Biographic Summaries for the Recommended Members
for the LLNA Peer Review Panel

Nathalie Alépée, Ph.D.

Dr. Alépée performed research leading to a Ph.D. in Medical Virology and Microbiology at the Centre national de la recherché scientifique research institute, Gif sur Yvette, France. She is currently the Global Pfizer Leader for photosafety, including the global portfolio support and Associate Research Fellow in Investigative Toxicology, at Pfizer Global Research and Development, Amboise, France. As a laboratory manager in the Molecular and Cellular Toxicology Group with Pfizer, she implemented the Local Lymph Node Assay in the laboratory. She serves on the European Centre for the Validation of Alternative Methods (ECVAM) Scientific Advisory Committee (ESAC), representing the European Federation of Pharmaceutical Industries Associations (EFPIA). She is also the Pfizer representative to the European Partnership on Alternative to Animal Testing (EPAA), in two working groups; Identification of Opportunities, Including R&D (working group 2), and Validation and Acceptance (working group 5). She served as a peer reviewer of the reduced LLNA test protocol and prediction model for ESAC in 2007 and has been designated as an ESAC peer reviewer for ECVAM's performance standards for the standard LLNA.

Ann Marie Api, Ph.D.

Dr. Api received a Ph.D. from Aston University in Birmingham, England and is currently Vice President of Human Health Sciences at the Research Institute for Fragrance Materials (RIFM), as well as the Scientific Director. She is responsible for the human health scientific program, and the investigation and initiation of new research and testing projects for RIFM. She is also Adjunct Assistant Professor at the University of Medicine and Dentistry of New Jersey. She is a member of 10 professional organizations, including the American Contact Dermatitis Society, the European Society of Contact Dermatitis, and the Society of Investigative Dermatology. She participated in the WHO International Workshop in Skin Sensitization in Chemical Risk Assessment held in Berlin, Germany in 2006. She is author of over 100 publications and presentations relevant to dermatology and dermatotoxicology.

Nancy Flournoy, M.S. Ph.D.

Dr. Flournoy received a M.S. degree in Biostatistics from the University of California at Los Angeles, and a Ph.D. in Biomathematics from the University of Washington. She is Professor and Chair of the Department of Statistics at the University of Missouri-Columbia. Her research interests include adaptive designs, bioinformatics, chemometrics, clinical trials, and environmetrics. She has an extensive list of edited volumes and papers on statistical theory, statistical genetics and immunology, epidemiology in immune suppressed subjects, clinical trials for prevention and treatment of viral infection, transplantation biology and its effects on digestion, lungs, eyes, mouth, and central nervous system, optimization of statistical processing, and additional papers, interviews, and technical reports. She has editorial responsibilities for numerous statistical journals, serves on numerous advisory boards, and nominating committees. She is a member and

past Chair of the Council of Sections of the American Statistical Association, and served in various other statistical, medical and toxicological societies or programs as Chair or as a member of the Board of Directors. She is a former member of SACATM. She also served on the Expert Panels for the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) that evaluated the Revised Up-and-Down Procedure; the Current Validation Status of In Vitro Test Methods for Identifying Ocular Corrosives and Severe Irritants; and Five In Vitro Pyrogen Test Methods.

Thomas Gebel, Ph.D.

Dr. Gebel received a Ph.D. in Toxicology from the University of Mainz and is certified as a toxicologist by the German Society of Toxicology. His scientific interests are in biomonitoring, genetic toxicology, environmental hygiene, and occupational toxicology. He has published over 40 papers in peer-reviewed scientific journals. He is employed by the German Federal Institute for Occupational Safety and Health, and is an Associate Professor at the University of Goettingen. Dr. Gebel is currently a member of the Organisation for Economic Co-operation and Development (OECD) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) expert group on sensitization and head of the German advisory committee on classification and labeling of existing substances and biocides. Dr. Gebel also is head of the German Delegations to the United Nations Economic and Social Council (ECOSOC) Sub-Committee of Experts on the GHS, and to the OECD Task Force on Harmonisation of Classification and Labeling. He participated in the World Health Organization (WHO) International Workshop in Skin Sensitization in Chemical Risk Assessment held in Berlin, Germany in 2006.

Sidney Green Ph.D., F.A.T.S.

