Combating Counterfeit Drugs: Use of RFID

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Basic FDA Position

Counterfeiting drugs is a particularly heinous crime

For FDA - Counterfeiting drugs is a significant patient safety and public health issue

Basic FDA Policy

Fighting counterfeit drugs is high priority of the FDA

The fight must be proactive – we can not wait for people to die from counterfeit drugs before we act – that is too late

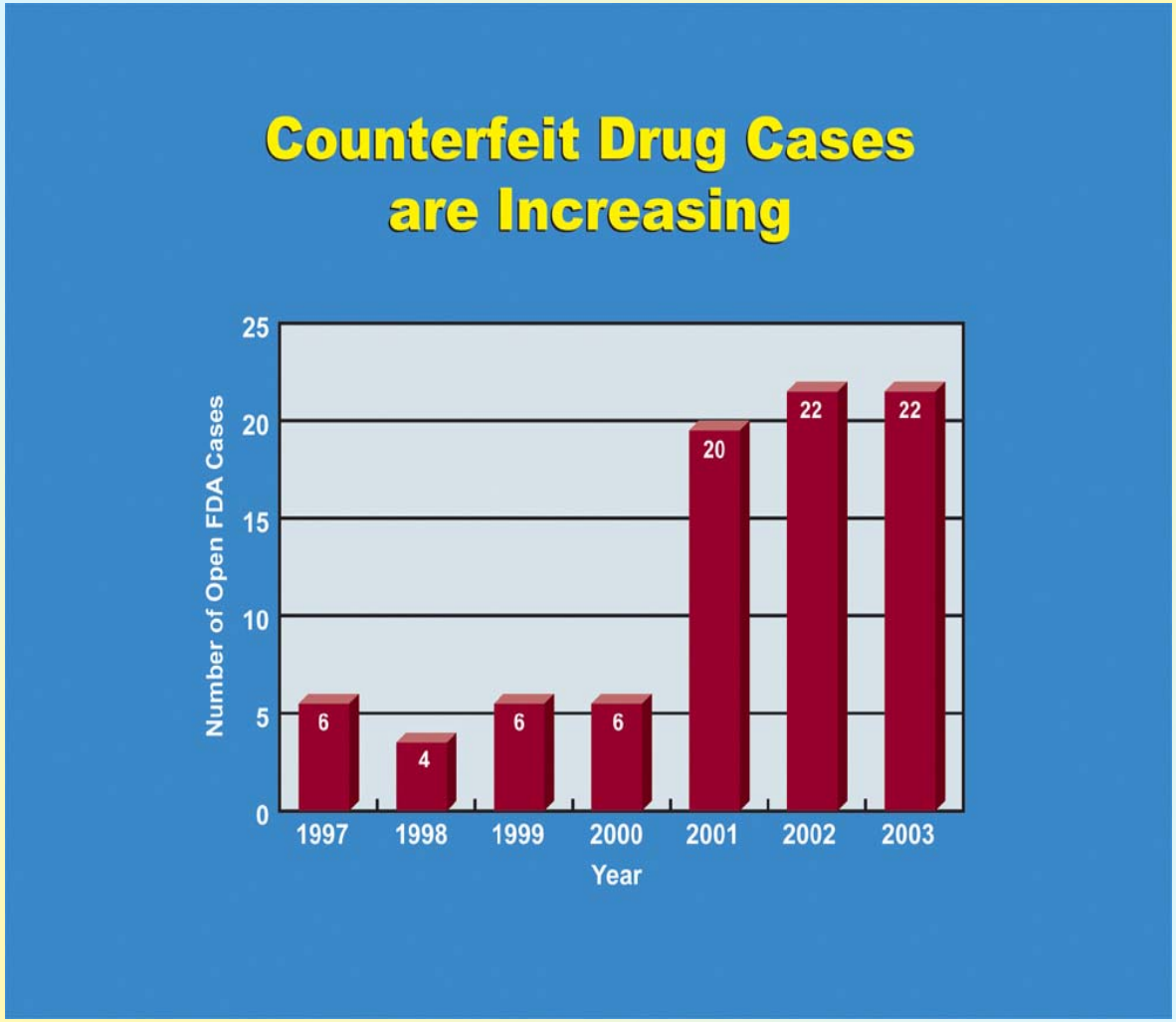
Current Status

- U.S. Drug Supply is the safest in the world – counterfeit drugs comprise less than 1% of market
- Estimates of counterfeit prevalence in other countries are unreliable - in some underdeveloped countries counterfeits may comprise 50% of all drugs (e. g., anti-malarials)
- FDA investigations have dramatically increased since 2000
- However, focusing on the number of investigations may actually underestimate the problem

The Counterfeiters

- Have access to sophisticated technology enabling them to counterfeit final dosage forms and their packaging
- Have access to significant financing
- Have organized global networks
