

Pharma AntiCounterfeiting NEWS

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BrandWatch Offers 4-Level Authentication

BrandWatch Technologies, a Portland, Oregon-based developer of brand protection solutions, has introduced a new variety of its up-converting taggant technology that combines four levels of covert protection in one product. This, it claims, is the only marker that provides multiple simultaneous product identification and offers brand owners a unique fingerprint to embed into their products or packaging.

The company, founded as Stardust Technologies in 2001, was acquired by a group of private investors in 2007, renamed and restructured with a new management line-up. It produces micro-tagchants based on inorganic up-converting anti-Stokes phosphors together with proprietary handheld readers.

One of the first developments under the new ownership was *SpectraTagg*. This range of tagchants has now been tuned to offer a combined UV and IR response with two other covert markers, yielding four distinct layers of protection which can be identified simultaneously by the company's *Reveal* detectors.

According to Steve Delepine, newly appointed VP for Business Development, this product is unique and makes it possible to create a covert protective shield around a product that is statistically impossible to circumvent.

In addition to *SpectraTagg*, the company also offers *MicroTagg*, an up-converting phosphor material with dual

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Tougher US Anti-Counterfeiting Legislation

Over the last seven years bills have been introduced in the US Congress to expand FDA authority to combat the distribution and sale of dangerous counterfeit medications. The latest attempt by Rep Steve Israel (D - N.Y.) is called the 'Counterfeit Drug Enforcement Act of 2009'. It has garnered important endorsements from consumer and public interest groups and by safe medicine and anti-counterfeiting organizations, who support efforts to reform the US pharmaceutical and medical device distribution supply chain to protect consumers against counterfeit and adulterated products.

'Consumers have a right to trust the products their doctors say will make them better. This year alone, an estimated 35 million prescriptions will be filled with counterfeit medicine. My legislation will empower the FDA to crack down on counterfeiting and increase the criminal penalties for the outlaws who are compromising our

health,' said Rep Israel. 'This will be a tough fight, and I'm proud to have the nation's top consumer and public health advocates as partners pushing with me to ensure that the domestic drug supply chain is secure for every American.'

The Bill, HR 2627 (also called 'Tim Fagan's Law', after a 16 year old New Yorker who was injected with counterfeit drugs after an emergency liver transplant), will:

- Provide the FDA with the authority to require companies to use anti-counterfeiting technology;
- Require the FDA to remove the stay placed on paper pedigree requirements, which were mandated in the Prescription Drug Marketing Act of 1988;
- Give the FDA recall authority, the same way the FDA can recall faulty medical equipment;
- Increase criminal penalties for counterfeiting;
- Mandate that drug manufactur-

ers alert the FDA within two days when they learn that one of their drugs has been counterfeited;

- Authorize funds specifically for spot-checking (\$300m over five years);
- Authorize \$5m for each year between fiscal years 2010 and 2014 for educating the public and health care professionals on how to identify counterfeit drugs;
- Authorize the FDA to issue subpoenas with respect to preventing threats to public health.

'Tim Fagan's Law' will increase criminal penalties - up to life in prison - for selling counterfeit prescription drugs, require a chain of custody for a drug from manufacturer to wholesaler to pharmacist, and require drug companies to use anti-counterfeiting technology.

For further information: <http://www.thomas.gov/cgi-bin/query/D?c111:1:/temp/~c111ri58fE::>

News

New NAFDAC DG Makes the Rounds

It has been a busy inaugural period for Paul Orhii, Director General of NAFDAC, the Nigerian National Agency for Food and Drug Administration and Control. Dr Orhii is a physician and attorney by training and has taught pharmacology at the University of Jos, Nigeria, and the University of Texas Health Science Center at San Antonio. He was a biomedical scientist at the Center for nearly twenty years and has authored or co-authored more than twenty peer-reviewed scientific publications. He took on the mantle of Professor Dora Akunyili, who headed NAFDAC for more than nine years, and who was appointed minister of information by the President, Umaru Yar'adua.

