

FDA News

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Shelhigh Enters Consent Order with FDA

Agrees to Halt Distribution Until Manufacturing Deficiencies Have Been Corrected

Under a court order signed today, Shelhigh, Inc., of Union, N.J., agreed to stop distributing its implantable medical devices, used in heart surgery and other procedures, until the company brings its production processes in line with FDA standards.

The United States District Court for the District of New Jersey entered the consent order of injunction agreed to by Shelhigh. The consent order forbids Shelhigh from distributing all devices until its manufacturing methods, facilities, and controls are in compliance with FDA's current good manufacturing practice (CGMP) and Quality Systems (QS) regulation for medical devices and the medical device reporting (MDR) requirements. On April 17, 2007, U.S. Marshals seized all finished devices and components of the devices at Shelhigh's manufacturing facility due to concerns of potential risk of nonsterility.

Shelhigh manufactures 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.

"It is critical that companies comply with FDA's manufacturing rules so that medical devices, especially the kind of implantable devices made by Shelhigh, are safe and effective," said Daniel Schultz, M.D., director of FDA's Center for Devices and Radiological Health.

The consent order requires that the company hire independent expert consultants to inspect its facility and certify to FDA that corrections have been made. FDA will continue to monitor these activities through its own inspections. FDA did not invoke the Federal Food, Drug, and Cosmetic Act to mandate that Shelhigh recall its devices, and Shelhigh did not conduct a recall of its devices.

Shelhigh may resume manufacturing, but not distributing, devices in phases, after FDA has approved its plan for bringing its seized products and

manufacturing processes into compliance with FDA law. After Shelhigh has completed corrective actions and been allowed to resume manufacturing, the company must hire an independent auditor to inspect its facility at least once a year. Results of these audit inspections will be reported directly to FDA.

If Shelhigh fails to comply with any provision of the consent order, or violates FDA law or regulations, FDA may order the company to again cease manufacturing and distributing its devices, to recall the devices, and to take other actions deemed necessary by the agency, including payment of money for continuing violations.

The consent order was signed by Shlomo Gabbay, Shelhigh's president and chief executive officer and medical director, and Lea Gabbay, the company's general manager. The order was entered today in the U.S. District Court for the District of New Jersey.

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