- Can sell over the Internet
- Can take advantage of larger import flows into the US
- They target high volume, high cost drugs

FDA Investigations



Basic FDA Findings

Overview

- All stakeholders have a responsibility to keep to keep the drug supply safe
- All stakeholders need to take action and be accountable

A secure drug supply must address supply chain vulnerabilities in the following areas:

- The Product and Packaging - Technology
- The Movement of Drugs and Providing Appropriate Regulatory Oversight
- Criminal Penalties
- Reporting, Education, and Awareness
- International Collaboration

The report is available at www.fda.gov

RFID: The Cornerstone in the Fight Against Counterfeit Drugs

- A reliable pedigree from the point of manufacture to the point of dispensing is essential to assuring a safe drug supply
- RFID can provide such a pedigree
- Therefore, FDA has identified RFID as the cornerstone in the fight against counterfeit drugs

What is RFID?

Track and Trace Technology

It consists of 2 things:

- ***Mass Serialization***

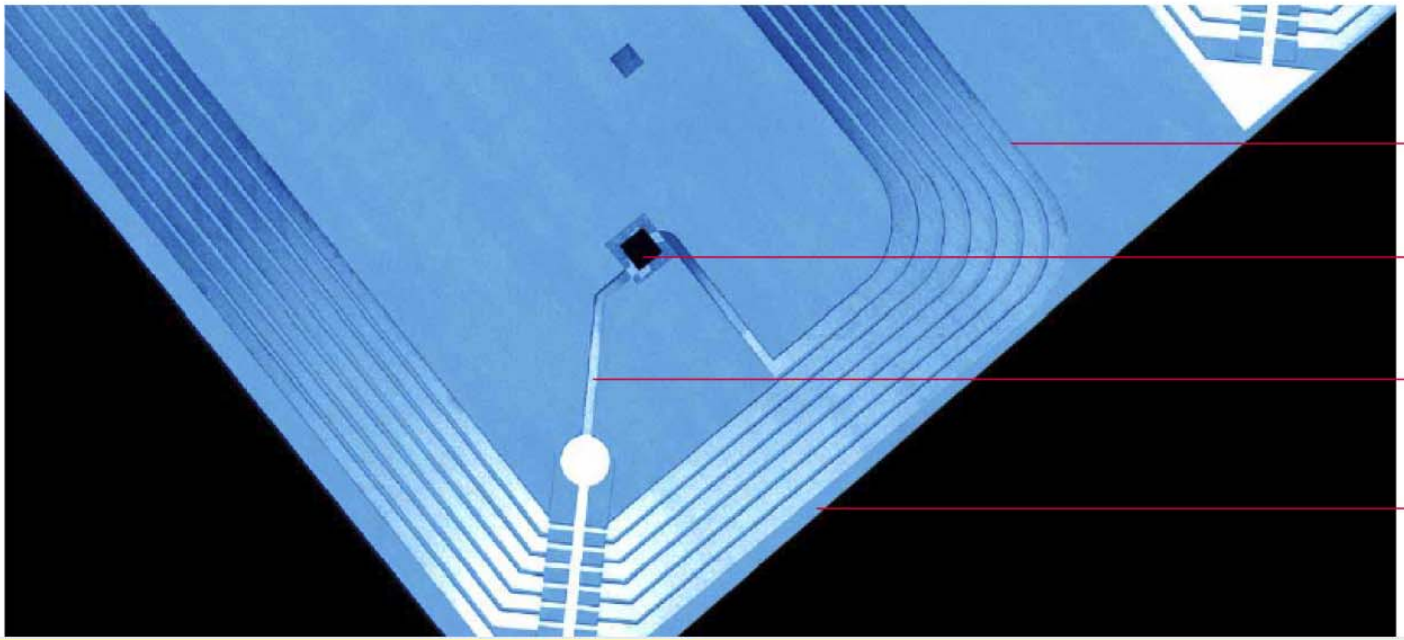
  and an infrastructure:

- ***Tags, readers and an information infrastructure***

What does an RFID tag look like and what does it contain?

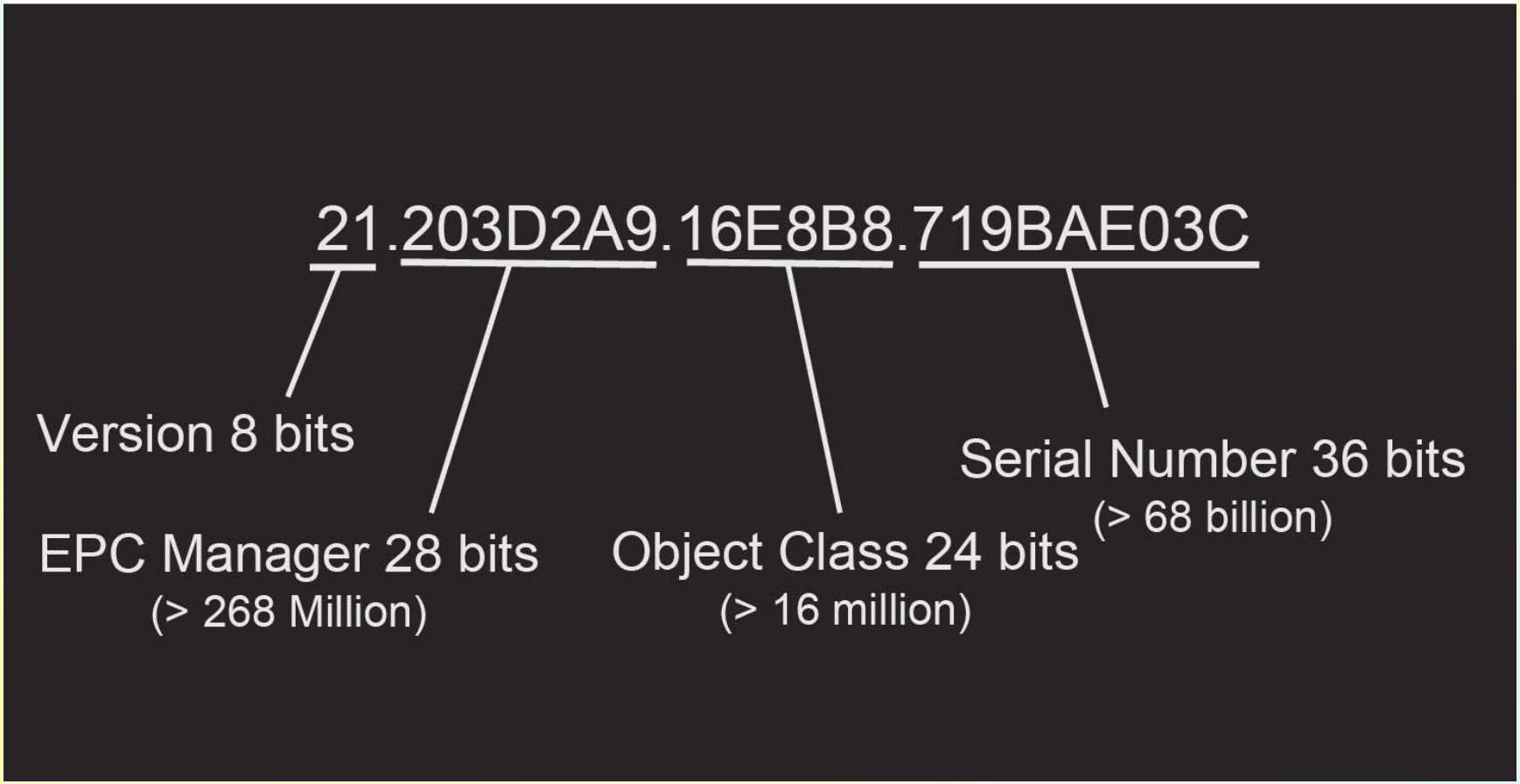
AUTO-ID CENTER

1. RFID TAGS



AUTO-ID CENTER

2. EPC: 96-BIT VERSION



Track and Trace Technology

- RFID is the most promising technology for implementing mass serialization
- 2D bar codes can also contain a unique serial number and may be of some use for authenticating and tracking products BUT RFID offers many advantages over 2D bar codes – most importantly, ability to perform non line of sight reading at production speeds

FDA Policy on RFID

It is the policy of the FDA to encourage rapid adoption of RFID in the pharmaceutical supply chain

The FDA believes that widespread adoption of RFID is feasible by 2007

We intend to monitor the adoption of RFID and take appropriate action to facilitate it’s adoption

Drivers of RFID Adoption

- Purchaser requirements: DOD, Wal-Mart, Tesco and others
- Florida pedigree law
- Benefits in inventory control, theft prevention, diversion, recalls, reduction in medication errors (transmission of product info etc.)
- Decrease in cost of tags and readers as volume increases
- Development of interoperable readers (a reader that can read tags and bar codes)

Current Use of RFID

Consumer Products - RFID is in commercial use

Pharmaceutical Products – feasibility studies underway

- DOD/Wal-Mart – Case & Pallet Jan 2005
- Wal-Mart – C2's – item level - now
- Accenture, PA Consulting – selected products
- Multiple other studies planned

What FDA is doing

- We stayed the regulations implementing the pedigree provisions of the PDMA until December 2006 in order to allow industry to focus its resources on adoption of RFID
