From: Joanne Kelleher [mailto:jkelleher@securerf.com]
Sent: Friday, May 09, 2008 11:01 PM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Comment on drug anti-counterfeiting efforts

To: European Commission, Directorate-General for Enterprise and Industry

SecureRF Corporation, a small business headquartered in Westport, CT, USA is submitting comments to the European Commission in preparation of a legal proposal to combat counterfeit medicines for human use.

SecureRF provides secure radio frequency identification (RFID) solutions for high value asset tracking, monitoring and anti-counterfeiting applications in the pharmaceutical, food, defense, homeland security and other sectors. The company's technology, based on a breakthrough in cryptography that is lightweight yet highly secure, provides authentication and data protection security for RFID tags.

*4.1.4. Centrally accessible record to facilitate traceability of batches throughout the distribution chain*
SecureRF agrees that as pharmaceutical items move through the supply chain that ownership and transactions should be tracked via a pedigree process and the record should be accessible by all actors in the distribution chain. This pedigree should be electronic, not paper based. Paper pedigrees are expensive to produce and can be forged and lost. The pharmaceutical industry is investigating ways to create electronic pedigrees for drugs through track and trace technologies.

*4.1.5. Mass serialisation for pack-tracing and authenticity checks on a case-by-case basis*
SecureRF agrees with the requirement to trace each pack and perform authenticity checks via a mass serialisation feature on the outer packaging. We recommend that the technical details be further defined by standardization or pharmaceutical industry organizations, rather then by legislation.

RFID is one technology that should be considered by the pharmaceutical industry to protect the efficacy of the products and patient safety. RFID can assist with supply chain management and inventory control and can help prevent counterfeiting. It can be an enabling technology for an easier, more accurate and error free, use of e-pedigrees. RFID tags can be used to authenticate drugs in the supply chain and automate the Pedigree reporting process by maintaining data and digital signatures. Passive RFID tags are more efficient than bar codes because they can be read automatically as unopened boxes pass by electronic readers in a warehouse.

But if RFID tags are implemented without suitable security, the pharmaceutical industry is introducing a new set of risks. According to Sara Shah, an analyst at ABI Research, "Security is definitely on the

minds of supply chain managers, consumers, and technologists. Security has been something that hasn't been completely lacking, but definitely lacking from the RFID market -- especially the UHF market. It hasn't been a huge issue in the consumer-goods retail supply chain market, but with the pharmaceutical market, security is a much bigger issue. SecureRF and others have identified this." (see New Security-Laden RFID Tag Targets Pharma, RFID Update, November 17, 2006, http://www.rfidupdate.com/articles/index.php?id=1248)

Unsecured RFID systems face security threats that include clandestine scanning, tracking, cloning, and eavesdropping. Using RFID tags without suitable security will simply require the additional step of producing a cloned RFID tag to enable the continued distribution of the counterfeit product. Unprotected tags can be scanned to obtain detailed data on the tagged asset. If the tag contains a unique ID then an unauthorized party can track the movements of the asset even if they did not read the actual descriptive data contained on the tag. Even in the case where a key is used to protect data on a tag, unless the key can be changed the reader/interrogator that receives the key now has access in perpetuity.

RFID security is the prevention of unauthorized reading, changing or cloning of RFID data. RFID data security means protecting the data on the tag and the data transmitted between the tag and reader to ensure it is accurate and safe from unauthorized access. In addition, security includes preventing unauthorized access to the reader from the air interface. SecureRF encourages organizations who are considering implementing an RFID solution to complete a security audit to identify potential risks and then select a RFID system which will meet the confidentiality, integrity, availability, authentication and other security needs of their firm and their constituents.

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Best regards,
- Joanne

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