

Porzio Pharmaceutical Alert

FDA Lifts Stay on PDMA Pedigree Provisions: Is Your Company Prepared?

Volume II, No. 6 (June 26, 2006)

By: Frank Fazio, Esq., John Patrick Oroho, Esq. and Sarina D. Rivera, Esq.
Managing Editor: Steven P. Benenson, Esq.*

Introduction

On June 9, 2006, the Food and Drug Administration (“FDA”) released the Counterfeit Drug Task Force Report: 2006 Update (the “Report”). This is the FDA’s third report since 2004 and specifically reviews the impending expiration of the stay of the pedigree provisions of the Prescription Drug Marketing Act (“PDMA”), in addition to the progress the industry has made with respect to electronic pedigree technology. In the Report, the Task Force recommends that the stay be allowed to expire.

In conjunction with the forthcoming implementation of the PDMA pedigree provisions, the FDA also posted on June 9, 2006, a Draft Compliance Policy Guide (the “Guide”) to clarify the FDA’s enforcement efforts with respect to the pedigree requirements for certain prescription drugs during the next year.

The decision by the FDA to finally implement the pedigree provisions of the PDMA will undoubtedly make it more difficult for counterfeiters to introduce fake products into the supply chain. However, with only six months remaining before the expiration of the stay, manufacturers and wholesalers will have limited time to ensure that their systems comply with the federal requirement in a regulatory landscape that has literally changed overnight.

PDMA Pedigree Requirement

The PDMA, as modified by the 1992 amendments, contains its own provisions requiring each person engaged in the wholesale distribution of prescription drugs to provide a pedigree to the person who receives the drug. A pedigree is typically defined as a document or electronic file

* Frank Fazio and John Patrick Oroho are principals, and Sarina D. Rivera is an associate with the law firm of Porzio, Bromberg & Newman, P.C., with offices in Morristown, New Jersey and New York City. They are members of the firm’s Pharmaceutical Marketing & Sales Compliance and Litigation Department. Steven P. Benenson is a principal of the firm and a member of the Department.

containing information verifying the authenticity of a drug at every link of the distribution chain from manufacture to final sale at a pharmacy or other dispenser.

In 1999, the FDA issued rules to implement the pedigree provisions, but subsequently delayed the effective date.

Most recently, in 2004, the FDA again delayed the effective date until December 1, 2006 to allow the industry time to adopt electronic technology for tracking and tracing drugs through the supply chain. The FDA issued a series of communications and reports noting that such technology should be feasible by 2007.

FDA Counterfeit Drug Task Force Report

The FDA's Counterfeit Drug Task Force Report dated June 8, 2006 is the federal government's latest effort to protect the nation's drug supply against the growing problems of counterfeiting and diversion of drug product. The Report, posted on the FDA's website, addresses new technologies aimed at ensuring the integrity of the drug supply and the FDA's plan to fully implement the pedigree provisions of the PDMA by lifting the stay of the December 1, 2006 effective date.

According to the FDA's Report, based upon fact-finding efforts conducted in February of 2006 regarding the implementation of electronic or e-pedigrees, the majority of commentators advised the FDA to implement the regulations and let the stay expire.

In addition, the Report expressed the concern that based on the progress made by the industry, the 2007 goal for industry-wide adoption of track and trace technology would not be met. However, the Report concluded: "The PDMA was signed into law in 1988. We believe the FDA can no longer justify delaying the implementation of these regulations."

Accordingly, the stay, which will expire on December 1, 2006, will not be continued.

It should be noted that the federal PDMA does not preempt state law. Indeed, the Report acknowledges that many states have already moved forward with their own pedigree requirements "which often contain requirements in addition to those in the PDMA." According to the Report, "We are aware that stakeholders are preparing to meet these states requirements, both electronic (to meet California law) or otherwise. *Consequently, they should be that much closer to meeting the federal PDMA requirements as well.*" (emphasis added).

The Report stresses the Agency's belief that all entities in the drug supply chain should be able to implement e-pedigrees in the near future. The Report, however, also acknowledges that a

hybrid approach using both paper and electronic pedigrees will be required during a “transition period.”

In numerous places, the Report stresses the Agency’s willingness to provide Congress with technical assistance if legislation is considered relating to e-pedigrees or the adoption of a uniform pedigree requirement.

FDA Draft Compliance Policy Guidance

In addition to the Report posted on its website, the FDA also issued a Draft Compliance Policy Guide to clarify for FDA personnel and the regulated industry how the Agency will prioritize its enforcement efforts with respect to pedigree during the next year.

The Guide contains a number of factors that the FDA will consider for enforcement focus. According to the Guide, the FDA intends to take a risk-based approach and give higher priority to enforcement efforts for prescription drugs that fall into the following categories:

1. High Value in the U.S. Market
2. Prior Indicators
3. Reasonable Probability (for newly approved drugs)
4. Other Violations of Law

With respect to the first factor, “High Value in the U.S. Market,” the FDA will consider the following: whether a drug product has a high sales volume or price in the U.S., is a specialty item used for serious life threatening disease, is in high demand, and if there is a shortage of the drug.

The second factor, “Prior Indicators,” focuses on the history of the drug’s use in the U.S., i.e. whether the drug is susceptible to counterfeiting and diversion and whether there is a history of false pedigrees associated with the drug.

The third factor, “Reasonable Probability,” is intended to identify those drugs that may not fall within the other factors due to the lack of significant marketing history, but that may nonetheless be susceptible to diversion based on the first two risk factors.

Finally, the fourth factor, “Other Violations of Law,” addresses the Agency’s commitment to hold accountable wholesale distributors and others who are engaged in the manufacture or distribution of counterfeit drugs, or engaged in the manufacture or distribution of prescription drugs that otherwise violate the Act or other laws.

Conclusion

Although the FDA assures in its report that the implementation of the federal pedigree law will not unduly burden companies already in the process of complying with state pedigree laws, the practical consequence of FDA's pronouncement will be a rush on the part of all affected entities to comply. Many states that have pushed pedigree bills through the legislature have done so primarily because the federal government had so long delayed the implementation of its pedigree law.

Now, companies that had previously been concerned with ensuring that their systems would meet the pedigree requirements of the few states that have effective laws, must consider whether their systems will also meet the requirements of the federal pedigree law applicable to all states.

In addition, many states have already passed pedigree laws that contain provisions that are more stringent than the federal law. Therefore, a company shipping drug product into a state with more stringent laws will have to ensure that it complies with both the federal law and that state's law. With respect to states that have no pedigree laws or that have pedigree bills pending, those states may or may not choose to defer to the federal law and are still free to impose more restrictive requirements.