- We think RFID can accomplish the goals of the PDMA more cost effectively and with less burden on industry
- We are working with sponsors and participants of pilot studies to identify and address issues such as labeling, electronic records requirements, and product quality issues that could affect those studies – draft guidance in process

What FDA is doing

Recognizing that the pharmaceutical industry is different - we are working to identify, and find ways to address, the unique hurdles that need to be overcome in order to have as many stakeholders as possible decide to be early adopters of RFID

As experience with RFID is gained we intend to take steps to minimize regulatory obstacles to widespread adoption of RFID (Parts 11, 211, 314)

What FDA is NOT doing

- No requirements – could stifle technological progress and increase costs

Issues FDA is Watching

- Standards development – should occur simultaneously with pilot studies, waiting to begin implementing RFID until standards are fully developed may be problematic
- Technical issues - optimal use of frequencies in the supply chain, obtaining 100% read rates
- Product Quality – voluntary collection of data on the effect of RF energy on drugs to inform future testing requirements (if any) – special attention to liquids and biologics
- Privacy – Industry very sensitive to this issue
- Database – security, access, ownership

RFID and Business Practices

When RFID is in widespread commercial use in the pharmaceutical industry:

Would participants in the drug supply chain, when appropriate, consider limiting their business partners to those who are RFID enabled?

RFID - Conclusions

RFID is here and we believe that RFID will be adopted according to the FDA timeline