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

UPDATED 10/14/10

On October 8, 2010, United States District Judge Joanna Seybert granted a motion permitting the parties to have through June 30, 2011 to re-open RxUSA Wholesale, Inc. v. HHS. (See RxUSA Wholesale, Inc, v. Department of HHS, 467 F. Supp. 2d 285 (E.D.N.Y. 2006), aff'd, 2008 U.S. App. LEXIS 14661 (2d Cir. 2008)). The case has been administratively closed since January 7, 2009. While the case is administratively closed, the preliminary injunction issued by the District Court on December 8, 2006 and affirmed by the U.S. Court of Appeals for the Second Circuit on July 10, 2008 remains in effect.

The preliminary injunction prohibits the FDA from implementing a regulation that requires that certain information be included in an identifying statement (also known as a pedigree), which documents the chain of custody of certain prescription drugs in the drug supply chain. The FDA issued the regulation to implement provisions of the Prescription Drug Marketing Act of 1987 (PDMA), as amended by the Prescription Drug Amendments of 1992 (PDA). The regulation can be found at 21 CFR § 203.50(a). It became effective on December 1, 2006.

The PDMA requires, among other things, that certain wholesalers, commonly called "secondary wholesalers," provide 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.

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

• First, the district court's order enjoins the 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 district court's order enjoins the FDA from implementing language in section 203.50(a) that specifies the different types of information, including lot numbers and container sizes, that must be included in a pedigree.

The district court's order does not affect the fundamental pedigree requirement in the PDMA, however; nor does it affect 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, non-ADRs may provide pedigrees that include information regarding transactions going back to either the manufacturer or the last authorized

distributor of record that handled the drugs. As specified in the statute, all pedigrees also have to include dates of the listed transactions and names and addresses of all parties to those transactions.

The 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. The FDA believes that limiting application of the injunction to either the named plaintiffs or to distributors in 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.

The FDA intends, therefore, 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, the 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 ADR that handled the drugs.

In December 2006, the FDA posted information on its Web site 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 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 is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM134399.pdf. These materials are not affected by the Second Circuit decision affirming the decision of the district court nor by the current (administratively closed) status of the case.