Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

October 30, 2003

Food and Drug Administration, HHS - Anti Counterfeiting Drug Initiative
Comments to Task Force's Interim Report (Docket No. 2003N – 0361)

Dear Sirs,

We applaud the FDA's initiative to develop an effective strategy for counterfeit drug protection and appreciate the opportunity to provide our input into the process.

In response to the task force's Interim Report published on October 2, 2003, we are pleased to present our comments herewith. In preparing our response, we have relied on our core competency in authentication technologies: InkSure specializes in comprehensive solutions that are designed to protect products and documents of value from counterfeiting, fraud, and diversion. Employing a team of technology experts with an extensive experience working in government security laboratories, we understand security and maintain a successful track record of system implementations. While we develop machine-readable covert systems, we have also accumulated experience with overt features as well as multi-tiered solutions, the result of which we are happy to share with you.

Specific comments to questions raised in the Interim Report are set forth beginning on page 4 of this submission. We are also including a brief description of our machine-readable, Field Forensic encoded ink technology. While we utilize both organic and inorganic markers, depending upon the application, our solutions provide features and benefits which are not ordinarily associated with "taggant" technologies (as categorized in the Interim Report), such as multiple code authentication with a single reader and production-speed, mass quantity verification. Below you would find a

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summary of our position with regards to the issue of anti-counterfeit technologies raised in the report:

The October Interim Report properly categorized Overt and Covert counterfeit detection system. With Overt solutions the pharmaceutical industry has the ability to develop a broad consumer/patient and health care official training campaign to look for easily recognizable security features. However, most of the overt solutions in use today can be duplicated by counterfeiters to levels sufficient to dupe the average individual. For that reason, a second covert feature must be added to all overt solutions to increase their overall security and improve their effectiveness.

In addition to covertly protected overt features, the FDA panel should strongly urge pharmaceutical companies to adopt a second covert feature separate from the overt one. The second selected technology should remain confidential to the pharmaceutical company and select law enforcement agencies. The second, separate covert feature will allow the package to be authenticated even in the event of a counterfeiter collecting used packaging and reusing the overt feature on counterfeit packages.

In addition, tamper evident seals must be used in all dosage forms to prevent repackaging or tampering. However, tamper evident seals and tamper evident closures must include at least one overt/covert feature for all the reasons stated above.

Covert features must be 100% machine-readable, which means that the detection device performs complete item analysis and returns a positive or negative response. The device should not require the operator to interpret the response through visual analysis of a pattern or change of color. It should also not require any type of database to operate, but be used as a stand-alone tool; otherwise the strength of the technology and its practical use will rely on the frequency and quality of updating the database and the ability to connect or download data in remote areas.

Detection devices with positive responses that do not require any field training carry the additional advantage of portability. This way, when a counterfeiting problem occurs in a

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particular market or region, additional readers can be easily deployed to local law enforcement officials for specific tasks without complex set up of infrastructure.

Finally, when choosing a covert feature we recommend that field detection technology would provide conclusive results that are as close to forensic level as possible: the strength of the barrier to counterfeiters depends on the strength of detection equipment in the field.

We believe that this information would contribute to the FDA's evaluation process. We hope you find this information useful and encourage you to contact us for any further questions

Sincerely,

Dana Kaplan
VP Marketing and Business Development
InkSure Technologies Inc

32 Broadway, Suite 1314
NYC, NY 10004
Tel: (212) 269-0370
Fax: (212) 269-0371
Email: dana@inksure.com

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1. Specific comments to questions raised in the FDA's Interim Report:

Section IV. A – Questions Concerning Technology (Options 1-9)

The following responses refer only to those questions that are relevant to our field of expertise:

- Q#1: "Discuss the advantages and disadvantages of unit of use packaging":
    - o Assuming that the requirement for unit of use packaging would eliminate 3rd party re-packagers, overall number of parties with potential access to security features for packaging and labeling would be reduced and by that enable Pharma manufacturers to tighten control over the anti-counterfeit technologies that are implemented onto their products.
    - o Unit of use would also ensure higher security for the products themselves, as each single dosage is protected when moving from manufacturer to end-user, leaving fewer opportunities for counterfeit products to enter the supply chain.

