Pharma AntiCounterfeiting NEWS

the newsletter for pharmaceutical anti-counterfeiting

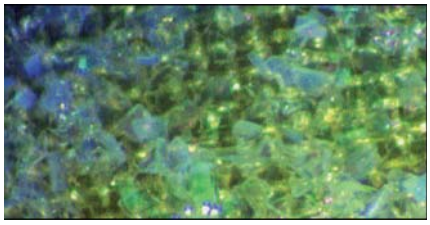
www.pharma-anticounterfeiting.info

ISSN 1756-6290

Issue No 1 - August 2009

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.



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

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.

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

Continued on page 3

INSIDE THIS ISSUE

Editorial: AntiCounterfeiting a Global Need	2
FDA Guidance on Use of In-Dose Identifiers	2
New Security Seal for Endoscope Cases	3
NanoGuardian Partners with SDI for Supply Chain Integrity	4
OpSec Study Identifies Alarming Trends in Pharma Counterfeiting	4
EFPIA Data Matrix Pilot	5
End-To-End Protection – from API to Patient	6

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

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

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.

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

Company News

NanoGuardian Partners with SDI for Supply Chain Integrity

NanoGuardian, the brand protection division of NanoInk that specialises in brand protection solutions for pharmaceuticals based on its proprietary nanolithographic encryption technology, has announced a partnership with SDI, a leader in analytics for the pharmaceutical and healthcare industries, to deliver its *Closed-Loop Protection*™ market monitoring program.

According to the company, Closed-Loop Protection combines the on-dose authentication and tracing benefits of its *NanoEncryption*™ technology with a proactive pharmacy auditing program to identify counterfeit or illegally-diverted pharmaceuticals entering the global supply chain.

NanoEncryption technology incorporates semi-overt, covert, and nano-scale forensic features at the unit dose level. Termed *NanoCodes*™ , these features can be linked to on-package technologies such as radio frequency identification (RFID) and 2-D barcodes for a comprehensive, multi-layered, protective shield that certifies not just the package but the product itself. Whereas, says the company, technologies such as RFID, color shifting dyes, and marking schemes work overtly or at the package level, NanoEncryption is the only technology that provides deeply covert traceability at the unit level.

The NanoCodes themselves can be associated with an unlimited amount of data including, but not limited to, product information (strength, expiration date), manufacturing information (location, data, batch and lot number) and distribution information (country, distributors, wholesalers etc).

Closed-Loop Protection, meanwhile, is a market-monitoring program that works hand-in-hand with NanoEncryption technology to provide manufacturers with an 'early warning system' in the detection of counterfeit and diverted product. Through random audits at retail pharmacies, NanoGuardian's Closed-Loop Protection can proactively detect counterfeit and diverted product providing manufacturers with early detection of problems, says the company.

The partnership with SDI is designed to strengthen this offering. According to Dean Hart, executive VP of NanoGuardian, 'to ensure the success of Closed-Loop Protection it was vital to partner with an organization such as SDI, that has the regulatory experience in conducting proactive market monitoring services and that can manage networks of pharmacies and physicians'.

Contact: www.nanogaurdian.com

OpSec Study Identifies Alarming Trends in Pharma Counterfeiting

OpSec Security has released the findings of a two-year study into pharmaceutical counterfeiting which shows substantial trends of increased illicit behavior by trade board sellers that offer bulk pharmaceuticals and active pharmaceutical ingredients (APIs) to buyers and intermediaries, and internet pharmacies that sell drugs directly to consumers.

The study revealed a 30% rise in the number of listings offering bulk pharmaceuticals and APIs across multiple highly-trafficked B2B trade boards. According to the company, the availability of bulk pharmaceuticals on such trade boards, which are unregulated environments, provides a global sourcing platform for buyers and intermediaries in the pharmaceutical supply chain. None of the pharmaceutical wholesalers mentioned pedigree information, even when offering to ship to the US where the FDA requires pedigree tracking by each entity in the distribution chain.

Suspicious Online Pharmacies

Among internet pharmacies, there has been a 65% increase in those that do not require a prescription or only require an online consultatoin. Furthermore, 33% of those researched exhibited all four signs of 'highly suspicious behavior' indicative of illicit drug sales.