Dr Orhii has a large assignment. NAFDAC, a parastatal of the Federal Ministry of Health, is responsible for all control measures on food, drugs, cosmetics, water and chemicals for both preventive and curative health care.

A major part of Dr. Orhii's remit is the education of not only his countrymen, as shown in a paper he gave on the regulations concerning new drugs

in May in Abuja, but also further afield. In Washington, DC, for example, he spoke at the American Enterprise Institute to donors, DRA personnel, international aid agencies, and suppliers of anticounterfeiting systems on the global impact of fake medicine and his program.

He announced that NAFDAC have introduced new techniques for combating fake drugs. Orhii said regulatory officers would be trained to use technologies such as Raman Spectrometry, mobile laboratories and *Truscan* (from Ahura Scientific) to test and detect quality and efficacy of drugs and other products.

He noted that NAFDAC will partner with the private sector to build drug distribution hubs in the six geopolitical zones to help sanitize the current chaotic drug distribution network.

Another initiative concerns India, where discussions regarding drugs originating there and also passing through from other sources took place with the Indian FDA and other organizations.

The NAFDAC boss explained in a conference in Singapore that one of the



Paul Orhii, Director of NAFDAC

new strategies adopted by the agency was to put the power of detecting and reporting incidence of counterfeit medicines in the hands of consumers, using short message service (SMS) based technology like GSM phones. This last initiative is directly in line with the theme of the 5th *Global Forum on Pharmaceutical AntiCounterfeiting*, being held in Miami on 24-26 February, 2010, by addressing the role of the patient in fighting counterfeit medicines and related products.

Contact: www.nafdacnigeria.org/
www.ahurascientific.com

PHARMORX Offers End-to-End Tracking and Authentication Solution

Pharmorx Security Inc (pronounced 'far more ex') has made two additions to its new pharma tracking platform launched earlier this year. One is in the form of an iPhone application that will be unveiled at the forthcoming Brand Protection Show in London (see page 6). The other is a license to deploy Sun Chemical's security taggants.

Pharmorx Security is based in Massachusetts and was founded in 2004. Its flagship technology is *AuthentiTrack™*, a suite of technologies that provides what it terms an end-to-end solution encompassing serialization, track and trace and authentication. Unique identification is provided through codes generated from its proprietary high magnification imaging technology, variable data printing or unique numbers or barcodes (1 and 2D) with specialty inks, including invisible inks, and through RFID.

All levels of the packaging hierarchy



The iPhone application for the AuthentiTrack pharma tracking platform

from the pallet down to the unit level can be serialized, with AuthentiTrack automatically aggregating and disaggregating the serial numbers while maintaining parent-child relationships at every stage of the packaging process. The system can be used to track and capture every event or 'touch' of each product unit, giving clients the ability

to monitor their products through the supply chain.

Real-time access to the data behind these events is provided via the company's customizable web-based *Security Dashboard*, which provides information from product metrics to security alerts. The system also provides data mining, enabling identification of fraudulent patterns of activity.

AuthentiTrack also comprises a range of authentication technologies, including multi-wavelength taggants and invisible inks, for authentication in the field using hand-held Field Authentication Units or phones. The latest addition to this platform is the iPhone application developed by Pharmorx which capitalises on the varifocal lens feature of the new generation of cell phones to scan and transmit the codes.

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ARmark and Smiths Launch IntelliMark

ARmark Authentication Technologies has announced a partnership with Smiths Detection to launch *IntelliMark*, which it terms a complete product identification system.

The IntelliMark system features ARmark's microscopic covert markers that are integrated into products and then viewed and identified with Smiths Detection's *Identify IR* and *Illuminat IR* instruments. The system also offers investigators a secondary level of verification through Smiths *Touchback* spectral reading and confirmation service.

The polymer-based markers are less than the diameter of a human hair and can contain multiple layers of information, including text and graphics. They are custom-designed for each application and can be applied to products via a number of standard processes including aerosols, inks, varnishes, adhesives or in films and paper pulp.

