

RCRI appoints new Chief Operating Officer

RCRI is delighted to announce the appointment of David Meyer as Chief Operating Officer for the company.

David brings over 25 years of financial and administrative management experience to RCRI with 18 years experience in the medical technology arena. David has held significant roles in a number of emerging medical technology companies in the Twin Cities such as Deltec Inc. and XRT Corp. as well as having served with Medtronic.

“We are looking to David to have a major impact on RCRI’s business” said Jennifer Marrone, Founder, Principal Advisor and Vice President at RCRI. “As well as having responsibility for the day to day management, David will also be instrumental in positioning RCRI for growth and will be actively involved in bringing new services to RCRI’s portfolio.”

For further information contact RCRI at 952-746-8080 x 250 or email info@rcri-inc.com

RCRI, d-TARGET and KJ International at RAPS in Baltimore; RCRI at Medical Alley Annual Conference in St. Paul

Attendees at the **RAPS Annual Conference in Baltimore, October 20—22** are invited to visit RCRI (booth 415) and our partners d-TARGET (booth 417) and KJ International (booths 414/416).

d-TARGET is a leading European clinical research organization specializing in medical devices and in-vitro diagnostics. Founded in 1997, d-TARGET offers full support and management of clinical investigations, including pre- and post- marketing trials as well as in European regulatory matters including CE marking. For more information about d-TARGET’s services, visit their Web site at www.d-target.com.

KJI is a full-service translation firm bringing together state-of-the-art technology and business-savvy language consultants to help clients of all sizes communicate effectively across language and cultural barriers. With clients in medical, software, industrial manufacturing, legal and scientific sectors, KJI helps clients navigate cultural differences, regulatory requirements and international law. Capabilities include print, graphic design and layout, web translation and localization, conversational and group interpretation, voice-overs, and more. For more information on KJI, please visit www.kjinternational.com.



Also, Jennifer Marrone, Principal Advisor at RCRI, will be moderating a panel session on "General Versus Specific Indications for Your Medical Device Label" on Tuesday, October 21 at 4pm. The session discusses the application of the Guidance for Industry, General/Specific Intended Use

and the factors that can help industry in determining whether new risks are introduced when a specific use is desired for a currently/previously marketed device.

RCRI is also sponsoring and exhibiting at the **Medical Alley Annual Conference at Rivercenter, Touchstone Energy Place in St. Paul on November 12**. RCRI will be moderating a panel on “New Treatments in Heart Failure” at 10:30am. We look forward to seeing you at booth 39 on November 12.

For further information on upcoming events, contact RCRI at 952-746-8080 x 250, email: info@rcri-inc.com or visit our website at www.rcri-inc.com.

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Inside MDUFMA

While we are all aware of the major provisions of MDUFMA (establishment of user fees for pre-market reviews, third-party inspections, requirements for reprocessed single-use devices etc.) how many of us have taken a look at Section 301(a) of the act which states that the device manufacturer must be identified on the device itself?

That's right, MDUFMA requires that a device must "*prominently and conspicuously*" bear the name of the manufacturer or a generally recognized abbreviation or a unique label identifying the manufacturer. The FDA may waive the requirement if it is "*not feasible for the device or would compromise the safety or effectiveness of the device.*" This requirement will become effective on April 26, 2004 and, thereafter, a device will be deemed misbranded if it does not bear the manufacturer's name or generally recognized abbreviation or symbol, unless the FDA grants a waiver.

While it would appear that device manufacturers should begin implementing this requirement into their device design plans for new products or modifications to existing products **NOW** in order to meet the April, 2004 deadline, the recently issued draft guidance titled "*Compliance under Section 301 of MDUFMA 2002—Identification of Manufacturer of Medical Devices*" states that when exercising enforcement discretion, the agency intends not to raise objections if a manufacturer has not implemented the changes required under Section 301 for a period of 18 months after the agency issues the final guidance. One might ask why not set the date at October 26, 2005 right at the beginning?

Another section of MDUFMA required the FDA to establish an office of combination products which is required to have appropriate scientific and medical expertise and is responsible for:

- Promptly assigning each combination product to the agency center with primary jurisdiction (based on the product's primary mode of action).
- Overseeing the regulation of combination products to ensure timely and effective pre-market reviews, and coordinating reviews by more than one center.
- Ensuring the consistency and appropriateness of post-market regulation of like products.
- Resolving any disputes regarding the timeliness of reviews of combination products (unless they are clearly premature) and making recommendations to the commissioner with regard to the resolution of substantive disputes that arise during the review process. Such disputes must first be considered by the center with primary jurisdiction, using its scientific dispute resolution procedures.
- Reviewing each agency agreement, guidance, or practice regarding the assignment of combination products to agency centers to determine whether each is consistent with the new law. These may be modified, revised, or eliminated as necessary (but FDA may follow these agreements, guidance documents, and practices in the meantime).

