SOLVAY PHARMACEUTICALS

Solvay Pharmaceuticals, Inc. appreciates the opportunity to respond to Docket No. 2005N-0510, which requests public comment on industry implementation of RFID and on issues related to electronic pedigree. Solvay Pharmaceuticals, Inc. is a research-driven pharmaceutical company that seeks to fulfill carefully selected, unmet medical needs in the therapeutic areas of cardio-metabolic, gastroenterology, influenza vaccines, neuroscience and men's and women's health. Solvay Pharmaceuticals, Inc. is part of the global Solvay Pharmaceuticals organization whose core activities consist of discovering, developing and manufacturing medicines for human use. Solvay Pharmaceuticals is a subsidiary corporation of the worldwide Solvay Group of chemical and pharmaceutical companies headquartered in Brussels, Belgium. Solvay Pharmaceuticals, Inc.'s product portfolio includes nearly one dozen brands comprising 25 packaging configurations (excluding samples) for the U.S.; three of these brands are DEA Class III-scheduled products comprising seven packaging configurations. Solvay Pharmaceuticals, Inc. also co-promotes several additional brands.

Solvay Pharmaceuticals, Inc. (heretofore referred to as "Solvay Pharmaceuticals") is committed to assuring public safety through the distribution of authentic products via a secure pharmaceutical supply chain, as well as to providing its medications to the American public at an affordable cost. The company supports the position set forth by the Pharmaceutical Research and Manufacturers of America (PhRMA) – of which Solvay Pharmaceuticals is a member – in its white paper published on May 12, 2005. In accordance with PhRMA's position paper, Solvay Pharmaceuticals urges prompt implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and supports states' efforts at immediate implementation of paper pedigree requirements. Solvay Pharmaceuticals is actively engaged in fulfilling Florida's upcoming paper pedigree requirement and will do so by providing advanced shipping notices (ASNs) and compliant barcode labeling to wholesalers to support distribution of Solvay Pharmaceuticals' products in the state of Florida. Additionally, Solvay Pharmaceuticals is working to ensure it meets additional state pedigree requirements as they become effective. In the longer term, Solvay Pharmaceuticals supports the development of a standardized electronic pedigree. However, like many of its partners in the pharmaceutical supply chain, Solvay Pharmaceuticals requests that the FDA provide a pedigree standard which all states can readily adopt and with which all members of the supply chain can comply.

In addition to its immediate efforts to address state pedigree requirements, Solvay Pharmaceuticals has engaged an internal team to research RFID and other technology solutions (including linear barcodes and two-dimensional data matrix tags) that could enable serialized identification of its products. In the near term, Solvay Pharmaceuticals will work with external experts to evaluate its business systems and IT infrastructure and draft a roadmap for phased implementation of a "track and trace" capability that will align, ideally, with an emerging electronic pedigree standard. Obstacles to full-scale RFID implementation at Solvay to date have included the following:

- Lack of standardized technology specifications
- Lack of standardized electronic pedigree fields and format
- Lack of agreed-upon business processes and rules for data sharing among supply chain partners
- Lack of a definitive federal guidance that stipulates timing and strategy for phased or blanket implementation
- Concern about impact of radiofrequency energy on stability of Solvay Pharmaceuticals' products
- Concern about radiofrequency interference with Solvay Pharmaceuticals' particular packaging configurations (all of Solvay Pharmaceuticals' products currently contain metal foil, and several are liquid/suspensions)
- Concern about actual and perceived impact of RFID tagging to patient privacy
- Logistical challenge of implementing unified tagging solution across multiple contract packagers
- Concern that downstream supply chain partners are not currently equipped to read tags for verification purposes at the point of dispensing
- Concern about the cost to install and maintain required technology and its impact on the affordability of medications for the American public

Solvay Pharmaceuticals will continue its efforts to prevent counterfeiting of its products within the U.S. pharmaceutical supply chain and looks forward to further direction from the FDA on required timing and strategy for implementation of electronic pedigree and track and trace technologies.

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