



Together, we can save a life

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July 22, 2002

Docket Management Branch (HFA-305)
Docket No. 02N-0159
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration. (67 FR 36613-36615; May 24, 2002; Docket No. 02N-0159)

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross' Biomedical Services (Red Cross) concerning the Food and Drug Administration's (FDA's) Federal Register Notice: "*Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration*" (hereafter referred to as *Focus Groups*).

The Red Cross is committed to the safety of our volunteer blood donors, the patients, and the public we serve. With the help of more than four million donors, the Red Cross collected approximately 6,100,000 whole blood units last fiscal year. The Red Cross also annually recovers approximately 1,000,000 liters of volunteer blood donor plasma which is processed to manufacture numerous plasma derivatives that are distributed to healthcare providers throughout the country. Furthermore, the Red Cross supplies a significant portion of the nation's tissue for transplantation and provides clinical laboratory and therapeutic services on behalf of numerous providers across the country.

Since the activities noted above are regulated by the FDA, the Red Cross is very interested in commenting on information collection provisions relating to *Focus Groups*.

The Red Cross relies on the collection of information from the public, particularly with regard to the blood and tissue donation process. It is imperative to better understand donors throughout the entire donor lifecycle including awareness of the need for blood, donor recruitment, the donation process and post-donation communication. Focus groups can help identify potential donors as well as provide insight into the needs and motivations of both donors and potential donors. In addition, focus groups are one of several techniques that have been used to help the industry and the FDA understand how well donors comprehend health screening questions.

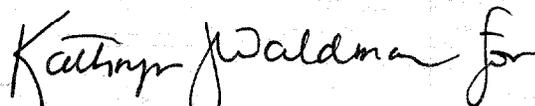
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Red Cross supports "clearance" for the above purpose since focus groups, if well defined, can be a useful mechanism for aiding donor recruitment programs and development of donor screening questions.

Red Cross appreciates this opportunity to comment on *Focus Groups*. If you have any questions, please contact Anita Ducca, Director of Regulatory Affairs, at 703-312-5601.

Sincerely,



Gary Dolch, Ph.D.
Senior Vice President
Quality and Regulatory Affairs
Biomedical Services