kezzler

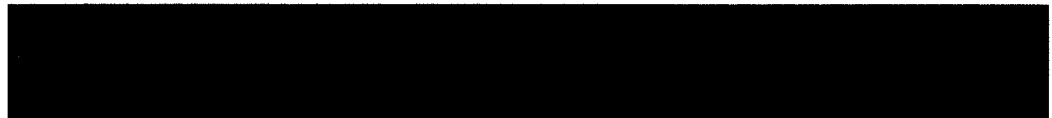**MAKING EVERY SINGLE PRODUCT ITEM UNIQUE, SAFE AND INFORMATIVE**

November 2, 2003

Introduction

In the FDA Counterfeit Drug Task Force Interim Report publicized on in October, 2003 the FDA presented a list of anti-counterfeit technologies that potentially might be used for protecting drugs in the USA.

After having studied this list Kezzler wants to contribute to the FDA project by pointing out that *"numbering technologies"* has not been mentioned and discussed. Kezzler believes that numbering technologies have many of the capabilities that FDA and the industry have been searching for in this project, and that they should be mentioned and explained in the final report that is going to be issued in January 2004.

Kezzlercoding

Kezzlercoding is a numbering technology that uniquely marks and identifies every single drug unit. A major part of this numbering system is a computer software that manages the use and checking of the codes.

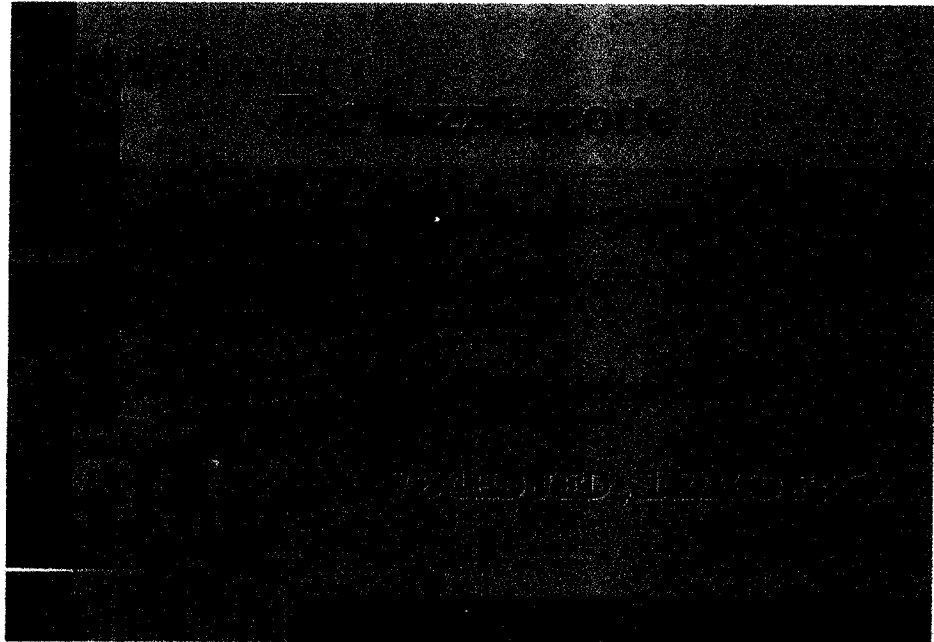The kezzlercode has the following technical characteristics:

- Every single code is unique and non-recurring (and hence the product itself)
- The codes are random
- Scaleable to billions and billions of codes
- No database storage of generated/authenticated codes (self-contained)
- Secure
- User friendly product business logic for both brand owner and product consumers

Basic product features

The system "fingerprints" every single suitable pharmaceutical unit such as drug vial, blister pack, packaging, bottle or individual pill. This is achieved by marking every single unit as mentioned above with a 16 character long alpha numeric. Every such identification number is unique, non re-occurring and randomized, making it possible to both authenticate and track-and-trace drug products. One of the prominent technical characteristics with kezzlercoding is the capability to mark billions and billions of product items without effort due to the fact that kezzlercoding does not store any of the generated/authenticated codes.

The control and daily management of the products

The kezzlercoding system is software based, providing the involved parties with *product business logic* that helps control and inform about the product during market circulation. For instance product recalls and expiry dates are automatically managed on batch level only using the software.

