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DRUG INFORMATION ASSOCIATION

In collaboration with the International Scientific Association for Probiotics and Prebiotics

FIRST INTERNATIONAL DIA CONFERENCE:

Developing Probiotics as Foods and Drugs – Scientific and Regulatory Challenges

October 16-17, 2006 | Marriott Conference Center
University of Maryland College Park Campus, Adelphi, MD

PROGRAM CHAIRS

PATRICIA HIBBERD, MD, PhD
Tufts-New England Medical Center, Boston, Massachusetts

JAMES HEIMBACH, PhD
JHeimbach, LLC, Washington, DC

FREDDIE ANN HOFFMAN, MD
HeteroGeneity LLC, Washington, DC

PROGRAM PLANNING COMMITTEE

JONATHAN (JOSH) BERMAN, MD, PhD
Office of Clinical and Regulatory Affairs, National Center for Complementary and Alternative Medicine, National Institutes of Health, Bethesda, Maryland

JOHANNA DWYER, DSC, RD
Office of Dietary Supplements, National Institutes of Health, Bethesda, Maryland

GREGOR REID, BSc, Hons, PhD, MBA
Canadian Research and Development Centre for Probiotics, The Lawson Health Research Institute and Professor Departments of Microbiology and Immunology, Surgery, University of Western Ontario, London, Ontario Canada

DONNA JEAN ROBIE, PhD
Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, College Park, Maryland

JENNIFER ROSS, PhD
Division of Vaccines & Related Products Applications, Center for Biologics Evaluation and Research, FDA, Rockville, Maryland

MARY ELLEN SANDERS, PhD
International Scientific Association for Probiotics and Prebiotics (Dairy & Food Culture Technologies Centennial, Colorado)

CARMEN TAMAYO, MD
Natural Health Products Special Interest Area Community (SIAC) Drug Information Association, Bethesda, Maryland

PROGRAM ADVISORS

CARY FRYE
International Dairy Foods Association, Washington, DC

SHERWOOD GORBACH, MD
Tufts University School of Medicine, Boston, MA

MAYA PINEIRO, PhD
Food and Agriculture Organization, FAO

DANIEL FABRICANT, PhD
National Nutritional Foods Association, Washington, DC

JON VANDERHOOF, MD
Mead Johnson, Evansville, Indiana

ALLAN WALKER, MD
Harvard Medical School, Boston, Massachusetts

CONFERENCE OBJECTIVES

This Conference will provide an overview of the historical and current human use of probiotics, what is known regarding the properties of the organisms, mechanisms of action, and the translation of basic science advances into clinical studies and potentially new probiotic applications. The current level of scientific evidence supporting the use of probiotics in the management of disease conditions or in maintaining well-being will be discussed. The conference will also address the US regulatory status of probiotics, both as "foods" – including dietary supplements, and as "drugs." This discussion will include a review of the global marketplace for probiotics, as well as the current US regulatory milieu and its impact on scientific research and evaluation of safety and biologic activity. Finally, gaps in knowledge will be highlighted as fertile ground for additional research, discussion, and for potential funding.

TARGET AUDIENCE

- Scientists including microbiologists, nutritionists, physicians, nurses, pharmacists, and others involved in the research and development of probiotics; regulators and policy makers; probiotic product and ingredient manufacturers, suppliers, representatives from the food, dietary supplement and drug industries.

Continuing education credits are available for professionals including, but not limited to, physicians, pharmacists, and dieticians. See page 2 for details.

EXHIBITOR OPPORTUNITY

CONTACT INFORMATION

Tabletop Exhibits: Erin Gilliland
Phone +1-215-442-6149/email Erin.Gilliland@diahome.org

Meeting: Amanda Carmody
Phone +1-215-442-6176/email Amanda.Carmody@diahome.org

THIS PROGRAM WAS DEVELOPED BY THE NATURAL HEALTH PRODUCTS SPECIAL INTEREST AREA COMMUNITY

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DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

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The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.4 continuing education units (CEUs) to participants who successfully complete this program.

Commission on Dietetic Registration (CDR)
This program has been approved by the Commission on Dietetic Registration for 16 CPEUs.

