MEMORANDUM OF MEETING

between the Food and Drug Administration and the Healthcare Distribution Management Association, Consumer Healthcare Products Association, Generic Pharmaceutical Association, the Auto-ID Center, Massachusetts Institute of Technology, and Others

September 17, 2002
Parklawn Building
Rockville, Maryland

Attendees:

HDMA
Michael Gallo, Associate Director, Distribution Logistics

CHPA
William Solar, Senior Vice-President and Director of Science & Technology
David C. Spangler, Vice-President, International and Assistant General Counsel

Generic Pharmaceutical Association
Steven Bende. Vice-President, Science, Professional & Regulatory Affairs

Teva Pharmaceuticals
Vincent Andolina, Director, Generic Regulatory Affairs

McKesson Pharmaceuticals
Ron Bone, Senior Vice-President, Distribution Support

Bayer Consumer Care
Jean S. Mazet, Manager, Regulatory Affairs

Proctor & Gamble
Christine Moorman, Senior Scientist, Regulatory Affairs Manager

Barr Laboratories
Sal Peritore, Associate Director, Regulatory Affairs

FDA
Margaret M. Dotzel, Associate Commissioner for Policy
Thomas McGinnis, Office of Policy, Planning, and Legislation
Philip L. Chao, Office of Policy, Planning, and Legislation
Steven Tucker, Office of Policy, Planning, and Legislation
Mary Gross, Center for Drug Evaluation and Research
Jerry Phillips, Center for Drug Evaluation and Research

FDA began the meeting by explaining that its goal and that of Secretary Thompson was to increase patient safety through a bar code system.

The focus of the meeting was to share views related to the state of identification technologies. HDMA and others encouraged FDA to consider both current and future technologies when developing a rule on medication errors. They stated that such consideration would maintain maximum flexibility for the industry and allow for innovative solutions to healthcare supply chain concerns, such as patient safety, product labeling, diversion, recalls and detection of counterfeit drugs. The use of bar codes is one method of reducing medication errors, but product identification system architecture, including databases, software and hardware, could provide many opportunities to leverage even greater information and benefit from an investment in auto-id technology. Thus, the group stressed an approach to regulation in which the FDA would mandate a desired outcome for patient safety and would give industry the flexibility to develop innovative solutions.

The CHPA representative mentioned that the OTC drug industry has estimated that fewer than 10 percent of its products are commonly used in hospitals and that it uses mainly UPC bar codes on its drug products.

The group stated that its ultimate goal is to increase patient safety and alleviate the mistakes that are occurring and they believe this can best be accomplished through the flexible application of innovative technology.

The Auto-ID Center and the Electronic Product Code was introduced by the HDMA representatives, and a request was made for a follow-up meeting to introduce this concept in greater detail.