Pharma AntiCounterfeiting NEWS

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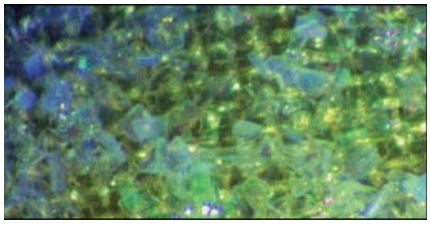
TruTags Provide Edible, Low Cost Authentication

Cellular Bioengineering Inc (CBI) of Honolulu has announced the development of *TruTag*™ – edible and inert encoded microtags with a high temperature resistance at a cost of less than a penny each. Potential applications include not only pharmaceuticals and consumable products but also industrial components, high value goods and currency.

TruTags are made from high purity porous silica, which is generally considered by the FDA to be safe, rendering them biologically inert and edible. The porous silicon wafers are etched with unique spectral codes chosen from over one trillion possibilities, which can be measured and authenticated via a portable spectrometer-based optical reader. The system can be designed to be self-authenticating or can rely on external product information stored remotely, for example, in a secure online database.



Pictured here are hundreds of TruTags in a space about the size of a pinhead.

The self authentication process includes both a cryptographic code on the packaging and code stored in the tag that combine to form a digital

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EFPIA Data Matrix Pilot

The European Federation of Pharmaceutical Industry Associations (EFPIA) has launched a pilot project of its 2D data matrix barcode identification system in Sweden with the co-operation of Apoteket retail pharmacy chain, wholesalers Tamro and KD.

EFPIA established an AntiCounterfeiting Working Group in 2004, following an earlier task force study of counterfeiting as it affected its members. The Working Group published a white paper - The Anti-Counterfeiting of Medicines - in 2005, which recommended establishing a European system for tracking medicines, based on the standard Electronic Product Code.

This recommendation was further pursued by EFPIA through a Technical Committee, which researched marking and tracking methods. In due course this committee selected the 2D data matrix barcode as the preferred method. One objective was to keep the cost of the marking to under 0.5 cents a pack, with minimal disruption to packaging design and graphics and production or packaging line. The printed data matrix delivers on these objectives.

The 2D data matrix holds the product code, a unique serial number, product expiry date and batch number, all encoded and also stored on a central database. At the point of dispensing, the pharmacist scans the code which is checked against the database. This will verify that the record exists and matches the data on the product being scanned; that it has not already been marked as dispensed or sold, and it will alert the pharmacist if there are any recall notices or similar. EFPIA acknowledges that the systems checks the code, not the product, so it does not necessarily authenticate that the medicine is genuine, but it will identify that the code is genuine and it has not been previously scanned for prescribing.

The pilot project, which will run until December, involves around 50 pharmacies with an anticipated 100,000 coded packs to be dispensed. The scanning and network system is integrated with Apoteket's existing IT system, so it does not require additional hardware at the pharmacist.

A sample pharmaceutical pack showing the EFPIA 2D data matrix.

EFPIA will evaluate the results of the pilot during the first half of 2010, to make adjustments to the scheme later in the year, and expects full implementation to take 3-5 years.

Contact: www.EFPIA.eu.

Editorial

AntiCounterfeiting a Global Need

Kenya, a relatively stable African country, with a major pharmaceutical counterfeits problem.

The US, still the richest country in the world with a relatively small pharma counterfeits problem.

Kenya and the US are at the opposite ends of the spectrum as far as the problem of counterfeit medicines are concerned. Yet this issue of Pharma AntiCounterfeiting News reports new official action from both countries: new, albeit draft guidance on anti-counterfeiting additives from the US FDA (see below), and a new - yet to be implemented - Anti-Counterfeiting Act in Kenya.

The US guidance is, partly at least, a belated FDA response to moves by some pharma companies to use inert taggants in their medicines. To date, these have been approved by the FDA on a case-by-case basis, but this will become impractical if the use of such taggants becomes more common. In a strictly regulated medicines jurisdiction, such guidance from the regulator is necessary, both for its actual guidance but also as a tacit sign of approval; users, or those thinking of using taggants, can rest easy knowing the FDA will approve the changed constituents of their medicines if they have followed these guidelines.