Authentication of pharmaceutical products/units

To authenticate a drug item the user reads and keys1 in the code on a designated web page and the code will instantly be either be validated or rejected as being genuine.

If the drug is accepted any information for the particular batch, LOT or similar in question is automatically displayed, such as user prescriptions, product alerts, product recalls, expiry dates, intended market, guidelines, consumer information, etc.

Tracking pharmaceutical products in the supply chain

"Logical points", (manufacturer, wholesaler, repacker, pharmacy, hospital, retailer, transport company, customs or government agency) will track product units by resolving a tracking kezzlercode via the Internet, most practically using Web Services and similar techniques for larger environments.

Controlling the product information displayed in the supply chain

Kezzlercoding is a computer based authentication/track-and-trace system enabling the pharmaceutical manufacturers to grade and distribute different levels of information made available to various groups of users. Typically the group of users are divided into public end users (if appropriate) and further covering group levels such as hospitals, doctors, pharmacies and at the top level government agencies.

Key capabilities requested by the FDA in the project

- The use of **cost effective technologies** to authenticate and track drugs, to deter and detect counterfeit drugs
- exercise of a **high level of diligence by purchasers** to ensure that drug products are authentic
- a regulatory scheme that **minimizes the burden** placed on each participant in the system
- well **informed** stakeholders and consumers

Cost of adopting Kezzler's technology

- Low cost purchase of the service (technology) (Price ranges from 4 to1 USD per 1000 codes)
- No need of associated equipment such as barcode scanners/RFID receivers or access to electronic databases
- Easy to integrate the technology into the manufacturing process
- Low cost of implementing infrastructure as it is Internet being used for the Kezzler system
- Easy to use and minimum burden on the consumers especially

Benefits of adopting Kezzler's technology in addition to preventing counterfeits

- Instant authentication and critical updated information for every single unique drug unit
- Rapid alert system
- Detection and reduction in the amount of diverted products
- Effective tool for issuing product recalls
- Do not need to consider new anti-counterfeiting measures as old ones are defeated.
- Consumers or other end users (doctors/pharmacies can easily identify the authenticity of a drug). Different user group will access different information.
- Electronic Pedigree paper can immediately be easily implemented at every level, case, pallet and package (no need for a phased in approach)
- The technology and solution is on the market now and it may be implemented by the pharmaceuticals normally within 2-3 months (after signing contract, training personnel, informing the involved parties, etc

Government control and surveillance

One of the most intriguing capabilities for the system offered by Kezzler is the fact that government agencies such as the FDA and US Customs can check any single product item (for batch and other info) without the need to get assistance from the manufacturer. This is very useful and powerful for detecting both counterfeits and diversion.
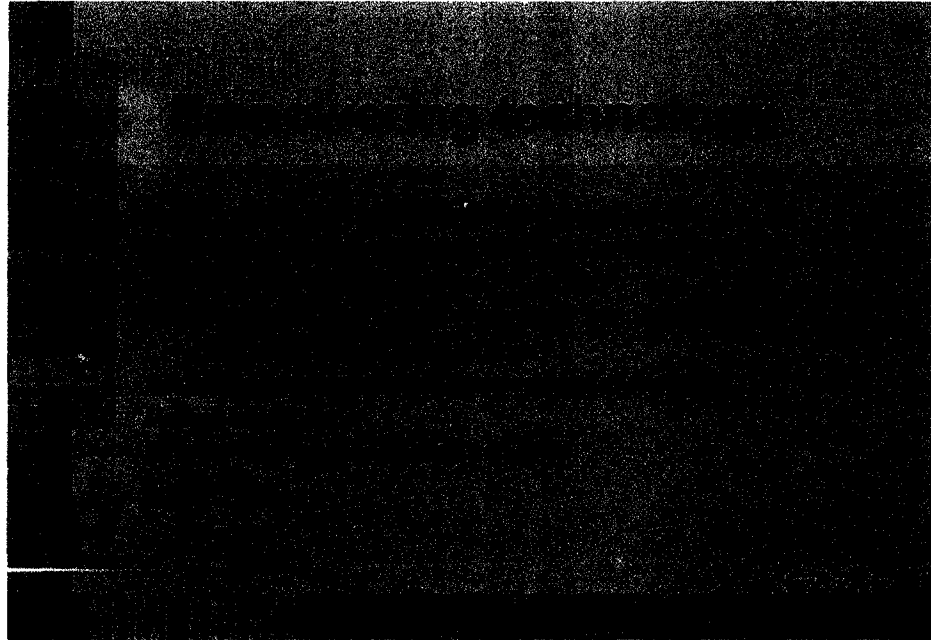
Documents

For the sake of clarity we have attached two documents for further information about the Kezzlercoding numbering technology.

