

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2005N-0510]

Anti-Counterfeit Drug Initiative Workshop and Vendor Display

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop and vendor display.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop and vendor display on the use of electronic track and trace technology to combat counterfeit drugs. The purpose of the meeting is as follows: To identify incentives for widespread adoption of radio-frequency identification (RFID), as well as obstacles to the adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles; to solicit comment on the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of an electronic pedigree (e-pedigree); and to learn the state of technology development related to electronic track and trace and e-pedigree technology solutions.

To address these issues, we are inviting interested individuals, organizations, and other stakeholders to present information to FDA's Counterfeit Drug Task Force. We are also inviting vendors of track and trace technologies and e-pedigree solutions relevant to the drug distribution system to display their products for the educational benefit of FDA and attendees. (For this meeting, we are only interested in displays from vendors of track and trace technology and e-pedigree solutions for the PDMA requirement, as opposed to covert or overt counterfeiting technologies, such as holograms or color-shifting inks.)

DATES AND TIMES: The public workshop and vendor display will be held on February 8 and 9, 2006, from 9 a.m. to 5 p.m. See section V of this document for information on how to register to attend, present at the workshop, or participate in the vendor display. If you would like to present at the workshop or participate in the vendor display, you must register by January 27, 2006.

We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket at the address below by February 24, 2006.

ADDRESSES: The public workshop and vendor display will be held at Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For information about this document: Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: poppy.kendall@fda.gov.

For information about registration or if you need special accommodations due to a disability: Isabelle Howes, Graduate School, U.S. Department of Agriculture, 490 L'Enfant Plaza, Promenade Level, suite 710, Washington, DC 20024, 202-314-4713, FAX: 202-479-6801, e-mail: Isabelle_Howes@grad.usda.gov.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding a Public Workshop and Vendor Display?

On February 18, 2004, we issued a report entitled “*Combating Counterfeit Drugs: A Report of the Food and Drug Administration*” (Counterfeit Drug Report) (http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html). This comprehensive report highlights several measures that can be taken to better protect Americans from counterfeit drugs. These measures address a range of critical areas:

- Securing the actual drug product, its packaging, and the movement of the product as it travels through the U.S. drug distribution chain;
- Enhancing regulatory oversight and enforcement;
- Increasing penalties for counterfeiters;
- Heightening vigilance and awareness of counterfeit drugs; and
- Increasing international collaboration.

We issued an update to the Counterfeit Drug Report in May 2005. (See <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>).

We have worked with manufacturers, wholesalers, pharmacies, consumer groups, technology specialists, standard-setting bodies, State and Federal agencies, international governmental entities, and others to advance the measures outlined in the Counterfeit Drug Report.

In the Counterfeit Drug Report, we stated that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that, if properly implemented, this technology would help secure the integrity of the supply chain by providing an accurate drug “pedigree,” an electronic record (also known as an “e-pedigree”) documenting the distribution of the drug from the point of manufacture to the final dispenser. We particularly supported the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need. RFID

technology involves tagging the drug product package with a tiny radio frequency chip containing essential data in the form of an electronic product code (EPC) or unique electronic serial number. If implemented properly, RFID could allow supply chain stakeholders to track the chain of custody (or pedigree) of every package of medication through every step of the supply chain. A unique electronic serial number could also be embedded in some types of barcodes.

As discussed further in this document, we have delayed the effective date of certain regulations related to the PDMA until December 1, 2006. We delayed the effective date in 2004 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree across the drug supply chain and to consider the effects of adoption of electronic track and trace technology on certain PDMA requirements. We are also soliciting comment on issues related to the delayed effective date, as discussed more in section III of this document.

Progress has been made towards adoption of RFID and implementation of an e-pedigree across the U.S. drug supply chain, although more slowly than originally anticipated. Several issues have surfaced that, left unresolved, may slow or impede the adoption of RFID. These issues merit a public discussion as RFID standards are being developed and greater experience with RFID is gained. Therefore, we have reconvened FDA's Counterfeit Drug Task Force, which decided to hold this public workshop to address these and other related issues. This public workshop will focus on securing the product and its movement through the supply chain.

This workshop and vendor display have the following three objectives:

- Identify incentives for widespread adoption of RFID, as well as obstacles to the adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of technology development related to electronic track and trace and e-pedigree technology solutions.

After taking into account public comment provided at the meeting or submitted to the docket, the Task Force may develop and issue recommendations.

II. What Issues Are We Interested in Seeking Comment on at the Meeting Related to RFID and E-pedigree?

Please fully explain your rationale and reasons for your answers and comments to the following questions.

