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MAKING EVERY SINGLE PRODUCT ITEM UNIQUE, SAFE AND INFORMATIVE

FDA Anti-counterfeit drug project

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.

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The kezzlercode

- Every single code is unique and non re-occurring
- The codes are random
- Scaleable to billions and billions of codes
- No storage of codes (self-contained)
- Secure
- Provides user friendly product business logic for both the brand owner and product consumers

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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 to 1 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.

The slide features a light blue background with a vertical bar on the left containing faint, overlapping text and a barcode at the bottom. The main content is centered and includes the following text:

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Empowering technology

- Unique protection of HIGH VOLUME products**
- Instant verification of products without ambiguity**
- Targeted value added product information**
- Communication with users enabled by the product itself !**
 - ... for every single product item**
- Control, documentation and traceability of products**
- Market intelligence**
- Easy to use, no special tools required**
- Low cost**

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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

Intenor 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