If you would like to receive a statement of credit, you must attend the program and return the credit request and evaluation forms to the DIA. Statements of credit will be issued within 30 days of receipt of these forms.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives: At the conclusion of this meeting, participants should be able to:

- Describe the current and historical use and basis for use of probiotics.
- Recognize and assess the impact of current research on the clinical evaluation of probiotics both as foods and as drugs.
- Understand the basis upon which probiotics are currently being marketed in the United States and how this may impact clinical intervention and investigation.
- Identify scientific areas for which additional research is needed to support the clinical use of probiotics.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

SUNDAY • OCTOBER 15

18:00-20:00 REGISTRATION

MONDAY • OCTOBER 16

7:15-8:15 REGISTRATION, CONTINENTAL BREAKFAST, AND TABLETOP EXHIBITION

8:15-8:30 WELCOME AND OPENING REMARKS

Patricia Hibberd, MD, PhD
Director, Division of Clinical Research Resources, Institute of Clinical Research and Health Policy Studies
Tufts-New England Medical Center

8:30-9:00 **PLENARY ADDRESS – HISTORICAL PERSPECTIVE**

PROBIOTICS: DEFINITION, SOURCE, SELECTION AND USES
Mary Ellen Sanders, PhD
President, International Scientific Association for Probiotics and Prebiotics

9:00-9:30 **PLENARY ADDRESS – THE FUTURE OF PROBIOTICS AS CLINICAL AGENTS**

HOW SCIENCE WILL HELP SHAPE FUTURE CLINICAL APPLICATIONS OF PROBOTICS
Gregor Reid, PhD
Director, Canadian Research and Development Centre for Probiotics, The Lawson Health Research Institute, University of Western Ontario

9:30-11:00 SESSION I

CURRENT USE AND MARKETS

SESSION CHAIRPERSON
Mary Ellen Sanders, PhD
President, International Scientific Association for Probiotics and Prebiotics

A review of the formulations, applications, current marketplace and changes in the marketplace.

US PERSPECTIVE
Jon Vanderhoof, MD
Vice President, Global Medical Affairs, Mead-Johnson Nutritionals

JAPANESE PERSPECTIVE
Harunobu Amagase, PhD,
Director, Research and Development, Wakunaga of America Co., Ltd.

European Perspective
Maija Saxelin, PhD
Research Manager, Valio Ltd. R&D

QUESTION AND ANSWER PERIOD

11:00-11:30 **REFRESHMENT BREAK AND TABLETOP EXHIBITION**

11:30-12:50 SESSION II

Scientific Overview – What Do We Know, What Do We Need to Know?

Session Chairperson

Sherwood L. Gorbach, MD
Professor, Departments of Public Health and Family Medicine, Medicine, and Microbiology and Immunology
Tufts University School of Medicine

Overview of the current state of the science, key issues and gaps for product development.

Impact of the Intestinal Microbiota and Probiotics on the Development of Mucosal Defense

H. Rex Gaskins, PhD
Professor of Immunobiology, Division of Nutritional Sciences, University of Illinois

Mechanisms of Action of Probiotics

Allan Walker, MD
Conrad Taff Professor of Nutrition and Pediatrics
Harvard School of Medicine
Director, Division of Nutrition, Harvard Medical School
Director, Mucosal Immunology Laboratory at Massachusetts General Hospital for Children

QUESTION AND ANSWER PERIOD

12:50-14:15 **LUNCHEON AND TABLETOP EXHIBITION**

14:15-15:15 SESSION III

Current Research in Probiotics – Part One [Preclinical]

Session Chairperson

Gregor Reid, BSc, Hons, PhD, MBA
Canadian Research and Development Centre for Probiotics
The Lawson Health Research Institute and Professor Departments of Microbiology and Immunology, Surgery
University of Western Ontario, London, Ontario Canada

Summary of current in vitro and in vivo animal assays and models, considerations for conducting preclinical research and where more research is needed.

Probiotic Functionality: Products versus Strains

Nicolas Gausseres, PhD
Director, Nutrition Research Department
Danone Research, France

Preclinical Testing in the Development of Probiotics: A Regulatory Perspective using Bacillus Strains as Examples

Iryna B. Sorokulova, PhD
Professor of Microbiology, Auburn University, Auburn, AL
Head, Deptartment of Standardization of Biological Products, National Control Authority for Biological Products, Kiev, Ukraine

QUESTION AND ANSWER PERIOD

15:15-16:45 SESSION IV

Current Research in Probiotics – Part Two [Clinical]

Session Chairperson

Jonathan (Josh) Berman, MD, PhD
Director, Office of Clinical and Regulatory Affairs, National Center for Complementary and Alternative Medicine, National Institutes of Health

Review of the clinical studies being conducted, new approaches and regulatory needs.

