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The deadline for submitting comments is May 19, 2008.

War on Counterfeit Drugs Intensifies:

FDA Soliciting Comments for E-Pedigree Standards and Technologies

The war on counterfeit drugs is about to take a big leap forward, with the track and trace industry coming out as a winner. For years, the Food and Drug Administration ("FDA") has recommended that pharmaceutical companies employ radiofrequency identification ("RFID") or other technology to create an e-pedigree that would effectively fight the rampant drug counterfeiting problem. But due to costs, lack of standards, and other concerns, drug companies have not implemented the FDA's proposal on a widespread basis.

That is about to change. In September 2007, Congress passed the Food and Drug Administration Amendments Act of 2007, P.L. 110-85 ("FDAAA"), which requires the FDA to develop standards and identify and validate effective technologies for developing an e-pedigree that tracks the drugs' history at every point along the supply chain. Specifically, the FDAAA requires the FDA to develop an identification standard to uniquely identify pharmaceuticals at the unit level within 30 months of the act's passage. The FDA is also directed to develop a standard compatible with "promising technologies."

To that end, the FDA is now accepting comments to assist it in guiding the development of standards and technologies to track and trace prescription drugs. The deadline for submitting comments is May 19, 2008.

The FDA has tentatively concluded that RFID is a "promising technology" as a means to achieve e-pedigree, but it is also looking at nanotechnology, encryption, and other technologies, including bar codes. The FDA notes that since it released its Counterfeit Drug Task Force Report on the threat of counterfeit drugs in 2004, it has met with officials of various technology companies and has become somewhat educated on the strengths and weaknesses of various track and trace technologies. But now, in order to fulfill its requirements under the FDAAA, the FDA has determined that it must seek more information in the form of comments from technology vendors and other interested parties.

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The FDA is seeking comments on the following topics:

I. Standards

1. Characteristics of a standard numerical identifier.

2. Standards for validation of prescription drugs.

3. Standards for tracking and tracing of products in the supply chain.

4. Standards for authentication of products in the supply chain.

5. Priorities for the development of standards.

II. Promising Technologies

1. Relevant technologies for e-pedigree.

2. Information regarding these technologies' strengths and limitations for identification, validation, tracking and tracing, and/or authentication of prescription drugs, including:

   (a) costs of implementation and use;

   (b) benefits to the public health;

   (c) feasibility for widespread use; and

   (d) utility for e-pedigree.

3. Is the suggested technology interoperable with other technologies? How so?

4. What standards are necessary for supply chain use of the suggested technology? What is the status of development of such standards?

Implementation of an e-pedigree will exponentially increase the demand for any track and trace technology that is endorsed by FDA. This proceeding offers a unique opportunity for manufacturers and vendors to have their voices heard by the federal government. If you would like more information, or if you are interested in submitting comments, please contact Ronald E. Quirk, Jr. at (202) 344-4677, requirk@venable.com.

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