In addition to the above, these signs include pharmacies that mask their WHOIS location and contact details; who are included on the NABP's 'Not Recommended' List and who are registered outside the US, but target US customers.

The study also noted a 300% increase in internet pharmacies offering 60-80% discounts below retail prices from 2007 to 2009. Of the hundreds of unaccredited internet pharmacies researched, the average price of prescription drugs across a representative sampling of top-selling drugs was 78% below the average price on the National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) accredited sites.

Dangerous Promotions

In addition, consumers are often targeted with potentially dangerous promotions offered when buying drugs online. One network of sites, for example, offered free erectile dysfunction pills with any purchase – a promotion which would be especially dangerous for patients taking medications to prevent a heart attack or stroke.

According to Jeffery Unger, OpSec's President of Brand Security: 'the continued rise of these trends reveals increasing risks to consumers who buy drugs and companies that source pharmaceutical products online. Unfortunately, the easy anonymity, lax regulations, and global reach of the Internet allow counterfeit drugs to enter into the legitimate supply chain.'

Contact: www.opsecsecurity.com

World News

Kenya's AntiCounterfeiting Act - Part of a Wider Agenda

The Government and the World Health Organisation (WHO) announced that they have launched a major fight against counterfeit and sub-standard drugs. A part of this is Kenya's new Anticounterfeiting Act. This was passed in December 2008 and is expected to take effect within weeks. It has seriously ruffled Indian feathers due to its possible effect on the supply of generic medicines.

Medical Services Minister Anyang' Nyong'o put brokers and middle men who supply poor quality drugs on notice and said strict rules to curb the vice would be put in place, stating that: 'we need to stop sub-standard and counterfeit medicines, which find their way into our country and compromise our efforts to ensure a healthy nation.'

WHO Country Director David Okello said Kenya must implement a stringent regulatory environment to ensure essential drugs are affordable. 'Supply of sub-standard medicines compromises disease control strategies for killer diseases. This cannot be taken lightly,' Dr Okello said.

Vigilance System

Nyong'o and Okello spoke during the launch of Mission for Essential Drugs and Supplies (Meds), a quality control lab accredited by the WHO. 'The Government is working round the clock to fight this menace and the ministry has come up with guidelines,' said Nyong'o, adding that a national vigilance system for pharmaceuticals has been established.

In a full-page advertisement, the Government denied that counterfeit drugs had found their way into the market. 'We would like to assure the public that the Government has taken adequate precautions and steps to safeguard their health by sensitising, campaigns, sanctions and destruction of impounded counterfeits,' the statement said.

The implementation of the Anti-Counterfeiting Act has been delayed due to institutional changes that need to be made. These primarily deal with the establishment of an anti-counterfeiting agency and all the personnel and rules that implies. However, there have been legislative challenges brewing that may affect the program as well. This month, three HIV/AIDS patients announced they will petition the country's Constitutional Court to declare the new anti-counterfeiting act illegal because it could deny them access to generic medicines. The move, which has the support of public health groups, seeks to have the Act made unconstitutional on the grounds that it could rob them of their right to life.

Medical Services Minister Anyang' Nyong'o commissions the WHO pre-qualified drug quality control laboratory in Nairobi. At left is Joseph Wasonga of ACK and behind the minister, WHO Country Director David Okello. [PHOTO: JONAH ONYANGO/STANDARD]

The issue is of life-and-death importance in Kenya where HIV/AIDS patients can usually only afford generic drugs which are up to 90% cheaper than their brand-name counterparts. The international donors who fund some drug distribution, including the US President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria, rely almost exclusively on generics manufacturers for their supply.

This new Act introduces some new thinking which caused India to call a meeting of ambassadors of all African countries to register strong protest at what it sees as discriminatory action against Indian pharmaceuticals.

At issue is the interpretation that Kenya, Uganda, and now Tanzania have recently come out with, which seek to classify drugs patented anywhere in the world as counterfeits. The briefing paper issued by Health Action International relating to the new Kenyan legislation reminds us that the World Health Organization defines a counterfeit medicine as 'a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.'

According to the WHO a counterfeit medicine is the deliberate or intentional (criminal) nature of the mislabelling of a product.

A generic medicine is an equivalent version of an originator medicine but the way a counterfeit is defined in the Act leaves open the interpretation that a generic product could be deemed a counterfeit product. More particularly, it leaves open the possibility of the big pharmaceutical company patent holders driving generic manufacturers out of business.

