Food and Drug Administration

Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science

Chair

Charles Cooney, Ph.D. Expertise: Biomedical Engineering Term: 01/30/03-10/31/06 Professor of Chemical and Biochemical Engineering Department of Chemical Engineering Massachusetts Institute of Technology Room 56-469b, 25 Ames St Cambridge, Massachusetts 02139

**Paul H. Fackler, Ph.D.

Expertise: Industry Representative Generic drug issues, pharmaceutical bioavailability and bioequivalence Term: 07/13/04-10/31/07 Vice President, Generic Research and Development Teva Pharmaceuticals USA 1090 Horsham Road North Wales, Pennsylvania 19454-1090

Carol A. Gloff, Ph.D.

Expertise: Pharmaceutical Sciences Term: 07/11/05 – 10/31/08 Carol Gloff & Associates 6 Langdon Road Natick, Massachusetts 01760

Meryl H. Karol, Ph.D.

Expertise: Immunochemistry Term: 01/30/03-10/31/06 University of Pittsburgh Department of Environmental and Occupational Health 130 DeSoto Street Pittsburgh, Pennsylvania 15261

Melvin V. Koch, Ph.D.

Expertise: Analytical Chemistry Term: 02/20/04-10/31/07 Director, Center for Process Analytical Chemistry University of Washington 141 CHL, Box 351700 Seattle, Washington 98195-1700

**Gerald P. Migliaccio

Expertise: Industry Representative, Quality Operations and Systems, Pharmaceutical Manufacturing Operations Term: 02/02/04-10/31/07 Vice President, Global Quality Operations Pfizer, Inc. 235 East 42nd Street New York, New York 10017

Expertise:

* Consumer Representative ** Industry Representative – NON VOTING

Designated Federal Officer

Mimi T. Phan, Pharm.D. Advisors and Consultants Staff Center for Drug Evaluation and Research Food and Drug Administration (HFD-21) 5600 Fishers Lane Rockville, Maryland 20857 (301) 827-7001 Fax: (301) 827-6801 Email: mimi.phan@fda.hhs.gov

Members

Kenneth R. Morris, Ph.D.

Expertise: Pharmaceutical Material Science Term: 08/01/04-10/31/08 Professor Department of Industrial and Physical Pharmacy School of Pharmacy 1336 Robert E. Heine Pharmacy Building Room G18B Purdue University West Lafayette, Indiana 47907-1336

Cynthia R.D. Selassie, Ph.D.

Expertise: Chemistry Term: 01/30/03-10/31/06 Professor of Chemistry, Department of Chemistry Pomona College Seaver North, Rm. 219, 645 N. College Avenue Claremont, California 91711-6338

Nozer Singpurwalla, Ph.D.

Expertise: Statistician Term: 02/20/04-10/31/07 Director, Institute for Reliability and Risk Analysis Distinguished Research Professor, Professor of Statistics George Washington University 2201 G Street Room 315 Washington, DC 20052

* Marc Swadener, Ed.D.

Consumer Representative Teacher Education Computers/Imaging Statistics Term: 01/30/03-10/31/06 2235 Dartmouth Avenue Boulder, Colorado 80305-5207

Jürgen Venitz, M.D., Ph.D.

Expertise: Clinical Pharmacology Term: 02/20/04-10/31/07 Associate Professor, Dept. of Pharmaceutics Virginia Commonwealth University School of Pharmacy PO.Box 980533, 410 N 12th Street Richmond, Virginia 23298-0533