



Food and Drug Administration
Rockville MD 20857

August 9, 2000

2135 00 AUG 15 19:50

Jane Henney, MD
• Commissioner of Food and Drugs
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Dr. Henney:

We thank you for agreeing to take part in the International Workshop on Diagnostics for Transmissible Spongiform Encephalopathies (TSEs) on September 20-22, at the National Institutes of Health, Lister Hill Conference Center, Bethesda, Maryland. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) are sponsoring the workshop.

The workshop will discuss diagnostic tests for human and animal TSEs. The objectives are to identify criteria for evaluating tests to diagnose TSEs and to detect TSE agents. We will also discuss tests for proteins FDA has prohibited in ruminant feeds to reduce the risk of TSE transmission. During the workshop, attendees will have an opportunity to hear from you and others about the development and validation of TSE diagnostic tests and to discuss their introduction into regulatory practice. We expect participants from several international organizations and government agencies as well as from industry.

We are enclosing a copy of the Preliminary Program. We would welcome any suggestions you may have about the program we are organizing.

We invite you to open the workshop on Wednesday, September 20, and to deliver welcoming and introductory remarks. Your presentation, scheduled for 8:00 a.m., is allotted 10 minutes. We understand that your schedule is very crowded, and we and all the other workshop participants are honored and delighted that you will open the event.

If you have not already done so, would you please send a biographical sketch and abstract of your presentation. **Please send them by August 28** to Carla Battle (FDA@courtesyassoc.com), or by mail at 2000 L Street, N.W., Suite 710, Washington, DC 20036) so we can incorporate them in the materials distributed at the workshop. **Please also complete the enclosed registration form indicating full name, titles and degrees the way you would like them to appear on the participants' list and return it to Carla Battle.**

We will have overhead, slide, and PowerPoint projectors available for your use. If you need any other audiovisual equipment, please let me know by August 21. We have arranged to transcribe the workshop, and intend to prepare a summary report of the workshop to be published, with the entire proceedings, in the open scientific literature.

99P-0033

LET4

For information on the program or your presentation, please contact:

Dr. David M. Asher, 301-594-6432, 301-827-4622 (fax), asher@cber.fda.gov or
Dr. Kiki B. Hellman, 301-443-7158, 301-594-6775 (fax), kxh@cdrh.fda.gov

For information on logistics, please contact:

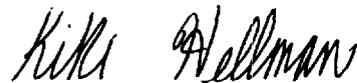
Carla Battle, 202-331-2000, 202-331-0111(fax), cbattle@courtesyassoc.com

Again, thank you for agreeing to take part in this important and unique workshop. We look forward to seeing you in September.

Sincerely,



David M. Asher, M.D.
Director, Laboratory of Special Pathogens
Division of Emerging and Transfusion-
Transmission Diseases
Office of Blood Research and Review
Center of Biologics Evaluation and Research



Kiki B. Hellman, Ph.D.
Senior Scientist
Coordinator for Biotechnology
Center for Devices and Radiological Health

Enclosures

Preliminary Program
Workshop Announcement
List of Workshop Participants
Registration Form
Abstract Form

PRELIMINARY PROGRAM

International Workshop on Diagnostics
For Transmissible Spongiform Encephalopathies (TSEs)

Sponsored by
US Food and Drug Administration (FDA)
and
US National Institutes of Health (NIH)
National Institute of Neurological Disorders and Stroke (NINDS)

September 20-22, 2000

Lister Hill Conference Center
National Institutes of Health
Bethesda, Maryland, U.S.A.