Kezzlercoding – technology, areas of applications and capabilities

Intentor recorded demonstration

The recorded demonstration gives a feel for how the system is operated and the general concept of the software for generating, authenticating and managing the codes. Please note that the demo mostly depicts the work by professional pharmaceutical company, as the consumer only has to verify the product by simply keying the codes into a web page.

Kezzler's request for participating on Public Meeting in Bethesda, Maryland on October 15, 2003

1.
The greatest advantage with using unit packaging is that this makes it easier to apply anti-counterfeit technologies and security to the drug product. If the packaging for the drug is consistent and not changed after production and shipping it is possible to pass crucial information about the drug to relevant parties when necessary at any time. Unit packaging makes it possible to record and manage data and crucial information about the drug since it can be traced back as part of a batch/shipment.

3. Tamper evident packaging is a very effective way to protect both the content integrity and the authenticity of a drug. Tamper evident technologies are very useful for enhancing the security capabilities provided by online Product Authentication (oPA) and Track-and-Trace (TaT) systems.

5. An optimum number of solutions seem to be at least three. Combined these should cover these three basic security aspects:

- Tamper evidence
- Unambiguous product authentication
- Product traceability, documentation and information about the affected drug

Kezzler believes it is important to use anti-counterfeit measures on all individual drug units for all available drugs. Reasons for this approach:

Security consistent and predictable within the industry
All-for-one approach economically sound
The user accustomed to checking drugs will be frustrated trying to authenticate a drug being unaware of that it might not protected at all.
The lack of or inconsistency of anti-counterfeiting measures on a drug unit hence may even lead to wrong conclusions and confusion by the user.

6.
There should at least always be one overt technology. This ensures rapid and uncomplicated authentication. Normally these are available to all users and makes it easier to check the highest possible number of drug products. Secondly there should possibly be a covert technology that supports the initial conclusions and findings by the overt solution. The covert technology makes it easy to check suspected products with even higher reliability and scrutiny when needed.

7.
No, but there are technologies such as delivered by Kezzler that targets and protects that targeted information is accessible only to the indented receiver group, typically consumer, manufacturer, doctors, pharmacies, governments, etc.

8. See comment for A1.

10.

The manufacturers and the industry itself must take this decision as they are expected to have the experience and knowledge to determine different technologies practical applicability and efficiency for different given conditions.

12.

Kezzler would like to comment that barcodes and RFID are not track-and-trace technologies! They are merely data carriers, and only constitute a fraction of what is considered to be a complete and working track-and-trace system. A track-and-trace system most of all is the computer system managing vital information about the product to prevent counterfeit and diversion, product information and supply chain analysis.

Advantages:

The consumer can authenticate the drug product without effort and without any special knowledge and tools. This makes the public more aware of their safety and they are contributing to uphold it.

Governments can access information about any drug and drug individual drug unit that is in the market at any time without having to consult any other party (such as the manufacturer)

Crucial updated targeted information about the drug on an individual basis or batch basis might be given concerning recalls, prescriptions, warnings, intended market, ect.

Another distinqtive advantage with oPA and TaT is the fact that is works independent of the structure of the supply chain, hence there is no need to change the supply chain to solve this particular problem.

Disadvantages:

Using RFID as a data carrier is very expensive and complex, systems are immature and it will definitely leave out the consumer and a large portion of the supply chain.

13.

The cost of the for instance Kezzler system is very low for both the manufacturers, governments, distributors and consumers since the only needed infrastructure is Internet or phone access.

14.

Kezzler is of the opinion that these data is the property of the manufacturer (brand owner) and is created under their supervision and legal control. It must also be the manufacturers responsibility that their system is safe and secure at all times. The manufacturer determines the access to the data.

15.See A12.

18.

Yes. The counterfeiter will only move to the next easy target and therefore drug security must be based on the security principle that counterfeiting attacks are expected, taking a pro-active approach instead of a re-active approach with safety.

kezzler

16.09.2003

Food and Drug Administration
Office of Policy (HF-11)
5600 Fishers Lane
Rockville, MD 20857
The United States of America

Attn.: Karen Strambler   (kstrambler@oc.fda.gov)

Concerning Docket No. 2003N-0361

Anti-Counterfeit Drug Initiative; Public Meeting

Kezzler is hereby requesting to display and educate about our product as invited by the above docket invitation.

Presenter's name:	Kezzler AS
Address:	Kezzler AS Box 2311 Solli N-0201 Oslo, Norway
Telephone:	+47 928 33 445
Email:	mal@kezzler.com
Affiliation:	International Chamber of Commerce – Counterfeiting Intelligence Bureau (ICC-CIB)
Product(s) for display:	Kezzlercoding Product Authentication Kezzlercoding Track-and-Trace

Brief summary of how the anti-counterfeit technology meets the criteria listed in the previous list items:

The products delivered by Kezzler are in production and commercial use in the pharmaceutical industry. The products are especially suited and designed to be applied to pharmaceutical products. Easy to implement, secure and low cost.

Basic product features

The two displayed products "fingerprint" every single suitable pharmaceutical unit such as drug vial, blister pack, packaging, bottle or individual pill. This is achieved by marking every single unit as mentioned above with a 16 character long alpha numeric. Every such identification number is unique, non-reoccurring and randomised, making it possible to both authenticate and track-and-trace drug products.

One of the prominent technical characteristics with kezzlercoding is the capability to mark billions and billions of product items without effort due to the fact that kezzlercoding does not store any of the generated/authenticated codes. For every single batch of codes there is a limit of 50 million product items.

The control and daily management of the products

The kezzlercoding system is software based, providing the involved parties with *product business logic* that helps control and inform about the product during market circulation. For instance product recalls and expiry dates are automatically managed on batch level only using the software.

Authentication of pharmaceutical products/units

To authenticate a drug item the user reads and keys[1] in the code on a designated web page and the code will instantly be either be validated or rejected as being genuine.

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[1] The checking can be automated for larger business environments using for instance barcoding or RFID equipment.

Track-and-trace capabilities of Kezzlercoding

Kezzlercoding Track-and-Trace is capable of tracking every unit throughout the complete supply chain from the point of manufacture to and including the end user where and if appropriate. The system automatically handles the different mode "levels" that pharmaceutical products may be transported in, typically when the product splits from a pallet --> box --> carton --> single item.

The system provides a detailed "pedigree report" on demand for every item at any time. Further the system has business logic for automatic surveillance concerning for instance diversion and other key information essential for the manufacturer and other involved parties.

Applying kezzlercodes to the drug packaging:

The codes are easily incorporated into the manufacturing process by existing equipment. The codes are applied to the drug packaging using standard in-line jet printers, print-and-apply systems for labels, or pre-printed standard labels.

The data carrier (representation) for the code ranges from overt/covert printing, bar-coding to covert RFID / forensic nanocoding depending on the combination of desired enhanced security and level of automation / readability.

Regards,

Magnar Løken d.y.
CEO, Kezzler AS

KEZZLERCODING is the numbering technology used in Kezzler's authentication system specially designed for the unique marking and authentication of high volume products. Every single product item is marked with a unique randomized alphanumeric code. Ordering and generation of kezzlercodes is carried out on demand by the brand owner, and all associated information is managed online by the brand owner. The information can be added/ updated/changed at any time. Business logic handles information behavior based on rules and dates, and expiry dates will for instance be automatically controlled.

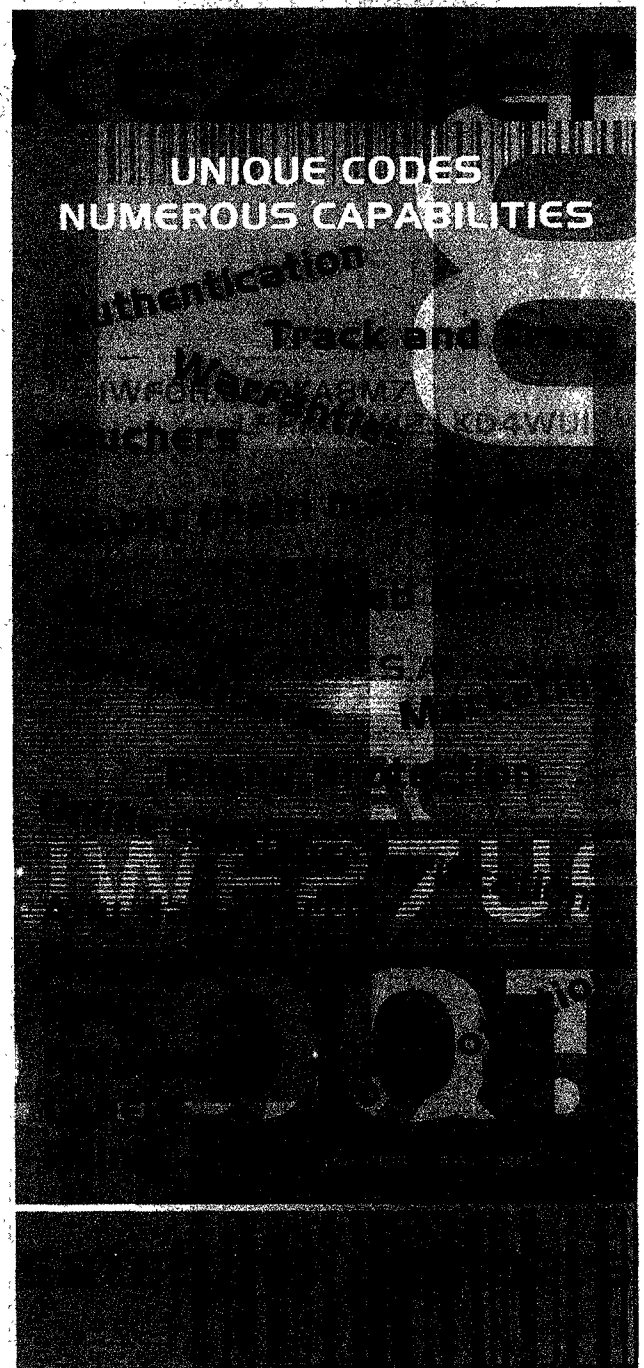**AUTHENTICATION** Some unique key features in the authentication system are:
- Instant verification free-of-charge using the web
- No special tools required
- Every single item uniquely protected and authenticated
- Suited for high volumes, the codes are self-contained and not stored in any database.
- Accommodates the brand owners own look and feel
- Authentication behavior statistics
- Activation and deactivation governed by dates

ATTACHED TAGGED INFORMATION (ATI)
Whenever a product reaches an end user the brand owner may want to initiate a dialogue and pass on further information such as:
- Product information
- User manuals
- Customer support
- E-mail links
- Recall alerts

The ATI offers a unique solution. When a consumer authenticates a product, ATI will immediately display pertinent information concerning the specific product. The information itself can be governed by business logic. The ATI information can be added, modified or updated at any stage for products in market circulation.
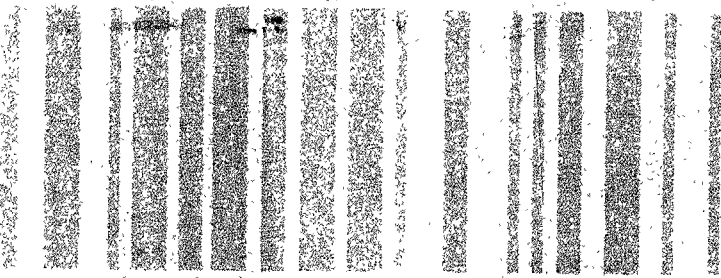
KEZZLER'S UNPRECEDENTED CONCEPT

is based on marking and identifying products. Kezzler has the capability of marking and administrating billions of product items, each with their own unique and randomized alphanumeric code that can be instantly verified free-of-charge via Internet.