No doubt, however, that however good and positive the FDA's intentions, there will be some criticism of this move, either in general or with regard to the specifics of the guidance. But this will be very different in type and tone from the criticisms of Kenya's Anti-Counterfeiting Act.

First, this Act is to be welcomed. Anything which puts more weight and resources behind the fight against counterfeits in a country like Kenya is to be welcomed. And the exposure it gives, the raising of public awareness of the problem, is a part of the benefit of such an Act. But the Act shows the difficulty of drafting which applies to any new law, but especially where intellectual property is concerned. And so it has opened to the public an issue that has been exercising specialists in the pharma sector for years: when is a copy a counterfeit or when is it a valuable generic drug?

This newsletter is not on the topic of intellectual property so we will skip over the complex issues raised by the Kenyan Act (at least for now). What we will say is that the interests of the patient should be paramount, and that means allowing access to low-cost medicines while preventing access to counterfeits. Those low-cost medicines can be made available in a variety of ways: subsidised by the multinationals; generics from countries which don't recognise drug patents; or supplied by a low-cost licensed manufacturer. What is certain is that counterfeits can be made available in 10 times - or 20 times - more ways.

Which is why Kenya's attempt to strengthen its legislation and enforcement against counterfeits, with the active support of the WHO, is to be welcomed, even if it raises some important issues. Hopefully those issues can be - will be - resolved to the benefit of all involved, but most of all the patients.

And ultimately the US FDA's concern is to prevent counterfeit medicines from reaching patients. Two countries separated by the South Atlantic and an ocean of relative wealth, but each endeavouring to take steps to improve their fight against counterfeit pharmaceuticals. What better way to demonstrate that the fight against counterfeits concerns all countries, rich and poor, developed and developing. The criminals know no borders - combating them must also be a global response.

FDA Guidance on Use of In-Dose Identifiers

The US Food and Drug Administration (FDA) has responded to the increasing interest in the use of taggants and other authentication additives by using draft guidance on the use of what it terms 'physical-chemical identifiers' (PCIDs) in tablets. It is inviting comment on the guidance, which is published as Draft Guidance for Industry: Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting, and which is available from the FDA's website (see below).

The Guidance refers to PCIDs as 'a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies and authenticates a drug product or dosage form' and gives the examples of inks, pigments, flavors and molecular taggants. Previously the FDA focused on the tracking of medicines as a way to combat counterfeits. Following the 2004 report of its Counterfeit Drug Task Force the Administration strongly supported RFID as a key anti-counterfeiting technology, anticipating that this would be a realistic widespread and available technology by 2007, but by 2006 the FDA had recognized the relatively slow progress in making this an affordable approach, turning its focus to more general electronic track and trace and e-pedigree solutions. It has always recognized that physical authentication devices have a role to play in combating counterfeit medicines, but this Guidance is the first specific statement on an authentication approach which is on or in the medicine, rather than tracking it.

The Guidance is a response to the increasing interest in inert additives as an authenticator within the pharmaceutical industries. US taggant producers such as Authentix and NanoGuardian have supplied pharmaceutical customers but they have had to seek FDA approval individually. This draft Guidance is the first official codification of procedures and processes for the use of taggants in tablets (which the FDA refers to as 'solid oral dosage form drug products) or the case of capsules. Presumably it is also considering guidance for their use in other dosage forms, including capsule contents and liquid medicines.

The document states that in some cases, the PCID may be easily detected by wholesalers or pharmacists to determine if they have authentic products. In other cases, special analytical instruments may be necessary to identify whether the PCID is present. Strangely, it mentions photolithography and holography as means of 'presentation and detection of PCIDs', although these are more likely to be used as overt (ie visible) authentication devices.

Comments on the Guidance should be submitted to the FDA's Division of Dockets Management, referencing HFA-305, but there is no deadline given for such comments.

