

January 9, 2012
Reference No.: FDAA12001

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

VIA WEB

SUBJECT: Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563; Request for Comments; **Initial Comment**
[Docket No. FDA-2011-N-0719]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major collectors of Source Plasma and manufacturers of plasma derived products and recombinant analogues, collectively referred to as plasma protein therapies, which 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 members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

Introduction

PPTA is pleased to provide these written comments to FDA's review of the "Bar Code Final Rule," under Executive Order 13563, "Improving Regulation and Regulatory Review." PPTA had provided comments to the proposed rule in 2003. Our comments at the time supported the use of automated technology in human drug and blood products; however, we voiced concerns that limiting technology to linear bar coding in a regulation may inhibit advances in labeling technology. As such, we recommended that, ". . . the regulation address the standard, not the technology. Specific technologies could be described in a guidance document that is more easily revised as technology advances." In essence, our thoughts remain the same.

General Comments

In general, today PPTA still supports rule-making that requires the use of automated technology and the adoption of a standard with data identifiers that are technology independent. We suggest that FDA engage in the development of a global standard, such as GS-1. Acceptable technology(ies) should be addressed in guidance that is more easily updated as technology changes over time. FDA's request for comments and information includes a comprehensive list of questions of concern to you as you review the existing regulation. While we are unable to address each comment, we have the following specific comments:

FDA Q1: *Is there a need for alternative technologies to the linear bar code? Does the current linear bar code requirement meet the current needs of the health care industry and health care providers?*

While the linear bar code may meet the current needs of the health care industry for the identification products, requiring the specific technology in a regulation does not allow innovation. Establishing a more general regulatory requirement that is supplemented by guidance provides for change and flexibility.

FDA Q2: *How has product coding technology changed since FDA issued the Bar Code Final Rule on February 26, 2004? Please provide information about the maturity, degree of adoption, cost, and ease of use of coding technologies that may be considered as alternatives or in addition to the linear bar code.*

As mentioned in the Federal Register notice, alternatives include 2D barcodes and RFID technology. It is important that regulators and industry engage in the development of acceptable global standards that address the goals and needs of any coding system.

FDA Q3: *What factors other than those listed in question 2 should FDA take into account in considering technologies alternative to or in addition to the linear bar code?*

Other factors the agency should take into account include the need to integrate the various goals and uses of labeling and coding:

- Global standardization is important. While some regulatory requirements may differ in terms of information required to be coded, it is extremely important that a global standard be adopted.
- While the standardized numerical identifier was developed to address one issue (serialization) and the bar-code rule was developed to address another (reduction in medication errors), it is important to integrate the two and determine which data elements are needed. Flexibility will be required to

have one standard that also incorporates different national product identification formats.

- Clarify the functional requirements of the bar-code whether for identification, lot & expiry, serial numbers (necessary for track and trace).

Conclusion

PPTA appreciates the opportunity to comment on FDA's review of the "Bar Code Final Rule," under Executive Order 13563, "Improving Regulation and Regulatory Review." PPTA looks forward to continued work with FDA on its effort to review and, as necessary, update and integrate regulations. PPTA welcomes from FDA any questions regarding these comments and/or requests for additional information.

Thank you for your consideration.

Respectfully Submitted,



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