NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

3051 '03 JUN 19 A10:15

June 12, 2003

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Bar Code Label for Human Drug Products and Blood; Proposed Rule

Dear Sirs:

Thank you for the opportunity to comment on the proposed bar code label requirements for human drugs and biologicals published in the March 14, 2003 *Federal Register*. The National Hemophilia Foundation (NHF) is the national voluntary health organization dedicated to improving the health and welfare of people with hemophilia, von Willebrand disease, and other bleeding disorders.

In reviewing the notice, NHF and the hemophilia medical and scientific community strongly encourage the Food and Drug Administration (FDA) to strengthen the proposal by requiring the inclusion of additional product information on the bar code. We understand FDA proposes to include only the National Drug Code in the bar code, but feel the bar code label for clotting factor products should include all of the following information:

1. The product brand name,
2. Lot number,
3. Expiration date, and
4. Number of units contained in the vial.

NHF recognizes the potential difficulties of this latter point, as the units per vial for these products vary between lots within an approved range. Labeling must occur on both the package box and the vial, as persons with hemophilia and other bleeding disorders often carry vials, but not always the box, with them.

Overall, the additional product information on the bar code will improve product tracking when needed for adverse events, recalls and withdrawals and will provide better information about the efficacy of the product, i.e., did the patient achieve the expected hemostatic response given the units administered.

02N-0204 C112

116 West 32nd Street • 11th Floor
New York, NY 10001
(800) 42-HANDI • (212) 328-3700 • fax (212) 328-3777
www.hemophilia.org • info@hemophilia.org

Founded 1948

NHF also encourages the development of similar bar coding requirements for implantable medical devices, such as ports, central lines, and artificial joints, as this information currently is inconsistently recorded.

Thank you again for the opportunity to comment on the proposed bar coding rule. We applaud FDA's efforts to reduce medical errors and support the inclusion of additional information on the bar code to further support this goal.

Sincerely,

Gina A. Shreve

Gina Shreve, Ph.D.
President