- Q#3: "Discuss the advantages and disadvantages of using tamper evident packaging on drug products. Please provide any information on the economic impact of requiring tamper evident packaging features on these products":
    - o While the use of tamper evident seals increases drug protection, it is not, by itself, a sufficient safeguard as it can be imitated, as mentioned in the report, and therefore requires an additional security layer or "safeguard" which is a covert, machine-readable feature incorporated directly into the seal and immediately identifies it, and consequently the product, as genuine.
    - o Machine-readable taggants incorporated into tamper evident packaging enable such covert, Field Forensic protection while adding only tenths of a cent to the cost of the tamper evident feature.

- Q#5: "What, if any, minimum number of anti-counterfeiting technologies should be utilized on packaging and labeling? Should technologies be utilized on all dosage forms and products or just dosage forms and products at high risk of being counterfeited?":
    - o Effective anti-counterfeit protection should consist of at least 2 features – one overt with a covert machine-readable back-up element layered within it and the second

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covert/forensic feature that is known only to the manufacturer and the FDA.

- o Initial focus should be on the broadest category of risk drugs. If an anti-counterfeit campaign is initiated on a narrow range of products, counterfeiters will quickly shift to those products that are unprotected. As the shift occurs, industry will lose confidence in the war on counterfeiters. We believe that it is better to start with a broad approach and force counterfeiters to shift out of the pharmaceutical industry altogether.

- Q#6: "Should any specific anti-counterfeiting technologies be utilized? Should overt technologies always be utilized? Should covert technologies always be utilized?":
  - o Any anti-counterfeiting campaign should involve the consumer as an authenticating agent and therefore overt features are recommended. Relying only on those features however, might create a false sense of security without a mechanism in place to safeguard overt features from simulation. We therefore recommend that both overt and covert features be always used.
  - o Machine-readable taggants provide the most conclusive and quick differentiation between genuine and counterfeits and reduce the time and costs associated with processing suspect products. This technology is best characterized as Field Forensics: covert features that provide both on-the-spot and conclusive identification.

- Q#7: "Should some anti-counterfeit technologies only be identifiable by the manufacturer and/or the FDA?":
  - o We strongly recommend the implementation of covert machine-readable technologies that are only identifiable by the manufacturer, the manufacturers packaging vendors and/or the FDA, in order to maintain the highest security barrier for counterfeiters and enable quick and scientific authentication when other features are inconclusive.

- Q#8: "On what dosage forms and products should taggants, other markers, or unique characteristics be utilized? All dosage forms and products? High-risk dosage forms and products?"
  - o As mentioned in our response to question number 6, machine-readable taggants cover both covert and Field Forensic levels and therefore any dosage or product that carries them – and we recommend that the broadest range of risk drugs be protected – essentially gains double coverage. This is especially important when considering

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the high benefits of the technology and ease of application, compared to its low cost.

- Q#9: "What role should the FDA play in reviewing the use of anti-counterfeiting technologies incorporated into the packaging and labeling?":
  - o We recommend that the FDA issue broad recommendations with regards to technology levels to be incorporated on all products.
  - o In addition, we believe the FDA should set up requirements for technology levels to be implemented on high-risk products and dosage forms.

- Q#10: "How should "validation" of an anti-counterfeiting measure be determined? Should only "validated" anti-counterfeiting measures be used? Who should do the validation?":
  - o Since they are currently no available standards to "validate" anti-counterfeiting measures, the industry should be responsible for choosing the best technologies that fit their needs, knowing that manufacturers face liability issues if the measures they chose are inadequate.

- Q#12: "Discuss the advantages and disadvantages and the role of track and trace technologies, in particular bar codes and RFID":
  - o Barcodes:
    - At the moment barcodes are not secure and are easily copied or manipulated.
    - Barcodes can be secured through use of machine-readable taggants, which are incorporated within the barcode itself.

- Q#15: "Are there additional benefits beyond the ability to detect counterfeit products that anti-counterfeiting technologies can provide for the industry?":
  - o Machine-readable taggants enable more efficient and cost effective processing in return centers, by enabling the immediate separation of genuine and fake drugs. This efficiency is increased even more with the use of a high-speed OEM authentication unit integrated into inspection systems.