MDUFMA contains some very significant dates. Are you ready?

While this may improve FDA's handling of combination products, there are some areas of concern, especially in the definitions of the terms drug, device, and biological product where there is substantial overlap. Because a product that meets the definition of a device may also meet the definition of a drug, it gives the FDA very broad discretion over whether to regulate a product as a drug or a device. To add to the confusion, products that meet the definition of a biologic also meet the definition of a drug, and in some cases (such as tissues intended to perform a mechanical function in the body) may also meet the definition of a device.

Further confusion arises when determining the "primary mode of action" of a combination product. Frequently, a combination product has two modes of action, neither of which can be said to be dominant or "primary." Nonetheless, the FDA is required to designate one mode of action as primary allowing FDA extremely broad discretion in this regard. Hopefully, clarification will be forthcoming...sooner rather than later.

MDUFMA also contains a number of significant dates which are rapidly approaching:

October 1, 2003—New fee structure for FY 2004 applications becomes effective (see chart on following page).

January 26, 2004—Requirement for labeling of reprocessed single-use devices becomes effective.

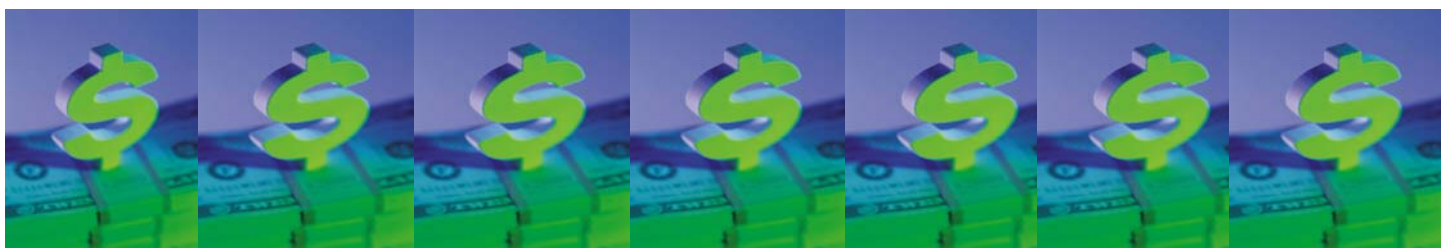
April 26, 2004—Requirement for a device to conspicuously bear the name of its manufacturer becomes effective.

For further information or help with these issues, contact Jennifer Marrone at 952-746-8080 x 223 or email info@rcrri-inc.com.

Device User Fees for FY 2004

The FDA recently announced the medical device user fee rates for the coming fiscal year commencing October 1, 2003. In FY 2004, the two tier fee rate for 510(k)s goes into effect for the first time and FDA anticipates that about 80% of 510(k) submissions will qualify for the small business rate (\$2784) as opposed to the full rate (\$3480). Companies with revenues equal to or less than \$30 million qualify for the reduced rate. The full rates are:

	FY 2003 Fee Rates		FY 2004 Fee Rates	
	Full	Small Business (<\$30M revenue)	Full	Small Business (<\$30M revenue)
PMA	\$154,000	\$58,520	\$206,811	\$78,588
180 Day Supplement	\$33,110	\$12,582	\$44,464	\$16,896
Real Time Supplement	\$11,088	\$4,213	\$14,890	\$5,658
510(k)	\$2,187	\$2,187	\$3,480	\$2,784



Small Business Qualification Guidelines

Firms with annual gross sales and revenues of \$30 million or less, including gross sales and revenues of all affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA, and for lower rates for subsequent PMAs, pre-market reports, supplements, and pre-market notification submissions.

Even if a firm qualified under MDUFMA as a small business in FY 2003, it must obtain a new small business certification and decision number for FY 2004 and for each subsequent fiscal year. This can be initiated any time after the publication of this notice. For FY 2004, firms that have not received a FY 2004 small business qualification decision number from the FDA will not be permitted to submit the reduced small business fees. The FDA urges firms to apply for this qualification 60 days before they intend to submit their application and fee.

To qualify, you are required to submit the following:

- Certified copies of your Federal Income Tax Return for the most recent taxable year (2002 or later), including certified copies of the income tax returns of your affiliates, partners, and parent firms.
- A certified list of all parents, partners, and affiliate firms since October 1, 2002.

You can find information for determining if an applicant qualifies for a small business first-time PMA waiver and lower rates for subsequent applications on the FDA Web site at <http://www.fda.gov/oc/mdufma>.

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More than a CRO

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Be sure to visit RCRI at:

RAPS 2003 Baltimore

Oct 20-22

Booth 415

Medical Alley Conference

Nov 12 St. Paul

Booth 39

Contact Information

Your comments, questions and general feedback are very important to us. Please address comments to us at the above location or send email to info@rcri-inc.com.

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