A. Implementation of RFID

1. What incentives are needed for more rapid and widespread adoption of RFID in the U.S. drug supply chain? How can these incentives be achieved?
2. What are the current obstacles to widespread adoption of RFID in the U.S. drug supply chain? How can these obstacles be overcome?
3. What is FDA's role in further facilitating adoption of RFID across the drug supply chain?
4. What is the timetable for widespread adoption of RFID across the drug supply chain, with and without additional incentives?

B. RFID Standard Setting

1. Who should set the standards for RFID? Currently we are aware of the efforts of only one organization, EPCglobal, to develop standards for the use

of RFID in the drug supply chain. Are there other entities within the United States or abroad that are also developing standards for the use of RFID for the drug supply chain?

2. Role of FDA

- Is there a role for Federal leadership by FDA to advance the standard setting efforts? What is that role? Is there a role for other Federal entities, such as the Drug Enforcement Administration or the Department of Defense?

- Should standards remain voluntary? Why?

C. Specific Drug Supply Chain RFID and E-pedigree Issues

We have been approached by a number of stakeholders for our advice and thoughts on various issues that have surfaced as a result of RFID pilot studies, standards development, and e-pedigree implementation. We would like to discuss these issues at the public workshop.

1. Mass Serialization

In the Counterfeit Drug Report, we advocated the use of mass serialization, which involves the incorporation of unique identifier numbers on each drug package in order to track the individual drug package as it moves through the supply chain. We still believe that this is an important element for the success of electronic track and trace in the drug supply chain.

- What numbering conventions currently are being used or considered for mass serialization?

- Should there be a single numbering convention or are different conventions compatible?

- Should the national drug code (NDC) be part of the unique identifier or should the identifier be a randomly generated number? Concerns have been

raised that use of the NDC raises privacy issues. What is the extent of these concerns and how should they be addressed?

- What is the timetable for widespread mass serialization for prescription drug products, with and without additional incentives?

2. Universal Pedigree Fields

FDA regulations at 21 CFR 203.50 (currently stayed) list the information that must be provided in the pedigree. This is the minimum information that was also set forth in the PDMA. These requirements were established at a time when a paper pedigree was the only mechanism available for passing a pedigree. An e-pedigree not only requires additional information because of its technological nature, but it may also facilitate the inclusion of more information. In addition, some States are requiring that specific information be included in pedigrees passed with drugs sold in their State. Consequently, pedigree information required by one State may be different than the pedigree information required in the next State where the drug is received. Some States now also require that all wholesalers (both primary and secondary) pass pedigrees.

- Are there logistical concerns or barriers to passing a pedigree for a drug that moves from one State to another with different pedigree requirements?
- Would a universal pedigree alleviate these concerns or barriers? How?
- What common fields/information are the most important in a pedigree?

Why?

- How can a universal pedigree be achieved?

3. Data Management and Security

For e-pedigree transmission from manufacturer to dispenser to be successful, business partners must be able to share information specific for the

product that is the subject of the pedigree. We are aware that there is a great deal of interest in the management and sharing of pedigree information among business partners.

- One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges information with other systems) should be used. Can/should the pedigree information be passed and authenticated using either model? If some stakeholders subscribe to a central database and others use a distributed approach, can the pedigree information still be passed and authenticated?

- If there is to be a central database, who should host it? Why?
- What types of encryption or other data security measures are available to ensure the authenticity of the information being passed and digitally signed?
- What measures can be taken to secure the databases themselves in either the central database or distributed approach?

D. Privacy Issues

The use of RFID in the drug supply chain raises a number of privacy issues. It is important to fully understand the issues and ensure that measures are in place to protect patient privacy. We have also heard concerns that thieves or others could unscrupulously identify a drug product if its identity is concealed.

1. Disclosure of Information

Is it possible for someone to read the information from an RFID tag on a drug product without the possessor of the product knowing it? If it is possible, what information would they learn, and how could the information be used?

2. Turning off the RFID Tag

Some people have suggested that the RFID tag could be “turned off” before it leaves the pharmacy, or that patients could be given the choice of whether it is “turned off.” Is it possible to “turn off” the RFID tag? What are the advantages or disadvantages of “turning off” the RFID tag?

3. Consumer Education

What type of consumer education is needed as the use of RFID in the drug supply chain becomes more prevalent? What messages should be conveyed? Who should develop consumer education program(s)? Should there be a notice on the product package that an RFID tag is affixed to the product package? If so, what should the notice say?

E. Public Health Emergency Use

In certain public health emergency situations, it is essential to promptly and efficiently deploy vital medications from Federal or State stockpiles to locations that need them the most, as well as rapidly identify and reroute vital medications from other sources when there is a national shortage. Such situations could include anti-viral drugs for pandemic influenza, countermeasures for bioterrorist incidents, or antibiotics or other essential medications for natural disasters, such as hurricanes. Electronic track and trace technology, such as RFID, could enable public health officials to know what medications are available to meet their needs from the closest stockpile, how much is available, track its location en route to the site, as well as provide a means for inventory control onsite.