To date, the detection of the markets has been via optical readers only, including high-powered magnification devices and digital microscopes. The new field instruments from Smiths, however, now enable a spectral reading to be taken as well. This reading can then, through the *TouchBack* system, be relayed via a mobile communication link to a central database to validate the marker and provide additional information, such as where



Microscopic markers are at the heart of a revolutionary product identification system that enables genuine brand authentication.

the product has been in the supply chain, in real time.

Commenting on the new partnership, ARmark's general manager Jeff Roberston said: 'the IntelliMark system allows for an extension of detection capabilities beyond optical detection. Combined with the capability of Smiths *Touchback* system, IntelliMark now brings a complete information service to brand owners regarding their product supply chain.'

Smiths Detection is part of the global technology business Smiths Group, a leading developer and manufacturer of sensors that detect and identify explosives, chemical and biological agents, weapons, and contraband.

IntelliMark has already been successfully deployed in the pharmaceutical industry for chemical verification of drug content in branded consumer drugs. Another key target sector for the system, according to ARmark, is food.

Contact: www.rmark.org

Technology News

Pharmorx...cont'd

One of the company's key routes to market is through a partnership with the Irish packaging company MSO Group, 40% of whose business is pharmaceutical packaging products and whose clients include Johnson & Johnson, GSK and Reckitt-Benckiser. MSO has exclusive rights to use Pharmorx's tracking technology in Europe in exchange for Pharmorx distributing MSO's packaging in North America.

The portfolio of technologies is strengthened by a recently signed agreement between MSO and Sun Chemical, the world's largest producer of printing inks and pigments, to incorporate its covert taggants into MSO's security packaging. MSO now has an exclusive, worldwide license for the technology and will, in turn, make it available to Pharmorx as a way of adding authentication to products.

Pharmorx is privately owned and has funded itself through seed capital and ongoing projects. The pharmaceutical industry is its major focus, initially with an important product announcement due in October 2009. This relates to an innovative drug delivery system which will be launched with full overt and covert authentication and on-line tracking from packager to patient (a paper on the topic is promised for the Global Forum on Pharmaceutical AntiCounterfeiting to be held in Miami next February).

Contact: www.pharmorx.com

New Coded Tamper-Evident Seal from Tesa-Scribos

German company tesa scribos, part of the tesa tapes subsidiary of the Beiersdorf company, has introduced *CodeSeal* to its range of optical product protection labels. *CodeSeal* integrates item-level codes with visible authentication on a tamper-evident label.

Tesa scribos specialises in the production of encoded and/or holographic security labels. The company has the facilities to generate unique encrypted codes that meet international coding standards, and has drawn on its parent company's expertise in the development and



A CodeSeal two-layer label

production of self-adhesive tapes,

films and labels to produce innovative security labels.

CodeSeal follows this tradition. It is a two-part laminated label which carries a unique item-level product code on each layer. On the top layer - the layer that is visible under normal circumstances - the code can be printed in human-readable alpha-numerics and/or in a bar code or data matrix. The ingenious aspect is that the code is also printed through this top layer to the bottom layer, so when the two are separated, the code can be checked to ensure that they match.