- Q#18: "Should all products be considered at high risk of being counterfeited? How can products at high risk of being counterfeited be identified?":
  - o These are the criteria we believe should be considered when determining high risk products (in descending order of importance):

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- Wholesale and retail prices of products
- Type of products/dosage forms and ease of counterfeiting (e.g. clear solutions)
- Sales volume, on unit and dollar basis
- Current and potential misuse of the product, e.g. "street value"
- Length of remaining patent life for the product
- Other products in same class with counterfeit history (counterfeit shift)

- Q#19: "Discuss what could be included in an FDA guidance on the use of anti-counterfeiting technologies":
  - Location, number and type of security feature (on labels and various packaging levels)
  - Location (within the supply chain) of security feature application
  - Check points for authenticity (e.g. guidelines for Customs for checks in points of entry; who should conduct checks in the marketplace, where and how)
  - Reporting guidelines
  - Time frame for implementation

- Q#20: Should FDA conduct research on development or evaluation of anti-counterfeit technologies?":
  - No. We believe that the market will naturally pursue the development and evaluation of the best technologies necessary to meet the broad guidelines required by the FDA.

- Q#21: "Discuss what could be included in an FDA guidance on physical site security and supply chain integrity":
  - "Electronic Pedigree": until such tool is fully developed and operational, an interim solution to guarantee the integrity of the Statement of Origin is best addressed by the use of machine-readable taggants to protect the paper document from counterfeiting and alteration.

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2. Additional Information on Machine-readable Authentication for Pharma Products - Field Forensics by InkSure

InkSure Technologies' machine-readable product marking solutions are designed to provide **"Smart Protection"**, by which new applications for in-print or coating taggants (covert chemical markers) provide not only yes/no authentication, but also tools that assist in effectively managing product integrity in a complex environment.

InkSure's authentication solutions are based on product marking using machine-readable covert codes (**SmartInk™**), which are created by mixing special chemical markers (taggants) into commercial inks, coatings and other media, and applying them, using standard printing processes, onto product packaging, labels and documents. **SmartInk** codes are verified only by InkSure's range of readers by utilizing advanced algorithms and unique electro-optical techniques to enable the following tasks:

- **Manufacturer Exclusive Codes:** InkSure's suite of handheld, stationary and application-specific readers employ multiple and configurable illuminators and receptors which work throughout the UV, visible and IR spectrums, providing InkSure with the largest variety of special electro-optic materials for incorporation into its SmartInk solutions. This enables InkSure to create an endless supply of custom chemistries – or codes – for its customers.

- **Multiple Code Authentication:** InkSure's SignaSure™ handheld readers can store up to ten unique codes, allowing manufacturers the ability to identify multiple, distinct covert signatures with a single reader. With multiple code authentication, products can utilize different secured codes based upon the respective manufacturing sites, distribution centers or markets associated with such products.

- **High Speed/mass volume verification:** a revolutionary innovation in applied security that allows code reading at speeds of up to 33 feet/sec with definitive pass or reject indications within 18

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32 Broadway, Suite 1314
New York NY 10014
Tel: (212) 269 0370
Fax: (212) 269 0371
Toll-Free: (888) 437 0888

milliseconds. Such abilities facilitate the following improvements in security applications:

- o In-line quality check for printing presses, enabling monitoring of code application quality during production and offering code performance guarantees
- o Return center and distribution center verification, confirming authenticity of returned goods

In pharmaceutical products, SmartInk covert codes are placed within pre-defined areas within the packaging or label during standard production. InkSure also enables cost efficient multi-tiered protection by adding covert signature codes to overt features. SmartInk codes allow the encoding of various overt elements, making **color-shifting inks, holograms** and **tamper proof seals** machine-readable and offering an all-in-one, easily customized security feature that applies to various audiences in a cost effective manner – without presenting hidden costs in the form of implementation via multiple and separate processes for each additional element.

