



JOHNSTON MEMORIAL HOSPITAL 6 JAN -6 P12:12
HOSPITAL

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Division of Dockets (HFA-305)
Food and Drug Administration
5530 Fishers Lane, Room 1061
Rockville, MD 20852

12/13/05

Re: Comments on FDA Draft Guidance, Collection of Platelets by Automated Methods

We are writing as the medical director and supervisor of a donor center servicing the blood product needs of two hospitals in southwest Virginia. We are the largest supplier in our rural region of the Commonwealth of Virginia.

With regards to donor selection, our instrument manufacturer has recommended that a prospective donor have a platelet count of at least 150,000/uL. The draft guidance also recommends a predonation WBC count, but offers no guidance as to what constitutes an acceptable count or the rationale for performing this count, e.g., prevention of disease transmission to the recipient, detection of undiagnosed hematologic malignancy, etc.

We believe that increasing the deferral period for ASA containing compounds from the currently recommended 36 hours to the proposed 5 days, and for NSAIDS from no deferral to 3 days, will create confusion and donor shortages. Donors are capable of remembering OTC medications that they have taken over the past day or two, but the longer the interval from medication to interview, the more errors are made.

We also think that reducing the number of allowable collections in a given year will cause donor shortages. Counting triple donations as three components and thus limiting those donors to eight donations per year will obviously cause a need for more pheresis donors. This might not be possible in rural areas. Under the current rules, which we believe to provide adequate protection, we will draw a pheresis donor once per month, up to twelve times per year. Under the proposed rule, if we are able to collect a triple product with each donation that donor will be limited to eight donations per year. Additional donors will be required to make up that deficit. Additionally, the guidance specifies that a post-donation platelet count be performed after each collection, but does not specify a time frame; immediately post collection would likely not reflect an accurate count, but a prolonged delay and an additional needle stick would likely cause problems with donor cooperation and retention.

Sincerely,

David R. Hudgens, MD
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