

FDA Docket 2005D-0385

Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability.

Kezzler AS appreciates the invitation to comment, suggest and provide some input about the practical operation of this type of new supplemental information channel.

As a response to the FDA Anti-Counterfeiting Initiative Kezzler suggested the use of a unique digital identification (serialization) for individual product items (Docket 2003N-0361 [Ref 01](#), [Ref 02](#)). The product identity is used to establish the authenticity of the product.

By taking advantage of the unique identity already in place on product items linked, a number of additional services may be provided for both health care professionals and consumers based on a *single and common product identity*.

<h3>One unique product identity – many applications</h3>
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In principle all relevant applications can be triggered and launched by this identity.

Such applications include, but are not limited to:

Product recall, anti-counterfeiting, diversion control, bedside bar-coding, general product information, electronic pedigree, documentation of use.

Product recalls

Directly relevant for electronically propelled product recalls. There are two principal modes of recalls.

Traceforward recall mode

The *traceforward recall mode* is a situation where the manufacturer actively contacts the users and supply points to recall the products known to be affected. This can be done by sending email messages, SMS, application warnings, etc. This mode requires that users and their products have previously been checked or registered by their product identity, enabling the manufacturer's system(s) to filter out and identify the affected users.

Traceback recall mode

Checking the recall status of a drug item can be initiated at any time by a health care professional or consumer by authenticating the product identity with the manufacturer's product identity system, typically over the Internet or phone networks.

Product recalls can routinely be carried out as needed.

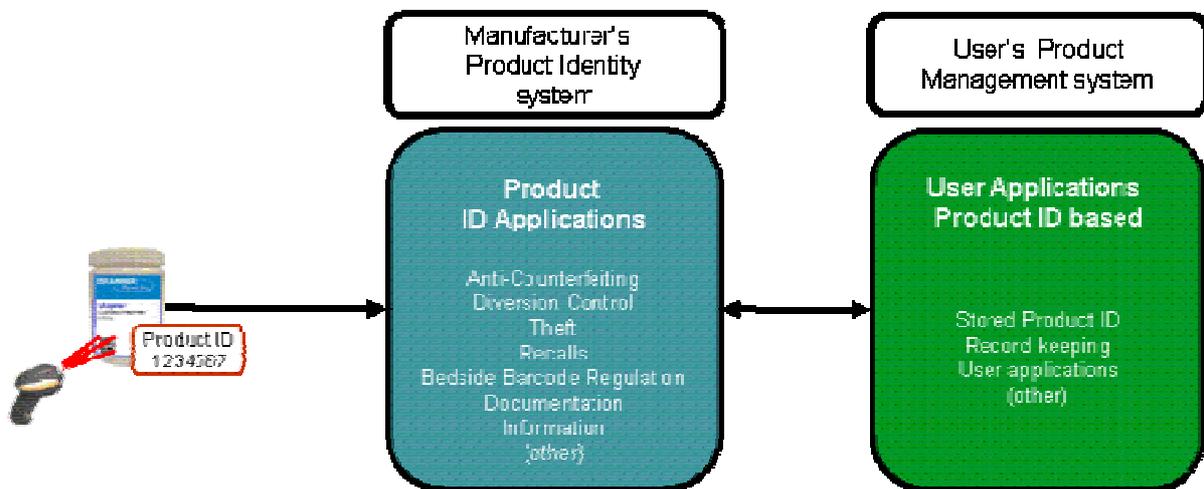
Monitoring recall operations

This type of system gives minute-to-minute crucial information about the progress of a recall, conveying statistics about the amount of products that have been successfully retrieved and contained.

Three key system capabilities

Kezzler believes there are three factors that must be observed in the design of such a system;

- 1 scalability in terms of users and products items managed
- 2 information confidentiality for users
- 3 interoperability for all drugs (and manufacturers)



The illustration above suggests a system architecture that takes into consideration these three capabilities.

Kezzler further believes the solution for a recall application based on product identity, lies in the introduction of local product identity management user systems, either in the form of small free-of-charge downloadable applications for the consumer or larger professional enterprise systems for the health care industry such as hospitals, pharmacies, doctors, etc.

This will allow for **confidential** processing of recall information encompassing all **drug products from all the different manufacturers** at the local application with a push and pull approach, taking the strain and complexity out of the enormous amounts of users and information that otherwise would have to be managed centrally by many different brand owners.

About Kezzler AS

Kezzler delivers secure track and trace solutions to the pharmaceutical and fast moving consumer goods industry. Kezzler's award winning software and technologies manage every single product item and logistical unit with a digital identity (kezzlercoding) giving the brand owner full visibility of the supply chain.

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