Wednesday, September 20

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|-----------|--|---|
| 8:00 a.m. | Welcome and Introductory Remarks | Jane Henney, MD Commissioner of Food and Drugs FDA Kathryn C. Zoon, PhD Director, Center for Biologics Evaluation and Research (CBER), FDA David W. Feigal, Jr, MD, MPH Director, Center for Devices and Radiological Health (CDRH), FDA |
| 8:30 | Background and Overview | Rapporteurs Kiki B. Hellman, PhD CDRH, FDA David M. Asher, MD CBER, FDA |
| 8:50 | Development of New Diagnostic Tests for Infections: Guiding Principles | Donald Burke, MD Johns Hopkins University School of Medicine Baltimore, MD |

NIH
Hamilton, MT

11:40 Potential Validation and Standardization of Assays for Diagnosing TSE Infections and Detecting TSE Agents Anna Padilla Marroquin, PhD
World Health Organization
Geneva, Switzerland

12:00 p.m. Discussion

12:30 Lunch

Session 2. Detection of Protease-Resistant Prion Protein as a Diagnostic Test

Co-Chairs: Gerald A.H. Wells
Department of Pathology, Veterinary Laboratories Agency
Addlestone, Surrey, UK

(Co-Chair: Stanley B. Prusiner, MD - tentative)

1:30 Introduction and Overview Co-Chairs

1:50 High-Affinity Receptor Protein for PrP: Potential for Improved Detection of PrP^{sc} Neil R. Cashman, MD
Centre for Research in Neurodegenerative Diseases
University of Toronto
Toronto, Canada

2:10 Immunohistochemistry and Immunoblotting for Diagnosis and Typing of Human TSEs Pierluigi Gambetti, MD
Division of Neuropathology
Case Western Reserve University
Cleveland, OH

2:30 Immunohistochemistry for Post-mortem Diagnosis of Animal TSEs Allen Jenney, DVM
National Veterinary Services
Laboratories, Animal and Plant
Health Inspection Service
USDA
Ames, IA

2:50 Western Immunoblotting (1): Origins and General Principles Richard Kascsak, PhD
NY State Institute for Basic
Research in Developmental
Disabilities
Staten Island, NY

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|------|--|---|
| 3:10 | Western Immunoblotting (2): Optimization for Detection of Human PrP ^{sc} | Steven Petteway, PhD Bayer Corporation Research Triangle Park, NC |
| 3:30 | Western Immunoblotting (3): Experience with Commercial Diagnostic Testing | Bruno Oesch, PhD Prionics AG Zurich, Switzerland |
| 3:50 | Break | |
| 4:00 | ELISA Testing: Development and Optimization of a Sensitive and Specific ELISA Test | Jean Phillipe DesLys, MD Commissariat a l'Energie Atomique Fontenay-aux-Roses, France |
| 4:20 | EU Initiative for Comparison of Established Postmortem Immuno- diagnostic Methods | James Moynagh, DVM Directorate General XXIV, European Commission Brussels, Belgium |
| 4:40 | Premortem Immunodiagnostic Tests for Animal TSEs: Nictating Membrane | Katherine I. O'Rourke, DVM Agricultural Research Services, USDA Pullman, WA |
| 5:00 | Discussion | |
| 5:30 | Conclude Day 1 | |
| 6:30 | Dinner | |

Thursday, September 21

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| 8:30 a.m. | Welcome and Introductory Remarks | Yuan Yuan Chiu, PhD Center for Drug Evaluation and Research (CDER), FDA |
| | | Susan Alpert, PhD, MD Center for Food Safety and Applied Nutrition (CFSAN), FDA |

**Session 3: Novel Assays for Detection of Abnormal Prion Protein and Its
Characterization**

Co-Chairs: Jay S. Epstein, MD
CBER, FDA

(Co-Chair to be announced)

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|-------|--|--|
| 8:50 | Introduction and Overview | Co-Chairs |
| 9:10 | Conformation-Dependent Immunoassay | Jiri Safar, MD Department of Neurology University of California School of Medicine San Francisco, CA |
| 9:30 | Dissociation-Enhanced Lanthanide Fluoro-Immunoassay (DELFI A) | James Hope, PhD Institute of Animal Health Compton, Newbury Berkshire, UK |
| 9:50 | Capillary Electrophoresis Immunoassay | Mary Jo Schmerr, PhD Agricultural Research Service USDA Ames, IA |
| 10:10 | Cell-free Prion-Protein Conversion Assay: Potential to Predict Susceptibility to Infection | Suzette Priola, DVM Laboratory of Persistent Viral Diseases Rocky Mountain Laboratories NIAID, NIH Hamilton, MT |
| 10:30 | Discussion | |
| 11:00 | Break | |

