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Client Alert

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Without a Trace: FDA Proposes Change to PDMA Requirements

On July 14, 2011, the Food and Drug Administration (FDA) announced its intention to remove a provision of the Prescription Drug Marketing Act (PDMA) regulations that requires certain wholesale drug distributors to provide a pedigree that traces each prescription drug through the chain of distribution.[1] Currently, prior to the completion of any wholesale distribution of a prescription drug, "unauthorized distributors" of prescription drugs must provide a statement showing all previous sales, purchases, or trades of the drug tracing back to the manufacturer.[2] The statement, or pedigree, must include certain information about the drug and each prior sale, purchase or trade. The FDA will accept comments on the proposed rule until September 12, 2011.

The PDMA statutory provision in question, codified at 21 U.S.C. § 353(e)(1)(A), requires that a wholesale distributor who is not the "manufacturer or authorized distributor of record" provide a record of the drug's pedigree through the distribution chain that identifies each prior sale, purchase or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction). The FDA's implementing regulations interpret the statute to require that these unauthorized distributors provide the following:

1. proprietary and established name of the drug;
2. drug dosage;
3. container size;
4. number of containers;
5. drug's lot or control numbers;
6. business name and address of all parties to each prior transaction, starting with the manufacturer; and
7. date of each previous transaction.[3]

Unauthorized distributors argued that the information needed to create a pedigree back to the manufacturer could not be obtained because the intermediate authorized distributors, a major source of the purchased drugs, were not required to maintain such pedigree records. In December 2006, a U.S. District Court in New York issued a preliminary injunction stopping the FDA from implementing the regulation.[4] The U.S. Court of Appeals for the Second Circuit

1 76 Fed. Reg. 41,434.
2 21 C.F.R. § 203.50
3 21 C.F.R. § 203.50(a)
4 *RxUSA Wholesale Inc. v. Department of Health and Human Services*, 467 F. Supp.2d 285 (E.D.N.Y. 2006)

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upheld the injunction, allowing the FDA to require only pedigrees that trace back to *either* the manufacturer or the last authorized distributor of record.[5] Additionally, the ruling limited the additional pedigree information the FDA can require to "the date of the transaction and the names and addresses of all parties to the transaction," as specifically stated in the statute.

The FDA has exercised enforcement discretion, consistent with the court's opinion, since 2008. The FDA now proposes to remove § 203.50(a), leaving only the statutory pedigree requirement. Under the FDA's proposal, unauthorized distributors must provide a pedigree with information for transactions tracing back to *either* the manufacturer or the last authorized distributor of record, and the pedigree must include the listed transaction date and names and addresses of all parties to the transactions. The proposed rule notes that, while the proposal is pending, the agency will not initiate enforcement action if a pedigree satisfies the statutory requirements.

In conclusion, unauthorized distributors must ensure their pedigrees include the following:

1. information regarding transactions going back to either the manufacturer or the last authorized distributor of record that handled the drugs, consistent with the preliminary injunction order previously referenced; and
2. the date of the transaction and the names and addresses of all parties to the transaction, as required under the statute.

In addition, while the FDA is proposing to remove § 203.50(a) and intends to exercise enforcement discretion as discussed, the FDA encourages wholesale distributors to include the drug, dosage, container size, number of containers and the drug's lot or control numbers in the pedigree as well.

5 285 Fed. Appx. 809 (2d Cir. 2008)