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November 9, 2006

Andrew C. von Eschenbach, MD  
Acting Commissioner  
U.S. Food and Drug Administration  
Office of the Commissioner  
Parklawn Building  
5600 Fishers Lane, Rockville MD 20856

Dear Commissioner von Eschenbach:

On behalf of the Healthcare Information and Management Systems Society (HIMSS) and our 20,000 individual and 300 corporate members, we are pleased to provide comment on the Food and Drug Administration (FDA) Unique Device Identification (UDI) Request for Comments [FDA Docket Number 2006N-292]. As the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information and management systems for the betterment of healthcare, HIMSS is uniquely qualified to provide comment. Collectively HIMSS members' expertise covers a broad number of healthcare industry areas; however, for the purpose of the response we have confined our comments to device identification

The HIMSS Auto-ID and Bar Coding Task Force and the Supply Chain Management SIG collaborated with several of their colleagues to carefully review the FDA's Call for Comments on UDIs. HIMSS members are supportive of a uniformed UDI system for medical devices, as UDIs can advance healthcare delivery in several areas, including improving patient safety, materials management, and medical device tracking. The attached document provides specific comments in the areas of Barriers and Suggestions, Implementing UDIs, and Costs/Benefits, as well as perspectives on the implications of potential legislative action associated with either mandatory or voluntary adoption of regulations for use of UDIs in the healthcare industry.

Through our members, HIMSS seeks to shape healthcare public policy and industry practices through our educational, professional development, and advocacy initiatives. We look forward to continuing the necessary dialogue with the FDA and other federal agencies as we work to achieve a successful rollout of device identification and Auto-ID technology for care delivery safety. We would welcome the opportunity to meet with FDA personnel and other interested parties to provide clarification and additional input on the attached comments.

Sincerely,

H. Stephen Lieber, CAE  
President and CEO  
HIMSS

George T. Hickman, CPHIMS, FHIMSS  
Sr. Vice President and Chief Information Officer  
Albany Medical Center

cc:

Michael O. Leavitt, Secretary, U.S. Department of Health & Human Services  
Robert Kolodner, MD, Interim U.S. National Coordinator for Health IT