

April 16, 2009
Reference: FDAA09007

VIA WEB & USPS

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, RM 1061
Rockville, MD 20857

SUBJECT: Docket No. FDA-2009-D-0001, Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages

Dear Sir or Madame:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments on the Food and Drug Administration's (FDA) *Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages* [hereinafter, "Draft Guidance"]. PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat complex diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

I. Comments on Draft Guidance

Over the past several years, PPTA has submitted comments to FDA applauding the Agency's unrelenting efforts to combat counterfeit drugs. PPTA reiterates those prior sentiments and takes this opportunity to reaffirm its commitment to securing the pharmaceutical supply chain by finding solutions to the global counterfeit problem. 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.

PPTA understands that this Draft Guidance addresses provisions set forth in Section 505D of the Food, Drug and Cosmetic Act [as amended by the Food Drug Administration Amendments Act of 2007 (FDAAA)] and that this will be the first in a series of Draft Guidance documents issued by the Agency regarding the requirements

set forth in FDAAA. PPTA believes that this step-wise manner will assist in the long-term adoption of these initiatives. Additionally, PPTA agrees with other comments that issuing guidance on the Standard Numerical Identifier (SNI) requirement first is the most appropriate. The SNI provides the necessary foundation to any future supply chain security measures – validation, authentication, track and trace, etc.

PPTA supports adoption of unit level serialization, i.e., serialization at the lowest saleable unit, utilizing GS1's serialized GTIN (sGTIN) standard. The sGTIN provides the global solution that is necessary for the pharmaceutical supply chain. PPTA proposes using the sGTIN to develop a system in which the manufacture applies the serialized number (sGTIN) on the product and then provides a mechanism that would allow the end user to verify whether that product came from the manufacture by validating that serialized number, i.e. validation at point of entry and point of exit. This type of infrastructure provides patients near term protection and provides a pathway towards the future of track and trace.

FDA identified the SNI for most prescription drug packages to be the serialized National Drug Code (sNDC).¹ PPTA is supportive of FDA's choice of the sNDC for the SNI due to the ability of the sNDC to be incorporated into the sGTIN. However, some modifications of the sNDC requirements are needed. FDA states that the "sNDC is composed of the National Drug Code combined with a unique 8 digit numerical serial number generated by the manufacturer or repackager for each individual package."² PPTA believes that an 8 digit numerical serial number will not be sufficient to handle the volume of pharmaceuticals in the supply chain without repeating numbers within a few years. PPTA suggests that the 8 digit serial number be increased to adhere to the GS1 General Specification, which is defined as a serial number with a variable length, 20 character alphanumeric field. This will significantly decrease the probability of repeating serial numbers and provide greater flexibility to supply chain partners.

PPTA agrees with FDA's decision to not include lot number and expiration date as part of the sNDC as it would add complexity to the SNI. However, manufacturers should have the option to incorporate the lot number and expiration date onto their chosen data carrier (e.g. 2D Matrix barcode). PPTA understands that GS1 provides guidance for this and supports these efforts. For example, to represent additional data, GS1 recommends use of the GS1 Application Identifiers. The GS1 General Specification details how Application Identifiers are encoded into GS1 linear barcodes, GS1 DataBar,

¹ Draft Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages; p. 3

² Draft Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages; p. 3

and GS1 2D Data Matrix barcodes. The EPCglobal tag data standard details how Application Identifiers are encoded into EPC/RFID tags.

Additionally, PPTA is concerned about the amount of labeling space needed to carry both the existing linear bar code and an additional data carrier that contains the sNDC. PPTA members manufacture products that include small unit packages. There may not be enough space available on the package to have both. PPTA would like FDA to consider setting a sunset date on the linear bar code requirement. At which point, manufacturers would have the choice to code the NDC a single time with the carrier of their choice. The date for this allowance should coincide with the industry's readiness to use the serialized data encoded in GS1 2D Data Matrix and EPC/RFID carriers.

PPTA realizes that FDA did not specify a data carrier for the SNI and that the SNI identified is flexible for encoding into a variety of machine readable forms of data carriers.³ PPTA supports the use of 2D Data Matrix barcode as the carrier of the sNDC. PPTA understands that this will be an enormous undertaking for end users to move to a 2D Matrix barcode. PPTA members plan on working closely with their supply chain partners to ensure interoperability. PPTA would like to this opportunity to emphasize to FDA that any requirements need to bear this in mind and allow time for the entire supply chain to adopt.

II. Questions from Federal Register Notice (FR Vol. 74, No.11, January 16, 2009)

In addition to seeking comment on the Draft Guidance, FDA solicited comment on three specific questions.

A. Please comment on whether there are any standards that would be appropriate for serialization or other numerical identification at the case or pallet level.

PPTA is supportive of the standard setting efforts that continue to be under development through GS1 and understand that the GS1's GTIN, Serial Shipping Container Code (SSCC), and the Global Returnable Asset Identifier (GRAI) are suitable for the serialization purposes stated above. However, at this time PPTA supports the use of the sGTIN standard for item level serialization. As stated above, PPTA believes that a system that utilizes the sGTIN to provide validation at point of entry and point exit is the most appropriate. This type of system would not involve the need for case and pallet tracking and is something that manufacturers can begin implementing now.

³ Draft Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages; p. 5

B. Please comment on the necessity of having the serial number allow for alphanumeric possibilities and under what standards this might be achieved.

The sGTIN standard allows for alphanumeric capabilities if desirable. If the sNDC number is not increased to more than 8 digits, alphanumeric capabilities will be necessary due to the limitations of the available number. According to GS1, the GS1 standard for serial number is based on a system of standards that have been developed globally with multi industry input. The standard allows for a 20 character, alphanumeric field. This will give all manufacturers the flexibility to identify their products in a manner that best suits the particular needs of their customers, packaging limitations, and products. PPTA supports GS1's recommendation to allow the U.S. pharmaceutical supply chain to make full use of the GS1 Application Identifier for serial number.

C. Please comment on the standards for blood and blood components for the use of ISBT-128 or Codabar for product package identification.

PPTA commends FDA for recognizing that there may not be a single SNI for all prescription drugs, since some are different because they are linked to a single donor, i.e., blood components and hematopoietic stem cells. PPTA supports the use of ISBT-128 as the recommended SNI for blood and blood components and hematopoietic stem cells derived from peripheral and cord blood. Codabar is dated and does not provide a unique serialized identifier.

III. Conclusion

As stated above, PPTA commends FDA's continued efforts to combat the proliferating counterfeit problem. PPTA believes that with FDA's guidance and enforcement capabilities coupled with industry's continued vigilance and use of new technologies, America's drug supply will remain one of the safest in the world. PPTA appreciates the opportunity to comment and looks forward to working with FDA on this important issue. Should you have questions regarding these comments or would like to discuss these issues further, please contact me at the Association. Thank you for your consideration.

Sincerely,



Mary Gustafson
Vice President, Global Regulatory Policy
Plasma Protein Therapeutics Association