



ANNUAL REPORT
OF THE
BLOOD PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met five times during the reporting period. Meetings were held in Gaithersburg, Maryland and Rockville, Maryland.

The dates of those meetings were October 21-22, 2004, March 17-18, 2005, July 21, 2005, July 22, 2005, and September 29, 2005.

The meetings on March 17-18, 2005, July 22, 2005, and September 29, 2005 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

March 17-18, 2005. The Committee discussed and made recommendations on the following topics: the safety of albumin revisited, the review of standards for plasma products for transfusion, and a study design for abbreviated uniform donor history questionnaire. FDA is currently evaluating these issues. On March 18, 2005 in open session, the Committee reviewed and discussed the Laboratory of Molecular Virology. On March 18, 2005, the Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Virology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

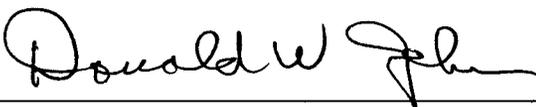
July 22, 2005 Subcommittee meeting. The Subcommittee discussed and made recommendations on the research programs in the Office of Blood Research and Review. These discussions related to components of the Strategic Plan of 2004 and FDA's Critical Path to New Medical Products. The Subcommittee held a closed session to permit discussion of personnel and program actions for the intramural programs in the Office of Blood Research and Review. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations will be discussed at a future meeting of the Blood Products Advisory Committee.

September 29, 2005. The Committee reviewed, discussed, and made recommendations on the safety of Exjade (deferasirox – tablets for oral suspension) for the treatment of chronic iron overload due to blood transfusions manufactured by Novartis Pharmaceuticals. FDA is currently evaluating the recommendations. The Committee also reviewed and discussed the research programs in the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review. The Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

Detailed information related to these meetings is available in the annual report.

20/26/05

 Date



 Donald W. Jehn
 Executive Secretary

Blood Products Advisory Committee

Committee Roster

Chairman

James R. Allen, M.D., M.P.H.

Expertise: Public Health, Epidemiology

Term: 02/08/02 - 09/30/06

President and CEO

American Social Health Association

P.O. Box 13827

Research Triangle Park, NC 27709

Judith R. Baker, M.H.S.A.*

Expertise: Consumer Representative

Term: 06/29/05-09/30/08

Regional Coordinator

Federal Hemophilia Treatment Centers/Region IX

Childrens Hospital Los Angeles

4650 Sunset Boulevard, Box 54

Los Angeles, CA 90028

Kenneth Davis, Jr., M.D.

Expertise: Trauma, Critical Care

Anesthesiology

Term: 02/08/02 - 09/30/05

Professor of Surgery and Clinical Anesthesia

Vice Chairman, Dept. of Surgery

231 Albert Sabin Way, ML 558

Cincinnati, OH 45267-0558

Donna M. DiMichele, M.D.

Expertise: Pediatric Hematology, Oncology

Term: 02/08/02 - 09/30/05

Associate Prof. of Clinical Pediatrics

Weill Med. College & Graduate School of

Medical Sciences

Cornell University

525 East 68th Street, Room P-695

New York, New York 10021

Samuel H. Doppelt, M.D.

Expertise: Orthopedic Surgery, Transplantation

Term: 02/08/02 - 09/30/05

Chief, Dept. of Orthopedic Surgery

The Cambridge Hospital

1493 Cambridge Street

Cambridge, MA 02139

Executive Secretary

Donald Jehn

Center for Biologics Evaluation and Research

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Judy F. Lew, M.D.

Expertise: Infectious Disease, Molecular Epidemiology

Term: 02/08/05 - 09/30/05

Asst. Prof. of Pediatrics

Univ. of Florida

Dept. of Pediatric Immunology & Infectious Diseases

P.O. Box 100296

Gainesville, FL 32610

Catherine S. Manno, M.D.

Expertise: Hematology, Oncology

Term: 11/30/04 - 09/30/07

Associate Professor of Pediatrics

The Children's Hospital of Philadelphia

Physician-in-Chief Office

9th Floor, Main Hospital

34th Street and Civic Center Boulevard

Philadelphia, PA 19104

Keith C. Quirolo, M.D.

Transfusion Medicine, Hematology, Biology

Term: 11/30/04 - 09/30/07

Hemoglobinopathy Pediatrician

Department of Hematology

Children's Hospital and Research Center at

Oakland

747 52nd Street

Oakland, CA 94609-1809

George B. Schreiber, Sc.D.

Expertise: Epidemiology, Health Studies

Term: 11/30/04 - 09/30/07

Associate Director for Health Studies

Westat

1650 Research Blvd., WB272

Rockville, MD 20850

Jonathan C. Goldsmith, M.D.
Expertise: Internal Medicine/Hematology
Term: 02/13/03 – 02/17/05
Vice President, Medical Affairs
Immune Deficiency Foundation
40 West Chesapeake Avenue, Suite 308
Towson, MD 21204

Donna S. Whittaker, Ph.D.
Expertise: Medical Technology, Transfusion
Medicine, Immunology
Term: 11/30/04 - 09/30/07
Director
Robertson Blood Center (MCXI-BBC)
36000 Darnall Loop, Box #7
Fort Hood, TX 76544

Louis M. Katz, M.D.**
Expertise: Industry Representative
Term: 06/29/05-09/30/08
Executive Vice President, Medical Affairs
Mississippi Valley Regional Blood Center
5500 Lake View Parkway
Davenport, IA 52807

Harvey G. Klein, M.D.
Expertise: Transfusion Medicine
Term: 02/08/02 - 09/30/05
Chief, Dept. of Transfusion Med.
National Institutes of Health
Warren G. Magnuson Clinical Center
10 Center Dr., Bldg. 10, Rm. 1C711
Bethesda, MD 20892

Matthew J. Kuehnert, M.D.
Expertise: Infectious Diseases, Internal
Medicine, Biochemistry and Cell Biology
Term: 11/30/04 - 09/30/07
CDR, U.S. Public Health Service Assistant
Director for Blood Safety
Division of Viral and Rickettsial Diseases
Centers for Disease Control and Prevention
(CDC)
1600 Clifton Road, Mailstop A-30
Atlanta, GA 30333

Suman Laal, Ph.D.
Expertise: Immunology, Microbiology
Term: 02/08/02 - 09/30/05
Assistant Professor
Department of Pathology
New York University School of Med.
423 East 23rd Street, Rm. 18124N
VA Medical Center
New York, NY 10010

*CONSUMER REPRESENTATIVE

**NON-VOTING INDUSTRY REPRESENTATIVE