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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
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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.

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, 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.

[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