Session 4. Surrogate Assays for Premortem Diagnosis of TSEs

Co-Chairs: Clarence J. Gibbs, Jr., PhD
Laboratory of CNS Studies, NINDS, NIH

(Co-Chair to be announced)

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| 11:10 | Introduction and Overview of CSF Tests | Co-Chairs |
| 11:30 | Comparison of Various Neuronal Proteins in CSF for Diagnosis of TSEs | Inga Zerr, MD German CJD Surveillance Unit Gottingen, Germany |

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| 11:50 p.m. | Molecular Biological Approaches for Improved Diagnosis of TSEs | John Sninsky, PhD Roche Molecular Systems Alameda, CA |
| 12:10 | Antemortem Immunodiagnostic Tests for Animal TSEs: Tonsil | Bram E.C. Schreuder, DVM Institute for Animal Science and Health Lelystad, Netherlands |
| 12:30 | Discussion | |
| 1:00 | Lunch | |
| Session 5. Detection of Prohibited Protein in Ruminant Feed | | |
| Co-Chairs: | Dan McChesney, PhD Center for Veterinary Medicine (CVM), FDA | |
| | Avraham Rasooly, PhD CFSAN, FDA | |
| 2:00 | Opening Remarks | Stephen Sundlof, DVM, PhD Director, CVM, FDA |
| 2:10 | Introduction and Overview | Co-Chairs |
| 2:30 | BSE in Europe | Lukas Perler, DVM Swiss Veterinary Authority, Switzerland |
| 2:50 | Animal Meal Safety | David Taylor, PhD Sedecon 2000 Edinburgh, UK |
| 3:10 | US Feed Prohibition | Dan McChesney, PhD CVM, FDA |
| 3:30 | US Rendering Industry Outlook | Don Franco, DVM, PhD National Renderers Association, Arlington, VA |
| 3:50 | Break | |
| 4:00 | Feed Microscopy | James Makowski, PhD Messiah College, Crantham |
| 4:20 | ELISA, British Experience | Mike Ansfield, PhD |

Veterinary Laboratories Agency
Ministry of Agriculture
Fisheries and Food
UK

- 4:50 PCR Michael J. Myers, PhD
Office of Research, CVM, FDA
- 5:10 Alternative Methods Dragan Momcilovic, DVM, PhD
Division of Animal Feeds, CVM,
FDA
- 5:15 Validation of Methods Christoph von Holst, PhD
European Commission
DG Joint Research Centre
Ispra, Italy
- 5:35 Discussion
- 6:00 Conclude Day 2

Friday, September 22

**Session 6. Possible Introduction of TSE Diagnostic Tests into Regulatory Practice:
Needs for Approved/Licensed Tests**

Co-Chairs: Paul W. Brown, MD
Laboratory of CNS Studies, NINDS, NIH

Bernard Statland, MD
CDRH, FDA

- 8:30 a.m. Opening Remarks Bernard A. Schwetz, DVM, PhD
Deputy Commissioner, FDA
- 8:40 Introduction and Overview Co-Chairs
- 9:00 Diagnostic Testing for TSEs in Emerging Economies P. Pawel Liberski, MD, PhD
Medical Academy of Lodz
Lodz, Poland
- 9:20 Needs Perceived by the National Institutes of Health George Nemo, PhD
National Heart, Lung, and Blood
Institute, NIH

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| | | Floyd J. Brinley, Jr, MD, PhD National Institute of Neurological Disorders and Stroke, NIH |
| 9:40 | Needs Perceived by the US Department of Agriculture | Linda Detwiler, DVM, USDA Animal and Plant Health Inspection Service, USDA Robbinsville, NJ |
| 10:00 | Needs Perceived by Industry | Taryn Rogalski-Salter, PhD Merck & Company, Inc. West Point, PA |
| 10:20 | Break | |
| 10:30 | Opportunities to Introduce New Tests into Practice: US-Govern- ment Programs to Facilitate Transition of Applied Health- Related Research into Small Businesses | Susan E. Pucie National Heart, Lung, and Blood Institute, NIH |
| 10:50 | The FDA's Program for Orphan Products | Marlene E. Haffner, MD, MPH* Office of Orphan Products Development, FDA |
| 11:10 | Session Reports | Session Co-Chairs |
| 12:10 | Concluding Remarks | Rapporteurs |
| 12:40 | Workshop Concludes | |