Contact: www.fda.gov/downloads

Technology News

New Security Seal for Endoscope Cases

Endoscopes by Karl Storz are used around the world. As techniques advance rapidly in line with new technologies, physicians regularly attend medical seminars, workshops and conferences to keep abreast of the latest developments. When the high-tech endoscopes and related products used at these professional events are supplied by Karl Storz, they are supplied in a case with a closure seal by Schreiner ProSecure. This guarantees that the products arrive intact and clinically clean, and reduces logistic requirements in the process.

A few facts and figures suggest the dimension of the savings the company achieves by using the new seal. Karl Storz ships up to 5,000 of the special cases containing high-end endoscopes to its customers per month - but not all of these cases are actually opened and the contents used. Up to 30% are returned unopened by the events' organizers. Nevertheless, the contents of each returned case required in-depth technical inspection and thorough cleaning. This complex, time-consuming and costly process tied up valuable human and material resources. To make the process leaner, Karl Storz commissioned Schreiner ProSecure to develop a seal that would reliably indicate that the case had been opened.

Reliable Opening Evidence

Although the product cases are used many times, they always have to arrive at the customer's location in impeccable external condition. Therefore, Schreiner ProSecure developed a seal with an attractive security hologram which can be applied to the thin aluminum strips of the cases. 'The major challenge was that the seal had to provide totally reliable adhesion and exclude any possibility of non-destructive tampering or peel-off. In addition, any adhesive residues left on the opened cases had to come off by simple washing to make the cases ready for reuse quickly,' said Thomas Völcker, marketing and sales director at Schreiner ProSecure. Therefore, Schreiner ProSecure adapted the adhesive used for this product specifically to these requirements. 'Our R&D testing lab proved the reliability of the self-destruction effect. In addition, the aluminum substrate is easy to clean after peeling off the label, and there are no residues left,' said Uwe Zeller, deputy head of technical inspections and congress logistics.

For reliable and easily visible indication of any attempt to open the case, the security seal has an integrated void effect. It is triggered when the seal is lifted off the substrate and exhibits a conspicuous checkered pattern. To ensure that this effect is also activated when the case is forcibly opened or in a jolt, Schreiner ProSecure has provided the label with an additional separating perforation.

With the new security seal, Karl Storz avoids unnecessary cleaning and inspection effort, now checking and cleaning only cases that were actually opened. The company benefits from leaner processes and lower inventories, as unopened cases can be immediately used after their return. This solution also visibly documents Karl Storz's quality standards. 'The seal significantly optimizes our workflow,' emphasized Zeller. 'And our customers perceive it as a seal of quality for endoscopes that have been duly inspected.'

Contact:www.schreiner-prosecure.com

TruTags... cont'd...

signature. Thus item and packaging are authenticated together; tampering with either the package, or the contents, would flag a security violation.

Additionally, each tag can reference a label in a secure database, where additional information about the item can be stored, such as a link to a future e-pedigree track and trace system.

The microtags are encoded with information purely in their depth, rather than along their surface. As a result, they can be broken into pieces, with each piece still containing all of the encoded information, making them suitable for forensic applications where the tag may be subjected to rough handling. As long as any piece of the tag can be recovered – even after use and disposal – the microtag will survive and the information is not lost. The company says this offers clear advantages over traditional tracking technologies such as RFID, which requires internal electrical connectivity, and UPC codes which requires the surface of the code to remain intact.

TruTags can be attached either to the outside of items to be read, for example, through clear plastic blister packs, or mixed into items as a forensic excipient, to be read as part of an inspection process or investigation. They range in size from 20 to 150 micrometers and can be made either in irregular, random shapes within a specified size range, or in regular shapes, such as discs or squares, via an optional photolithographic process. They have a high temperature resistance (with a melting point above 1600°C) and are suitable for use in or on products, packages, labels or security fibres. Methods of application include via sprays, coatings, inks, varnishes or as part of laminates or paper pulp.

CBI is a Hawaii-based accelerator of innovative technologies including cell matrix chip technology for homeland security. TruTag is a development of its Product Security Division and has been developed in cooperation with the US government to help combat counterfeit drugs.

Contact: www.trutags.com