Hence the concern of the Indian pharmaceutical companies, which have been instrumental in driving down the price of expensive products such as anti-retrovirals used in AIDS treatments. According to the UNAIDS 2008 report on the global AIDS epidemic, India is now the largest supplier of generic anti-retrovirals to low- and middle-income countries.

Kenya's Financial Express notes that 'since the global pharmaceutical market is likely to see $123-billion worth of products lose patents by 2012, there is good reason to believe that the Kenyan legislation has been influenced by vested interests'.

India exports $8 billion of pharmaceutical products annually, 14% is exported to Africa. Many of these are generics, and so it is inevitable that this new legislation will be closely scrutinized from a legal standpoint.

Events

End-To-End Protection – from API to Patient

The 5th Global Forum on Pharmaceutical AntiCounterfeiting will take place in Miami, Florida, from February 24-26, 2010. Event organisers Reconnaissance International have issued a call for papers on the theme of *End-to-End Protection: from API to Patient.*

Since 2002 the Global Forum has successfully brought together the most eclectic mix of stakeholders – from pharmaceutical companies, drug regulators, health professionals, patients groups and authentication provider – to stimulate wide-ranging discussion on the best way to combat counterfeit medicines and medical products. Previous Forums have led to new ideas, new collaborations, and numerous new projects on a global, national or company level.

The 5th Global Forum will continue this record by ensuring that discussion covers the whole gamut of how best to combat fakes, from the active pharmaceutical ingredients (APIs) to the patient. Key issues on which papers are invited include:

- Most effective balance between overt authentication techniques and covert techniques
- Roles of experts and patients
- Role of pharmacists
- Telecoms verification systems with reference to network coverage and vulnerabilities
- Tracking and authentication
- Communication and education regarding fake medicines
- Developed and developing world requirements and differences
- Role of government agencies, commercial organisations and healthcare professionals, and whether these matters are best dealt with on a global, regional or national basis.

Papers will be included from policy and law makers, drug regulators and other enforcement agencies, the pharmaceutical industry, healthcare professionals and their representative organisations, technology suppliers and patients' groups. Representatives from all of these organisations, and any others with an interest in this topic, are invited to submit a 150-200 word abstract and brief information about the author/s and their affiliation/s to Reconnaissance by August 31.

With the issue of the call for papers, sponsorship and exhibitor opportunities are open for reservation. By attracting senior anti-counterfeiting personnel from pharmaceutical companies, industry representatives and drug regulators, the Global Forum has proven to be a successful route for recognition by sponsors and exhibitors. First sponsorships have already been reserved. Sponsorships have been over-subscribed previously, so contact Alan Walp (Americas) or Ian Lancaster (elsewhere) at Reconnaissance to discuss your sponsorship interest, or to reserve an exhibitor booth.

www.pharma-anticounterfeiting.com

The New Newsletter for Pharma AntiCounterfeiting

Welcome to the latest issue of Pharma AntiCounterfeiting News™, a spin-off from the monthly international business newsletter Authentication News. Now relaunched in a new format and available to all with an interest in combating the scourge of fake pharmaceuticals and medical devices.

Authentication News is a source of comprehensive news and analysis on strategies and technologies for preventing or identifying counterfeiting and diversion, with a regular focus on pharmaceuticals. But, as organisers of the Global Forum on Pharmaceutical AntiCounterfeiting as well as publishers of Authentication News, we feel that the scope, range and pace of development and progress in the pharma sector – be this from governments, regulators, manufacturers or suppliers - warrants its own specific coverage.

Pharma AntiCounterfeiting News will be published monthly in electronic format and is available as a free download from our website. It will monitor, report on and analyse the key issues and developments that are shaping the solutions to pharma counterfeiting, many of which also form the core of the programme for the Global Forum.

Please feel free to send us your views and comments, as well as your news. In addition, those companies supplying solutions and services for pharma anti-counterfeiting can stake their claim in this sector by sponsoring Pharma AntiCounterfeiting News.

For details of sponsorship, editorial content and opportunities or to ensure that you are on our mailing list to receive notification of future issues, please contact us at:
www.pharma-anticounterfeiting.

RECONNAISSANCE international
PUBLISHERS AND CONSULTANTS

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