BACKGROUNDER re: RxUSA Wholesalers, Inc. v. HHS

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On July 10, 2008, the U.S. Court of Appeals for the Second Circuit affirmed the preliminary injunction issued by a federal district court in the Eastern District of New York on December 8, 2006 in RxUSA WHOLESALE 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. July 10, 2008)). The preliminary injunction prohibits 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 regulation, (21 CFR § 203.50(a)), which went into effect on December 1, 2006, was issued by FDA to implement provisions of the Prescription Drug Marketing Act of 1987 (PDMA), as amended by the Prescription Drug Amendments of 1992 (PDA).

FDA currently is reviewing the Second Circuit's opinion.

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 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 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 FDA from implementing the 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 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.

In December 2006, FDA posted 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 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. These materials are not affected by the recent Second Circuit decision affirming the decision of the district court.