



OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

725 15th Street, NW ♦ Suite 700 ♦ Washington, DC 20005 ♦ 202-393-5725 ♦ 1-888-USBLOOD ♦ FAX 202-393-1282
Web Site: <http://www.americasblood.org> ♦ e-mail: abc@americasblood.org

March 13, 2001

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

Re: Docket No. 00D 1618
Draft Guidance: Variances for Donors with Hereditary Hemochromatosis

To Whom it May Concern:

America's Blood Centers commends the Center for Biologics Evaluation and Research for the draft Guidance for Industry: *Variances for Blood Collection from Individuals with Hereditary Hemochromatosis*.

Blood collection agencies have been collecting and discarding blood from donors with hereditary hemochromatosis (HH) at the same time that collections of blood have declined nationwide. Since there is no evidence that blood from donors with HH have any added risk for recipients, we are pleased that CBER has created a way for collecting centers to obtain a variance that will allow them to use this valuable blood without labeling restrictions, should they find it appropriate to do so. We agree with CBER that eliminating the collection fee for all HH collections should alleviate any concerns about creating a financial incentive to donate.

We wish to congratulate CBER on the elegant simplicity of this document. The content of the variance requests is concise and reasonable, as is the safety data collection requirement.

We appreciate CBER's stated commitment to work with the Health Care Financing Administration in ensuring that financial incentives for persons with HH to donate blood for transfusion are removed. We urge CBER to continue this dialog.

Yours truly,

Mary Townsend, M.D., Chair
Scientific, Medical and Technical Committee
America's Blood Centers

00D-1618

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**America's Blood
Centers**

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