Contact: www.tesa-scribos.com

Company News

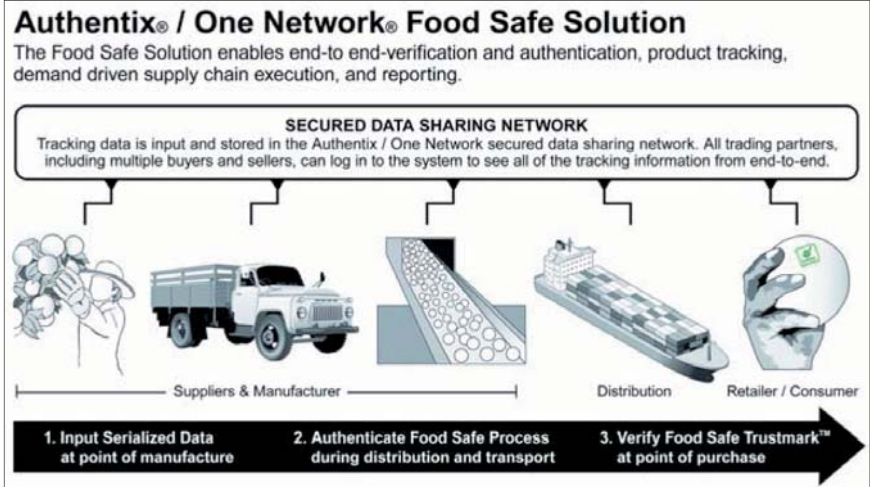
Authentix Solutions for Food and Pharma

In a move designed to widen its portfolio to clients in the food and pharma sectors, Texas-based security solutions provider Authentix has announced a partnership agreement with One Network, a specialist in community-based on-demand supply chain solutions based on SaaS (Software as a Service). According to the company, the partnership offers solutions for product authentication, e-pedigree compliance, returns and recalls, as well as detailed product usage data at a significantly reduced cost from traditional approaches.

The move has been made in recognition of the growing demand from these sectors for a complete service capable of tracking products in a secure environment and authenticating these. All parties will have full supply chain visibility so that they know the exact location and quantity of products anywhere in the chain, and will be able to verify that these products are genuine and safe for use.

Authentix also states that the two companies' approach is both unique and economical because it is being offered as a service, thereby reducing the need for companies to operate and administer their own tracking networks. The solution supports the Food Marketing Institute, SQF (Safe Quality Food) and USDA and FDA's Hazard Analysis and Critical Control Points (HACCP) programs.

At the point of manufacture, products will be marked with a barcode printed with inks containing covert nano-particles that will be used to authenticate the product. Products can be located and identified anywhere in the supply chain network – enabling



Conceptual representation of the supply chain using Authentix's Food Safe Solution

these to be tracked all the way from manufacturer to consumer, as well as facilitating swift recalls if food or product safety has been compromised and allowing information about the product to be tracked as well, such as expiration dates.

Commenting on the partnership, and resulting system, Greg Brady, chairman and founder of One Network said: 'the cost of authentication and tracking with current systems is impeding many companies. With our SaaS solution we are able to offer these capabilities at a significantly lower cost. We are able to authenticate each individual unit, no matter where it is in the value chain.'

This comes at a time when pressure is growing from governments and consumer groups for greater protection to the consumer. In the USA, a number of tracking initiatives for the pharma industry are in the pipeline following the failure of the FDA's well-intentioned attempt to mandate the use of RFID as

a way of creating an 'e-pedigree' for all pharmaceutical products. In the food sector, meanwhile, where the global cost of counterfeiting is estimated at \$49 billion, a bill is currently working its way through Congress aimed at enforcing food traceability as early as next year.

ISO Certification

In a separate development, Authentix has announced that it has achieved the new International Organization for Standardization (ISO) ISO9001:2008 world quality certification. This ensures that certified organizations involved in the design and development, manufacturing, installation and servicing of products adhere to specific quality and management procedures and, according to David Moxam, Authentix chairman and CEO, the company is one of the very first in the authentication industry to receive the certification.'

Contact: www.authentix.com

BrandWatch...cont'd

factor authentication that is readily incorporated into polymeric and other matrices. When irradiated with energy of a specific wavelength, the Micro-Tagg particles absorb the energy and re-emit it at a different wavelength, which is detected by the company's detectors. In addition to the visible response it produces when excited by an infrared source, this product also delivers an authentication signal, rec-

ognizable only by the Reveal detector.

The company's technology originated in military research and has received several certifications as to its stability, longevity and durability. The taggants share a set of common properties, being inorganic, inert and non-toxic, insensitive to sunlight and stable at temperatures up to 1000° C. They can be easily incorporated into inks, dyes, polymers, textiles and pulp, will

not alter the host's chemical make-up, have an extremely long shelf-life and are capable of being detected at low concentrations.

The line of proprietary handheld detectors can isolate a range of taggants and detect multiple types simultaneously, ever through product packaging or at distances of up to 20 ft.

Contact: www.brandwatchtech.com

Raising Awareness and Counterfeiting Penalties in India

The Indian Government, besides working with its international 'partners' such as Interpol and other governments (see the article on Nigeria in this issue), is encouraging an increase in the information flow regarding counterfeit medicines, and is starting the legislative process to raise the penalties for those convicted of counterfeiting offenses.