Dr. Green received a Ph.D. in Biochemical Pharmacology from Howard University. His research interests include toxicology, mutagenic assay systems, and alternatives to animals in toxicology. He is currently Graduate Professor of Pharmacology at Howard University and a faculty member at the Centers for Alternatives to Animal Testing at the Johns Hopkins University School of Public Health. Previously, he has been Director of the Department of Toxicology at Covance Laboratories Inc. and the Director of the Division of Toxicological Research at the U.S. Food and Drug Administration (FDA). Dr. Green is a Fellow of the Academy of Toxicological Sciences (F.A.T.S.). He has served on numerous expert panels and committees. He was a participant in an International Workshop organized by ICCVAM and NICEATM on *In Vitro* Methods for Assessing Acute Systemic Toxicity in 2000. He served on the ICCVAM/NICEATM Expert Panels that evaluated the Corrositex® Test Method for Assessing Dermal Corrosivity Potential of Chemicals, and *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants. He is a former member of the ICCVAM Advisory Committee on Alternative Toxicological Methods (ACATM) and of SACATM. He has authored over 60 publications for peer-reviewed journals.

Kim Headrick, B.Admin., B.S.

Kim Headrick received Bachelor of Administration and B.Sc. degrees from the University of Ottawa, Canada. She is currently International Harmonization and Senior Policy Advisor for Health Canada, and Chair of the UN Sub-Committee of Experts on Globally Harmonized System of Classification and Labelling of Chemicals (GHS). She manages the overall strategy for the implementation of the GHS in Canada. She was awarded the Queen Elizabeth Commemorative Golden Jubilee Medal in 2002, which focuses on the achievements of people who, over the past 50 years, have created the Canada of today. She is a member of the OECD Task Force on Harmonization of Classification and Labelling and the OECD Expert Group Meeting on Sensitization Hazards.

Dagmar Jírová, M.D., Ph.D.

Dr. Jírová received a Ph.D. from the Medical Faculty of Hygiene at Charles University in Prague. She is currently the Head of the Reference Center for Cosmetics, and Head of National Reference Laboratory for Experimental Immunotoxicology at the National Institute of Public Health in the Czech Republic. Her main responsibilities include safety assessment of consumer products, particularly cosmetics and their ingredients, performance of toxicological methods in vivo in animals, human patch testing for local toxicity assessment, and introduction of in vitro techniques for screening of toxicological endpoints using cell and tissue cultures. She represents the Czech Republic in the Standing Committee on Cosmetics of the European Commission. She is an ESAC-ECVAM member and was involved in Peer Review Panel for Skin Irritation Validation Study and LLNA test protocol and prediction model. She is author of more than 100 publications and presentations relevant to dermatotoxicology including recent presentation at the 6th World Congress on Alternatives & Animal Use in the Life Sciences, held in Tokyo, 2007, titled “Comparison of Human Skin Irritation and Phototirritation Patch Test Data with Cellular in vitro Assays and Animal in vivo data”.

Michael Luster, Ph.D.

Dr. Luster received a Ph.D. in Immunology from Loyola University of Chicago. He was formerly Chief, Toxicology and Molecular Biology Branch, Health Effects Laboratory Division, National Institute for Occupational Safety and Health (NIOSH), and currently serves as a senior advisor to the Director of the Health Effects Laboratories and the staff of Toxicology and Molecular Biology Branch at NIOSH. Program areas include neuroscience, dermatology, molecular carcinogenesis, molecular epidemiology, molecular toxicology, molecular epidemiology, and inflammation/immunotoxicology. In addition, Dr. Luster conducts basic and applied research in immunotoxicology including its application in risk assessment. Current research activities include molecular epidemiology studies of genetic polymorphism involved in workplace-related diseases and experimental studies involving occupational allergic rhinitis. Dr. Luster is also working with various staff at the EPA through the Risk Assessment Forum to develop immunotoxicity-testing guidelines. He also directed two studies for the NTP on the Toxicology and the Carcinogenesis of Promethazine and Ortho-phenylphenol, in 1990 and 1986, respectively. He is a co-author of over 300 publications in peer-reviewed journals.

Howard Maibach, M.D.

Dr. Maibach received an M.D. from Tulane University. He is currently a professor in the Department of Dermatology at the University of California, San Francisco (USCF), where he is also Chief of the Occupational Dermatology Clinic. In his 35 years at UCSF, Dr. Maibach has written and lectured extensively on dermatotoxicology and dermatopharmacology. His current research programs include defining the chemical-biologic faces of irritant dermatitis and the study of percutaneous penetration. Dr. Maibach served on the 1998 ICCVAM Peer Panel that evaluated the Murine LLNA. Dr. Maibach has been on the editorial boards of over 30 scientific journals and is a member of 19 professional societies including the American Academy of Dermatology, San Francisco Dermatological Society, and the International Commission on Occupational Health. He has co-authored over 1500 publications related to dermatology.

James McDougal, Ph.D., F.A.T.S.

