CENTER FOR DRUG EVALUATION AND RESEARCH

Wednesday, August 10, 2005

Office of the Center Director (HFD-001)
Steven K. Galson, MD, M.P.H.
301-594-5400
Deputy Center Director
Douglas Throckmorton, MD (Actg)

- Associate Director for Medical Informatics: Randy Levin
- Associate Director for Policy: Jane Axelrad
- Controlled Substance Staff: Deborah Leiderman, MD
- Drug Safety Oversight Board: Susan Cummins, MD., M.P.H.

Office of Medical Policy (HFD-040)
Robert Temple, MD
301-594-6758
Deputy Director
Rachel Behrman, MD, M.P.H.

- Div Scientific Investigations
- Div of Drug Marketing, Advertising and Communication

Office of Counter Terrorism and Pediatric Drug Dev (HFD-950)
Rosemary Roberts, MD
301-827-7777
Deputy Director
Shirley Murphy, MD (Actg)

- Division of Pediatric Drug Dev
- Division of Counter-Terrorism

Office of Clinical Pharmacology and Biopharmaceutics (HFD-850)
Lawrence J. Lesko, PhD
301-594-5690
Deputy Director for Science
Shiew-Mei Huang, PhD

- Div of Pharmaceutical Evaluation I
- Div of Pharmaceutical Evaluation II
- Div of Pharmaceutical Evaluation III

Office of Executive Programs (HFD-006)
Deborah Henderson
301-594-6779
Deputy Director
Jayne Ware

- Executive Operations Staff
- Quality Assurance Staff
- Advisors and Consultants Staff
- International Programs
- Ombudsman
- Organizational Development and Strategic Planning

Office of New Drugs (HFD-020)
John Jenkins, MD
301-594-3937
Deputy Director
Sandra Kweder

- Pharmacology/Toxicology Staff
- Program Management Team
- Study Endpoints and Labeling Development Team
- Pregnancy and Lactation Team
- Guidance Policy Team
- Regulatory Affairs Team

Office of Pharmacoepidemiology and Statistical Science (HFD-001)
Paul Seligman, MD
301-827-6276
Deputy Director
Jonca Bull, MD

Office of Management (HFD-010)
Russell Abbott
301-594-6741

- Div of Management and Budget
- Div of Management Services

Office of Regulatory Policy (HFD-005)
Jane Axelrad
301-594-5400

- Div of Regulatory Policy I
- Div of Regulatory Policy II
- Div of Information Disclosure Policy

Office of Pharmaceutical Science (HFD-003)
Helen N. Winkle
301-594-2847
Deputy Director
Ajaz S. Hussain, PhD

- Informatics and Computational Safety Analysis Staff
- Process Analytical Technologies
- Quality Implementation Staff
- New Drug Microbiology Team

Office of Drug Safety (HFD-400)
Ralph Lillie, R.Ph, M.P.H (Actg)
301-827-3219
Deputy Director
Anne Trontell, MD

- Div of Surveillance, Research, & Comm Support
- Div of Medication Errors & Tech Support
- Div of Drug Risk Evaluation

Office of Training and Communications (HFD-200)
Nancy Smith, PhD
301-827-1651
Deputy Director
John Friel

- Div of Training and Development
- Div of Drug Information
- Div of Library and Info Services
- Div of Public Affairs

Office of Biotechnology Products (HFD-121)
Steven Kozlowski, MD (Actg)
301-443-5089
Deputy Director
Elizabeth Shores, PhD (Actg)

- Div of Monoclonal Antibodies
- Div of Therapeutic Proteins

Office of Generic Drugs (HFD-600)
Gary Buehler
301-827-5845
Deputy Director
Robert West, R.Ph

- Div of Bioequivalence
- Div of Chemistry I
- Div of Chemistry II
- Div of Chemistry III
- Div of Labeling and Program Support

Office of Drug Evaluation I (HFD-101)
Robert Temple, MD (Actg)
301-594-6758
Deputy Director
Rachel Behrman, MD, M.P.H. (Actg)

- Div of Neurology Products
- Div of Psychiatry Products
- Div of Cardio-Renal Drug Products
- Botanicals Review Team

Office of Drug Evaluation III (HFD-103)
Florence Houn, MD
301-827-3144
Deputy Director
Julie Beitz, MD

- Div of Gastrointestinal and Coagulation Drug Products
- Div of Reproductive and Urologic Drug Products
- Div of Dermatologic and Dental Drug Products

Office of Biostatistics (HFD-700)
Robert O'Neill, PhD
301-827-3195
Deputy Director
Charles Anello, ScD

- Quantitative Methods & Research Staff
- Division of Biometrics I
- Division of Biometrics II
- Division of Biometrics III
- Biologic Therapeutics Statistical Staff

Office of Compliance (HFD-300)
David J. Horowitz
301-827-8910
Deputy Director
Betty L. Jones

- Div of New Drugs and Labeling Compliance
- Div of Manufacturing and Product Quality
- Div of Compliance Risk Mgmt and Surveillance

Office of New Drug Chemistry (HFD-800)
Moheb M Nasr, PhD
301-827-5918
Deputy Director
Chi-Wan Chen, PhD

- Div of New Drug Chemistry I
- Div of New Drug Chemistry II
- Div of New Drug Chemistry III

Office of Testing and Research (HFD-900)
Ajaz Hussain, PhD (Actg)
301-594-2847
Deputy Director
Vacant

- Lab. of Clinical Pharmacology
- Div of Applied Pharmacology Research
- Div of Pharmaceutical Analysis
- Div of Product Quality Research

Office of Drug Evaluation II (HFD-102)
Robert Meyer, MD
301-827-5920

- Div of Pulmonary Drug Products
- Div of Metabolic and Endocrine Drug Products
- Div of Anesthesia, Analgesia, and Rheumatology Products

Office of Drug Evaluation IV (HFD-104)
Mark Goldberger, MD, M.P.H.
301-827-2350
Deputy Director
Edward Cox, MD, M.P.H.

- Div of Anti-Infective and Ophthalmologic Products
- Div of Anti-Viral Drug Products
- Div of Special Pathogen and Immunologic Drug Products

Office of Information Management (HFD-140)
Steven Wilson (Actg)
301-594-5411
Deputy Director
Cathie Schumaker

- Business Information Staff
- Review Technology Staff
- Division of Records Management

Office of Information Technology (HFD-070)
Margo Burnette
301-827-6240
Deputy Director
Jim Shugars (Actg)

- Quality Assurance Staff
- Technology Support Services Staff
- Division of Applications Development Services

Office of Drug Evaluation VI (HFD-106)
Karen D. Weiss, MD
301-827-5098
Deputy Director
David Ross, MD

- Div of Review Management and Policy
- Div of Therapeutic Biological Internal Medicine Products

Office of Nonprescription Products (HFD-105)
Charles Ganley, MD
301-827-2250
Deputy Director
Brian Harvey, MD, PhD

Office of Oncology Drug Products (HFD-Pending)
Richard Pazdur, MD
301-594-2473
Deputy Director
Vacant

- Division of Biological Oncology Products
- Division of Oncology Drug Products
- Division of Medical Imaging Drug Products