micro authentication
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®mark INDISPUTABLE

Submitted Via FedEx and Electronic

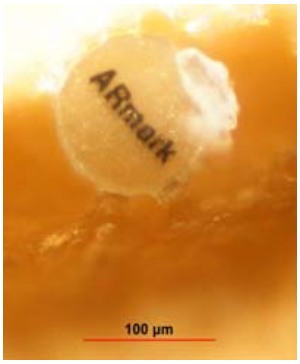
Attention:
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Rm. 1061
Rockville, MD 20852
http://www.Regulations.gov

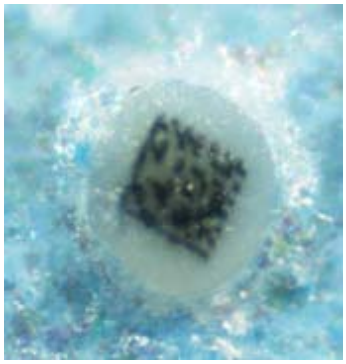
May 16, 2008

RE: Docket No. FDA-2008-N-0121
Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication

ARmark Authentication Technologies, LLC (AAT) would like to provide information on our company and ®Mark™ covert micro-tag technology in response to requested comments and information regarding technologies used for the identification, validation, tracking and tracing, and authentication of prescription drugs.

ARmark Authentication Technologies, LLC (AAT) is a designer and developer of customized covert markers. Typically these markers are approximately 75-100 microns in diameter (human hair diameter is about 120 microns). ®mark™ covert markers can contain large amounts of brand owner specific information in a very small space. It is this information and presence of the marker on the product or packaging that allows the brand owner to authenticate the product. The ability for the brand owner to choose what information they desire and how they choose to integrate the covert solution is unique to (AAT). The covert markers also can contain multiple levels of information such as a visible response, forensic level authenticators, and compositional signature. There is no other covert solution on the market today that can offer the flexibility of composition, the ease of integration into the product and simple detection that the ®mark™ brand covert marker solution offers.

1. 

2. 

Sample ®mark™ covert markers:

1. *"ARmark" text particle applied to the surface of a yellow pharmaceutical tablet*
2. *"2-D barcode" 160 micron particle applied to the surface of a blue pharmaceutical tablet*

The information contained in the covert marker is specific to a brand owner or issuing authority and therefore serves as a hidden "fingerprint". The "fingerprint" is easily and quickly revealed using ®vision™ detection systems. ®vision™ detection tools are handheld and field capable digital microscopes that are used by brand owners and field investigators to inspect products and/or packaging for the presence of the covert marker. ®mark™ covert markers used in conjunction with ®vision™ detection tools empower brand owners to identify sources of fake goods, identify sources of diverted goods, prosecute counterfeiters and most importantly protect the public.

AAT, would like to submit the following comments to the specific questions asked by FDA under Docket No. FDA-2008-N-0121:

1. What are the RFID technologies, encrypting technologies and nanotechnologies that are relevant? What are other relevant technologies?

Upon initial review, a fully deployed "whole product" RFID system looks appealing for disrupting the illicit intrusion of counterfeit pharmaceuticals into the US supply chain. However, due to a variety of barriers to adoption related to coordination and collaboration amongst trading partners and data sharing a fully deployed track and trace systems is probably a number of years away. At best, once fully deployed, this approach would permit for a rapid understanding of the flow of packaging through the supply chain. In many cases, the package with the RFID tag does not make it all the way to the patient due to repackaging that can happen at many different places and for different reasons.

Protecting the dosage itself, which is ingested by the patient, should be a critical concern in the hierarchy of counterfeit-resistant technologies. Protection must start with the identification and authentication of the dosage because the distribution process for drugs involves repackaging, which is a vulnerable point for counterfeit product introduction, where the dosage becomes separated from the "protected package". Dilution of authentic products with counterfeit products often occurs during repackaging. Counterfeit-resistant technologies for "protecting the package and supply chain" will be far more effective when the dosage itself is also protected with on-dosage identification and authentication technology.

On-dosage identification and authentication technologies can help mitigate the security concern of repackaging and "counterfeit salting". On-dosage technology can ensure that the dosage itself is identifiable, protected and authenticated.

®Mark™ covert marker technology is commercially viable today, and ensures pharmaceutical product authenticity at the dosage level. This taggant technology provides quick, confident, and economical identification and authentication of pharmaceutical solid dosages in the field.

