



Advancing Transfusion and
Cellular Therapies Worldwide

February 9, 2009

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

RE – Docket FDA-2009-D-0001, 16 January 2009, Guidance for Industry: Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

Via electronic submission:

<http://www.regulations.gov/fdmspublic/component/main?main=SubmitComment&o=09000064808236a9>

Dear FDA Dockets Manager:

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, and developing and delivering programs and services to optimize patient and donor care and safety.

AABB appreciates the opportunity to comment on this draft guidance document, *Guidance for Industry: Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages*.

AABB fully supports FDA's position that the use of ISBT-128 or Codabar labeling for blood and blood components and hematopoietic stem cells derived from peripheral and cord blood is equivalent to the standardized numerical identification (i.e., National Drug Code [NDC]) for product packaging. This decision is in agreement with comments submitted, January 24, 2007, by AABB to the proposed rule, *Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs*, Docket 2005N-0403, 29 August 2006.

Please direct all questions regarding these comments or requests for additional information, to me at 301-215-6515 or jgiglio@aabb.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joe Giglio'.

Joseph L. Giglio, MS, MT(ASCP)SBB, CSQE(ASQ)CQA
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