Overview: Clinical Indications

Sherwood L. Gorbach, MD
Professor, Departments of Public Health and Family Medicine, Medicine, and Microbiology, Medicine and Immunology
Tufts University School of Medicine

Novel Approaches/New Uses

Simin Nikbin Meydani, DVM, PhD
Director, Nutritional Immunology Laboratory
Associate Director, JM USDA Human Nutrition Research Center on Aging
Tufts University School of Medicine
Professor of Nutrition and Immunology, Friedman School of Nutrition Science and Policy, and Sackler Graduate School at Tufts University

Clinical Research Interface between Science and Regulation

Carmen Tamayo, MD
Chair, Natural Health Products Special Interest Area Community, Drug Information Association

QUESTION AND ANSWER PERIOD

16:45-17:15 **REFRESHMENT BREAK AND TABLETOP EXHIBITION**

17:15-18:20 SESSION V

Special Safety Considerations

Session Chairperson

Carmen Tamayo, MD
Chair, Natural Health Products Special Interest Area Community Drug Information Association

Key safety considerations, including bacteremia/septicemia, antimicrobial resistance, gene transfer, and how they are currently being addressed; Impact of wide-spread clinical use on the environment and potential regulatory considerations.

Safety Considerations for Probiotics

David Snydman, MD
Chief, Division of Geographic Medicine and Infectious Diseases
Tufts-New England Medical Center

Environmental Assessment and Impact

Ann Sutton, MPH
Senior Consultant, Biologics Consulting Group, Inc.

QUESTION AND ANSWER PERIOD

18:20-18:30 DAY 1 CLOSING REMARKS

18:30 DAY 1 ADJOURNS

18:30-20:00 **NETWORKING RECEPTION**

TUESDAY • OCTOBER 17

7:30-8:30 **REGISTRATION, CONTINENTAL BREAKFAST, AND TABLETOP EXHIBITION**

8:15-8:30 WELCOME AND OPENING REMARKS

Patricia Hibberd, MD, PhD
Tufts-New England Medical Center

8:30-10:00 SESSION VI

US Regulations for Label Claims on Food Products

Session Chairperson

Barbara Schneeman, PhD
Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN, FDA

Discussion of US regulations for label claims on food products, the nature of claims that are allowed, evidence to substantiate claims, and ingredient requirements. The session will also include a presentation on marketing claims for products with probiotics.

Regulation of Substances in Foods
Antonia Mattia, PhD
Director, Division of Biotechnology and GRAS Notice Review
CFSAN, FDA

Label Claims for Food Products
Barbara Schneeman, PhD
Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN, FDA

Marketing Claims for Food Products
James Heimbach, PhD
President, JHeimbach, LLC

QUESTION AND ANSWER PERIOD

10:00-10:30 **REFRESHMENT BREAK AND TABLETOP EXHIBITION**

10:30-12:00 SESSION VII

Live Biotherapeutics: US Regulation of Probiotics as "Biologic Drugs"

Session Chairperson

Jennifer Ross, PhD
Regulatory Reviewer, Project Manager
Division of Vaccines and Related Products Applications, CBER, FDA

Overview of probiotics including product and clinical considerations for development.

Probiotics as Biologic Drugs
Julienne Vaillancourt, RPh, MPH
Senior Regulatory Reviewer, Project Manager
Division of Vaccines and Related Products Applications
CBER, FDA

Product Development for Probiotics as Biologic Drugs
Speaker Invited

Live Biotherapeutics: Clinical Development
Patricia Rohan, MD
Medical Reviewer, Division of Vaccines and Related Products Applications, Office of Vaccines, CBER, FDA

QUESTION AND ANSWER PERIOD

12:00-13:30 **LUNCHEON AND TABLETOP EXHIBITION**

13:30-15:00 SESSION VIII

Impact of US Regulations on the Development of Probiotics

Session Chairperson

James Heimbach, PhD
President, JHeimbach, LLC

Legal status of foods and biologics in the United States, impact on scientific assessment, and business considerations for product development pathways both as " foods" and as " drugs."