Dr. McDougal earned a Ph.D. in Pharmacology/Toxicology at the University of Arizona. He is currently Professor and Director of Toxicology Research in the Department of Pharmacology and Toxicology at Wright State University's Boonshoft School of Medicine. Prior to his appointment at Wright State, he worked in the Air Force toxicology research organization for about 17 years. He has active skin research programs related to dermal pharmacokinetics, molecular biology of skin irritation, dermal risk assessment, and biologically based mathematical modeling. He has served on many national committees, published more than 75 manuscripts, and consults for a wide variety of government and industry organizations. Dr. McDougal is a member of the National Academy of Sciences (National Research Council) Committee on Toxicology and the American Congress of Governmental Industrial Hygienists Threshold Limit Value Committee for Chemical substances. Dr. McDougal is also past president of the Dermal Toxicology Specialty Section of the Society of Toxicology

Michael Olson, Ph.D.

Dr. Olson received a Ph.D. in Toxicology from the University of Arkansas for Medical Sciences, with dissertation research conducted at the U.S. FDA National Center for Toxicological Research. Following graduate training, he served as NIEHS NRSA Post-doctoral Fellow in the Department of Pharmacology, School of Medicine - University of North Carolina. Currently he is Director, Occupational Toxicology, Corporate Environment Health and Safety for GlaxoSmithKline. Dr. Olson is a Fellow of the Academy of Toxicological Sciences (ATS). His research interests include mechanisms of chemically induced toxicity; genetic toxicity; xenobiotic metabolism; alternative methods in toxicology; hazard evaluation, risk assessment, and communication. Dr. Olson has authored a number of peer-reviewed manuscripts and book chapters in these areas as well as preparing many occupational health effects reviews for pharmaceutical active ingredients, isolated intermediates, and associated chemicals. He has served as an editorial board member and *ad hoc* referee for numerous toxicology and biosciences journals. In addition, he has worked as a Visiting Scientist, U.S. EPA, as well as advisor to U.S. EPA Risk Assessment Forum, U.S. National Institutes of Health (Toxicology Study Section I), U.S. Air Force, Transportation Research Board, and the National Research Council - National Academy of Sciences. A member of several biomedical

professional societies, Dr. Olson has served in elective and appointed positions in the Society of Toxicology, including Chairman of the SOT Occupational Health Specialty Section.

Raymond Pieters, Ph. D.

Dr. Pieters received a Ph.D. at Utrecht University and is currently an Associate Professor at the Institute for Risk Assessment Sciences, and Group Leader for Immunotoxicology at that institution. In 2007, he presented a paper on Development of Strategies to Assess Drug Hypersensitivity at the Congress of the European Societies of Toxicology. He was involved in the development of the Reporter Antigen Popliteal Lymph Node Assay, an assay to assess the immunomodulating potential of chemicals, which enables differentiation between immunosensitizing chemicals (sensitizers), immunostimulating chemicals (irritants), and chemicals that have no apparent immunological effects. He has published over 70 papers on sensitization and other subjects in immunotoxicology in peer-reviewed journals, including a review article, *Murine Models of Drug Hypersensitivity*, in 2005.

Jean Regal, Ph.D.

Dr. Regal received a Ph.D. in Pharmacology from the University of Minnesota. She is currently a Professor in the Department of Pharmacology, Department of Biochemistry & Molecular Biology and Associate Dean of Faculty Affairs, Medical School Duluth, University of Minnesota. Her current research is focused on respiratory allergy, especially asthma. She has served on multiple NIH review panels regarding asthma, as an immunotoxicologist in 2000 for an Institute of Medicine Committee on Health Effects Associated with Exposures Experienced during the Persian Gulf War, as well as on the 1998 ICCVAM Peer Panel that evaluated the Murine LLNA. In 2007 she served as an ad hoc reviewer for the NTP Board of Scientific Counselors for two nominations: Artificial Butter Flavoring Mixture & O-phthalaldehyde, at NIEHS. Also in 2007, she served on an NIEHS Center in Environmental Toxicology pilot project program for the University of Texas Medical Branch at Galveston. She is currently Vice-President-elect of the Immunotoxicology Specialty Section of SOT and Associate Editor of the Journal of Immunotoxicology. Dr. Regal has authored over 50 research articles and reviews in peer-reviewed journals and holds two patents on pulmonary administration of sCR1 and other complement inhibitory proteins.