Highlights:

1. *Field Forensics*[TM]: Extremely high security, conclusive result within one second adapted to field use with on-the-spot results.
2. Simplicity of application – all printers can apply InkSure's SmartInk on any product packaging using any common printing methods
3. Simplicity of operation of hand held battery readers - no need for specially trained field personnel
4. Cost effectiveness and easy integration into production
5. Flexibility to support variety of clients with various characteristics; Customized to meet existing operation environment
6. Custom chemistry codes enabling pharmaceutical companies to maintain high security with unique chemistries. Unlike other ink-based solutions, InkSure can create hundreds of unique codes for customer specific applications thereby enabling the highest chain of custody level of security
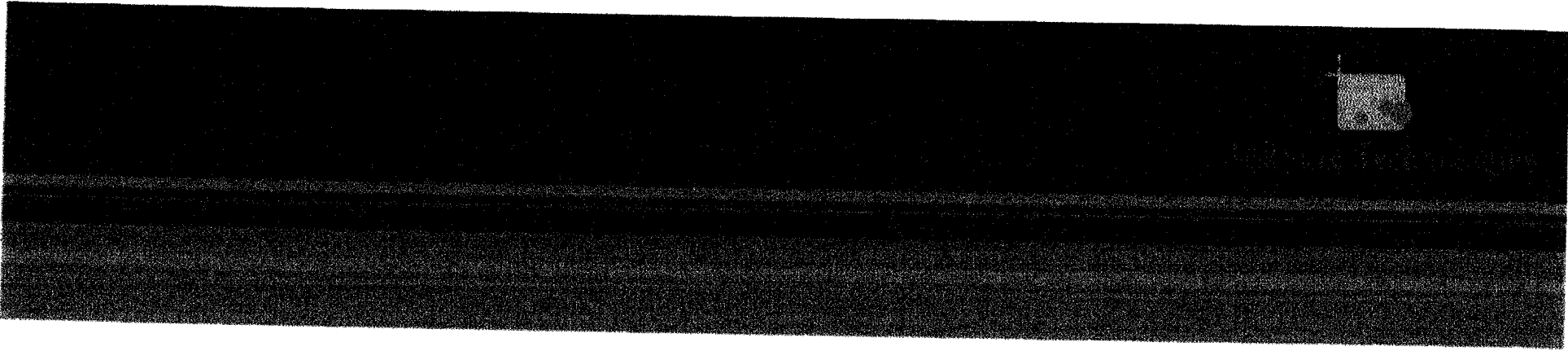7. Highly flexible, fully scalable system – evolving technology

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8. Easily upgraded or expended to support a "phase-in" approach

9. Innovative integration with common overt security products such as Holograms

10. Custom chemistry codes to offer a simple first level track-and-trace solution

11. High reliability and easy servicing

3. Additional Information:

Please refer to the enclosed PowerPoint presentation, for additional details about InkSure's technology and solutions for pharmaceutical products.

Machine-Readable Authentication - Field Forensic Solutions by InkSure

Helping companies and organizations worldwide regain
control over their most valuable assets:
Their products. Their reputation. Their revenues

October 2003

InkSure Technologies

- Provider of machine readable security solutions to protect branded products and documents of value from counterfeiting, fraud and diversion

- Utilizes cross-disciplinary technological innovations to create seamless, easily administered solutions for data and asset integrity

- Proven track record of implementing successful systems

- Winner of the 2000 Product & Image Security Award for outstanding achievement in product and document authentication

- U.S. corporation (OTCBB: INKS), operating in North and South America, Europe and Asia

Technology Introduction

InkSure provides covert, machine readable authentication solutions based on cutting edge technology:

- SmartInk™:chemical marking of inks and coatings with electro - optical detection

- Each item is invisibly marked with SmartInk during standard production, using standard ink/coatings as carriers

- SmartInk: An InkSure code embedded within the carrier ink, creating a unique, fingerprint signature

- InkSure's range of proprietary readers are used to conclusively authenticate products by detecting electro-optical material behavior and providing a pass/reject indication in less than one second

SmartInk Codes

- Special molecular sized "taggants" (markers) are mixed with carrier (ink, varnish, resin) and incorporated into existing printing process, either analog or digital
  - o Any printer can apply
  - o Secure SmartInk distribution
- The code is resistant to copying, alteration or tampering
- The code is customer/application exclusive
- The coded ink is visually identical to the standard ink and maintains original performance characteristics
- The code can be applied to any color, including black and clear overcoat
- Latest field-proven applications – Clear Tear Tape and Black InkJet

