



3 May 2007

Shelhigh Response to the FDA Questions and Answer Document

Following is a copy of the FDA Questions and Answers document that the FDA posted on its website on 2 May 2007, and Shelhigh's response to the FDA statements contained in that document.

Q: Why did FDA seize Shelhigh's medical devices?

FDA: Under order from U. S. District Court in New Jersey, FDA and U.S. Marshals seized all products and product components at the firm's facility in Union, N.J., after FDA found significant deficiencies in the company's manufacturing processes. The deficiencies may compromise the safety and effectiveness of the products, particularly their sterility.

Shelhigh: The FDA presented its allegations of deficiencies to the U.S. District Court in a unilateral move for which the "significance" will be determined by the evidence. The company provided comprehensive responses in early February and April 2007. It appears that the FDA did not review our responses based on some of the claims in their complaint. Shelhigh believes that it has evidence to contradict FDA allegations and for which ultimately the Federal Court will determine the outcome

Q. At which locations were the devices seized?

FDA: The devices were seized at the firm's manufacturing facility in Union, N.J. Products have also been embargoed by the state of New Jersey at a Shelhigh distributor.

Shelhigh: The FDA statement is acceptable but Shelhigh has claimed the devices that are quarantined at its facility and will contest FDA allegations.

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Q. Shelhigh claims that the seizure was unwarranted, that there is no evidence that their devices are not sterile, and that they are safe to use.

FDA: Shelhigh devices are intended for use in open-heart surgery for valve replacement; and repair of soft tissue structures during abdominal, pelvic, heart, lung, brain, shoulder, and spine surgery. These devices are permanently implanted into infants, children and adults during surgical procedures. In the complaint filed in federal court, FDA has alleged that Shelhigh's manufacturing processes are deficient in many respects.

http://www.fda.gov/ora/frequent/483s/shelhigh/Complaint_shelhigh_20070416.pdf. The company's own records indicate a number of sterility test failures and that the tests and retests were not properly performed. The violative manner in which the products were made increases the likelihood that the products are not sterile and are deficient in other respects. FDA has determined that use of these devices, if not sterile, poses a reasonable probability of serious adverse events or death. We recommend that hospitals and physicians consider using alternate products.

Shelhigh: The FDA claim that Shelhigh records "indicate a number of sterility test failures and that the tests and retests were not properly performed" is misleading at best.

At no time during the inspection or through the documentation of FDA observations (FORM FDA 483) 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.

If the FDA truly believes what it claimed, then the FDA is negligent and guilty of professional misconduct for permitting the use of Shelhigh products during the 10 weeks when 2-3 FDA inspectors were present at the Shelhigh facility and for 4 months afterwards. Shelhigh is confident that its devices are safe and effective when used as directed.

The public allegation by the FDA on 17 April 2007 was the first indication to the firm that the FDA believed the sterilization method to be "improper." Sterility testing of Shelhigh products is performed by an independent International Standards Organization (ISO) certified contract laboratory. Shelhigh sterility testing procedures have been in effect since prior to 2000 and these have been reviewed through numerous FDA inspections of the Shelhigh facility without any indication of concern. For the FDA to now assert that these procedures are in alleged violation of regulations is inaccurate and misleading.

Q: Is it true, as Shelhigh claims, that the seizure only prevents the company from shipping specific identified products from the facility?

FDA: All products at the Union, N.J. facility are affected by the seizure. None of the seized product may be shipped. The United States Marshal's Service did not physically remove the products from the facility, but instead "seized them in place," meaning Shelhigh cannot remove, attempt to remove or in any way interfere with the products at the facility without the prior written permission of the U.S. Marshal. The U.S. Marshal often seizes products in place when there are too many to move to another location or when removal would be impractical.

Shelhigh: The FDA statement is acceptable as it applies only to identified products, and reflects information that Shelhigh has already provided to the Public. The devices remain in quarantine until disposition is determined through litigation.

Q: What was the basis for the seizure?

FDA: Shelhigh failed to adhere to the Quality System (QS) regulation (which describes current good manufacturing practice), required by law, and failed to correct its problems despite several warnings from the FDA. When a medical device manufacturer does not adhere to the QS regulation requirements, the manufacturer cannot assure the public that the finished products are safe and effective, or that products labeled as sterile are in fact sterile. Shelhigh's violations include: manufacturing products in a facility with a poorly constructed and poorly maintained cleanroom 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. More details on FDA's concerns are described in the complaint for seizure filed in the U.S. District Court of New Jersey:
http://www.fda.gov/ora/frequent/483s/shelhigh/Complaint_shelhigh_20070416.pdf.

Please note that these are the government's allegations that must be proven in court.

Shelhigh: The key part of the FDA statement is the last sentence -- "these are the government's allegations that must be proven in court." The FDA, however, insists on stating their opinion as fact by using terms like "violation." Shelhigh has not yet had its day-in-court and maintains that the alleged violation claims made by the FDA will be challenged through Court procedures.

Q: Is it true that Shelhigh was not aware of FDA's concerns with its manufacturing processes and that FDA was not willing to meet with Shelhigh officials?

