

**BLOOD PRODUCTS ADVISORY COMMITTEE**  
**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**  
March 18-19, 2004

**EXECUTIVE SECRETARY**

Smallwood, Linda A., Ph.D.  
Office of Blood Research and Review  
Center for Biologics Evaluation  
and Research, FDA, (HFM-350)  
1401 Rockville Pike, Suite 200N  
Rockville, MD 20852-1448  
TEL: (301) 827-3514  
FAX: (301) 827-2843  
E-MAIL: Smallwood@cber.fda.gov

**COMMITTEE MANAGEMENT SPECIALIST**

Muckelvene, Pearlina K. 10/16/04 10:37  
Scientific Advisors & Consultants  
Staff  
Center for Biologics Evaluation  
and Research, FDA, (HFM-71)  
1401 Rockville Pike  
Rockville, MD 20852-1448  
TEL: (301) 827-1281  
FAX: (301) 827-0294  
E-MAIL: Muckelvene@cber.fda.gov

**CHAIRMAN**

Nelson, Kenrad E., M.D. 9/30/04  
Professor, Dept. of Epidemiology  
Johns Hopkins University  
School of Hygiene & Public Health  
615 N. Wolfe, Room E-7132  
Baltimore, MD 21205

**MEMBERS**

Allen, James R., M.D., M.P.H. 9/30/05  
President and CEO  
American Social Health Association  
P.O. Box 13827  
Research Triangle Park, NC 27709

Cunningham-Rundles, Charlotte,  
M.D., Ph.D \* 9/30/04  
Professor, Departments of Medicine,  
Pediatrics, and Immunobiology  
Mount Sinai Medical Center  
1425 Madison Ave., 11<sup>th</sup> Floor, Rm. 20  
New York, NY 10029

Davis, Kenneth, Jr., M.D. 9/30/05  
Professor of Surgery and Clinical  
Anesthesia  
Vice Chairman  
University of Cincinnati Med. Ctr.  
Dept. of Surgery  
Div. of Trauma/Critical Care  
231 Albert Sabin Way, ML 558  
Cincinnati, OH 45267-0558

DiMichele, Donna M., M.D.\* 9/30/05  
Associate Prof. of Clinical  
Pediatrics  
Weill Med. College & Graduate  
School of Medical Sciences  
Cornell University  
525 East 68<sup>th</sup> Street, Room P-695  
New York, NY 10021

Doppelt, Samuel H., M.D. 9/30/05  
Chief, Dept. of Orthopedic Surgery  
The Cambridge Hospital  
1493 Cambridge Street  
Cambridge, MA 02139

Goldsmith, Jonathan C., M.D.\* 9/30/04  
Vice-President, Medical Affairs  
Immune Deficiency Foundation  
40 West Chesapeake Avenue, Suite 308  
Towson, MD 21204

4025 R

**MEMBERS** (Continued)

Klein, Harvey G., M.D. 9/30/05  
Chief, Dept. of Transfusion Med.  
National Institutes of Health  
Warren G. Magnuson Clinical Center  
10 Center Dr., Bldg. 10, Rm. 1C711  
Bethesda, MD 20892

Laal, Suman, Ph.D. - 9/30/05  
Assistant Professor  
Department of Pathology  
New York University School of Med.  
423 East 23<sup>rd</sup> Street, Rm. 18124N  
VA Medical Center  
New York, NY 10010

Lew, Judy F., M.D.\* 9/30/05  
Asst. Prof. of Pediatrics  
Univ. of Florida  
Dept. of Pediatric Immunology &  
Infectious Diseases  
P.O. Box 100296  
Gainesville, FL 32610

**CONSUMER REPRESENTATIVE**

Vacant

**NON-VOTING INDUSTRY REPRESENTATIVE**

Strong, D. Michael,  
Ph.D, BCLD(ABB) 9/30/04  
Executive Vice President, Operations  
Puget Sound Blood Center  
921 Terry Avenue  
Seattle, WA 98104

**TEMPORARY VOTING MEMBERS**

Chamberland, Mary E. M.D., M.P.H.  
Deputy Director  
Div. of Viral & Rickettsial  
Diseases, NCID  
CDC and Prevention  
1600 Clifton Road  
Building 3, Rm. 117, MS A30  
Atlanta, GA 30333