International Workshop on Diagnostics for Transmissible
Spongiform Encephalopathies (TSEs)

September 20-22, 2000

Lister Hill Conference Center
U.S. National Institutes of Health
Bethesda, Maryland

LOCATION

Lister Hill Conference Center, Building 38A, National Institutes of Health
8600 Rockville Pike, Bethesda, MD 20894
(Rockville Pike and Center Drive)
with overflow at
Bethesda Ramada Hotel, 8400 Wisconsin Avenue, Bethesda, MD 20814

SPONSORS

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
U.S. National Institutes of Health
National Institute of Neurological Disorders and Stroke

WORKSHOP GOALS AND OBJECTIVES

- To identify criteria for evaluating tests to diagnose TSEs and to detect TSE agents.
- To describe the different types of *in vivo* and *in vitro* assays for TSE agents in humans and animals.
- To promote development and validation of TSE diagnostic tests.
- To discuss tests for prohibited proteins in ruminant feeds to reduce the risk of TSE transmission.
- To discuss the need to introduce diagnostic tests into regulatory practice.

TARGET AUDIENCE

This program will be of interest to anyone with a background in research, regulatory affairs or experience with TSE diagnostic testing and assay design for the detection of TSE agents.

WORKSHOP STEERING COMMITTEE

David Asher (co-chair), Floyd J. Brinley, Jr., Elisa Elliot, Claudia Gaffey, Susan Gerhold, Steve Gutman, Kiki Hellman (co-chair), Shirley Meeks, Paul Mied, Dragan Momcilovic, George Nemo, Merlyn Rodrigues, Bernard Schwetz, Gail Sherman, Rolf Taffs, Carol Vincent, Melanie Whelan, Joseph Wilczek

REGISTRATION

There is no registration fee for this meeting; however, seating is limited at Lister Hill to the first 175 registrants. Overflow seating will be provided at the Bethesda Ramada Hotel. To register for the workshop, please complete the registration form included with this packet. Registration cut-off is August 29th. For a seat at Lister Hill, please register early!!

SPECIAL NEEDS

If you require assistance, please contact Carla Battle, Logistics Coordinator at 202-331-2000 or by fax 202-331-0111 at least five business days in advance of the workshop.

OVERNIGHT ACCOMMODATIONS

We are holding a block of rooms at the Bethesda Ramada Hotel, 8400 Wisconsin Avenue, Bethesda, MD at a rate of \$118.00 plus tax. Please call 1-877-795-7842 to reserve a room. When making reservations, please make reference to our group number **7309G**. Reservations must be made by August 29th.

DIRECTIONS AND PARKING

NIH Campus is located on Rockville Pike (Rt 355) in Bethesda. There are only limited spaces for short-term metered parking or daily garage parking (up to \$12/day) for visitors. Please check the website www.nih.gov/about/maps.html for more information. The Lister Hill Center is within easy walking distance of the Medical Center Metro Station (Red Line) at the NIH Campus.

CONTACTS

For program information – Dr. Kiki Hellman 301-443-7158 or Dr. David Asher 301-594-6432
For logistics information – Carla Battle 202-331-2000 or Amy Hartlaub 202-331-2000

**International Workshop on Diagnostics
for Transmissible Spongiform Encephalopathies (TSEs)**

September 20-22, 2000

NIH Lister Hill Conference Center
Bethesda, Maryland

The U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) will convene an international workshop in September to discuss diagnostic tests for human and animal transmissible spongiform encephalopathies (TSEs). The objectives of the workshop are:

- To identify criteria for evaluating tests to diagnose TSEs and to detect TSE agents.
- To describe different types of *in vivo* and *in vitro* assays for TSE agents in humans and animals.
- To promote development and validation of TSE diagnostic tests.
- To discuss tests for prohibited proteins in ruminant feeds to reduce the risk of TSE transmission.
- To discuss the need to introduce diagnostic tests into regulatory practice.

