



**FOR IMMEDIATE RELEASE**

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**New eCTD Submission Created Using  
PharmaReady 4.0 Passes FDA Validation**

*Southeast Asia company, Dabur Ltd, receives the FDA seal of approval*

**Raleigh, N.C., October 30, 2007** – TAKE Solutions, today announced a recent drug master file (DMF) submission created with the company’s PharmaReady product V4.0 passed the U.S. Food and Drug Administration (FDA) Validation. The DMF was submitted by Dabur Ltd., one of the leading Bio Pharma companies based out of Southeast Asia.

“Companies in the life sciences arena must demonstrate that they have a stable process in place to submit electronically,” stated Suren Dheenadayalan, Director of Regulatory Operations for TAKE Solutions. “The PharmaReady product has proven itself time and time again as a reliable, regulatory compliant software solution.”

TAKE Solutions is a global company helping biological and pharmaceutical companies across the globe do electronic submissions to regulated markets. The PharmaReady Submissions Management Solution is designed specifically for management of standard operation procedures (SOPs), work instructions, training records, submission documents and all other documents within business areas regulated by the FDA. PharmaReady is a web-based regulatory compliant information management solution based on Microsoft Windows technology.

“We are very satisfied with the software solution PharmaReady offered for our ongoing eSubmission program,” said Prafulla Nandi, Joint Director of Regulatory Affairs for Dabur. “In fact, TAKE Solutions is excellent in providing the post-sales service too. PharmaReady lays the groundwork for the journey towards the paperless regulatory submission.”

**About Dabur India Limited**

Dabur Ltd. is the fourth largest fast moving consumer goods company in India with interests in health care, personal care and food products that are marketed in more than 50 countries. Building on a legacy of quality and experience for more than 100 years, Dabur

has annual revenues of 22.3 billion Indian rupees (\$569 million U.S. dollars) from sales of powerful brands like Dabur Amla, Dabur Chyawanprash, Vatika, Hajmola and Real.

### **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.

[www.PharmaReady.com](http://www.PharmaReady.com)

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