Harvath, Liana, Ph.D. 9/9/05  
Deputy Director  
Div. of Blood Diseases and Resources  
National Heart, Lung, and Blood  
Institute  
National Institute of Health  
6701 Rockledge Drive  
Rockledge II, Room 10170  
Bethesda, MD 20817

Hollinger, F. Blaine, M.D.  
Professor of Medicine, Virology  
And Epidemiology  
Director, Eugene B. Casey Hepatitis  
and HIV Research Center and  
Diagnostic Laboratory  
Baylor College of Medicine  
One Baylor Plaza, BCM-385  
Houston, TX 77030

Hoofnagle, Jay H., M.D.  
Director  
Division of Digestive Diseases and  
Nutrition  
National Institute Diabetes and  
Digestive and Kidney Diseases  
National Institutes of Health  
Democracy II  
6707 Democracy Blvd, Room 677  
Bethesda, MD 20817

Knowles, Katharine E.  
Executive Director  
Health Information Network  
7211 Greenwood Avenue N  
Seattle, WA 98103-0762

Liang, T. Jake, M.D.  
Chief  
Liver Diseases Section (HNC682)  
National Institute of Diabetes and  
Digestive and Kidney Diseases  
National Institute of Health  
Building 10  
Magnuson CC, Room 9B16  
10 Center Drive  
Bethesda, MD 20892

Linden, Jeanne V., M.D., M.P.H.  
Director, Blood and Tissue Resources  
New York State Department of Health  
Wadsworth Center  
Empire State Plaza  
Albany, NY 12201-0509

McGee, Daniel L., Ph.D.  
Professor, Department of Statistics  
Florida State University  
Tallahassee, Florida 32306-4330

TEMPORARY VOTING MEMBERS (Cont.)

Quirolo, Keith C., M.D.  
Hemoglobinopathy Pediatrician  
Department of Hematology  
Children's Hospital and Research  
Center at Oakland  
747 52<sup>nd</sup> Street  
Oakland, CA 94609-1809

Schreiber, George B., Sc.D.  
Associate Director for Health  
Studies  
Westat  
1650 Research Blvd., BB272  
Rockville, MD 20850

Whittaker, Donna S., Ph.D.  
Lt. Colonel, Medical Service Corps  
United States Army  
Chief, Blood Services  
Department of Pathology & Area  
Laboratory Services (MCHE-PLP)  
Brooke Army Medical Center  
3851 Roger Brooke Drive  
Fort Sam Houston, TX 78234-6200

**SPEAKERS**

Busch, Michael P. M.D., Ph.D.  
Vice President, Blood Systems  
Director, Blood Systems Research  
Institute  
Professor of Laboratory Medicine  
University of California,  
San Francisco  
270 Masonic Avenue  
San Francisco, CA 94118

Hu, Dale J., M.D., M.P.H.  
Acting Associate Director for  
Science  
Division of AIDS, STD and TB  
Laboratory Research  
Centers for Disease Control and  
Prevention (CDC)  
1600 Clifton Road, Mailstop A-12  
Atlanta, GA 30333

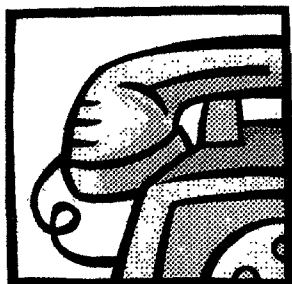
Kuhnert, Wendi L., Ph.D.  
Chief, Hepatitis Reference Lab  
Division of Viral Hepatitis  
Center for Disease Control  
and Prevention  
1600 Clifton Road, N.E, MS A-33  
Atlanta, GA 30333

Leparc, German F., M.D.  
Chief Medical Officer  
Florida Blood Services, Inc.  
10100 Dr. Martin Luther King Jr.  
Street North  
St. Petersburg, FL 33716

Lok, Anna S., M.D.  
Professor of Internal Medicine  
Director of Clinical Hepatology  
University of Michigan Medical  
Center  
3912 Taubman Center  
1500 East Medical Center Drive  
Ann Arbor, MI 48109-0362

Stramer, Susan L., Ph.D.  
Executive Scientific Officer  
American Red Cross  
9315 Gaither Road  
Gaithersburg, MD 20877

\*WILL NOT ATTEND  
Revised: March 17, 2004



## **FDA ADVISORY COMMITTEES BY PHONE 1-800-741-8138**

The FDA Advisory Committees Information Line provides public access by telephone to the Federal Advisory Committees process in a convenient and timely manner.

