



June 6, 2005

Margaret R. Reagan
Corporate Vice President, Advocacy
Premier, Inc.
444 North Capitol Street, N.W.
Suite 625
Washington, D.C. 20001

Dear Ms. Reagan:

Thank you for your letter of May 9, regarding medical devices and bar coding. Your letter asked the Food and Drug Administration (FDA) to reexamine the possibility of requiring bar codes on medical devices as the next step towards promoting patient safety, improving quality of care, and encouraging cost-effectiveness and supply chain efficiency for medical devices.

On April 14-15, FDA, in conjunction with the Food and Drug Law Institute, held a meeting to discuss the issue of unique identification of medical devices. Participants included the medical device industry, research and trade associations, FDA, and other federal agencies. One topic of discussion was the potential for developing a public-private partnership with the goal of promulgating a voluntary program for a unique identification system for devices.

It was evident from the meeting that the widespread use of a system of unique identification for devices, integrated with a database that aggregates information about devices supplied by manufacturers, has the potential for improving the cost-effectiveness of health care and greatly facilitating collecting public health, patient safety, and research data.

We look forward to working with federal agencies, industry, public health organizations, health professionals, and standard setting organizations to explore the feasibility and value of promoting standards for a unique identification system for devices. The agency would like to discuss such issues more detail with the hospital community. We are particularly interested in getting data that relates unique identification of devices to improvements in patient safety and the quality, timeliness, and effectiveness of care.

Thank you again for sharing your views. A similar letter is being sent to the other cosigners.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs