

April 18, 2011  
Reference No.: FDAA11009

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**VIA U.S. MAIL**

**SUBJECT: Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop [Docket No. FDA-2010-N-0633]**

Dear Sir or Madam:

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma derived products and recombinant analogues, collectively referred to as plasma protein therapies. The therapies are used in the treatment of a number of rare diseases. The diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. The therapies include clotting-factor therapies for individuals with hemophilia A and B and other bleeding disorders; immunoglobulins to treat a complex of diseases in individuals with immune deficiencies; therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset emphysema and limits substantially life expectancy; and albumin, which is used in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA member companies are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

### **Introduction**

PPTA would like to thank the Food and Drug Administration (FDA) for the opportunity to participate in the public workshop on the Determination of System Attributes for the Tracking and Tracing of Prescription Drugs, held on February 15-16, 2011,<sup>1</sup> and is pleased to provide these written comments. PPTA welcomes the opportunity to discuss plasma protein therapies at public workshops and via written submissions. PPTA appreciates FDA's efforts to provide a forum for discussing potential approaches toward a track and trace system and for obtaining input from supply chain partners on attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages and to further the Agency's goal of protecting public health by securing the supply chain against the introduction of counterfeit and other substandard drugs.<sup>2</sup>

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<sup>1</sup> See Federal Register / Vol. 76, No. 5 / Friday, January 7, 2011 / Notices, pp. 1182-3

<sup>2</sup> See Federal Register / Vol. 76, No. 5 / Friday, January 7, 2011 / Notices, p. 1183

The public workshop did explore approaches for achieving an effective and feasible track and trace system for finished prescription drug products from the supply chain point of view, including industry and the public, and obtained views on system attributes and standards that would facilitate identification, authentication, and tracking and tracing of prescription drug packages.<sup>3</sup> PPTA appreciated FDA's discussions with stakeholders of the necessary elements to accomplish effective authentication and to identify desirable features of a track and trace system.<sup>4</sup>

### **Channel integrity**

Since the formation of the first Counterfeit Drug Task Force in 2003, PPTA has supported FDA in its multilayered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit drugs.<sup>5</sup> PPTA was active throughout the development process of FDA's current recommendation for standardized numerical identification (also known as serialization) for prescription drug packages (Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages – Final Guidance). PPTA is pleased that comments made by the Association and industry materialized to changes in the final guidance. In particular, FDA adopted PPTA's recommendation that the serialized National Drug Code include a serial number of variable length of no more than 20 characters. In those comments by PPTA, as well as comments over several years prior, the Association has applauded FDA's unrelenting efforts to combat counterfeit drugs. PPTA reiterates those prior comments and reaffirms its commitment to securing the supply chain by finding solutions to the global counterfeit problem.

### **System design**

Now that FDA has developed a standard for the standardized numerical identifier, the Agency's next priority should be for a clear and definitive statement of the requirements of track and trace; FDA needs to define at what level track and trace will be implemented. Without such defined guidance, industry is unable to implement or move forward. PPTA echoes public workshop participants' sentiments that having a clear set of requirements is far more important than FDA determining the design of information technology (IT) infrastructure.<sup>6</sup> While FDA should focus on obtaining and consolidating the interests of all stakeholders to create the most feasible and appropriate set of requirements, data systems experts and solution providers can craft most efficiently IT infrastructure designs, tailored to individual stakeholder needs, from those requirements. FDA should take a global, policy-based approach; others can implement best the corresponding details.

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<sup>3</sup> Federal Register / Vol. 76, No. 5 / Friday, January 7, 2011 / Notices, p. 1183

<sup>4</sup> See Federal Register / Vol. 76, No. 5 / Friday, January 7, 2011 / Notices, p. 1183

<sup>5</sup> See Federal Register / Vol. 76, No. 5 / Friday, January 7, 2011 / Notices, p. 1183

<sup>6</sup> See Summary, p. 4

### **Harmonization**

As PPTA noted during the public workshop, harmonization, particularly internationally, is vital. To implement meaningful standards, FDA must ensure that the standards will work in a global market. PPTA represents global companies and encourages FDA to work internationally to ensure that solutions to counterfeiting are indeed harmonized so as to provide global solutions. Developing standards that are not compatible internationally only will complicate further the supply chain, possibly causing more opportunities for counterfeiters to infiltrate the system. As such, PPTA echoes the sentiments in the FDA Public Workshop Summary [hereinafter, "Summary"] that harmonization in the U.S. would overcome any difficulties posed by varying state requirements and that harmonization of U.S. and E.U. requirements would support the global market.<sup>7</sup>

### **Risk-based approach**<sup>8</sup>

Consistent with other aspects of FDA regulation, a risk-based approach for determining the scope of products to be included in a track and trace system is warranted.

### **Inference**

Inference, an essential element of a workable track and trace system, permits the substitution of aggregate-level (e.g., pallet or case) tracking for item-level tracking provided that certain additional considerations for product and package integrity are maintained throughout distribution. Allowing inference ensures implementation will proceed unimpeded with bar code technology at the package level. If inference were not allowed, then each pallet and case would need to be opened and scanned manually, resulting in an intense amount of manual labor that would slow down the supply chain, as well as unnecessarily increasing manual manipulation of product. It is critical that the supply chain continues to function safely and efficiently, ensuring patient access to needed therapies.

FDA's allowance or disallowance of inference is critical in the design of the system and costs; inference would enable the use of the 2D matrix bar code at the package level. As the 2D matrix bar code will be used widely as a data carrier, the allowance of and rules and standards for inference are very important and crucial for a functioning operation of the supply chain, especially between manufacturers and distributors.

PPTA stresses inference's importance to members and encourages FDA to continue to seek guidance from stakeholders on the issue. In fact, as described by Executive Officer Virginia Herold during the public workshop, the California State Board of

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<sup>7</sup> See Summary, p. 1

<sup>8</sup> See Summary, p. 1

Pharmacy most likely will resume work on pedigree requirements, including regulations to specify inference, in fall, 2011. As do some public workshop participants, some PPTA members rely on inference to process efficiently and distribute large amounts of inventory; inference does minimize the risk of security breaches by keeping cases or pallets sealed.<sup>9</sup>

### **Pilot and roll-out perspectives**

PPTA urges FDA first to adopt a “bookend” approach to a track and trace data management system and then to phase in remaining players.<sup>10</sup> In 2008, PPTA contracted with experts on supply chain management at the Massachusetts Institute of Technology (MIT); in 2009, the Association presented the MIT recommendations at the Plasma Protein Forum and used the recommendations as a foundation of policy in comments submitted to FDA. In its analysis, MIT recommended such a “bookend” approach.

### **Conclusion**

PPTA appreciates the opportunity to comment on the Determination of System Attributes for the Tracking and Tracing of Prescription Drugs and looks forward to continued work with FDA on its efforts to further its goal of protecting public health by securing the supply chain against the introduction of counterfeit and other substandard drugs. PPTA welcomes from FDA any questions regarding these comments and/or requests for additional information. Thank you for your consideration.

Respectfully Submitted,



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<sup>9</sup> See Summary, p. 4

<sup>10</sup> See Summary, p. 5