

BACKGROUNDER re: *RxUSA Wholesalers, Inc. v. HHS*

On December 8, 2006, a federal district court in the Eastern District of New York issued a preliminary injunction in *RxUSA WHOLESALERS v. HHS* to prohibit FDA from implementing a regulation that requires that certain information be included in a pedigree, which documents the custody of certain prescription drugs in the drug supply chain. The regulation, (21 CFR § 203.50(a),) which went into effect on December 1, 2006, was issued by FDA to implement the Prescription Drug Marketing Act of 1987 (PDMA), as amended by the Prescription Drug Amendments of 1992 (PDA).

FDA continues to believe that its regulation faithfully interprets the Federal Food, Drug, and Cosmetic Act (specifically, the PDMA and the PDA) and intends to defend both the regulation and the statute as the litigation continues.

The PDMA requires, among other things, that certain wholesalers, commonly called “secondary wholesalers,” provide a statement of origin (also known as a pedigree) prior to each wholesale distribution of prescription drugs. The requirement to pass a pedigree applies to those wholesalers who are *not* authorized distributors of record (ADRs) for the prescription drugs that they distribute.

The pedigree requirements do *not* apply to manufacturers or to ADRs. This means that ADRs are not required to pass a pedigree. The PDMA defines an ADR as a wholesale distributor that has an "ongoing relationship" with a manufacturer. The PDMA does not define "ongoing relationship."

In the preliminary injunction, United States District Judge Joanna Seybert enjoined FDA from implementing 21 CFR § 203.50(a). By enjoining section 203.50(a), the court's order covers two significant issues.

- First, the court's order enjoins FDA from implementing the language in 21 CFR § 203.50(a) that requires a pedigree to identify each prior sale, purchase, or trade of a drug back to the drug's original manufacturer.
- Second, the court's order enjoins FDA from implementing the language in section 203.50(a) that specifies the different type of information, including lot numbers and container sizes that must be included on a pedigree.

The court's order does not erase the fundamental pedigree requirement in the PDMA, however, nor does it mention any of the other provisions in 21 Part 203 (including the definition of "ongoing relationship" in 21 CFR § 203.3(u), which serves to define who qualifies as an authorized distributor). Rather, the injunction affects only the regulation that specifies the type of information that the pedigrees must contain and how far back in the distribution chain drugs must be traced.

Under the court's order, the statute notwithstanding, pedigrees passed by non-ADRs only have to track back to the manufacturer *or* the last authorized distributor that handled the drugs. As specified in the statute, all pedigrees also have to include the dates of the listed transactions and the names and addresses of all parties to those transactions.

FDA is mindful that wholesale distributors operating outside the Eastern District of New York have been following this case and may have questions on whether (or how) the court's preliminary injunction could affect them. FDA believes that limiting application of the injunction to either the named plaintiffs or the Eastern District of New York could lead to confusion and possible disruptions or delays in the nation's drug distribution system and could provide undue advantage to certain wholesale distributors.

Therefore, FDA intends to exercise enforcement discretion in a manner that is consistent with the court's opinion. To this end, as long as the court's order is in effect, FDA does not intend to initiate any enforcement actions against any wholesalers solely for:

- failing to include lot numbers, dosage, container size, or number of containers on a pedigree; or
- failing to provide a pedigree that goes back to the manufacturer so long as the pedigree otherwise identifies the last authorized distributor of record that handled the drugs.

FDA has posted new information on its website at

http://www.fda.gov/cder/regulatory/PDMA/pdma_addendum.pdf that explains its interpretation of the court's order in more detail and further clarifies its expectations regarding compliance with the PDMA and its implementing regulations. These new materials also explain how the court's order affects both the Q&A Guidance and Compliance Policy Guide that FDA issued in November 2006 and which can be seen at

http://www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf and http://www.fda.gov/cder/regulatory/PDMA/PDMA_CPG.pdf.

On December 4, 1999, FDA published in the *Federal Register* (64 FR 67720) final regulations regarding the PDMA that, among other things, defined an ongoing relationship to include a written agreement between a manufacturer and wholesaler (21 CFR § 203.3(u)) and set out certain requirements related to pedigrees (21 CFR 203.50). With respect to this latter regulation, 21 CFR 203.50(a) delineated the type of information that must be included in a pedigree and specified that a pedigree must identify each prior sale, purchase, or trade of the drug all the way back to the drug's original manufacturer.

Due to concerns raised at the time, FDA delayed the effective date of sections 203.3(u) and 203.50. On June 14, 2006, however, FDA announced in a Notice in the *Federal Register* (71 Fed. Reg. 34429) that it would no longer delay the effective date, and that the two provisions would become effective on December 1, 2006. The reasons for the agency's decision are described in that *Federal Register* Notice and its 2006 update to FDA's Counterfeit Task Force Report.

On September 20, 2006, several wholesale distributors of prescription drugs filed a complaint in federal district court in the Eastern District of New York seeking, among other things, a declaratory judgment that 21 CFR § 203.50 is unconstitutional because it violates due process and equal protection. On November 22, 2006, the wholesalers moved for a preliminary injunction seeking to stay the effective date of section 203.50 until final resolution of the case.