



February 24, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

**RE: Anti-Counterfeit Drug Initiative Workshop and Vendor Display; 71 Fed. Reg. 1759;
January 11, 2006 [Docket No. 2005N-0510]**

Dear Docket Officer:

Thank you for the opportunity to provide testimony on behalf of the Healthcare Distribution Management Association (HDMA) earlier this month and to provide additional perspectives on the Food and Drug Administration's (FDA) Anti-Counterfeit Drug Initiative. Our detailed comments, contained in the attachments to this letter, are intended to help demonstrate our industry's strong commitment to the continued safety, security and efficiency of the U.S. healthcare supply chain.

HDMA represents the nation's primary, full-service healthcare distributors. Our 42 members are national and regional companies, as well as publicly traded companies and family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 142,000 pharmacies, hospitals, nursing homes and clinics across the United States. HDMA members serve as the central link in a sophisticated supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient health. We take this mission very seriously, and we support manufacturers, pharmacies and the government in the ongoing efforts to ensure the U.S. system remains secure, efficient and highly regulated.

Below is a synopsis of the central points that HDMA feels are most important when evaluating the status of Radiofrequency Identification (RFID) and the Prescription Drug Marketing Act (PDMA) Final Rule:

- Patient safety is of paramount importance to HDMA and our distributor members. We believe that Electronic Product Codes coupled with Radiofrequency Identification (EPC/RFID) hold the most promise for improving the security of the healthcare supply chain. In order to become a reality, mass serialization at the item-level is required.
- HDMA supports implementation of the Final Prescription Drug Marketing Act (PDMA) Rule, in tandem with necessary improvements that reflect the 2006 marketplace. In Attachment 1, we describe specific elements of the Final Rule that we believe FDA should address.
- Today's distribution system consists of legitimate distributors maintaining one primary supply channel with a variety of routes by which prescription drugs may reach the dispenser or administrator on behalf of the patient. HDMA urges FDA to recognize this supply system, which is based on the requirements of manufacturers, dispensers, and ultimately, patients.

- Counterfeit drug prevention is less effective within the current framework of a patchwork of highly variable state requirements. Further, efforts to research and implement EPC/RFID are being slowed due to the diversion of resources to address the varying and often contradictory state legislative or regulatory requirements. A single uniform federal standard the licensure of prescription drug distributors and a national pedigree standard are both urgently needed.
- In the fight against counterfeit drugs, strengthening requirements for wholesale distributor licensure will provide one of the most immediate and effective methods of preventing the entry of counterfeit drugs into the marketplace. HDMA offers suggestions for these improvements and we urge FDA to issue them concurrently with those that address the final PDMA rule as a priority anti-counterfeit effort.

I would like to close by commending FDA for its leadership in addressing this important matter. With the continued commitment of the FDA, state governmental officials, all members of the supply chain, and the public, the threat of counterfeit drugs can be significantly diminished.

If you have any questions concerning these comments or if HDMA can provide further information that may be helpful, please do not hesitate to contact Scott Melville, Senior Vice President of Government Affairs at Melville@hdmanet.org, 703-885-0233, or Anita Ducca, Senior Director, Regulatory Affairs and Healthcare Policy at aducca@hdmanet.org, 703-885-0240.

Sincerely,



Scott M. Melville
Senior Vice President, Government Affairs

Attachments

1. Comments of the Healthcare Distribution Management Association (HDMA) on the Anti-Counterfeit Drug Initiative.
2. *HDMA Commitment to Patient Safety Through Supply Chain Integrity – A strong Record of Efforts for Healthcare System Security & Efficiency*
3. State Wholesale Distributor Licensing Legislation Enacted (2003 - 2005)
4. HDMA Response to Key FDA Questions Regarding EPC/RFID

cc: Randall Lutter, Ph.D.
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