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FDA Requests Recall of All Shelhigh Medical Devices

The U.S. Food and Drug Administration (FDA) today issued a formal written request to Shelhigh, Inc. to recall all of its medical devices remaining in the marketplace, including hospital inventories, because of sterility concerns.

On April 17, 2007, U.S. Marshals, at FDA's request, seized all medical devices including components at Shelhigh's Union, N.J. facility after finding significant deficiencies in the company's manufacturing processes. During the seizure, Shelhigh was asked to perform a voluntary recall of its products, but the company declined.

FDA recommends that doctors and hospitals consider using alternative products. Physicians and patients concerned about Shelhigh devices can visit www.fda.gov/cdrh/safety/041907-shelhigh.html and www.fda.gov/cdrh/medicaldevicesafety/atp/041907-shelhigh.html for more information, including a list of the company's products.

"Since these are critical devices implanted into seriously-ill patients, ensuring their sterility is absolutely essential to prevent infection," said Daniel Schultz, M.D., director, FDA's Center for Devices and Radiological Health. "FDA will continue to provide up-to-date information to patients and physicians about this ongoing public health matter."

The company's deficiencies, described in a complaint filed with the U.S. District Court of New Jersey, may compromise the safety and effectiveness of the devices. Shelhigh's own records indicate a number of sterility test failures and that its testing and retesting procedures were not properly performed.

Shelhigh devices are used in infants, children and adults. The products include pediatric heart valves, tube-like devices for blood flow (conduits), surgical patches, dural patches to aid in tissue recovery after neurosurgery, annuloplasty rings to help repair heart valves, and arterial grafts.

Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), fax (800-332-0178), or regular mail (use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787).

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Questions and Answers

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