SmartInk Covert Applications

- Standard mark size: 1sq. cm.
- Printing – background, uniform layout design
  - o Offset, Flexo, Litho, Gravure, Silk Screen,
- Printing – variable details, barcodes
  - o Inkjet, Thermal Transfer
- Coating and lamination
- Labels
- Seals
- Foils
- Packaging (primary/secondary – blister packs, vials)
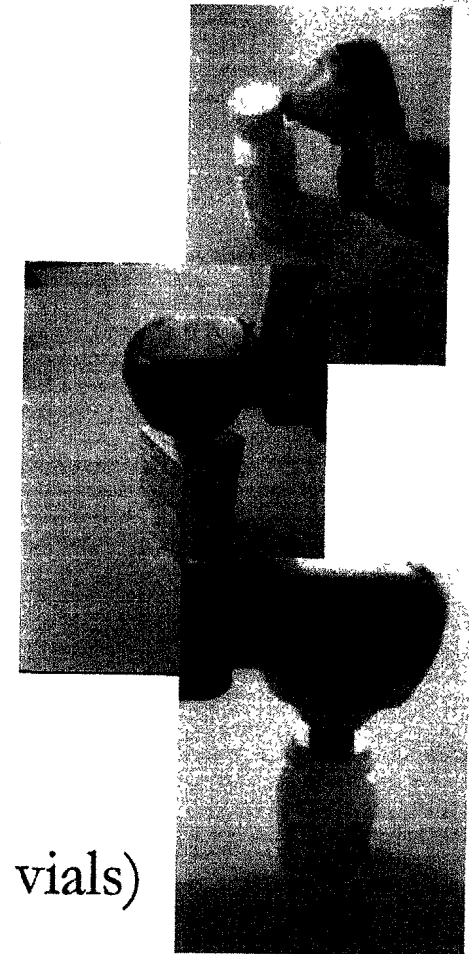
Multi-Layered Solutions – Code Overlay

Taggants and codes are combined with overt and other features to enable multi layered security:

- Holograms
- Color shifting inks
- Intaglio
- UV
- IR

Reader Technology

- Detection concept is based on electro optical measuring of various spectral phenomena and using complex mathematical algorithms for comparison modeling and QA applications

- Scalable and flexible to allow post-integration system upgrades

- Offering added value through enhanced reader functionality, including –

    o multiple code authentication

    o sequential code identification

    o in-production, high-speed verification

- PC data collection or data storage for offline downloads

- Multiple configurations: handheld, fixed enclosures and OEM kits

SignaSure Readers

- Simple & intuitive user interface; light weight, ergonomic design

- Pass/reject indication in less than a second

- Audible and visual confirmation/alert

- Detects all InkSure codes:
    - Custom or general
    - Invisible, IR or UV visible and combinations
    - Codes incorporated into overt for multi-layered security

- Stores up to 10 different codes

- Adaptable platform for easy code update

- Rechargeable Batteries; USB Connectivity
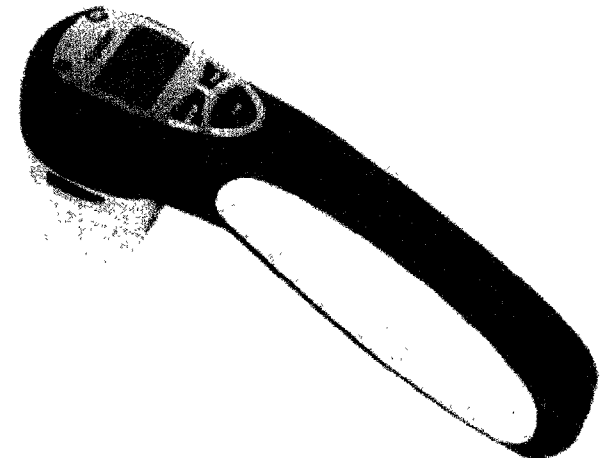
SignaSure Readers (Cont')

- Multiple light Sources and receptors

- Multi-Peak to Full Curve Analysis

  - Wavelength measured at up to 30 points on curve

- Absorption and/or decay time also measured

- Compensates for different background colors

- Self-learning algorithms distinguish printing variations and fraudulent simulations

- Creates endless supply of codes from large variety of taggants

SortSure Readers

- High speed/mass volume applications

- OEM kits, embedded in backroom processing units, distribution/return centers and printing presses