Legal Issues
Fred Degnan, Esq.
Partner, King and Spalding

Research Implementation
Patricia Hibberd, MD, PhD
Director, Division of Clinical Research Resources
Institute of Clinical Research and Health Policy Studies
Tufts-New England Medical Center

Business Considerations
Freddie Ann Hoffman, MD
CEO, HeteroGeneity, LLC Consulting Services

QUESTION AND ANSWER PERIOD

15:00-15:30 **REFRESHMENT BREAK**

15:30-17:10 SESSION IX

Role of Stakeholders and Future Research and Policy Needs for the United States

Session Chairpersons

Johanna Dwyer, DSc, RD
Senior Nutrition Scientist, Office of Dietary Supplements
National Institutes of Health

Marguerite Klein
Program Officer, National Center for Complementary and Alternative Medicine, National Institutes of Health

BRIEF 5 MINUTE PRESENTATIONS FROM KEY STAKEHOLDERS AND AUDIENCE DISCUSSION OF THE FOLLOWING GUIDELINES:

- What are the "gaps" in our knowledge regarding the clinical use and evaluation of Probiotics?
- What preclinical research is needed to address these gaps—regarding safety, efficacy, regulatory requirements?
- What are the "gaps" in our knowledge regarding the development of Probiotics for commercialization in the US market both as "foods" and as "drugs"?
- What are the needs of investigators who are interested in conducting research in the field of Probiotics?
- What strategies are needed to raise awareness among health care professionals, clinical investigators, patients and consumers regarding research and use of Probiotics?
- What additional policy discussions are needed (if any) regarding Probiotics being developed in or for the United States?

Panelists

Robert Garfield
Executive Director
National Yogurt Association

Linda D. Meyers, PhD
Director, Food and Nutrition Board
Institute of Medicine, National Academies

Maya Pineiro, PhD
Officer in Charge, AGNSp Food and Agriculture Organization, Italy

Jane Robens, DVM, PhD
National Program Leader, Food Safety & Health, Agriculture Research Service, US Department of Agriculture

Mary Ellen Sanders, PhD
President
International Scientific Association for Probiotics and Prebiotics

Daniel Fabricant, PhD
Vice President, Scientific Affairs
National Nutritional Foods Association

17:10-17:30 DAY 2 CLOSING REMARKS

17:30 CONFERENCE ADJOURNS

TRAVEL AND HOTEL The most convenient airport is Baltimore International Airport and attendees should make airline reservations as early as possible to ensure availability. The Marriott Conference Center, University of Maryland is holding a block of rooms at the reduced rate below until September 25, 2006, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $189 **Double $189**

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GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! ***All 4 individuals must register and prepay at the same time – no exceptions***. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

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Participants with Disabilities: *DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.*

DRUG INFORMATION ASSOCIATION http://www.diahome.org

Horsham, PA, USA
Tel: +1-215-442-6100 • Fax: +1-215-442-6199
email: dia@diahome.org

Basel, Switzerland
Tel: +41-61-225-51-51 • Fax: +41-61-225-51-52
email: diaeurope@diaeurope.org

Tokyo, Japan
Tel: +81-3-5511-1131 • Fax: +81-3-5511-0100
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1ST INTERNATIONAL DIA CONFERENCE

Developing Probiotics as Foods and Drugs – Scientific and Regulatory Challenges

In collaboration with the International Scientific Association for Probiotics and Prebiotics

Meeting ID #06028
Marriott Conference Center
University of Maryland College Park Campus
Adelphi, MD, USA

OCTOBER 16-17, 2006

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the meeting and during receptions (if applicable).

Meeting information: Contact Amanda Carmody at the DIA office by telephone +1-215-442-6176, fax +1-215-442-6199 or email Amanda.Carmody@diahome.org.

Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.

❑ **To receive a tabletop exhibit application, please check.**

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Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions.
See page 5 for complete details.

Registration Fees *If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.*

MEMBER EARLY-BIRD OPPORTUNITY *Available on nondiscount member fee only*	On or before SEPT. 25, 2006	After SEPT. 25, 2006
Member Fee	US $1125 ❑	US $1300 ❑

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Nonmember Fee US $1430 ❑

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	US $ 300 ❑	US $ 430 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 650 ❑	US $ 755 ❑

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CANCELLATION POLICY: On or before OCOTBER 10, 2006

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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Job Title

Company

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City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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