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SUMMARY MINUTES

OF THE

HEMATOLOGY AND PATHOLOGY DEVICES PANEL MEETING

OPEN SESSION

December 15, 1999

**Conference Room 20 B
Corporate Building
9200 Corporate Boulevard
Rockville, Maryland**

Hematology and Pathology Devices Panel

December 15, 1999

Acting Chair

Diane D. Davey, M.D.

Executive Secretary

Michelle Stuart

Voting Members

Mary Nielsen, M.D.

Juan C. Felix, M.D.

Simon Ogambi, Ph.D.

Temporary Voting Members

George G. Birdsong, M.D.

Diane H. Norback, M.D., Ph.D.

Margaret S Pepe, Ph.D.

Andrew A. Renshaw, M.D.

Robert J. Williams, Jr., M.D.

FDA

John Dawson

Statistician

Louise Magruder

FDA Reviewer

Steve Gutman

Director, Director of Clinical and Laboratory Devices

DECEMBER 15, 1999--OPEN PUBLIC SESSION

The session was called to order at 9:04 a.m. Panel Executive Secretary Michelle Stuart read the conflict of interest statement, noting that potential or perceived conflicts had been considered regarding Drs. Davey, Birdsong, and Felix, but their full participation was allowed. Ms. Stuart then read appointments to temporary voting status for Drs. Birdsong, Norbeck, Pepe, Renshaw, Williams, and Davey, as well as an appointment to serve as acting chair for Dr. Davey. She asked the members of the panel to introduce themselves and state their areas of expertise.

Open Public Hearing

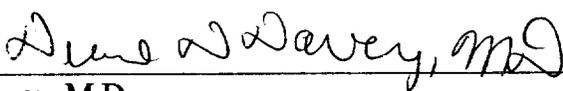
Panel Chair Dr. Diane Davey invited public attendees to address the panel. There were no requests to speak. A scheduled update on postmarket evaluation was cancelled.

The Open Session was adjourned at 9:20 a.m.

I certify that I attended the Open Session of the Hematology and Pathology Devices Panel on December 15, 1999, and that this summary accurately reflects what transpired.


Michelle Stuart
Executive Secretary

I approve the minutes of this meeting as recorded in this summary.


Diane D. Davey, M.D.
Acting Panel Chair

Summary minutes prepared by
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