®Mark™ covert micro-tags are applied to solid dosage forms as well as to packaging(bottles, blisters, printed labels), and package inserts to provide an "inside-out" approach. This technology employs FDA approvable excipients on the surface of a pill, usually applied in a film coating on the surface of tablets or incorporated into the shell of capsules. The micro-tag, comprised of the FDA approvable excipients, embodies unique indicia (customized to the requirements of the pharmaceutical manufacturer to include any desired information (such as encrypted codes, NDC code, manufacturing site, export/import information, channel of distribution, manufacturer logo,

etc.) that can be readily identified through optical magnification. ®Mark™ micro-tag technology is anticipated to be interoperable with Track and Trace ePedigree systems. The micro-tag indicia can include a 2D barcode for electronic scan-ability of the individual pills. Encrypted codes can be incorporated into the indicia. The indicia on the pill can be linked to package serialization, bar codes, RFID codes or similar micro-taggant indicia included on drug packaging. This linkage establishes the parent-child relationship between the pill and the package.

Self Authenticating System Comments

The "on-dosage" taggant technologies discussed above can also be applied "on package" or linked to the package, for example via bar coded information. In this way, the information contained in the on-package taggant or bar code must "match" the information contained in the on-dosage taggant. In its simplest form, a match provides a "self-authentication" of the solid dosage without the need for a sophisticated database for track and trace. A mismatch or pills with no microtag indicia indicates a counterfeit replication of the drug. If, for example, an on-dosage microtag contains a bar code that carries the same information as a bar code on the package, then the dosage is authenticated. Encryption of the information can further secure this self authentication process. This information can be electronically linked with RFID, thereby completing the ePedigree track and trace objectives from the manufacturer to the patient at all levels of distribution right down to the point of dispensing of the drug. With an electronically scannable pill, the benefits can extend beyond anti-counterfeiting authentication to include patient safety aspects of reduced medication error in pharmacies, healthcare facilities, etc. by eliminating human error during dispensing. ePrescribing could then be linked to eDispensing to ensure that the right patient receives the right drug at the right time.

2. Please provide information related to: Strengths for identification, validation, track and trace, or authentication;

The ®Mark™ covert marker technology provides absolute identification and authentication and is expected to be interoperable with track and trace systems. The identification and authenticating strength of the micro-tag is derived from:

- Its unique indicia link with each drug (e.g. manufacturer, NDC code, manufacturer logo, product name/logo, etc.)
- The indicia is known only to the pharmaceutical manufacturer and the taggant manufacturer (AAT). The pharmaceutical manufacturer can change the taggant indicia at-will during production, and in this way only the pharmaceutical manufacturer will know the proper micro-taggant indicia for a specific drug manufacturing location, lot number, etc.
- The indicia cannot be manufactured by the counterfeiter. It would be extremely hard for a counterfeiter to figure out how to produce these microtags due to a complex manufacturing process, and the layering of forensic signatures within the ®mark™ covert marker. If that capability were somehow to be overcome by the counterfeiter, then the pharmaceutical manufacturer could change or vary the micro-taggant indicia information as a moving target to prevent a supply chain security breach by a counterfeiter.
- The supply chain for the microtag is secure (Proprietary trade secret & manufactured in the United States)
- The pharmaceutical manufacturer can change the taggant indicia based upon manufacturing lot, location of manufacture, etc. The actual materials used in the taggant would remain the same. Only the indicia would change thereby mitigating any concern about changes in the qualitative formulation.

2. Continued: Please provide limitations for identification, validation, track and trace, or authentication

There are no limitations related to identification, validation or authentication. Track and Trace interoperability will be dependent upon the standards set by FDA.

2. Continued: Please provide costs of implementation and use;

®Mark™ covert micro-taggants can be applied to film coated pills for nominally one cent per tablet in the manufacturing process (Nominally a $1.00 increase in manufacturing cost for 100 tablets). Example, 100 tablets selling at $10/tablet would have a selling price of $1000. Adding the cost of the on-dosage anti-counterfeitng taggants, the selling price would increase to nominally $1001.00.

Micro-taggants can be applied to tablets with existing pharmaceutical manufacturing facility film coating equipment. No additional capital investment is required to add micro-taggants to the film coated tablet and the inclusion of the micro-tag has no effect on productivity.

2. Continued: Please provide benefits to the public health;

Counterfeit Prescription Drug Prevention: Pharmaceutical counterfeiting is a global problem affecting the health and lives of people around the world. Counterfeit drugs present a global financial burden as well as a health and safety burden, currently projected to approach $75 billion (U.S. Dollars) in lost pharmaceutical sales revenues by 2010. In 2006, 3.4 billion prescriptions were dispensed in the U.S. If only 1% of those drugs were counterfeit (current estimate of counterfeit drugs within the United States is under 1%), 34 million U.S. prescriptions would be affected. Globally, the WHO estimates that 10% of the global drug supply is counterfeit.

