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FOR IMMEDIATE PRESS RELEASE

2008 eCTD Guidance Webcast

“Webcast to feature updated FDA regulations and ICH eCTD Submissions guidance”

Raleigh, N.C. November 6, 2007 — Today, TAKE Solutions announced another exciting event in their 2007 webcast series, “Preparing eCTD Submissions”. This webcast will be conducted on November 28th at 2:00 pm EST for the US & Canada and November 29th at 10:00 am CET for Europe.

“Beginning January 1, 2008 CDER will no longer be accepting eNDA’s. This fact has helped the industry to adopt the eCTD standard. We’re conducting this webcast to help companies understand what this new requirement means and how to address it at their specific organization,” stated Jay Johnson, Senior Life Sciences Analyst for TAKE Solutions.

“The move from paper to paperless offers a higher quality, easier to review submission. The major advantage an eCTD submission offers is the ability to manage a submission through its lifecycle process; this was not as seamless a process with the old format,” continued Johnson.

This one-hour webinar will discuss eCTD submissions as well as recent changes within the regulations which will affect companies now and into 2008. At the end of the session each attendee will have the opportunity to download an eCTD checklist.

For more information on the webcast email Contact@TAKESolutions.com.

About PharmaReady™

PharmaReady is a fully integrated web-based Document Management, Training Records Management, Structured Product Labeling and eCTD Publishing Solution Suite. PharmaReady is specifically designed for life science organizations where ease of installation, ease of use, Part 11 compliance, and affordability are the primary business drivers. The PharmaReady solution suite is designed specifically for management of SOPs, work instructions, training records, submission documents and all other documents within business areas regulated by the FDA. PharmaReady is a fully 21 CFR Part 11 compliant solution based on Microsoft Windows technology.

About TAKE Solutions

TAKE Solutions is a leading international technology company with products and services in life sciences backed by strong domain expertise to provide cost-effective regulatory compliant business solutions. With more than 500 current employees, TAKE Solutions Global Life Sciences headquarters are in Princeton, N.J., USA.

TAKE Solutions is assessed at Level 5 of the Capability Maturity Model Integration (CMMI), Software Engineering Institute, Carnegie Mellon University, USA. TAKE Solutions is a Microsoft Gold Certified Partner, a Charter Member of the Microsoft BioIT Alliance, and is a Registered CDISC Solution Provider. TAKE Solutions conducts business today in 12 countries with more than 150 FORTUNE 1000 customers.

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