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Press Release

Shelhigh and FDA Reach an Agreement

A no-fault settlement provides a clear path to resumption of operations at Shelhigh, including product shipment.

Union, NJ, 25 June 2007: Shelhigh announced today that it has reached a no-fault settlement agreement with the U.S. Food and Drug Administration (FDA) that provides a clear path to the resumption of operations at Shelhigh, including product shipment.

"I am extremely pleased that the FDA and Shelhigh were able to reach a settlement that will permit us to resume shipments of our life-saving products to patients around the world," said Dr. Shlomo Gabbay, Chief Scientific Officer for Shelhigh.

The FDA acknowledges that it did not mandate a product recall, Shelhigh did not conduct a recall, and no product recall is required by the settlement just announced.

The agreement calls for independent experts to inspect and certify that Shelhigh's manufacturing processes are in substantial compliance with Federal regulations. These independent inspectors have already begun their review and the firm anticipates that any required changes will be easily implemented. Upon completion of the experts' certification, the FDA will conduct normal inspections to confirm that the requested changes were made. Importantly, this approach will provide the fastest means for Shelhigh to resume product shipment.

This was not an agreement ordered by the court, but rather a mutual no-fault settlement that the court agreed to sign so that FDA and Shelhigh can resume good relations, and Shelhigh can resume delivering its life-saving products. Shelhigh is pleased to announce that FDA declared, "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 has always been committed to maintaining a good working relationship with the FDA, while providing its life-saving products to patients in need," said Dr. Gabbay. "As is well-documented, Shelhigh's track record of providing effective and revolutionary products is extraordinary, and we are pleased to demonstrate that our manufacturing process is exact and complete, and in full compliance."

For Immediate Release

About Shelhigh

Shelhigh is known for its proprietary No-React[®] tissue products that utilize the widely accepted glutaraldehyde fixation process while avoiding the acknowledged problems that accompany glutaraldehyde. No-React tissue products have over 10 years proven performance of resisting infection and calcification, even in cases of active infective endocarditis. Today Shelhigh offers a wide variety of cardiothoracic surgical solutions, all incorporating No-React tissue for superior performance. To learn more about Shelhigh and its products please visit www.shelhigh.com. Visitors may also sign up for the [Shelhigh newsletter](#) for automatic updates.

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