ALERTS AND UPDATES

FDA Issues Proposed Rule to Withdraw Regulations Related to Prescription Drug Marketing Act Pedigree Requirements

July 20, 2011

On July 14, 2011, the U.S. Food and Drug Administration (FDA) published a proposed rule to withdraw 21 CFR § 203.50(a). The original rule was first proposed on March 14, 1994, as part of the Prescription Drug Marketing Act amendments to the federal Food, Drug, and Cosmetic Act. That proposed rule was finalized in December 1999 and included a pedigree requirement that would require an unauthorized distributor to include all prior sales, purchases or trades of the drug, starting with the manufacturer. Because of industry objections, implementation of the rule was delayed until June 14, 2006, with an effective date of December 1, 2006. On December 8, 2006, the U.S. District Court for the Eastern District of New York preliminarily enjoined implementation of the rule. Subsequently, the U.S. Court of Appeals for the Second Circuit affirmed that order.[1] In essence, the district court and the appellate court accepted the argument that unauthorized distributors of record could not provide pedigree information all the way back to the manufacturer because authorized distributors of record were neither required nor unwilling to provide pedigree information for all transactions between the manufacturer and that particular authorized distributor of record, leaving a potential gap in the pedigree. The FDA is now proposing to withdraw § 203.50(a).

Following the withdrawal, however, unauthorized distributors should continue to comply with the pedigree requirements as set forth in the *RxUSA* injunction. FDA plans to exercise enforcement discretion and require, pursuant to § 503(e)(1)(A) of the Food, Drug, and Cosmetic Act, unauthorized distributors to provide pedigrees that:

- Include information regarding transactions going back to either the manufacturer or the last authorized distributor of record that handled the drugs; and
- Include the date of the transactions and the names and addresses of all the parties to the transaction.

In addition, FDA is encouraging wholesalers to include the drug, dosage, container size, number of containers, and lot or control numbers of the drug in the pedigree.

For Further Information

If you have any questions concerning this *Alert*, please contact Frederick R. Ball, any other member of the Pharmaceutical, Pharmacy and Food industry group or the lawyer in the firm with whom you are regularly in contact.

Note

1. *HHS v. RxUSA Wholesale, Inc.*, 285 Fed. Appx. 809 (2d Cir. N.Y. 2008).