Kezzler's Catalytic Digital Information (CDI) technology does not store any codes in a database for authentication. The self-contained Kezzlercodes are reconstructed securely using the high performance CDI method, which makes Kezzlercoding particularly safe and extremely scaleable.

Management of Kezzlercodes and associated communication business logic is carried out online by the brand owner, using Kezzler's Intentor software.

THE PRODUCT SECURITY COMPANY

kezzler productline:

KEZZLER PRODUCT AUTHENTICATION

Kezzlercoding is the numbering technology used in Kezzler's Product Authentication system specially designed for the unique marking and authentication of high volume products.

KEZZLER MARKETING

Kezzler links business opportunity and business intelligence to each and every product item. Following a successful verification, any type of information and communication exchange, such as consumer competitions or promotions, can take place with customers and consumers.

KEZZLER TRACK AND TRACE

Kezzler's track and trace application manages the complex task of following a product throughout the supply chain.

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Track and Trace

KEZZLER'S TRACK AND TRACE SOLUTION provides the brand owner with accurate and timely information about the products throughout the supply chain, from shipping to the consumer. The system uniquely marks and identifies every tracked item. Business logic manages the relationships of every packaging level in order to trace back any unit to its origin.

KEZZLER'S CDI technology separates the authentication, tracking and tracing processes completely. While authentication is the capability to securely and uniquely verify the authenticity of a unit and display information to this effect, tracing is the accumulated individual written and documented history of an authenticated and tracked unit.
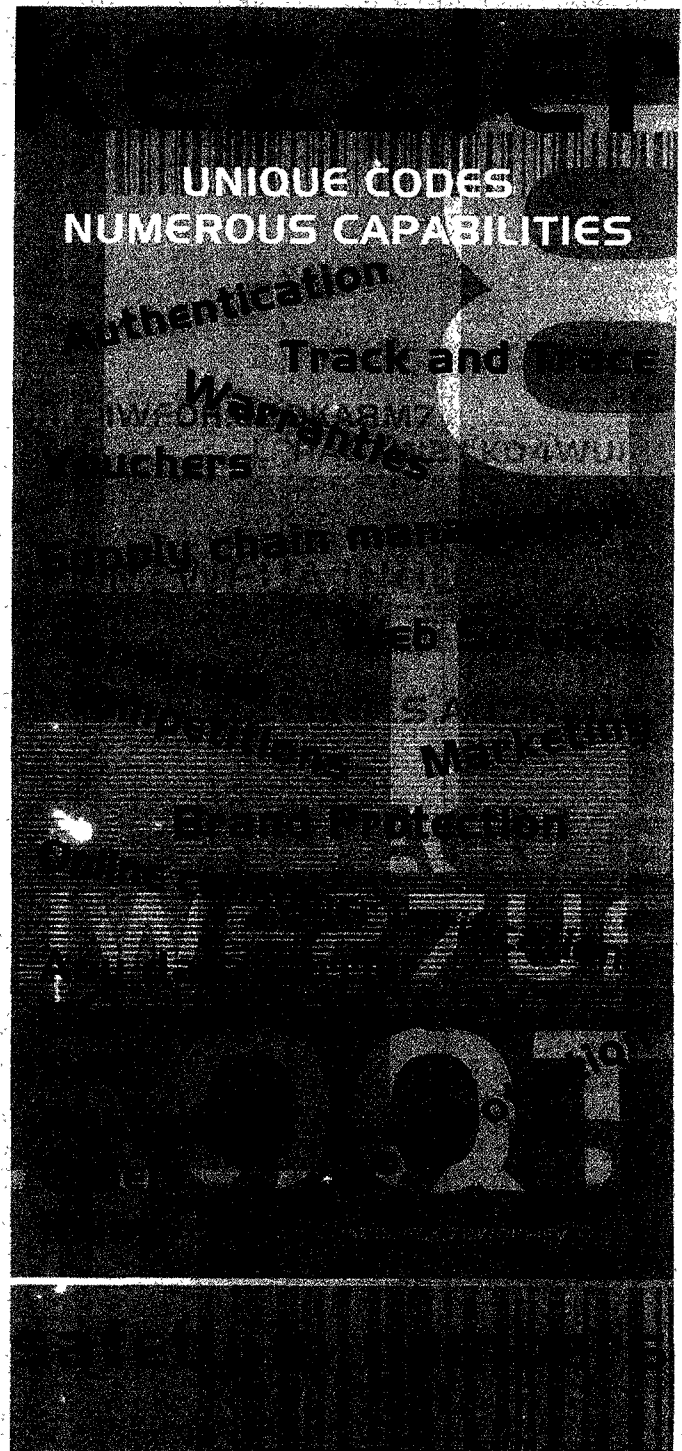
KEZZLER'S TRACK AND TRACE application assists brand owners in:
- obtaining information about the product flow
- preventing counterfeits from breaking into the supply chain
- avoiding and detecting diversion
- obtaining market intelligence
- understanding and improving the "mechanics" of their supply chain
- better serving customers

