February 24, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2005N-0510 - Anti-Counterfeit Drug Initiative Workshop and Vendor Display

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) respectfully submits the following comments regarding Docket No. 2005N-0510 - Anti-Counterfeit Drug Initiative Workshop and Vendor Display on the use of electronic track and trace technology to combat counterfeit drugs.

The stated purpose of the workshop was to: to identify incentives for widespread adoption of radio-frequency identification (RFID), as well as obstacles to the adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles; to solicit comment on the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of an electronic pedigree (e-pedigree); and to learn the state of technology development related to electronic track and trace and e-pedigree technology solutions. NCPA's comments will focus on the implementation of PDMA and electronic track and trace technology at the community pharmacy level.

The NCPA represents the pharmacist owners, managers, and employees of nearly 25,000 independent community pharmacies across the United States. Independent pharmacists, more than 60,000 nationwide, dispense nearly half of the nation's retail prescription drugs. Despite this volume, pharmacy profit margins are extremely low and subject to further tightening under Medicare Part D. This constrained environment requires careful consideration of any additional financial or staffing burden on the community pharmacist. And while ePedigree and electronic track and trace technology has the potential to increase patient safety and security while maintaining the integrity of the drug supply chain in the US, it also carries significant cost and personnel burdens many community pharmacists will not be able to bear. For this reason and those that follow, NCPA respectfully requests that FDA extend the PDMA stay indefinitely.

NCPA supports select national, uniform licensing standards for all wholesale distributors including secondary wholesalers. We urge the FDA to recognize the importance of legitimate secondary wholesalers as an integral part of our national supply chain and to weigh the impact of any proposed action on their ability to operate. Such wholesalers are particularly important for community pharmacists to obtain unusual products and to ensure marketplace competition.

Finally, as healthcare providers, we are committed to maintaining patient privacy. Prior to implementation we urge the FDA to put measures in place to ensure HIPAA standards will remain intact. For example, we recommend the option of deactivating the RFID devices prior to arrival at the retailer to ensure no patient is inadvertently sent home with an active device. We also recommend that extensive consumer education be developed around this technology before it is widely implemented.

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If the stay is lifted then we recommend the following with regard to the Pedigree and RFID track and trace technology:

- Phase-in implementation starting with the most highly diverted prescription medications or a select list of drugs designated by FDA
- FDA mandate universal ePedigree elements and software; the high cost and low value of a paper Pedigree makes it too unwieldy for consideration as an interim measure
- FDA mandate universal standards for track and trace equipment, frequency, and software; retail pharmacists cannot afford multiple types of equipment and training for each manufacturer's product
- The NDC number plays an integral role in the dispensing process and therefore must be part of the EPC code for patient safety and supply chain logistics
- FDA mandate and industry provide a central database linked to the EPC code; pharmacists do not have time or staff to check each company's database to match an EPC code to an NDC on each individual product or to check the product's transaction history in multiple databases
- Pedigree must originate from the manufacturer and be authenticated further up the supply chain (not at the retail level)
- 2D barcode technology at the retail level should remain an acceptable backup to RFID

NCPA would like to thank the FDA for the opportunity to submit these comments on behalf of the community pharmacists. We support FDA's efforts in combating counterfeit drugs and appreciate the FDA's continued support of our members and consideration of their concerns regarding implementation of PDMA and the use of track and trace technology.

Sincerely,

Bruce T. Roberts
Executive Vice President and CEO
National Community Pharmacists Association