



November 3, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 10-61
Rockville, MD 20852
Attn: Dockets Manager

RE: Comments - Anti-Counterfeit Drug Initiative - FDA Docket No. 2003N-0361

Dear Dockets Manager:

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) to comment on issues raised during the public meeting on the Anti-Counterfeit Drug Initiative convened by the U.S. Food and Drug Administration (FDA) in Bethesda, Maryland, on October 15, 2003 (FDA Docket No. 2003N-0361).

During the public meeting, the PPLA was encouraged by the numerous views expressed in support of packaging and labeling technologies as effective tools in fighting drug counterfeiting throughout the distribution chain, as well as at the point of sale. Particularly compelling were the testimonials relative to the feasibility of drug pedigrees that can help track distribution of pharmaceuticals from the time of manufacture through dispensing to the patient. The PPLA noted that support for such pedigrees – along with the printing of overt and covert anti-counterfeiting features – was widespread during the meeting.

Basis for Comments: PPLA Background

The PPLA is a not-for-profit trade association established in 2001 to serve as the voice of the pharmaceutical printing industry. PPLA members include printers of pharmaceutical inserts, labels and cartons, as well as suppliers to the pharmaceutical printing industry and machinery manufacturers. Our membership represents the majority of the North American pharmaceutical printed-insert industry, and the association strives to provide a forum for worldwide members to advance patient safety and risk communication. The PPLA supports health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. In addition, the PPLA is an educational resource for strategic partners and the public.

PPLA members play a key role in the supply chain for pharmaceuticals, linking product manufacturers with pharmacists, physicians, and patients. Our members are responsible for printing the majority of package inserts and medication guides distributed by pharmaceutical manufacturers in the United States today. The close association that our members have with pharmaceutical manufacturers qualifies us to comment on packaging security technologies that can strengthen supply chain integrity. Moreover, we can play a strategic role in implementing critical security features via the manufacture of specially equipped cartons and labels.

The PPLA also maintains that Current Good Manufacturing Practices (CGMPs) in printed packaging can be leveraged to drive drug authentication and track-and-trace capabilities. The pharmaceutical industry is served by a group of printed packaging suppliers that currently operate under CGMPs. Although not audited by FDA, suppliers that are held to the highest standards by the most demanding customers adhere to policies and procedures that can be expanded to better preserve authentication and track-and-trace security features.

Comments

Although the PPLA has no formal affiliation with the organizations that testified, we share views expressed by many, including FDA Commissioner Mark McClellan, that packaging and labeling technologies can readily and efficiently deter counterfeiting by enabling complete pedigrees and various means of drug authentication. In our view, the multi-layer approach recommended by FDA's Counterfeit Drug Task Force can go a long way in breaking down the profit motive of counterfeiters as many possible security elements require advanced equipment and multiple layers of security access to unravel and duplicate. At FDA's public meeting, we heard from numerous organizations that product offerings immediately available or on the immediate horizon can enable and preserve pedigrees from the point of manufacture to the point of sale.

The PPLA reiterates our testimony before FDA on July 31 that mandatory FDA-approved, manufacturer-produced printed information for consumers can help fight counterfeiting and empower consumers as the last line of defense in combating counterfeit drugs. Authentication features can be incorporated into patient package inserts and medication guides to maintain the security of the supply chain all the way to the end user. Patient-facing security enhancements also can be accomplished via manufacturers' self adhesive labeling, and folding cartons that require special equipment to produce and are therefore difficult to unlawfully duplicate.

The following comments are limited to packaging and labeling security tools that can quickly and cost effectively improve the integrity of the prescription (Rx) drug supply chain. They are provided in response to Section IV, "Questions Related to the Potential Options for Improving Prescription Drug Security," of the FDA Counterfeit Drug Task Force Interim Report.

- ***Advantages and disadvantages of unit-of-use packaging:*** The PPLA supports findings by FDA's Task Force regarding the role that unit-of-use package formats can play in deterring counterfeiting. We agree with the Task Force's interim observation that security technologies can be incorporated such that those technologies accompany the drug product throughout the distribution chain, but only if the product is distributed and dispensed in manufacturer-provided unit-of-use packaging. Without such packaging, the integrity of the supply chain between manufacturer and consumer is broken at the pharmacy stage, and counterfeit product can more easily be inserted into the supply circuit. Moreover, greater adoption of unit-of-use formats facilitates distribution of useful printed information from the pharmaceutical manufacturer for patients.
- ***Should the European Union requirements be used as a model for unit-of-use packaging:*** The PPLA asserts that adoption of EU requirements by the United States would offer multiple benefits for U.S. consumers. Drug products could be better protected, consumers would receive more useful and trustworthy information about their medications, and pharmaceutical efficacy would be enhanced. While the PPLA recognizes that pharmaceuticals have been counterfeited in European nations, we assert that, overall, the EU system of pharmaceutical distribution is vastly superior to the bulk distribution of drug products utilized in the United States.

- ***Should any specific anti-counterfeiting technologies be utilized:*** The PPLA maintains that leaflets and primary labeling can be essential security tools. They serve as the physical platform for overt and covert security features. They further increase the cost and complexity to duplicate and, therefore, may serve as a significant deterrent to would-be counterfeiters. Labeling and leaflets additionally reinforce consumer protection. If the label or leaflet lack authenticating features, or are missing altogether, the user is forewarned before ingesting a potentially dangerous product. The patient need not experience an odd taste or smell to be alerted to adulteration. Leaflets and labeling, moreover, are simple and relatively inexpensive security tools for legitimate manufacturers to produce; in turn, they serve as an additional burden and barrier to counterfeiters.

Additionally, FDA should encourage use of overt, covert and forensic security technologies at the point of manufacture. Layering them with track-and-trace technologies, particularly bar codes, can further assure and enable drug authenticity. The PPLA agrees with FDA that track/trace techniques should be employed throughout the distribution system, and inactivated/destroyed at the time of dispensing. While FDA's Interim Report states that key technologies to this end are several years away, paper-based pedigree methods can be established more quickly, and then complemented by electronic technologies, if desirable, when they are more widely available and feasible. The PPLA maintains that pedigrees are fundamental to drug safety and authentication, and therefore should be implemented as quickly as possible.

Several organizations testifying before FDA argued that electronic pedigrees would be superior to paper-based pedigrees. PPLA disagrees as an electronic system would mean delays in implementation and, if implemented before mature, could potentially open the distribution chain to technical tampering, lost or misdirected data, network malfunctions, and other ills.

The PPLA applauds the FDA in its efforts to aggressively address drug counterfeiting, and stands ready to assist the Agency in employing security technologies in packaging to advance anti-counterfeiting initiatives.

Sincerely,

Carl Treleven
Vice Chairman