



Date

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket No. 2005D-0330: Draft Guidance for Industry and FDA Review Staff
on Collection of Platelets by Automated Methods**

Dear Sir/Madam:

Baxter International Inc., through its subsidiaries, assists health-care professionals and their patients with the treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. Baxter appreciates the opportunity to provide comments on this draft guidance.

We offer the following comments:

III B2 – Donor Management

This draft Guidance includes a requirement to limit collections to 24 total platelet-pheresis doses in a 12-month period, rather than the current policy of 24 pheresis collections in a 12 month period, regardless of the volume. This could result in a decrease of single donor platelets by up to 67% from triple dose donors and by up to 50% from double dose donors. We believe that this change will have an adverse impact on the current blood component supply possibly creating a shortage of platelets available for critically ill patients. We are unaware of any data that would suggest the current collection practice has any adverse impact on the health of donors.

III D – Medical Coverage

We believe that the availability of a “qualified” physician be on the premises (or within 15 minutes away) at the donor collection center is overly burdensome and unnecessary. If a donor has a serious reaction, an emergency physician, not a transfusion medicine

physician, is needed. This is best achieved by calling emergency medical assistance (911).

III A – Donor Selection

You indicate that aspirin deferral for donors should be five days. The AABB Technical Manual, 15th Edition and the Standards for Blood Banks and Transfusion Services, 23rd edition (2004) both suggest that a period of 36 hours for Aspirin deferral is adequate. We refer you to a 1972 article published in *The New England Journal of Medicine*¹ that AABB bases its policy of a 3-day deferral. The FDA should adopt this as the standard.

III B4 – Donation Frequency

You indicate that the total volume of all blood components retained per collection should not exceed 500 mL for donors under 175 pounds and 600 mL for donors weighing 175 pounds or more. The AABB standard recommends that the total volume retained from a collection not exceed 10.5 mL/kg. The FDA should adopt this as the standard.

VI D Table 1 – Collection Performance Qualification Criteria

In this Table, the residual white blood cell (WBC) count should be $< 5.0 \times 10^6$ per pheresis collection and per component for double and triple collections, there should be $\geq 85\%$ component retention. The WBC limit should apply to platelet doses only and not to the parent product of the collection. Therefore, therapeutic doses derived from single, double and triple dose collections will have the same limit of 5.0×10^6 per dose.

We would like to understand what scientific or medical data caused the Food and Drug Administration to put forward these changes. We recommend that the Food and Drug Administration consider holding a Part 15 Public Hearing to gather and review data relevant to the proposed changes.

If you have any questions, please contact me at (301) 977-7795. Thank you for the opportunity to share Baxter's views with you.

Sincerely,

/s/

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Global Regulatory Affairs & Medical Vigilance
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¹ Stuart MJ, Murphy S et al. Platelet Function in Recipients of Platelets from Donors Ingesting Aspirin. NEJM 1972; 287:22, 1105-1109.