The Union Health and Family Welfare Minister Ghulam Nabi Azad expressed serious concern over the growing menace of spurious drugs and pointed out that the government had come out with a new policy to reward 'whistle blowers' providing information on manufacture of such drugs

Mr Azad said that the law would be amended suitably to effectively deal with the menace.

'The government plans to bring the Drugs and Cosmetics (Amendment) Bill for creating a Central Drug Authority. This will pave the way for making the regulatory mechanism

robust.' He went on that a 'whistle blower' scheme, under which anyone who provided information about the manufacture of spurious drugs would be given rewards ranging from Rs2 to 20 lakh, (\$0.40-\$41,222) was on the anvil. 'We expect a lot of people to come forward to provide information without disclosing their identity.'

The government proposes to set up special courts for speedy trials of those facing charges of spurious drug manufacture.

Noting that the law provided for a maximum punishment of life imprisonment for the offence and a fine of Rs. 10 lakh, he said, 'Left to me, I am for capital punishment. The menace could be checked even if life imprisonment [was awarded] to one or two such manufacturers.'

With this legislation and other actions, India is protecting its citizens and domestic manufacturers of genuine medicines and responding to the concerns of global neighbors.

EU Call for Research Project on Tackling Counterfeit Medicines

The European Commission (EC) has launched a call for proposals for research on methods to tackle counterfeit medicines, under a more general research area titled *Security Research Call 3*, identifier FP7-SEC-2010-1 within the FP7 research framework. The deadline for submission of proposals is 26 November 2009.

Security Research Call 3 covers a variety of security projects in the broad arena of citizen protection. Topic SEC-2010.1.3-2 is titled *Tackling counterfeit medicines and related criminal networks*, which will be a collaborative project requiring a minimum of three participants from at least two member states. Funding available to support projects under this call is €10m, to be split between over

30 individual research projects. The EC anticipates that funding will start in 2010.

On September 16 the EC's Research Executive Agency is running an 'Infoday' in Brussels covering this call, to explain it and how to establish a project to submit for support. The day will include break-out sessions where participants will be able to give a short presentation and also meet with project officers.

Registration for this day is required by 11 September, at http://cordis.europa.eu/fp7/security/events_en.html. The Security Research Call 3 and supporting information can be downloaded from the CORDIS website.

Contact: http://cordis.europa.eu/fp7/home_en.html

EU Counterfeits Double in 2008

The European Commission has published its annual statistics relating to counterfeit and pirated goods seized at EU borders in 2008, which show seizures up by 13% to 49,000 from the previous year. According to the EU, this demonstrates the improved cooperation between customs and industry, enabling the former to better target suspected shipments and to recognize IPR infringing goods. The number of articles detained more than doubled in 2008 to 178 million, some 20 million of which were potentially dangerous to health and safety.

Seizures of toys rose by 136%, of electrical equipment by 58%, of medicines by 57% and of personal care products by 42%.

Success of Medifake

In terms of the number of articles seized, there was a 118% increase in medicines, second only to DVDs. The significant increase in both the number of seizures and articles is attributed to a variety of reasons, including the EU-wide *Medifake* campaign of last autumn, a two-month long initiative which was the first of its kind to target customs control on illegal medicines entering the EU throughout all 27 member states. It led to over 32 million medicinal products being stopped by customs, of which more than 15% were suspected of infringing IPR. Also, during the course of the campaign, more than 25 million items containing drug precursors were also stopped, equating to the production of street doses with an estimated value of €50m.

India Prime Source

As in previous years, China remains the main source country for IPR infringing articles with 54% of the total amount. For medicines, however, India is the major source, accounting for 51%, followed by Syria (36%) and the UAE (8.6%).

The full report can be downloaded at http://ec.europa.eu/taxation_customs

Events

New Dates for Global Congress



The fifth **Global Congress on Combating Counterfeiting and Piracy** will now take place in Cancun, Mexico from December 1-3. The event was originally scheduled to take place from June 2-4, but uncertainties surrounding the outbreak of the influenza virus H1N1 (swine flu) in April led to its postponement.