The toll-free number is listed in telephone directories across the country so callers can learn, among other things, when and where upcoming meetings will be held, how to request documents under the Freedom of Information Act, how to nominate individuals to the advisory committees, and how to reach committee staffers.

Callers hear a recorded message providing general information and a menu directing them to choose the Center for which they seek information. Additional menus assist in selecting the type of information needed. Phone numbers of committee staff are included in the messages so that callers can call the appropriate office if additional information is needed.

Frequent callers who wish to learn dates and locations for a particular meeting can bypass the general menu and information by pressing a 10 digit identification number as soon as the line is answered. An identification number has been assigned to each committee and will appear in each Federal Register notice for the committee. The codes are listed below:

Allergenic Products Advisory Committee	3014512388
Biological Response Modifiers Advisory Committee	3014512389
Blood Products Advisory Committee	3014519516
Transmissible Spongiform Encephalopathies Advisory Committee	3014512392
Vaccines and Related Biological Products Advisory Committee	3014512391

Long distance callers will use 1-800-741-8138 to access the information line. Those within the Washington metropolitan area should use 301-443-0572 to access the information.

## **CBER Automated E-mail Lists**

CBER has established three automated e-mail lists to distribute information within CBER and to the public.

**CBERINFO** - *Members of this list will receive all FPRECALL and BLOODINFO documents, as well as all other new documents, including guidelines, points to consider, and other CBER information.*

**BLOODINFO** - *Members of this list will receive all FPRECALL notices, and other blood-related documents.*

**FPRECALL** - *Members of this list will receive notices of recalls and market withdrawals of fractionated products.*

To subscribe to any of these list go to CBER's home page at: [www.fda.gov/cber](http://www.fda.gov/cber) and click on the line that says "Subscribe to CBER". Follow the instructions from there.



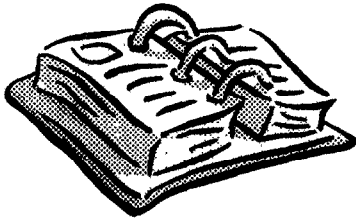
## **HOW TO ACCESS FDA ON THE WEB [www.fda.gov](http://www.fda.gov)**

New Drug and medical device approvals, the latest press releases and *Enforcement Reports*, *Federal Register* notices and much, much more vital information from the Food and Drug Administration is now available on the Internet's World Wide Web

The FDA Internet Home Page provides up-to-date authoritative information on food, human and animal drugs, biologics, medical devices, and more from the agency responsible for products that account for 25¢ of every consumer dollar. From the web page you can easily locate consumer education materials, press releases, industry guidance, bulletins for health professionals and a wealth of other useful documents and data from FDA's centers and offices.

### **ADVISORY COMMITTEE ROSTERS, CHARTERS, ETC.**

These can be accessed on the web at: [www.fda.gov/oc/advisory/acbiologics.html](http://www.fda.gov/oc/advisory/acbiologics.html)



### **BRIEFING MATERIALS AND TRANSCRIPTS**

[www.fda.gov/oc/advisory/acbiologics.html](http://www.fda.gov/oc/advisory/acbiologics.html)

Briefing materials should be posted 24 hours in advance of the meeting. Slides and other materials not received before the meeting will be posted shortly after the meeting.

The transcripts of the open portions from advisory committee meetings will appear on the FDA website about four weeks after the meeting.

Transcripts of the open session may also be requested in writing through the Freedom of Information (FOI) Office approximately 15 working days after the meeting at a cost of 10¢ per page. Written request should be made to: Food and Drug Administration, Freedom of Information Staff, HFI-35, Room 12A-30, 1500 Fishers Lane, Rockville, MD 20857. Questions may be directed to the FOI Staff at 301-827-6567 or faxes may be sent to 301-443-1726.