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September 3, 2002

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

Re: Docket No. 02D-0124: Draft Guidance for Industry: Notifying FDA of Fatalities
Related to Blood Collection or Transfusion.

Dear Docket Officer:

America's Blood Centers (ABC) appreciates the opportunity to comment on the Center for Biologics Evaluation and Research's draft guidance, *Notifying FDA of Fatalities Related to Blood Collection or Transfusion*. For your information, ABC is a national network of locally-controlled, not-for-profit community blood centers that collect almost half of the US blood supply from volunteer donors. Collectively, we operate in 45 states and serve patients at more than half of the nation's 6,000 hospitals. ABC members collected more than 7 million units of whole blood and apheresis platelets in 2001.

Although blood donor fatalities and patient fatalities related to blood transfusion are rare events, ABC appreciates CBER's efforts to standardize reporting of these incidents. We have the following specific comments on the draft guidance.

III. How to Notify FDA. The draft guidance allows for several forms of communication. We appreciate this flexibility.

ABC members request that the draft specify that submission by e-mail, fax, or telephone could be performed by a blood center using its existing communications technology, and that FDA will provide a confirmation receipt to verify voice mail notification.

IV. Initial Notification, Donor Fatality

ABC members request that FDA provide a reporting form to standardize the initial notification. It would be helpful if this form could be downloaded from the CBER Web site, then sent by e-mail, or printed out and sent by Fax.

The draft guidance requests that an overview of the health history be provided in the initial notification.

We recommend that the “overview” of health history be limited to the blood donor medical history (*i.e.*, only temperature, pulse, blood pressure, hematocrit at time of donation, and screening questions).

V. Seven Day Report.

We request that FDA standardize the seven day notification by providing a reporting form. As with the initial report, it would be helpful if this form could be downloaded from the CBER Web site, then sent by e-mail, or printed out and sent by Fax.

We also want to point out that blood donor facilities and transfusion services may require special permission to obtain the discharge summaries, death certificates, and autopsy reports requested in the draft guidance and that this permission could be denied.

A. Patient/Recipient Fatality. We would like to point out that some blood centers provide small hospitals with transfusion services either full or part time. These blood centers may not always be notified when a transfusion reaction fatality occurs at one of their hospital customers.

ABC suggests that the guidance make it clear that when hospital transfusion services are contracted to or run by a blood establishment, both the hospital and the blood center should have a clear understanding as to who is responsible for reporting fatalities to CBER. In addition, in cases where it is the hospital that reports a fatality to CBER, ABC recommends that the guidance require the hospital to provide a timely copy of its report to the blood center that runs its transfusion service so the blood center can investigate the fatality.

B. Donor Fatality. During the initial notification process, the requested information includes “an overview of previous donations.” The seven day report requests information on all donations during the past 2 years.

We recommend that the final guidance define “previous donations” as those donations *one* year from the date of the involved product.

We would also like FDA to acknowledge that donor facilities may not have access to the laboratory reports from healthcare facilities that could help determine the cause of the fatality.

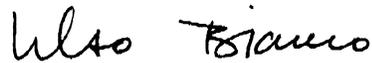
C. Fatality Associated with Therapeutic Apheresis or Certain Therapeutic Phlebotomies
The necessity for providing performance logs, maintenance records, manufacturer's notices or

recalls on machine parts during the past two years seems excessive for equipment without previous adverse incident.

We recommend that FDA change the timeframe in the requirement for performance logs and other equipment records to six months from the date of incident. This timeframe would provide FDA with data from six monthly and two quarterly quality control reports.

We appreciate the opportunity to comment on this proposed rule. I would be glad to answer any questions you might have on our comments.

Yours truly,

A handwritten signature in black ink that reads "Celso Bianco". The signature is written in a cursive style with a large initial "C".

Celso Bianco, M.D.
Executive Vice President