FDA News

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FDA Seizes All Medical Products From N.J. Device Manufacturer for Significant Manufacturing Violations

U.S. Food and Drug Administration (FDA) investigators and U.S. Marshals today seized all implantable medical devices from Shelhigh, Inc., Union, N.J., after finding significant deficiencies in the company's manufacturing processes. The deficiencies may compromise the safety and effectiveness of the products, particularly their sterility.

The products include pediatric heart valves and conduits (tube-like devices for blood flow), surgical patches, dural patches (to aid in tissue recovery after neurosurgery), annuloplasty rings (to help repair heart valves) and arterial grafts. The tissue-based devices are used in many surgical settings, including open heart surgery in adults, children and infants, and to repair soft tissue during neurosurgery and abdominal, pelvic and thoracic surgery. Critically ill patients, pediatric patients and immuno-compromised patients may be at greatest risk from the use of these devices.

All medical device companies must follow current good manufacturing practice, a set of requirements that help to ensure the safety and effectiveness of all medical products. Shelhigh's violations include: manufacturing products in a facility with a poorly constructed and poorly maintained clean room where sterilized devices are further processed; failing to adequately monitor critical manufacturing environments for possible microbial contamination; failing to properly test products for sterility and fever-causing contaminants; and failing to scientifically support product expiration dates.

Physicians should consider using alternative devices. Physicians should also monitor patients with a Shelhigh implant for infections and proper device functioning over the expected lifetime of the device. Patients who think they may have received a Shelhigh device during surgery should contact their physician for more information. FDA will issue a Preliminary Public Health Notification to physicians and other health care professionals and a Preliminary Advice for Patients shortly with more information; those documents will be posted to FDA's Web site.

The seizure follows an FDA inspection of the Shelhigh manufacturing facility last fall, as well as meetings with the company at which FDA warned Shelhigh that failure to correct its violations could result in an enforcement action. FDA also alerted the company to its manufacturing deficiencies and other violations in two warning letters.

Medical devices manufactured by Shelhigh include:

- Shelhigh Pericardial Patch
- Shelhigh No-React Pericardial Patch
- Shelhigh No-React PneumoPledgets
- Shelhigh No-React VascuPatch
- Shelhigh No-React Tissue Repair Patch/UroPatch
- Shelhigh Pulmonic Valve Conduit No-React Treated
- Shelhigh No-React Dura Shield
- Shelhigh BioRing (annuloplasty ring)
- Shelhigh No-React EnCuff Patch
- Shelhigh No-React Stentless Valve Conduit
- Shelhigh Internal Mammary Artery
- Shelhigh Gold perforated patches

- 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
- Shelhigh Injectable Pulmonic Valve System

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Additional Information
FDA Preliminary Public Health Notification
Preliminary Advice for Patients
Complaint for Forfeiture [pdf, 662 KB]

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