In addition, in times of crisis, we can anticipate an increase in devious and unscrupulous activities, such as drug counterfeiting and diversion of medicines that are in high demand for the public health situation at hand.

1. How can RFID be utilized in these types of public health emergencies, such as pandemic influenza? Should RFID be used on other types of medical countermeasures besides drugs in the Strategic National Stockpile?

2. What is the role of the Federal Government in encouraging or requiring RFID or other electronic track and trace technologies for drugs most likely used in these situations?

3. Are companies willing to explore the use of RFID for drugs most likely to be used in these situations?

F. Other

Are there other issues that need to be addressed to facilitate the widespread adoption of RFID across the U.S. drug supply chain?

III. What Issues Are We Interested in Discussing related to PDMA and E-pedigree?

The PDMA of 1987 (Public Law 100–93), as modified by the Prescription Drug Amendments of 1992 (PDA) (Public Law 102–353, Stat. 941), amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the act (21 U.S.C. 353(e)(1)(A)) requires that “each person who is engaged in the wholesale distribution of a drug* * * who is not the manufacturer or authorized distributor of record of such drug* * * provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)” This is the so-called “pedigree” requirement. The PDMA states that an authorized distributor of record is a wholesaler that has an “ongoing relationship” with a manufacturer

to distribute that manufacturer's drug; however, it does not define "ongoing relationship." (21 U.S.C. 353(e)(3)(A)).

In the **Federal Register** of December 3, 1999 (64 FR 67720), the agency published final regulations (the 1999 final rule) in part 203 (21 CFR part 203) implementing PDMA that were to take effect on December 4, 2000. After publication of the 1999 final rule, the agency received comments from industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" and set forth requirements regarding an identifying statement of origin (commonly referred to as a "pedigree").

Based on the concerns raised, the agency delayed the effective date for those provisions until October 1, 2001, (65 FR 25639) to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations requested that the agency review the potential impact that the regulation would have on the secondary wholesale pharmaceutical industry and prepare a report summarizing the comments and issues raised and the agency's plans to address these concerns.

The agency's report, which was submitted to Congress on June 7, 2001, concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes. However, to make some of the changes requested by the secondary wholesale industry, Congress would have to amend relevant provisions of section 503(e) of the act (see <http://www.fda.gov/oc/pdma/report2001/>). Since submitting the report to Congress, we have continued to delay the effective date of these provisions.

Most recently, on February 23, 2004 (69 FR 8105) (as amended on March 18, 2004 (69 FR 12792)), we further delayed the effective date of these particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would implement electronic track and trace capability by 2007. When widely adopted, this capability would create a de facto electronic pedigree that would follow the product from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, electronic pedigree could meet the statutory requirement in section 503(e) of the act.

The agency has been closely monitoring the implementation of electronic track and trace and electronic pedigree across the U.S. drug supply chain. As the expiration of the December 1, 2006, delayed effective date gets closer, it appears that the goals described previously may not be met. To guide the agency's decision whether to continue the delayed effective date, let the regulatory provisions go into effect, or take other steps, we are particularly interested in testimony and comments on the following issues:

Please fully explain your rationale and reasons for your answers and comments to the following questions.

A. 1999 Final Rule

1. Small Business Impact

At FDA's 2001 PDMA public meeting, we heard testimony and received comments that the 1999 final rule provisions at issue would have a significant impact on small businesses because these businesses would not be able to obtain the necessary information to adequately complete pedigrees and sell drug products. Since 2001, there have been a number of process changes in the way that wholesalers do business, such as increased use of computers and

barcodes, electronic track and trace solutions, and new state wholesaler laws, which could alleviate some of the earlier concerns. How has the potential impact of the 1999 rule on small businesses changed since the 2001 public meeting?

2. Delay of The Effective Date

- If the delay of the effective date is not extended, how will implementation of the rule affect primary and secondary wholesalers? Would it impact the distribution of drugs to smaller retail outlets or rural communities? Will secondary wholesalers have access to the information they need to meet the pedigree requirements?

- What is the regulatory significance of the fact that the current federal pedigree requirements apply only to wholesalers who are not authorized distributors of record? Please explain.

- Should the delay of the effective date be further extended? If so, how long should it be extended? Why?

- If the delay of the effective date is not extended, would the 1999 rule ensure that there is effective track and trace capability to combat drug counterfeiting? If not, why? In order to further address this question, we refer you to the 2001 Report to Congress at

<http://www.fda.gov/oc/pdma/report2001/>.

3. Minimum Standards for Wholesaler Licensing

- The PDMA required FDA to issue minimum standards for wholesaler licensing. ((21 USC 353(e)(s)(A)), codified at (21 CFR 205.3)). These standards were adopted by the states and incorporated into state law. How effective are these standards?

