

**Division of Dockets Management  
Docket # 2005N-0510**

George Schmitt & Co., Inc., (“George Schmitt”) thanks the FDA for the opportunity to share its comments on the use of electronic track and trace technology to combat counterfeits.

**George Schmitt supports the use of RFID for electronic tracking. Our real life experiences support this technology as a viable technology that is ready now for implementation.**

One of the obstacles to the widespread implementation of an RFID program is the quality and reliability of the RFID inlays themselves and the associated processing and re-work costs. Currently, inlay suppliers are still providing an unacceptable level of non functional or weak inlays on supplied rolls. Although the inlay supplier has attempted to mark defective units in some identifiable fashion, there still remain numerous instances of unmarked or weak inlays which may subsequently fail.

George Schmitt entered the RFID arena with the philosophy that nothing less than 100% readable inlays or labels were acceptable. In 2003, George Schmitt developed a patent pending system for isolating a single tag on a moving web, automatically rejecting bad items, and providing 100% readability for both converted inlays and RFID enabled printed and unprinted labels. This proprietary system has proven equally effective for both HF and UHF inlays.

Although the claim of 100% reliability is easy to make, it is difficult to prove without actual trials of the rolls in real life downstream applications. George Schmitt provides a source of proof that the RFID enabled labels are 100% readable by supplying a sequential listing of all unique identifying numbers of every tag contained within each and every roll shipped.

George Schmitt is the converting partner of a pharmaceutical manufacturer using RFID for electronic pedigree as well as the converter for their security labels. George Schmitt’s labels are used in this highly publicized application where RFID enabled labels are applied to item level containers (bottles) at production speeds and read during this process. In addition, individual containers with RFID labels are successfully read when packed in a 48 unit carton. The customer states that the read rate for George Schmitt RFID enabled labels is better than 99.99%.

This real life scenario and other pilots are successful because George Schmitt has identified and successfully addressed the five significant RFID enabled label concerns allowing guarantee of 100% readable tags/labels with patent pending technologies.

**-Non-readable tags/labels**-George Schmitt has addressed the high rate of defective tags from the manufacturer by developing an online reading system that automatically removes defective tags with parametric testing.

**-Variability in read range-**Labels/tags/inlays are read in real world conditions. Tags not successfully read at specified distances and thresholds are automatically rejected.

**-Erroneous information on tags-**George Schmitt's system reads the EPC code of each label/tag/inlay and automatically verifies a match to the EPC ordered code. Non conforming product is automatically removed.

**-Wrong tag/label combination-**George Schmitt's integrated verification system automatically cross references the EPC code of the RFID tag with the NDC number on the label at real time. Mismatches are automatically rejected and removed from the roll.

**-Duplicate license plates-**George Schmitt's process verifies that no duplicates exist by reading each tag individually and maintaining a database guaranteeing no duplicates. Any duplicates are automatically removed. A sequential roll map of license plates of every tag on every roll is supplied to customers.

## **Barcodes**

In some instances, a stakeholder may choose not to utilize RFID for a variety of reasons: cost, privacy issues, no higher tier requirements, etc. However, some elements of traceability and/or e-pedigree may be desired and the use of 2D barcodes has been a common approach to satisfy this need.

George Schmitt can accommodate requirements for 2D barcodes as a stand alone solution or can incorporate this technology with RFID. Information for the 2D barcode can take a variety of forms, can be encrypted and can be linked to the EPC number in the RFID tag.

## **Company History**

George Schmitt is a privately owned 132 year old vertically integrated graphic arts company headquartered in Guilford, CT with production facilities in Guilford, CT., Branford, CT., Richmond, VA. and Ireland.

George Schmitt is dedicated to meeting the strict requirements and standards of security printing with high quality. George Schmitt maintains the highest security standards allowing delivery of security labels and/or RFID enabled labels to government accounts, pharmaceutical companies, distilled spirits companies, food and beverage companies, consumer goods suppliers, RFID product/systems suppliers, other printers and partners. George Schmitt is a certified converter for most major label/tag manufacturers.

George Schmitt offers overt and covert features, a secure supply chain and project management services.

