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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Docket No. 2003D-0236

To Whom It May Concern:

We are writing to comment on "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis". We feel elimination of syphilis testing of blood donors should be discussed again for the following reasons:

- Last reported case of transfusion transmitted disease was in 1968
- Declining incidence of syphilis in the United States
- Current manufacturing and processing techniques for whole blood components and apheresis platelets makes the potential for transmission highly unlikely
- The low incidence of syphilis in the heavily pre-screened donor population, means that continued serologic screening has minimal effect on public health
- Expense (both in resources and money used to perform the testing as well as the donors lost because of the high incidence of false positive screening tests)
- Emotional trauma experienced by the donors due to false positive screening tests

We thank you for consideration of our comments.

Sincerely,

S. Breannan Moore, M.D.
Division Chair, Transfusion Medicine
Mayo Clinic Rochester

cc: Mary Foss
Sheryl Tran

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