America's Blood Centers

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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July 2 , 2001

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

Re: Docket No. 95P-0351: Hematology and Pathology Devices; Reclassification of Automated Differential Cell Counters (*Federal Register*, May 9, 2001)

Dear Docket Officer:

America's Blood Centers (ABC) is pleased to comment on the Food and Drug Administration's proposal entitled *Hematology and Pathology Devices; Reclassification of Automated Differential Cell Counters.* ABC is an association representing 75 independent blood centers responsible for the collection, processing and distribution of approximately half of the nation's blood supply.

ABC wishes to commend the agency on its proposal to reclassify automated differential cell counters (ADCC) from class III (pre-market approval) to class II (special controls). We agree with FDA that the *Guidance for Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance to Industry* is an adequate special control and thus provides reasonable assurance of the safety and effectiveness of the device.

ABC further agrees that reclassification of this device will reduce the regulatory burden with respect to the device and has the potential to increase competition in the marketplace by lowering manufacturers' cost. This increase in competition, with potential decreases in technology cost, is of particular importance to the blood banking industry since the choices of technology for counting residual white cells in leukoreduced products currently are limited to a single method (flow cytometry). The reliance of the blood community on a single, complex technology is of great concern to us. Recent developments in transfusion medicine highlight the need for multiple, robust cell-counting technologies, particularly the migration towards leukoreduced blood components.

The reclassification of the ADCC will remove barriers to the development of alternative testing thus ensuring that instrument specificity and sensitivity keep pace with the expectations of FDA and the blood industry.

Thank you again for the opportunity to comment on the proposed regulation.

Yours truly,

Celso Bianco (JS)

Celso Bianco, M.D.
Executive Vice President

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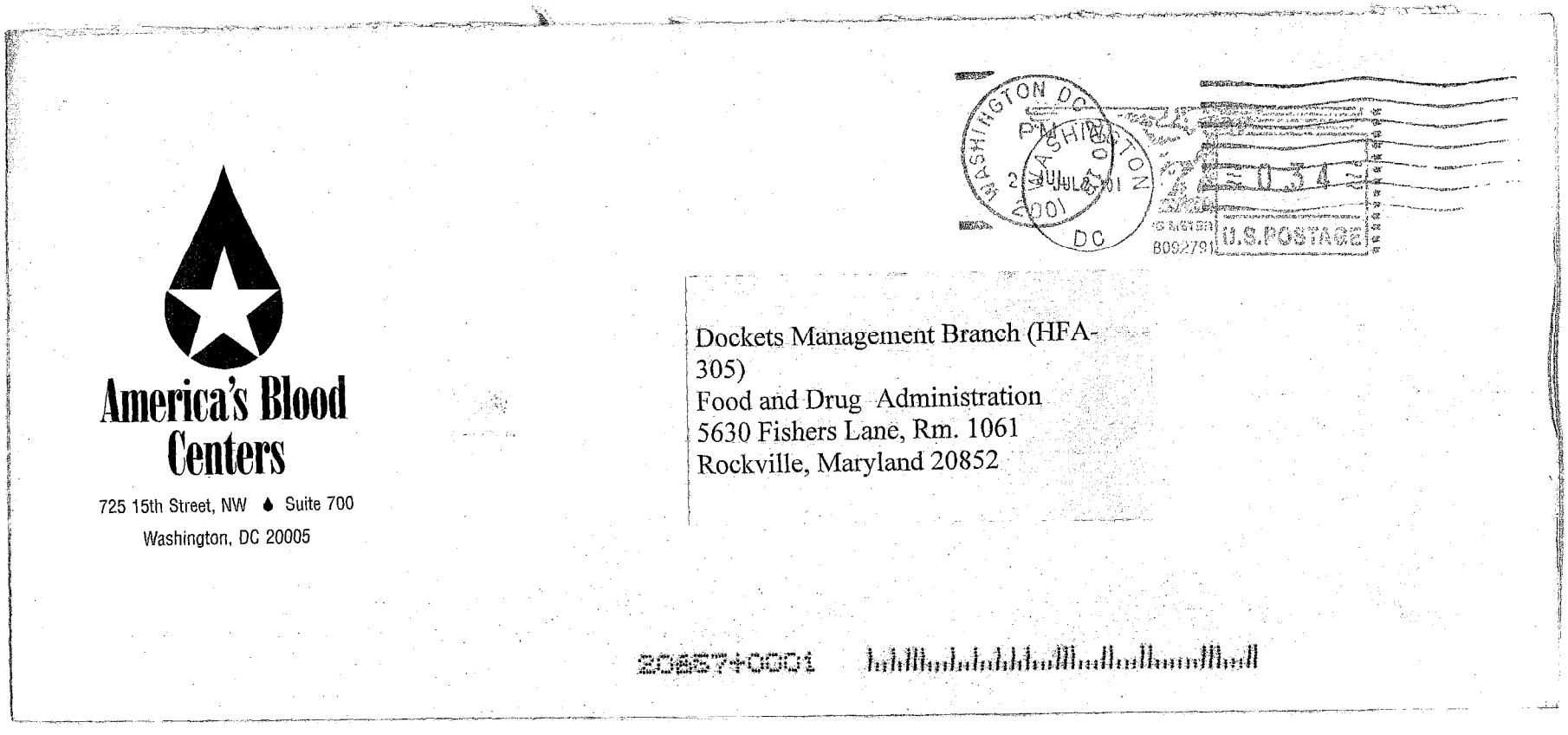

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