STERIS, FDA Reach Agreement

STERIS Corporation announces it has reached an agreement with the U.S. Food and Drug Administration (FDA) on the terms of a consent decree regarding its SYSTEM 1® liquid chemical sterilization system.

Included in the agreement is a Transition Plan with a Rebate Program for current SYSTEM 1 Customers in the U.S. The consent decree is subject to approval by the U.S. District Court for the Northern District of Ohio.

In general, the agreement resolves the government's complaint relating to the FDA's allegations in its May 2008 warning letter, prohibits the sale of liquid chemical sterilization or disinfection products that do not have FDA clearance, formalizes STERIS's Rebate Program and the continued support of SYSTEM 1 customers during the FDA authorized transition time period, and describes various process and compliance issues.

"We are pleased that our plans for financial assistance and other support we will provide SYSTEM 1 Customers during this transition are now final," says Walt Rosebrough, STERIS President and CEO. "We apologize to our customers for the uncertainty this situation created over the last several months. However, we believe the Transition Plan will allow health care providers the time, financial support, and information necessary to make the best possible decisions for patients and caregivers. We also appreciate the FDA's efforts to accommodate the needs of health care providers and the patients they serve during this transition."

The Transition Plan includes STERIS's continued support of SYSTEM 1 customers, including the sale of consumables, parts and service, and accessories through August 2, 2011 for those SYSTEM 1 Customers who document their need for continued support.

In addition, under the Transition Plan, STERIS is offering a Rebate Program that gives U.S. customers who purchased their SYSTEM 1 processors directly from STERIS, or who are current users of SYSTEM 1, the option of either a pro-rated cash rebate or a trade-in allowance toward the purchase of new STERIS capital equipment or consumable products. As a condition of participation in this Program, SYSTEM 1 units must be returned.

STERIS will also provide U.S. customers full credit for unopened SYSTEM 1 consumables and accessories within the current shelf life expiration date. For customers with service contracts, credit will be applied for the unused portion of the contracts based upon the date of de-installation. STERIS representatives will contact Customers shortly and provide specific Transition Plan information and certificates that must be completed and returned to permit continued support of their SYSTEM 1 processors.

As a result of the Rebate Program, the Company will record a liability of up to $100 million during the first quarter of fiscal 2011 that will result in a one-time reduction of revenue and operating income on a pre-tax basis.

As the Company previously announced, its new liquid chemical sterilant processing system, SYSTEM 1E™, was cleared by the FDA on April 5, 2010. SYSTEM 1E is cleared for the liquid chemical sterilization of cleaned, immersible, and reusable critical and semi-critical heat-sensitive devices. FDA has identified SYSTEM 1E as a legally available alternative to SYSTEM 1. STERIS will begin taking orders for SYSTEM 1E immediately, with delivery of the first units expected by the second quarter of fiscal 2011.

STERIS continues to believe that the SYSTEM 1 processor is safe and compliant. After more than 300 million uses, there have been no adverse health effects to patients known to STERIS when SYSTEM 1 is used as directed.

Nonetheless, STERIS believes it is in the best interest of all stakeholders to resolve the government's complaint and the SYSTEM 1 regulatory matter through this agreement with the FDA. STERIS's actions since January 2009, including the current Transition Plan, were and are not recalls, corrections or removals under FDA regulation.

For information, visit www.steris.com [1]

Source URL (retrieved on *04/18/2014 - 11:36pm*):
http://www.surgicalproductsmag.com/news/2010/04/steris-fda-reach-agreement?qt-most_popular=0

Links:
[1] http://www.steris.com/