FDA Honors HL7/PhRMA SPL Working Group with Commissioner’s Special Citation Award

ANN ARBOR, Mich.—May 31, 2005— The Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (HHS), has recently presented the Health Level Seven (HL7) and Pharmaceutical Research and Manufacturers of America (PhRMA) Structured Product Labeling (SPL) Working Group with the Commissioner’s Special Citation Award.

The SPL Working Group is a project team of the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee, whose mission is to develop standards to improve or enhance information management during research and regulatory evaluation of the safety and efficacy of therapeutic products or procedures worldwide.

Kristofer Spahr, associate director of regulatory and labeling applications at Wyeth Pharmaceuticals and chairperson of the SPL Working Group, accepted the award on behalf of the team on Friday, May 6, 2005 at the FDA Honor Awards Ceremony in Gaithersburg, Maryland.

“Everyone who has contributed to this effort is as proud as I am of this special recognition,” said Spahr. “To receive an award representing the Commissioner’s personal recognition of our efforts further emphasizes the importance of this honor.”

The effort for Structured Product Labeling (SPL), Release 1, which received approval by the American National Standards Institute (ANSI) in August 2004, was initiated in mid 2002 when the U.S. Food and Drug Administration (FDA) approached HL7 with an idea to develop a standard for drug product labeling based on another HL7 document standard — the Clinical Document Architecture (CDA). The FDA needed the standard to facilitate review of labeling and support the DailyMed initiative, which involves provision of up-to-date drug product labeling through a National Library of Medicine (NLM) database. The project was undertaken by HL7’s RCRIM Technical Committee.

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PhRMA has identified HL7, and in particular the RCRIM Technical Committee, as an organization developing standards of interest to the industry. In order to support and encourage the RCRIM efforts, PhRMA has encouraged its membership to participate directly in HL7. As a result, several PhRMA member companies have joined HL7 at various levels and have also provided volunteers to work on RCRIM projects, including SPL.

The SPL Working Group has a current membership of 94 individuals and is comprised of four teams: Leadership, Technical (standard development and enhancement), Process, and Testing. The group includes more than 30 Pharmaceutical firms of varying sizes, strong FDA representation, and more than a dozen commercial software vendors. It is currently focused on addressing SPL, Release 2 implementation issues and in collaboratively executing a testing phase with the FDA. SPL, Release 2 has passed HL7 committee-level balloting and is now in its reconciliation stage at the membership level. It will be submitted to ANSI for approval between now and the next HL7 working group meeting in September 2005.

The HL7 SPL Working Group is not the first RCRIM team to have been honored by the FDA Commissioner. In October, 2003 the RCRIM Annotated ECG Specification Team received the Food and Drug Administration’s Commissioner’s Special Citation Award “for development of a format for regulatory submission of annotated electrocardiographic waveform data to meet FDA’s needs in assessing the pro-arrhythmic potential of drugs.”

About PhRMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested an estimated $38.8 billion in 2004 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures.

About HL7

Founded in 1987, Health Level Seven, Inc. (http://www.HL7.org/) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7’s more than 2,000 members represent approximately 500 corporate members, including 90 percent of the largest information systems vendors serving healthcare. Recently, HL7 joined 12 other healthcare stakeholders in a collaborative response to the Request for Information (RFI) issued by the Office of the National Coordinator for Health Information Technology (ONCHIT) to learn how widespread interoperability of health information technologies and health information exchange could be achieved through a National Health (more)

HL7’s endeavors are sponsored, in part, by the support of its benefactors: Capgemini; Centers for Disease Control and Prevention (CDC); Documentum; Eclipsys Corporation; Eli Lilly & Company; the Food and Drug Administration; GE Medical Systems; Guidant Corporation; IBM; IDX Systems Corporation; InterSystems Corporation; Kaiser Permanente; McKesson Provider Technologies; Microsoft Corporation; Misys Healthcare Systems; NHS Connecting for Health; NICTIZ National ICT Institute for Healthcare in The Netherlands; Oracle Corporation; Partners HealthCare System, Inc.; Pfizer, Inc.; Philips Medical Systems; Quest Diagnostics Inc.; Science Applications International Corporation; Siemens Medical Solutions Health Services; the U.S. Department of Defense; Military Health System; the U.S. Department of Veterans Affairs; and Wyeth Pharmaceuticals.

International affiliates have also been established in 27 countries throughout the globe including Argentina, Australia, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, India, Ireland, Italy, Japan, Korea, Lithuania, Mexico, The Netherlands, New Zealand, Poland, Spain, Switzerland, Taiwan, Turkey and the United Kingdom.

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