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Press Release

Shelhigh Responds to FDA Recall Request

The FDA restates its prior claims but still offers no evidence of its various allegations.

Union, NJ, 3 May 2007: The FDA has again gone public with a press release, this time regarding a formal request to Shelhigh, Inc. to voluntarily recall all of its medical devices remaining in the marketplace, including hospital inventories, ostensibly due to sterility concerns.

“This is the first formal request by the FDA for Shelhigh to recall its products, and since the FDA allegations are unfounded, Shelhigh has no intention to initiate a product recall,” said Shelhigh founder, Shlomo Gabbay, MD. “The FDA should understand that it must prove its allegations before it can make a request and their newest statements do not provide any further factual support for their claims.”

The FDA in its current press release misleadingly states that Shelhigh's own records indicate a number of sterility test failures and that its testing and retesting procedures were not properly performed.

“At no time during the inspection or through the documentation of their observations did the FDA inspectors indicate that the sterilization method employed by Shelhigh was improper or would fail to produce the desired result. The sterilization method employed by Shelhigh has been validated on numerous occasions and has been included as part of required submissions to the FDA,” Dr. Gabbay said.

“Sterility testing of Shelhigh products is performed by an independent International Standards Organization (ISO) certified contract laboratory. Our firm has implemented sterility testing procedures that have been in effect since prior to 2000 and have been reviewed through numerous FDA inspections of the Shelhigh facility,” said Dr. Gabbay. “For the FDA to allege that these procedures are now in violation of regulations is inaccurate and misleading.”

The FDA also provided a separate questions and answers document that was apparently designed to counter statements made by Shelhigh in its earlier news releases.

“Our customers and the Public may go to the [Shelhigh web site](#) to view our responses to the answers that the FDA provided and I trust that they will be enlightened by the explanation that

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we provide,” said Dr. Gabbay. “I just hope that the FDA halts its public posturing and returns to discussions with Shelhigh. I prefer that we close out any remaining issues that the FDA may have through constructive dialog so that Shelhigh can return to the business of saving lives.”

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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