4. State Efforts

- How would the recent actions by various states that have implemented stricter wholesale licensing and oversight laws impact compliance with the 1999 final rule?

B. Adoption of E-pedigree Across the Drug Supply Chain

1. What is the status of developing standards that allow for interoperability of e-pedigree solutions across the drug supply chain?

2. To what extent are stakeholders using e-pedigree?

3. If you are not using an e-pedigree program now, do you anticipate having this capability in the future? If so, when do you plan to use e-pedigree?

4. What is the experience to date of interoperable e-pedigree solutions across the drug supply chain?

5. Paper to E-pedigree Transition

- Discuss the feasibility of a paper and e-pedigree system co-existing across the drug supply chain.

- Can the authenticity and validity of the pedigree be maintained in such a system? How can this be done?

- What capabilities would be needed for such a system?

- Please provide cost estimates for the minimal equipment and infrastructure needed for members of the supply chain to accept and pass a paper pedigree? Cost estimates for use of e-pedigree? Is there a difference in costs if the drug product has a unique identifier versus one that does not?

6. What is the timetable for widespread adoption of e-pedigree across the drug supply chain, with and without additional incentives?

IV. Technologies That Will Be Considered For Display At the Vendor Display

One purpose of this meeting is to gain greater understanding about electronic track and trace technology and e-pedigree. Therefore, we are inviting manufacturers and organizations that market or have in development an electronic track and trace product to display their product at this meeting. We are also inviting manufacturers and organizations that market, have in development, or are facilitating e-pedigree solutions across the U.S. drug supply chain to display their products. Although very important in the effort to combat counterfeit drugs, it is beyond the scope of this program to display overt and covert products and technologies used for anti-counterfeiting including, but not limited to, holograms, color-shifting inks, taggants, and nanotechnologies.

Questions about whether your product or technology would fall within the scope of this vendor display should be directed to the contact person for vendor displays listed at the top of this notice.

V. How Do You Register?

Registration is required if you would like to present at the workshop or participate in the vendor display. If you wish only to attend the workshop and vendor display, you should also register because space is limited.

Because of time constraints, you may register either to present at the workshop or participate in the vendor display. You may not register for both. If you choose to participate in the vendor display, you will have the opportunity to share information about your products with the FDA Task Force members through your participation in the vendor display.

You may register online to present at the workshop or participate in the vendor display at <http://www.fda.gov/RFIDmeeting.html> no later than January 27, 2006. The online registration form will instruct you as to the information

you should provide (such as name, address, telephone number, e-mail address, whether you wish to make a presentation or participate in the vendor display, summary of your presentation or product). To register to attend the workshop, go to this same Web site. Seating is limited to 400 persons and if capacity is reached, registration will close. If you register as a presenter or to participate in the vendor display, you do not need to also register as an attendee.

If you plan to present at the workshop, we will try to accommodate all persons who wish to make a presentation. We encourage persons and groups having similar interests to consolidate their information and present it through a single representative, if possible, to enable a broad range of views to be presented.

By February 2, 2006, we will schedule each appearance and, by e-mail or telephone, notify each participant who will present of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The time allotted for presentations may be between 5 to 15 minutes, depending on the number of people who wish to present.

At the time of registration, you will be asked to provide a short summary of your presentation. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF by 12 noon on February 6, 2006, to Isabelle Howes, Graduate School, U.S. Department of Agriculture, 490 L'Enfant Plaza, Promenade Level, suite 710, Washington DC 20024, 202-314-4713, e-mail: *Isabelle_Howes@grad.usda.gov*.

If you plan to participate in the vendor display, there will be no fee for participating in the vendor display. For the purposes of this meeting, we are only interested in displays from vendors of track and trace technologies and

e-pedigree solutions. At the time of registration, you will be asked to submit a short summary of your product.

We can accommodate 30 vendors at this meeting. When vendor registration reaches this number, additional vendor display registrants will be placed on a wait-list. If you have been placed on the wait-list, we will notify you by e-mail or telephone if you become confirmed. There will be no onsite registration for vendors. Each vendor will be provided with a 6-foot tabletop space. Please note that Internet access will not be available.

VI. How Should You Send Comments on the Issues?

If you would like to submit comments on any of the issues described in this document, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration of your comments, we must receive any written or electronic comments by the date indicated (see **DATES AND TIMES**).

VII. Will Meeting Transcripts Be Available?

The workshop will be transcribed. The transcript will be posted on FDA's Web site at *www.fda.gov*. You may request a copy of the transcript by writing to our Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857. We anticipate that transcripts will be available approximately 10 days after the public meeting at a cost of 10 cents per page. The transcripts will also be available for public

examination at the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

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