FDA: No. At the end of each day during FDA's inspection of the facility, FDA investigators told Shelhigh managers about their concerns. In addition, when the inspection was finished, FDA investigators left a 21-page list of observations with Shelhigh officials and further discussed those observations with them in two meetings, lasting about 12 hours. Many of FDA's concerns are detailed in the complaint filed with the court.
http://www.fda.gov/ora/frequent/483s/shelhigh/Complaint_shelhigh_20070416.pdf

Shelhigh: The FDA comments are disingenuous hearsay. FDA inspectors and their supervisors know full well that Shelhigh had identified numerous errors in their site report, several of which were substantive and would clearly give a misleading impression to third-parties. These inspectors refused to make changes that would properly reflect the facts. Further, Shelhigh has documented no less than 10 attempts to arrange the second meeting to which the FDA refers, spanning 2 months time, after which time the FDA reluctantly agreed to meet. And at that second meeting, the FDA representatives made it clear that they would not make corrections in their site report or discuss issues relating to the 2005 warning letter. FDA made promises to meet with Shelhigh and discuss the inspectional findings and Shelhigh's responses; the FDA did not honor its promise.

Q: What products are involved?

FDA: 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 the greatest risk from the use of these devices. A list of products manufactured by Shelhigh is included in FDA's April 17 press release at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01612.html>

Shelhigh: The FDA states the obvious – **IF** a medical device is defective or non-sterile, then patients may be at risk, especially critically ill patients. The fact is that neither Shelhigh nor the FDA has any evidence to support the FDA allegation that Shelhigh devices present any risk, and certainly not a risk of infection. FDA procedures require preparation of a Health Hazard Evaluation (HHE). Shelhigh repeatedly has requested a copy of the FDA HHE document, but the FDA has yet to produce any such document. If the FDA has evidence regarding device infection, then they should present the HHE report to Shelhigh for review and consideration.

Q: Why does FDA believe use of these devices could pose a serious risk to patients?

FDA: FDA investigators found deficiencies in the firm's manufacturing processes during inspections of the firm's facility in 2000 and 2005. The inspections resulted in warning letters to the firm in 2000 and in 2005. An inspection again in December 2006 revealed ongoing deficiencies, which led to the seizure action. The warning letters are available at http://www.fda.gov/foi/warning_letters/archive/g5674d.pdf and http://www.fda.gov/foi/warning_letters/archive/m3695n.pdf

Shelhigh: Past warning letters do not apply to the recent seizure action, and the content of the 7 year old, 2000 warning letter was addressed. The complaint filed by the FDA that lead to product seizure included different claims which Shelhigh believes are unsupportable and not related to any realistic possibility of unacceptable risks to patients. As noted earlier, the comments in the FDA warning letters are simply opinions of FDA personnel and do not establish any factual violation.

Q: What are FDA's recommendations for physicians and patients who may have one of the Shelhigh devices?

FDA: In light of FDA's inspectional findings and evaluation, physicians should carefully consider using alternate 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. Further recommendations for physicians are available at <http://www.fda.gov/cdrh/safety/041907-shelhigh.html>. Advice for patients is available at <http://www.fda.gov/cdrh/medicaldevicesafety/atp/041907-shelhigh.html>.

Shelhigh: Shelhigh believes that its products are safe and effective to use as indicated and that the FDA advice is irresponsible. Physicians are always encouraged to report potential product problems to the FDA and to Shelhigh – this is a normal occurrence in the medical device industry. No such incident reports received by Shelhigh or reported by the FDA, however, indicate the possible problems that the FDA is claiming.

Q. Will Shelhigh recall the devices remaining in the marketplace now?

FDA: At the time of the seizure, Shelhigh was asked several times to voluntarily recall all products remaining on the market. The firm declined to do so. On May 2, because of continuing concern for patient safety, FDA issued a letter to Shelhigh formally requesting that the company recall all devices which remain on the market, including those currently in hospital inventories. Before FDA issued the letter requesting a recall, the agency warned physicians, hospitals, and consumers of the potential risks associated with use of Shelhigh products.

Shelhigh: The FDA asked **if** Shelhigh intended to recall products and was advised that Shelhigh did not intend to recall products because there was no evidence that the products presented any patient health risk. Now that the FDA has made a formal request for Shelhigh to voluntarily recall its products, Shelhigh is asking the FDA to produce its Health Hazard Evaluation (HHE) for review and consideration by Shelhigh.

Q: Why didn't FDA request a recall sooner?

FDA: FDA's recent inspection of Shelhigh was not completed until late December, 2006. FDA then evaluated the findings of its investigators to determine the seriousness of the violations and whether legal action was appropriate. FDA ultimately decided that seizure was appropriate and necessary to protect the public and took steps to seize the products. Shelhigh was asked several times while the seizure was being executed to recall the products and Shelhigh declined. When it became clear that Shelhigh would not honor the government's verbal requests, FDA issued a formal letter requesting the company to recall all products remaining in distribution, including those in hospital inventories.

Shelhigh: The FDA answer makes no sense. Certainly if the alleged problems were as severe as the FDA claims, why did it wait 6 months to act? During this period of time no reports of adverse incidents have been reported to Shelhigh to support FDA concerns, and none have been received to date. During their seizure the FDA asked **if** Shelhigh would recall products and Shelhigh declined because there was no evidence or realistic possibility of product safety or sterility problems. The current FDA formal request is the first time that the FDA requested Shelhigh to recall products.

Q: If the firm doesn't recall, what is FDA's next step?

FDA: FDA is currently considering its options for further action with regards to Shelhigh, should they be necessary.

Shelhigh: Shelhigh awaits further documentation from the FDA and again requests that the FDA appear at the discussion table with Shelhigh rather than abuse its authority and deny administrative due process through irresponsible use of the Press.

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