

Docket Management Comment Form  
Docket: 2003N-0361 - Anti-Counterfeit Drug Initiative  
Comment Number: EC-10

7691 '03 OCT 29 19:59

**Submitter:**  
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**Date & Time:** 10/21/03 08:26

**Organization:** PharmaDocs, LLC

**Category:** Other Organization

**Issue Areas/Comments**

**General**

Proposal on Anti-Counterfeiting Measures: Since there is no single magic bullet against the growing number of sophisticated counterfeiters and a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method, the following proposal is offered for consideration. Using the existing, validated manufacturing technology infrastructure and information management systems available to drug manufacturers, the status of a product in the supply chain may be ascertained by the manufacturer at any time. In order to track a product to the dispensing site, a products packaging and professional labeling could be featured to authenticate a drugs pedigree. Albeit by proxy, a drug's printed components could be produced on-demand with variable information representative of the date of manufacture, product name, strength, date, lot numbers or other specific identifiers, which the manufacturer could use for authentication. An authorized dispensing site could learn of an incident of tampering by scanning the overt package barcode using a properly equipped computer workstation. This query would bring up the physical image of the product (1st level of security) and an electronic version of the package insert, P.I. for comparison to the containerized version (2nd level of security). Featured with uniquely located covert information, (3rd level of security) in the form of a data glyph, stealth dot, invisible bar code, or similar two-dimensional symbol on the professional labeling. The P.I. containing authentication information could then be scanned by personnel and a comparison made with the package information in the manufacturers database (4th level of security). By including a covert mark on the package and an overt mark on the PI, a comparison can be made in the monitoring system providing a means of rapid alert, identification, detection and response to a drug's pedigree. This would detect a product that has been opened and otherwise repacked. This process could occur at the wholesale distributor, major repacking site and dispensing sites of supply chain partners. Adulterated and tampered drugs in the supply chain are a multimillion-dollar industry problem and pose a serious threat to the health and welfare of patients throughout the world. I hope this proposal and the patent pending is given serious consideration by the industry.

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