

June 8, 2005

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

Re: [Docket No. 2005N-0017]
Proposed Rule: **Reclassification from Class III to Class II of Automated Blood Cell Separator Device Operating by Centrifugal Separation Principle**

Re: [Docket No. 2005D-0019]
Notice: **Draft Guidance on Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle**

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.

In the March 10, 2005 *Federal Register* (2005N-0017), the Food and Drug Administration (FDA) proposes to reclassify from class III to class II all automated blood cell separator devices operating by centrifugal separation principles. Automated blood cell separator devices operating by filtration principles intended for the routine collection of blood and blood components were reclassified to class II in February 2003. Also, in the March 10, 2005 *Federal Register* (2005D-0019), FDA published the availability of a draft guidance that will serve as the special controls for these devices. For currently marketed devices not approved under a Premarket Approval (PMA) process, the sponsor should file with the Food and Drug Administration (FDA) for three consecutive years an annual report on the anniversary date of the device reclassification from class III to class II, or, on the anniversary date of 510(k) clearance. These reports should include a summary of anticipated and unanticipated donor adverse device events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) requirements. The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation. The safety information submitted to FDA is not to be considered an admission of causation or liability.

Baxter appreciates the opportunity to provide comments on both the proposed rule and the draft guidance. Baxter endorses the reclassification of automated blood cell separator devices operating by centrifugal separation principle.

With regard to the draft guidance, Baxter believes there is ambiguity about the reporting requirements in the draft guidance. For example, do you intend to require three year annual reporting only for the initial 510(k) clearance for the automated blood separator? If not, what are the nature and significance of changes made to the medical device and/or its labeling that would prompt another three year period for reporting annual summaries of adverse events? If all changes require a new reporting period, sponsors may find themselves in a continual loop of reporting. Is it correct that for a device originally approved under the PMA process, then switched to a 510(k), annual reporting would not be required? Does this reporting requirement apply to all automated blood cell separators operating by centrifugal or filtration separation intended for routine collection of blood and blood components regardless of when the original clearance was granted? Would any pre-amendment devices be “grandfathered” in that the reporting would not be required? Baxter asks FDA to more clearly delineate the criteria that would result in the required three year reporting summarizing donor adverse events in annual reports.

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/

Marie A. Urban
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Cc: Kathleen Swisher (HFM-17), CBER, FDA