Medication Error Prevention: The National Institute of Medicine reported in 1999 that medical mistakes kill between 44,000 and 98,000 Americans each year. In 2006, the Institute reported that medication errors are among the most common medical errors harming at least 1.5 million patients every year. The medical cost impact of these medication errors is estimated to be a minimum of $3.5 billion a year.

Micro-taggant technology can serve a dual purpose in serving the public regarding the availability of safe drugs. The first benefit is in protecting the public against counterfeit drugs. The second benefit is in protecting the public against medication errors:

Counterfeit Drug Protection

- On-dosage micro-tag technology, if matched with on-package indicia can provide a "self-authenticating" process for a pharmacist to match drug information on the package with the drug information contained in the micro-taggant indicia contained on the surface of the solid dosage. The advantage of this on-package and on-dosage link is that the information can be changed by the pharmaceutical manufacturer "at-will" to provide a moving target authenticating system.
- On-dosage micro-tag technology can be simply applied to the solid dosage to provide a covert authenticator. Due to the secure supply chain and trade secret manufacturing

process of one manufacturer in the United States, it is unlikely that a counterfeiter would be able to manufacture the microtag indicia.

- On-dosage micro-taggants are being developed to enable bar code scanning of microscopic bar codes included in the micro-taggant indicia present on the film coating of tablets. These microscopic bar codes would be invisible to the human eye. This on-dosage micro-taggant technology is envisioned to not only be interoperable with ePedigree Track and Trace systems for anti-counterfeiting applications, but also provide an automated tablet counter/identification/authentication system to complement the triple check systems already in place in pharmacies. This would provide an automated system to reduce medication errors as well as authenticate and count tablets during the dispensing process. The system could also reduce the workload of the pharmacist during prescription dispensing.
- These quick identification and authentication systems are covertly applied to the dosage form, and can provide Customs Border Protection with efficient field determinations of a product's authenticity or counterfeit status since the micro-taggants can be read using a relatively inexpensive reader that could be used in the field.

Medication Error Prevention

- The development of the on-dosage 2D bar coded micro-tag interface with bar code scanning devices in pharmacies would enable a fast method to potentially identify and count (as well as authenticate) pills. This would enable the bar coded micro-tagged solid dosage to be interoperable with ePrescribing systems thereby aiding in the dispensing process to reduce medication error due to human error.

2. Continued: Please provide feasibility for widespread use

On-dosage micro-taggant technology can comply with global regulatory requirements. It is a technology that is very economical and can be applied by pharmaceutical manufacturers worldwide. Each product can be uniquely identified, and there is no limitation to the combinations of indicia available for product applications. Pharmaceutical companies worldwide can use the micro-tags in existing manufacturing facilities. No process changes are necessary. On-dosage micro-taggant technology can verify authenticity of solid dosages in 3rd world countries where there may be no network database available. The system does not require sophisticated equipment or the internet to function with complete reliability 24/7/365 anywhere in the world.

2. Continued: Please provide utility for e-pedigree

On-dosage micro-taggant technology can be linked with on-package bar code identification and RFID identification in a parent-child relationship. In this way micro-taggants can provide ePedigree and Track and Trace linkage from the manufacturer to the pharmacy at the point of dispensing. The use of micro-taggants would enable a patient to maintain privacy through the dispensing process since the micro-tag would be covert beyond the pharmacy.

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3. Is the technology interoperable with other technologies? If so, describe.

On-dosage micro-taggant technology is anticipated to be interoperable with electronic track and trace ePedigree technologies. It is also interoperable with packaging security technology.

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

The standards necessary for supply chain use of on-dosage micro-taggant technology include:

- Optical or electronic magnification device to read the micro-tag and authenticate the drug. Bar code scanning with magnification would enable electronic interoperability with bar code and RFID electronic Track and Trace systems
- Status of Development: Optical and electronic magnification devices are commercially available. Bar code scanning is in development, and anticipated to be commercial in 2008/2009. It is also anticipated that these systems will be interoperable with bar code anti-counterfeiting systems currently being developed in Europe.

We appreciate the opportunity to provide comment on Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication. Our firm is committed to providing authentication solutions for brand protection and product surety which augment patient safety.

Sincerely,

John D'Ottavio
Regulatory Affairs Manager