DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY - 2 2007

HAND DELIVERY

Shlomo Gabbay, M.D.
Founder and Chief Scientific Officer
Shelhigh, Inc.
650 Liberty Avenue
Union, New Jersey 07083

Dear Dr. Gabbay:

FDA requests that Shelhigh, Inc. initiate an immediate recall of all devices manufactured by your firm in Union, New Jersey. The products to recall include:

- Shelhigh Pericardial Patch,
- Shelhigh No-React® Pericardial Patch,
- Shelhigh No-React® EnCuff,
- Shelhigh BioRing™,
- Shelhigh No-React® Dura Shield (also sold as Endura™ No-React® Dural Substitute by Integra LifeSciences),
- Shelhigh No-React® Tissue Repair Patch/UroPatch™,
- Shelhigh No-React® VascuPatch™,
- Shelhigh No-React® PneumoPledgets,
- Shelhigh No-React® Pulmonic Valve Conduit Models NR-4000/NR-4000PA/NR4000PA-C,
- Shelhigh No-React® Stentless Valve Conduit Models NR2000/NR2000+/NR2000C+/NR2000C,
- Shelhigh Internal Mammary Artery (SIMA),
- Shelhigh Gold™ perforated patch,
- Shelhigh Pre Curved Aortic Patch (Open),
- Shelhigh NR2000 SemiStented aortic tricuspid valve,
- Shelhigh BioConduit stentless valve,
- Shelhigh NR900A tricuspid valve,
- Shelhigh MitroFast Mitral Valve Repair System,
- Shelhigh BioMitral tricuspid valve, and
- Shelhigh Injectable Pulmonic Valve System.

The environmental controls and processes used to manufacture and test devices within your facility can compromise the sterility and safety of these products, and there is therefore a reasonable probability that use of such products will cause serious adverse health consequences or death. Devices manufactured under these conditions are considered to be adulterated under 21

U.S.C. 351(h) of the Federal Food, Drug, and Cosmetic Act and Title 21 Code of Federal Regulations (CFR) Part 820.

The FDA is classifying this action as an FDA-Requested Class I recall and recommend that you perform level A (100%) effectiveness checks. We request that you contact all your consignees who received these products and request a recall to the consumer level and that you conduct any sub-recalls necessary to reach all products on the market. The FDA's policy regarding recalls is published in Title 21 CFR Part 7.

This letter is a follow-up to the multiple verbal requests made to Shelhigh (yourself, Mr. Peter Flosdorf and your attorney, Mr. Larry Pilot), simultaneous with the execution of the seizure that began on April 17, 2007, that you initiate a voluntary recall of all the devices Shelhigh manufactures. FDA understands that you have not committed to recalling these products and you have not notified your consignees of a recall.

FDA's New Jersey district office will provide you with guidance in implementing and assuring the effectiveness of your recall of these products, including reviewing any proposed recall communication to your consignees. We are requesting that you work closely with the district office and that you provide any necessary information regarding the recall in a timely manner.

Please respond to this letter by 4:30 PM, May 3, 2007. Your response to this letter should be directed to:

Douglas I. Ellsworth, Director,
New Jersey District, FDA
10 Waterview Blvd 3rd Fl, HFR-CE300
Parsippany, NJ 07054
(973)331-4901
Fax (973) 331-4931

Due to the seriousness of this situation, FDA has issued a press release recommending that doctors and hospitals consider using alternatives instead of Shelhigh products. Failure to comply with this request can result in further regulatory action.

Sincerely,

for

Margaret O'K. Glavin
Associate Commissioner
for Regulatory Affairs