- Provides inline quality assurance and audit functions

- Reading speed of 400 inches/sec, with pass/reject indication within 12 milliseconds

SortSure™
Sorting & Authentication

SortSure Readers (Cont')

Features:

- Serial connectivity or parallel signaling
- Output to PC for quality data collection
- 18 Discrete Input/ Output communication ports, including visual or audible alerts
- Fiber optics allows remote optics and electronics for ease of installation
- Available in various standard and customized configurations

SortSure™
Sorting & Authentication
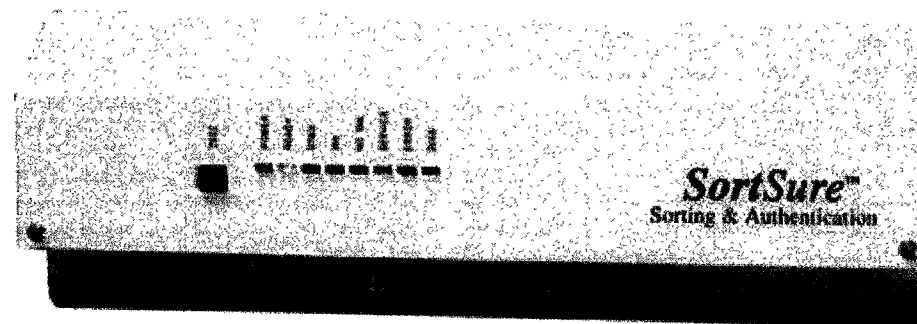
Key Installations

Public Busses

- Istanbul Greater Municipalities Public Transportation Co. (IETT) – one of the world's largest public transportation companies

- 2,600 buses – 130 million single ride paper tickets used annually

- Client estimated 10 to 15% counterfeit tickets

- Client required machine readable ticket enforcement and seamless patron acceptance of new ticketing technology
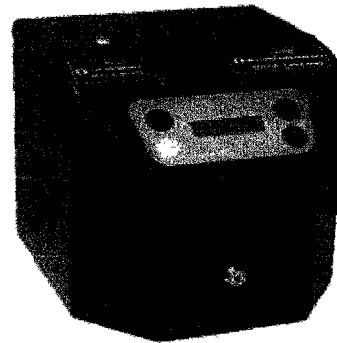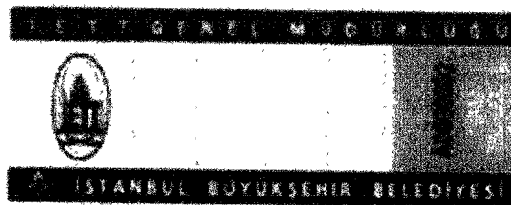
Public Busses – Cont.

- Smart-Ink system in use since January 2002

- InkSure ticketing solution in an on-bus reader that:

  o Authenticates single ride tickets while distinguishing between various fares

  o captures ticket after use

  o collects and downloads transaction data

  o uploads new codes for fare changes

- Sequential coding enabled multiple fare sets

- Client reports payback of under one year based on revenue increase from fraud reduction
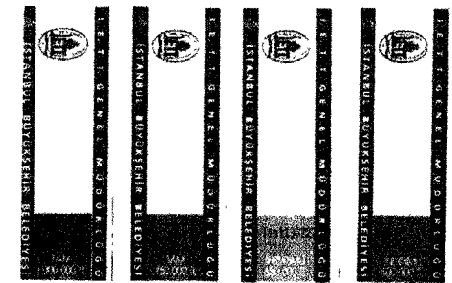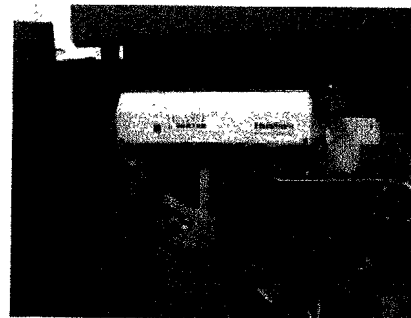
Different Fare Values
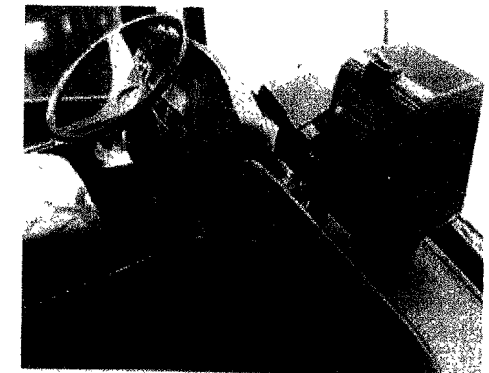
Check Sorters

