America's Blood Centers

It's About *Life.*

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May 14, 2004

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

Re: Docket No. 2004N-0101: Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; and
Requirements for Donor Notification

Dear Docket Officer:

On behalf of America's Blood Centers (ABC), thank you for the opportunity to comment on the reporting aspects of FDA's new requirements for testing human blood donors for evidence of infection due to communicable disease agents and for donor notification.

We have reviewed the tables containing the estimated annual reporting burden related to these new rules. Although we did not obtain detailed data from the ABC membership on the costs of producing the required reports, we have no reason to believe that these are not reasonable estimates. Furthermore, we do not believe that the estimated times constitute a burden on community blood centers.

Yours truly,

/gmf/

G. Michael Fitzpatrick, Ph.D.
Chief Policy Officer