the MedClose™ VCS was not a significant risk device in accordance with the requirements of 21 C.F.R. Part 812 as followed by MedEnclosure.

3. The clinical investigation proceeded to follow a protocol for investigation and informed consent which contained procedures previously identified by FDA personnel and additional recommendations as identified by the IIRB.
4. The conduct of this clinical investigation in the United States ("U.S.") did produce valid scientific evidence to support device safety and effectiveness and all such information required for submission to the IIRB as surrogate for the FDA was provided.
5. It appears that interference by the FDA caused the IIRB to surprisingly reverse its prior unanimous determination that the MedClose™ VCS did qualify as a "non-significant" risk device.
6. Upon receipt by MedEnclosure of the IIRB notification of its questionable reversal of the clinical investigation status, MedEnclosure suspended all clinical investigations in the U.S. and such investigations have not continued in the U.S.
7. Around the time of the U.S. clinical investigation, a clinical investigation in another country was approved by that government's responsible agency. This approval was consistent with applicable procedures described in 21 C.F.R. Part 812 including investigational review board ("IRB") review and identification as a "non-significant" risk device, as well as requirement for informed consent.
8. The clinical investigation outside the U.S. continues and is to be expanded. The results, again, have produced valid scientific evidence of safety and effectiveness. I understand further that there have been no unanticipated adverse events.

MedEnclosure is surprised by and remains disappointed in the conduct of your office and that of other personnel in the FDA who either failed to understand their responsibility under applicable provisions of law and/or regulations or simply intended to ignore such provisions of law and/or regulation. It is the desire of MedEnclosure to cooperate with representatives of the FDA, and it welcomes the opportunity to review the documents it has requested as well as those previously requested of the FDA.

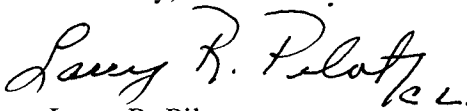
Because it is the policy of the FDA to release to the public copies of Warning Letters, MedEnclosure expresses the following:

1. Prior to any release to the public, redact from the Warning Letter all information that is of a confidential nature as described in FDA regulations appearing in 21 C.F.R. Part 20, relating to application of the Freedom of Information Act ("FOIA"), as well as those applicable to privacy.
2. Upon any release of the redacted Warning Letter on the FDA Website, you are requested and advised to publish this letter as the initial response of MedEnclosure to the Warning Letter.

Mary A. Malarkey
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In the meantime, I look forward to receipt of the documents that I have requested. Further, I welcome any further inquiries or clarifications that would be helpful to the mutual interests of MedEnclosure and the FDA.

Cordially,

A handwritten signature in black ink that reads "Larry R. Pilot". The signature is written in a cursive style with a large initial "L" and a distinct "P".

Larry R. Pilot

LRP:clb

cc: Med Enclosure, LLC