Stryker's Biotech Division Receives FDA Warning Letter

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KALAMAZOO, Mich., May 2 /PRNewswire-FirstCall/ -- Stryker Corporation (NYSE: SYK) announced today that its Biotech division has received a warning letter from the U. S. Food and Drug Administration (FDA) related to quality systems and compliance issues at its Hopkinton, Massachusetts location.

The warning letter concerns observations made during an inspection that was initiated in September 2007. The letter primarily cites issues relating to Stryker Biotech's handling of a past clinical study, its quality system including medical device reporting procedures, and the integrity of hospital Institutional Review Board (IRB) documentation used to approve implantation of Humanitarian Use Devices.

Several corrective actions and changes to processes put in place by Stryker Biotech were noted in the letter and future improvements are forthcoming as the division continues to work with FDA. No products have been recalled as a result of this warning letter. In addition, there were no observations related to any ongoing clinical trials or clinical trial IRBs.

"We take this matter very seriously, will continue to cooperate fully with FDA, and have initiated significant measures to address FDA's concerns," said Stephen P. MacMillan, President and Chief Executive Officer of Stryker Corporation.

In addition to specific corrective actions implemented at the Biotech division, Stryker recently launched a company-wide Quality Action Plan aimed at strengthening corporate-level oversight and at institutionalizing a more consistent implementation of best practices for meeting FDA requirements.

As part of its Quality Action Plan Stryker has:

- Strengthened roles and responsibilities to increase accountability for quality
- Established new company-wide standard operating procedures for quality processes that will be implemented consistently at each division
- Reorganized quality functions at the plant, division and corporate levels and increased third-party monitoring at all levels
- Tied a significant portion of senior management's compensation to meeting quality improvement measures

"We are committed to strengthening our quality systems to fully meet all FDA requirements. While we have made progress in fulfilling this commitment, we still have more work to do" MacMillan added.

Forward-Looking Statements

This press release contains information that includes or is based on forward-looking statements within the meaning of the federal securities law that are subject to various risks and uncertainties that could cause the Company's actual results to differ materially from those expressed or implied in such statements. Such factors include, but are not limited to: pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for the Company's products; regulatory actions; unanticipated issues arising in connection with clinical studies and otherwise that affect U.S. Food and Drug Administration approval of new products; changes in reimbursement levels from third-party payors; a significant increase in product liability claims; changes in economic conditions that adversely affect the level of demand for the Company's products; changes in foreign exchange markets; changes in financial markets; and changes in the competitive environment. Additional information concerning these and other factors is contained in the Company's filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

Stryker Corporation is one of the world's leading medical technology companies with the most broadly based range of products in orthopaedics and a significant presence in other medical specialties. Stryker works with respected medical

professionals to help people lead more active and more satisfying lives. The Company's products include implants used in joint replacement, trauma, craniomaxillofacial and spinal surgeries; biologics; surgical, neurologic, ear, nose & throat and interventional pain equipment; and endoscopic, surgical navigation, communications and digital imaging systems; as well as patient handling and emergency medical equipment. For more information about Stryker, please visit the company web site at www.stryker.com .

SOURCE:
Stryker Corporation

CONTACT:

Investors
Katherine A. Owen, Vice President, Strategy and Investor Relations
+1-269-385-2600

Media
Aaron Kwittken
+1-646-747-7144
stryker@kwitco.com
both of Stryker Corporation