- QwinSure authentication system for check sorters

- 50 check interrogations per second

- Successful Alpha test on IBM 3890 at QwinStar, MN
  - Provider of maintenance and refurbishing services for bank check-sorting systems

- Bank checks printed with SmartInk at Northstar, MN
  - Leader in bank forms and security documents
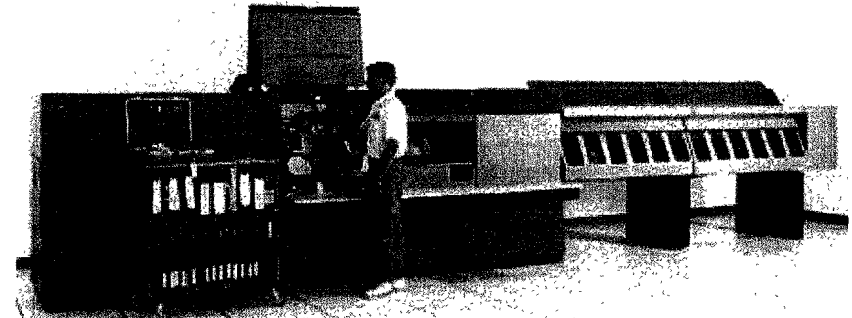
Sporting Events

- SmartInk technology is incorporated into tickets of a Big Ten football team

- All tickets for 2003 season games are covertly marked with an exclusive code

- Ticket authenticity verified with SignaSure handheld readers used by staff at points of entry and inside venues

- Project roll-out: August 2003

Wireless Equipment

- September 2003 - HoloSure™ machine-readable hologram technology selected by TTK, the Turkish Telecommunications Authority, to provide multi-layered security to wireless equipment imported into Turkey

- TTK purchases machine-readable holograms marked with SmartInk and requires that all imported equipment carry them

- TTK inspectors use InkSure's hand held readers during random checks in distribution and retail locations to positively identify illegally imported components

Security Approach

Various elements of the codes are kept under extreme security:

- Secure sources of taggant supply; production by InkSure specifications

- Proprietary algorithms determine customer exclusive codes

- Signals analyzed by the reader correlate with taggant behavior as determined by InkSure for a specific printed media

- Sequential coding: another layer of security is added by linking the code to predetermined sequences of marks and creating a security barcode

Security Approach – Cont.

- Close management of SmartInk delivery and consumption
- Reader protection from reverse engineering and tampering

- Technological flexibility enables quick introduction of changes to the system after it has already been implemented by remote change of codes in the readers or modification of the readers

InkSure Offering

- Supply customer exclusive and unique code

- Support in security design with regards to SmartInk code

- Delivery of ready-to-use SmartInk to the printing site

- Monitoring of the security code printing procedures; installing a QA/QC system at the code printing site

- Delivery of pre-programmed readers

- Post implementation servicing for system components

The SunSure™ Strategic Alliance

- In June 2003, InkSure has teamed up with Sun Chemical, a leading global ink manufacturer, in a joint marketing alliance under the trade name SunSure

- Sun Chemical has chosen SmartInk technology to support its customers' needs for effective anti-counterfeit measures

- SunSure™ tailored solutions harness Sun Chemical's high quality products, global distribution and support capabilities, together with the flexibility and affordability of InkSure's proprietary authentication technologies, to provide powerful security tools for users

SunSure™ is a trademark of Sun Chemical Corporation

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Summary

InkSure Security Systems offer the following benefits:

- Extremely high security, conclusive protection – Field Forensics

- User friendly - no need for specially trained field personnel

- Cost effectiveness and easy integration into production

- Flexibility to support variety of clients with various characteristics

    o Customized to meet existing operation environment

- Highly flexible, fully scalable system – evolving technology

    o Easily upgraded or expended to support a "phase-in" approach

- High reliability

- Easy servicing