American Red Cross

National Headquarters

March 16, 2001

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

RE: Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis; Docket # 00D-1618; 65 Fed. Reg. 79866

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) draft *Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis*, as published in the *Federal Register* on December 20, 2000.

The American Red Cross, through its 36 Blood Service regions, supplies almost half of the nation's blood component transfusion needs. ARC's top priority is the safety of the nation's blood supply and the patients we serve. As a result, we believe it is important to comment on the draft guidance relating to blood collection from individuals with hereditary hemochromatosis (HH). Previously, the FDA required that blood obtained by therapeutic phlebotomy, including collection from hemochromatosis patients, be "conspicuously" labeled with the donor's illness. Physicians, patients, and hospitals most frequently chose not to use this blood, and it was usually discarded. There is no risk of transmitting hemochromatosis through blood transfusion. However, the Red Cross has not accepted blood from people with hemochromatosis because they are not voluntary, altruistic donors. Voluntary, altruistic donation is one of the key components to ensure the safety of the blood supply and the patients we serve.

As the draft guidance notes, the FDA is now providing recommendations to blood establishments that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disease on the container label. The document also outlines the conditions under which FDA will consider approving variances to the current regulations, under the provisions of 21 CFR 640.120.

Our specific concerns relate to FDA's consideration of requests for variances to the labeling and physician examination regulations (21 CFR 640.3(d) and 21 CFR 640.3(f), respectively)). According to the draft guidance, variances would be considered by the Agency if the "blood center would not charge a fee for phlebotomies performed on individuals with HH, including those who do not meet allogeneic donor suitability requirements." Thus, in order to obtain a variance, blood establishments would have to phlebotomize all HH patients that present themselves to the blood establishment. ARC is concerned that this requirement introduces a

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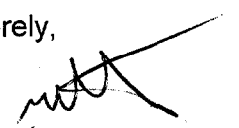
level of administrative and product management complexity into the blood donation process that could affect the integrity of our nation's blood supply. ARC understands that this document only provides guidance to industry and blood establishments are not obliged to request variances. However, it is essential that all blood establishments and the Agency take every step necessary to ensure the safest possible blood supply. This responsibility is compromised when a process is established that allows individuals to present themselves to blood establishments for therapeutic phlebotomies where some of these individuals would not meet current allogeneic standards for blood donation. Also, some of these individual could have other conditions that would make their care more complex than the normal donors presenting to the blood collection site.

It is also important to note that such individuals are not presenting themselves for purely altruistic reasons. Irrespective of whether the HH patient meets donor suitability requirements, such individuals are donating for treatment. Whether the blood establishment provides such service free of charge does not change this basic reason for donation. Relying on volunteer blood donors who donate blood purely for altruistic reasons is the first step in a multi-barrier system that is in place to ensure the safest possible blood supply to our nation.

The ARC has provided, and will to continue to provide, patient services such as therapeutic apheresis and therapeutic phlebotomy. However, these services are provided where it is clear that a patient, and not a donor, is involved in the process. Importantly, these services occur in a controlled environment that is different than the standard blood donation process.

The American Red Cross appreciates the opportunity to comment on the draft guidance relating to blood collection from HH patients. If there are any questions regarding these comments please contact Kurt Kroemer, Director, Regulatory Affairs at 202-639-3031.

Sincerely,



Glenn M. Mattei, Esq.
Interim Vice President
Quality Assurance and Regulatory Affairs
Biomedical Services
American Red Cross