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.
Accreditation and Credit Designation
The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 14.25 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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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.
- Discuss 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.

9:00-9:30  PLenary Address – The Future of Probiotics as Clinical Agents
HOW SCIENCE WILL HELP SHAPE FUTURE CLINICAL APPLICATIONS OF PROBIOTICS
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 Nutritional

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, Department 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 envi-
ronment 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.
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 Considerations for Probiotics as Biologic Drugs**

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

**Live Biotherapeutics: Clinical Development**

Patricia Rohan, MD
Medical Reviewer, Division of Vaccines and Related Products Applications, Office of Vaccines, CBER, FDA

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**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

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**Legal Issues**

Fred Degnan, Esq.
Partner, King and Spalding

**Impact on Design of Clinical Trials**

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
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.

To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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

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Tokyo, Japan  Tel: +81-3-5511-1131 • Fax: +81-3-5511-0100  email: diajapan@diajapan.org

17:30-17:50  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

Maria Oria, PhD
Senior Program Officer, Food and Nutrition Board
Institute of Medicine, National Academies

David Klurfeld, PhD
National Program Leader, Human Nutrition
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 ADJOURS

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

Please contact the The Marriott Conference Center by telephone at +1-800-676-6137 or fax at +1-301-985-7445 and mention the DIA meeting. The hotel is located at 3501 University Boulevard East, Adelphi, MD 20783, USA.

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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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Available on nondiscount member fee only

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Fee! Check if part of group registration

**Discount Fees**

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<th>Government (Full-time)</th>
<th>US $ 300</th>
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<td>Charitable Nonprofit/Academia (Full-time)</td>
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**CANCELLATION POLICY:** On or before OCTOBER 10, 2006

Administrative fee that will be withheld from refund amount:

- Member or Nonmember = $200
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- 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.

☐ I cannot attend but please keep me informed of DIA’s future events.

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☐ CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

☐ BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. You may pay in the currency of your choice. Your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your account.

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