Jonathan Richmond, BSc (Hons) Med.Sci., MB ChB, FRCSEd, FRMS

Dr. Richmond received a Bachelor of Science in Medical Science with Honors (BSc [Hons] Med.Sci.) and Bachelor of Medicine and Bachelor of Surgery (MB ChB) degrees with Distinction in Medicine and Therapeutics from Edinburgh University. Presently, he is head of the Animals Scientific Procedures Division at the Home Office. He is a Fellow of the Royal College of Surgeons of Edinburgh (FRCSEd) and a Fellow of the Royal Society of Medicine (FRMS). Other appointments include convener of the UK interdepartmental group on the 3Rs, board member UK National Centre for the 3Rs, convener of the International Standards Organization Technical Corrigendum 194/Working Group 3 (*Biocompatibility of Medical Device Materials*), and member of related expert working groups. He is a former member of the European Union (E.U.) Committee on Scientific and Technical Progress and past Chairman of the European

Commission Technical Expert Working Group on ethical review. He served as chair of the peer review panel for the reduced LLNA test protocol and prediction model for ESAC in 2007 and has been designated as an ESAC peer reviewer for ECVAM's performance standards for the standard LLNA. He served on the ICCVAM/NICEATM Expert Panel that evaluated five i*n vitro* pyrogen test methods. He has a variety of publications in peer-reviewed journals and national and international meetings, on the principles and practice of surgery, regulation of biomedical research, principles of humane research, bioethics, and public policy.

Stephen Ullrich, Ph.D.

Dr. Ullrich received a Ph.D. in Microbiology from Georgetown University. He is currently the Dallas/Fort Worth Living Legends Professor, and Professor of Immunology at the University of Texas, M.D. Anderson Cancer Center, where he is also Associate Director, The Center for Cancer Immunology Research. He is also a member of the Animal Research Strategic Advisory Committee. He has served numerous national review committees and panels, including the 1998 ICCVAM Peer Panel that evaluated the Murine LLNA. Dr. Ullrich has authored over 75 peer-reviewed publications, over 30 invited articles, and he holds four patents in the U.S., E.U., and Australia for a UV-induced Immunosupressive Substance. He is the past President of the American Society for Photobiology.

Michael Woolhiser, Ph.D.

Dr. Woolhiser received a Ph.D. in Pharmacology and Toxicology from the Medical College of Virginia at Virginia Commonwealth University. He is a specialist in immunotoxicology and is currently a toxicologist for the Dow Chemical Company where he serves as a Technical Leader for Immunotoxicology, and Polyurethane Business Toxicology Consultant. Dr. Woolhiser is also an Adjunct Professor at the Center for Integrative Toxicology, Michigan State University. He is a member of the Program Committee of the Society of Toxicology's Immunotoxicology Specialty Section. He has served on numerous working groups, including an LLNA Expert Working Group under the European Crop Protection Agency's Toxicology Expert Group, an ECETOC LLNA Task Force. He has authored 29 peer-reviewed publications.

David Lovell, Ph.D., FIBiol, CBiol, F.S.S., CStat

Dr. Lovell received a Ph.D. from the Department of Human Genetics and Biometry, University College, London. He currently holds the position of Reader in Medical Statistics in the Postgraduate Medical School at the University of Surrey, England. He is a Chartered Biologist (CBiol), Fellow of the Royal Statistical Society (F.S.S.) and a Chartered Statistician (CStat). His present research interests include bioinformatics and multivariate statistical analysis, pharmacogenetics/pharmacogenomics, experimental design and statistical analysis and quantitative risk assessment and mathematical modeling. He served on the ICCVAM/NICEATM Expert Panels that evaluated the Frog Embryo Teratogenesis Assay - Xenopus (FETAX), *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants, and Five *In Vitro* Pyrogen Test Methods. He has over 70 publications in peer-reviewed journals.

Peter Theran, V.M.D.

Dr. Theran holds a Doctor of Veterinary Medicine degree from the University of Pennsylvania. He has had many years of experience both as a veterinary internal medicine specialist at the Massachusetts SPCA's Angell Memorial Animal Hospital in Boston, and as the director of Boston University Medical Center's Laboratory Animal Science Center. He presently serves on a number of government committees as an animal welfare member, and is a member of the Board of Directors of the Institute for In Vitro Sciences in Gaithersburg, MD and Chimp Haven in Shreveport, Louisiana. He served on the ICCVAM/NICEATM Expert Panels that evaluated the *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants, and Five *In Vitro* Pyrogen Test Methods. He is a former member of ACATM and SACATM. He is presently working as a consultant.

Takahiko Yoshida, M.D., Ph.D.

Dr, Yoshida earned his M.D. and a Ph.D. in Medical Science from Tokai University. He is currently Professor in the Department of Health Science at Asahikawa Medical College. Prior to this appointment, he held the posts of Instructor, Assistant Professor and Associate Professor at the Tokai University School of Medicine. He has also been a Guest Researcher at NIEHS. He has also worked as an occupational physician for major Japanese corporations, including Toyota and Sony. Dr. Yoshida’s research interests include occupational health, public health, environmental health and preventative medicine. He is a member of the International Congress of Occupational Health, the Japanese Society of Hygiene, the Japanese Society of Immunotoxicology, the Japanese Society of Clinical Ecology, and the U.S. Society of Toxicology.