PACKAGING AND MARKING is crucial and challenging in a track and trace system. Kezzler's numbering technology, kezzlercoding, makes it possible to easily connect all units in a packaging level with previous levels. This ensures an efficient backtracing as a unit splits into an ever increasing number of units.

INTERNET provides the infrastructure necessary to link Kezzler's track-and-trace system together world wide. Tracking records are entered either by keying in a kezzlercode manually over the Internet, or through the use of scanners and RFIDs.
A unique communication channel between brand owner and distributors, wholesalers, retailers or consumers is established. Real time information exchange such as notification of possible product recalls, or other crucial product or shipping information can also take place.
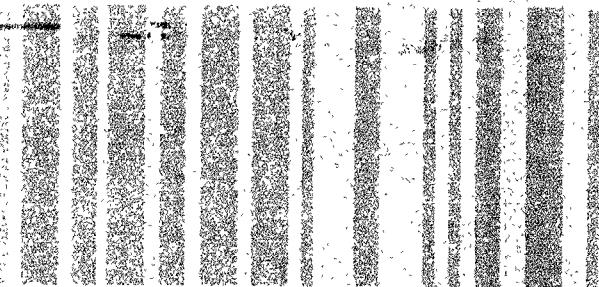
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KEZZLER'S PRODUCT AUTHENTICATION system gives the brand owner a targeted way to communicate with customers and consumers by linking business opportunity and business intelligence to each and every product item. Following a successful verification, any type of information and communication exchange can take place with customers and consumers.

CONSUMER COMPETITIONS consist of orders of kezzlercodes where brand owners can construct any number of winning levels. Different levels trigger individual and relevant events. Upon verification consumers are informed about their winning status and can securely claim their prices instantly.

VOUCHERS AND DISCOUNTS are kezzlers-codes with a value and set of rules for this value. Brand owners construct the vouchers and add them to orders of kezzlercodes. The consumer can instantly claim the value online, and a secure document may be generated for reimbursement at the point of sales.

WARRANTIES can be issued by brand owners and added to orders of kezzlercodes. Different warranties according to country, law, language etc. are embedded in the same code. The consumer claims the warranty online, and a warranty certificate may be generated for safekeeping.

CONSUMER SERVICE POINTS (CSP) provide the consumer with a protected individual "mailbox" for collection of kezzlercodes and related vouchers, discounts, warranties, prizes, user-manuals, etc. For the registered consumer a single click is sufficient to add the information to his/her CSP.

CLEARING CENTRALS securely and automatically reimburse selling points when a consumer claims discounts, vouchers or prizes. The Clearing Central minimizes administration and makes loyalty programmes less of a burden on stores and brand owners.
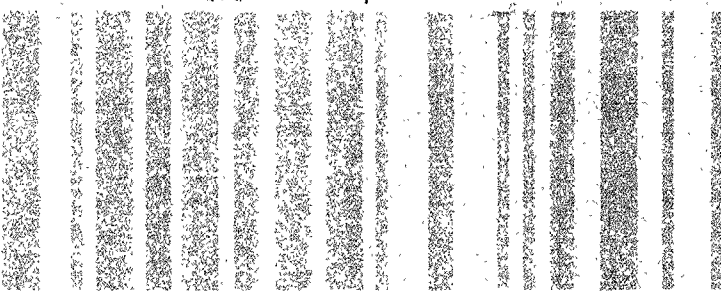
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