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February 24, 2006

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

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

Dear Sir or Madam:

The Food Marketing Institute (FMI) commends the Food and Drug Administration (FDA) on the Agency's work and outreach with respect to implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and respectfully submits the following comments in response to the Federal Register notice as well as the discussion at the recent public workshop that was held on the use of electronic track and trace technology to combat counterfeit drugs. 71 Fed. Reg. 1759 (Jan. 11, 2006). Our comments address the implementation challenges created by the PDMA as well as the solutions that are achievable through the use of electronic track and trace technology to combat counterfeit drugs. In addition, we are providing some suggestions regarding the application of the "authorized distributor of record" standard.

By way of background, FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI members operate approximately 26,000 retail food stores with combined annual sales of $340 billion, which represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-state chains, regional companies and independent grocery stores.

FMI members also operate close to 15,000 in-store pharmacies, which account for nearly 20 percent of all outpatient prescription drugs dispensed in America. As a result of the growing importance of pharmacy in the supermarket industry, FMI was actively involved as the PDMA legislation was being considered and debated by Congress and remains committed to participating in the resulting FDA rulemakings undertaken to implement the statute.

A. Implementation of Pedigree Requirement Should Be Delayed until Electronic Pedigree Can Be Realized

On the specific issue of implementing the PDMA pedigree requirements, we strongly urge FDA to extend the stay of the effective date until a uniform, track and trace electronic solution can be developed. Development of the interim paper pedigree system that would be necessitated by a failure to stay the regulations would be costly without adding any significant benefit since paper pedigrees are easily counterfeited. Accordingly, to divert resources to develop an ineffective paper-based system that will soon become obsolete would be a wasteful exercise that would further delay development and implementation of a meaningful electronic pedigree system.

Therefore, we urge FDA to hold the regulations requiring paper pedigrees in abeyance and instead work with all segments of the pharmaceutical industry – manufacturers, wholesalers and community pharmacies – toward the adoption of a single universal standard for electronic pedigrees, such as the one that is currently under development by the EPCglobal Alliance. This type of track and trace technology will be far superior to paper pedigrees in terms of improving supply chain security and fighting the threat of counterfeit drugs entering the drug distribution system.

Once electronic pedigrees become more widely available, FDA should work toward the orderly phase-in of a system, initially applying the requirements only to those prescription drugs that are most susceptible to counterfeiting. The application of an electronic pedigree to other classes of drugs should only be done when warranted in order to protect consumers from the threat of counterfeiting or for national emergency situations. Pedigrees should not be imposed on generic drugs since no economic incentives exist for counterfeiting generic drugs, unlike brand-name medications, such as Viagra and Lipitor.

Significantly, the electronic pedigree system that is implemented at the federal level by FDA must pre-empt all conflicting state pedigree requirements. While we believe that the Agency's comprehensive action to implement an electronic pedigree system should be construed to constitute implied preemption, an express statement by the Agency in the final rule or accompanying preamble would put all on notice of FDA's intent and interpretation of its regulations.

In the unfortunate event that FDA concludes that paper pedigrees are a necessary interim step, they should not be required for prescription drugs that remain in normal distribution channels, namely from the manufacturer, to authorized distributor of record and then to the ultimate retail dispenser.

B. "Authorized Distributor of Record" Standard Should Be Applied Fairly To Self-Distributing Retailers

The "authorized distributor of record" standard is an important one whose application to self-distributing companies should not be overlooked. Specifically, FDA's final rules should clarify that companies with warehouses that receive prescription drugs from an authorized distributor of record and then self-distribute those pharmaceuticals to the company's retail pharmacies should also be considered authorized distributors of record. Alternatively, FDA could exempt self-distributing warehouses from any pedigree requirements if the facility has obtained product from an authorized distributor of record because the self-distributing warehouse is clearly maintaining an "ongoing relationship" with an authorized distributor of record. By no means, however, should FDA define self-distributing warehouses as secondary wholesalers under the PDMA regulations.

Lastly, FDA should not impose any authenticity or validity requirements for a pedigree on a retail pharmacy. Similarly, retail pharmacies should not be required to affirm each time the product changes ownership as it moves through the supply chain from the manufacturer to the ultimate dispenser. The final rules should, however, expressly require authorized distributors of record to provide retail pharmacies with certification that the products that the distributor of record is handling have been purchased directly from the pharmaceutical manufacturer.

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In closing, FMI appreciates the opportunity to submit comments on this important proceeding relating to PDMA and the use of electronic track and trace technology to combat counterfeit drugs.

Sincerely,

Deborah White
Vice President &
Associate General Counsel,
Regulatory Affairs