According to the organisers, an excellent roster of speakers had been selected for the Global Congress and most have confirmed their commitment to the new dates. The agenda will include two keynote speeches, one on dealing with counterfeiting and piracy in a period of economic crisis and the other on the impact of counterfeiting and piracy on SMEs respectively. They will be followed by sessions on coordination and cooperation; improving criminal and civil legislation and enforcement; health and safety risks counterfeit products pose to consum-

ers; building anti-counterfeiting capacity and capabilities; raising awareness on the full economic and social costs of counterfeiting and piracy; free trade zones and transshipment countries and, finally, collaborating on fighting counterfeiting and piracy on the internet.

The Congress organizers include co-hosts Interpol and the Mexican Institute of Industrial Property (IMPI), together with World Customs Organization (WCO), the World Intellectual Property Organization (WIPO), the International Chamber of Commerce (ICC), the International Trademark Association (INTA) and the International Security Management Association (ISMA).

It will be accompanied by an exhibition of anti-counterfeiting systems and services, which is being organized by Reconnaissance International and the Counterfeiting Intelligence Bureau. Further details of the exhibition can be obtained from Ian Lancaster or Alan Walp at Reconnaissance

Details of the Congress itself can be found at www.ccapcongress.net

Brand Protection Highlighted in London



The **Brand Protection Show** debuts September 16 - 17 at London's Olympia exhibition centre, with a strong array of educational opportunities through the 35 seminars and over 100 organizations exhibiting. The seminars are to be given by anti-counterfeiting organizations, brand owners and experts in the field, covering such topics as:

- 'Authenticating your Brand' by the International Authentication Association
- 'Johnson & Johnson's Medical Devices and Diagnostics approach to brand protection and authentication'
- 'New technologies in brand protection' from the Technology Transfer Group
- 'Designing brand protection into

your product, packaging and business' from Kodak's Marketing Workflow Group

- 'The ICC's role in fighting counterfeits' - The International Chamber of Commerce explain how its Counterfeiting Investigation Bureau and BASCAP organisations help brand owners defeat counterfeiters globally.

Service providers and technology suppliers showcasing a wide range of solutions from security inks, holograms and track and trace technology to sophisticated internet monitoring tools, will be on hand throughout the event, along with anticounterfeiting associations. Entry to the Brand Protection Show is free to pre-registered visitors. Seminars cost £20 each to attend

For more details:

www.thebrandprotectionshow.com

Pharma Anti-Counterfeiting Forum

The program is taking shape for the fifth **Global Forum on Pharmaceutical AntiCounterfeiting**, in Miami, Florida, February 24-26 2010. Registration is now open for this influential event. Booking before November 30th 2009 saves 20% on the standard fee.

There has been a strong response to the Call for Papers, which closed on August 31, although the organisers will consider submissions until the program is finalised later this month. The theme is *End-to-End Protection - from API to Patient*. Sessions will cover the role of DRA's and other authorities in ensuring patient protection; information, communication and the role of the patient; the latest in authentication technologies and how to bring all this together for the most effective strategies for 'end-to-end protection.'

Previous Global Forums have been attended by DRAs, health professionals, the pharma industry and patients' groups. New initiatives emerged, and the Forum set the pattern for WHO's IMPACT. Reserve your place now.

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Pharma AntiCounterfeiting News® is the most informative and authoritative source of market intelligence on systems and solutions to deter and prevent the production and distribution of counterfeit drugs and medical devices. Other publications produced by Reconnaissance include: Authentication News, Currency News, Tax Stamp News and Holography News.

The editorial team welcomes your news, contributions and comments.

Contact us at:

2A High Street

Shepperton, TW17 9AW, UK

Tel: +44 (0)1932 269917

Fax: +44 (0)1932 269918

info@reconnaissance-intl.com

PO Box 684

Parker, Colorado, 80134, USA

Fax: +1 303 841 9887

www.pharma-anticounterfeiting.com

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