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Press Release

FDA Refuses to Disclose Facts

The FDA denies Shelhigh's repeated requests for proof of FDA allegations, opts instead for newscast that is far from the truth.

UNION, N.J., 6 June 2007 -- The FDA continued its attack against Shelhigh by releasing a newscast on its website this month, again promoting its unfounded allegations against the company. Meanwhile, the FDA continues to put up roadblocks to serious inquiries about its baffling actions against Shelhigh, Inc. by denying repeated requests from Shelhigh for proof of FDA allegations that Shelhigh products may present a health risk. There is **no recall** of Shelhigh products by either the FDA or Shelhigh.

"In an effort to get to the bottom of the FDA allegations we have repeatedly requested a copy of the FDA Health Hazard Evaluation (HHE). Rather than simply sending us a copy of this Evaluation the FDA has informed us that we needed to file a Freedom of Information Act (FOIA) request," said Douglas Goldman, Shelhigh Director of Marketing.

A Health Hazard Evaluation is mandated by Federal law and requires the FDA to prepare a report prior to requesting a product recall. The HHE must explain the basis for an FDA determination that a medical device can cause a patient health hazard and that the device should be recalled. The FDA has not explained why it will not provide the Health Hazard Evaluation to Shelhigh and why it is forcing Shelhigh to file FOIA requests, but the FDA admits that at the end of 2006 it had over 19,000 FOIA requests still pending with a typical processing period of over 8 months.

"The first questions to be answered in a Health Hazard Evaluation include a 'description of a defect, malfunction or error in use' of the device in question. Since there are no reported defects, malfunctions or errors with Shelhigh devices of which I am aware, the FDA doesn't have facts to support its request for a recall," said Goldman. "The FDA is acting irresponsibly and abusing its authority by continuing to claim that Shelhigh products present a health risk without presenting evidence."

Shelhigh notes that it is being forced to respond to a fog of confusion created by the FDA, and that the FDA is struggling to find any shred of evidence since its April 2007 quarantine in order to defend its actions. "In the meantime, by halting shipments of Shelhigh products, the FDA is harming our small firm and is threatening the livelihoods of 60 professionals," said Goldman.

For Immediate Release

Shelhigh has posted detailed information on its web site regarding the FDA allegations and actions – see <http://www.shelhigh.com/support-news.htm>

Related links

FDA Freedom of Information Annual Report – FY2006
<http://www.fda.gov/foi/annual2006.html>

Acknowledgement from the FDA regarding Shelhigh FOIA requests
<http://shelhigh.com/support-news.htm>

21CFR Sec. 7.41 - Federal requirement for an FDA Health Hazard Evaluation (HHE)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=7.41&SearchTerm=health%20hazard%20evaluation>

Example FDA Health Hazard Evaluation (HHE) form
<http://www.fda.gov/cdrh/oivd/hheform.html>

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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