

## **Minneapolis-based RCRI, Inc. Wins FDA Reclassification Petition**

FOR IMMEDIATE RELEASE: Juli Denny, 952-224-2263, [jdenny@rcri-inc.com](mailto:jdenny@rcri-inc.com)

(Minneapolis, MN: June 2, 2008) In a rare event that has changed the Food and Drug Administration (FDA) regulatory oversight requirements for external tissue adhesives, the Minneapolis-based organization Regulatory and Clinical Research Institute, Inc. (RCRI, Inc.) announces that the FDA has accepted its petition to down-classify tissue adhesives for topical approximation to the skin from Class III to Class II. Out of 17 petitions of its kind in the last six years, this petition represents one of only two reclassifications petitions that the FDA has approved.

Representing a leading manufacturer in the medical industry, RCRI, Inc. developed the petition and presented their case to FDA's General and Plastic Surgery Devices Advisory Panel. RCRI, Inc. and leading experts offered significant evidence supporting the safety and effectiveness of this device type as well as evidence that the design and manufacturing of such tissue adhesives was controllable and well understood. As a result, RCRI proposed that general and special regulatory controls will be adequate to provide reasonable assurance of the safety and effectiveness of future tissue adhesives and therefore the regulatory oversight requirements of Class III devices, including the Premarket Approval Application (PMA) submission, are no longer necessary.. The panel unanimously agreed and recommended the reclassification of tissue adhesives for the topical approximation of skin from Class III into Class II and that a guidance document which includes several voluntary consensus standards serve as the Special Control for the reclassified device type.

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The FDA agreed with the panel's recommendation and after periods of review and public comment, this Reclassification Order has been granted concluding that these devices will now be cleared for commercial distribution via a Premarket Notification 510(k) submission rather than a Premarket Approval application (PMA). As suggested by the Special Controls guidance document, this will mean that clinical trials will likely only be required for external tissue adhesives utilizing new materials, new technology or new indications..

The order reclassifies tissue adhesives for topical skin approximation into Class II under the generic name "Tissue Adhesive for Topical Skin Approximation," and identifies the special controls FDA guidance document entitled "Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin, Guidance for Industry and FDA Staff."

Dr. Tierney Norsted, Executive Vice President and Sr. Principal Advisor of RCRI, Inc, stated, *"This is a significant and rare regulatory event for FDA, the tissue adhesive industry and for the clinical community. Down-classifying the regulatory oversight requirements for a medical device is not something FDA takes lightly. Their decision was based on the huge body of evidence that exists supporting the clinical benefits of tissue adhesives while clearly characterizing the risks. FDA now believes that they understand tissue adhesives well enough that special controls, along with general regulatory controls will provide adequate regulatory oversight for this device type. This is exceedingly important for the tissue adhesive industry, as topical tissue adhesives will now be reviewed by FDA via Premarket Notification 510(k) submissions, pre-PMA manufacturing inspections will no longer be required and clinical trials may only be needed for new formulations, technologies or clinical indications.*

For more information, contact Tierney Norsted, Ph.D. at 952-746-8021, [tnorsted@rcri-inc.com](mailto:tnorsted@rcri-inc.com) or Juli Denny at 952-224-2263, [jdenny@rcri-inc.com](mailto:jdenny@rcri-inc.com) Web site: [www.rcri-inc.com](http://www.rcri-inc.com)

**About Regulatory and Clinical Research, Inc.** RCRI, Inc, was founded in 1999 and has helped more than 350 medical device, IVD, and bioscience companies worldwide translate their medical device plans into successful revenue generating businesses. RCRI is ISO 9001: 2000 certified to provide expertise service in regulatory affairs, clinical trial design and management, database development, reimbursement strategy, health economics, quality systems and compliance, biostatistics, and venture capital due diligence.

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