This international workshop will convene representatives from regulatory authorities, national and international standard-setting organizations, and industrial groups who share a need for validated TSE diagnostic tests. Internationally renowned scientists will make oral presentations on approaches to developing TSE diagnostics, and will discuss general guiding principles and performance criteria for diagnostic tests. Besides invited presentations, interested individuals are invited to submit abstracts for poster presentation, which the workshop's steering committee will review. The workshop proceedings and summary will be published in the open scientific literature.

This workshop is a follow-up to discussions of TSE diagnostic assays raised at the June 1998 Workshop on TSE Risks in Relation to Source Materials, Processing, and End-Product Use (sponsored by FDA and the University of Maryland) and at the September 1999 Workshop on Clearance of TSE Agents from Blood Products and Implanted Tissues (sponsored by FDA's Center for Biologics Evaluation and Research and Center for Medical Devices and Radiological Health).

Interested individuals from the public and private sector are welcome to attend. *There is no registration fee for attendance.* However, since space is limited, registration will be accepted on a first-come, first-served basis. For further information on registration and poster presentations, please contact Carla Battle by phone (202-331-2000), fax (202-331-0111), or e-mail (cbattle@courtesyassoc.com).

International Workshop on Diagnostics for Transmissible
Spongiform Encephalopathies (TSEs)

September 20-22, 2000
Lister Hill Conference Center
U.S. National Institutes of Health
Bethesda, Maryland

REGISTRATION FORM

RSVP by August 29th

Please print or type all information as you would like to see it appear in the program or list of attendees.

Prefix: _____ First Name: _____ Last Name: _____

Title: _____

Department: _____

Organization: _____

Address: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____

E-mail: _____

Are you a medical doctor? _____

Please mail or fax this registration form to:

Carla Battle
Diagnostics Workshop
2000 L Street, NW, Suite 710
Washington, DC 20036
Phone: 202-331-2000
Fax: 202-331-0111

International Workshop on Diagnostics for Transmissible Spongiform Encephalopathies (TSEs)

September 20-22, 2000

**Lister Hill Conference Center
U.S. National Institutes of Health
Bethesda, Maryland**

POSTER SESSION – CALL FOR ABSTRACTS

On September 20-22, 2000, the U.S. Food and Drug Administration (FDA) and U.S. National Institutes of Health (NIH) will convene an international workshop concerning the development of diagnostic tests for human and animal transmissible spongiform encephalopathies (TSEs). The objectives of the workshop are to identify criteria for evaluating tests to diagnose TSEs and to detect TSE agents; describe different types of *in vivo* and *in vitro* assays for TSE agents in humans and animals; promote development and validation of TSE diagnostic tests; discuss tests for prohibited proteins in ruminant feeds to reduce the risk of TSE transmission; and discuss the need to introduce diagnostic tests into regulatory practice.

The sponsors invite those interested in these topics to participate in the workshop's poster session. Potential presenters are asked to submit a one-page abstract about their poster. Those accepted to the session will have their abstracts distributed to workshop participants. Abstracts should include:

- Title of Poster
- Name, affiliation, mailing address, e-mail address, telephone and fax number
- Detailed description of poster and its relation to the workshop's objectives

For the body of your one-page abstract, use single-spaced 10-point Times Roman (or a similar typeface) with 12 point interline spacing in a single-column format. Make the title 14-point boldface upper case, centered over the column. For author name(s) and affiliation(s), use 12-point, non-boldfaced centered type. Subsection headings should be 11-point boldface type, flush left.

Submission Deadline: August 4, 2000

Author Notification: August 21, 2000

Abstract should be submitted electronically to Amy Hartlaub at hartlaub@courtesyassoc.com.

Authors will be notified of acceptance by the date above. The submission of an abstract will be considered as evidence that upon acceptance the author(s) will present a poster at the workshop.

Full Disclosure of Speaker Financial Interests or Relationships

It is the policy of the Accreditation Council for Continuing Medical Education (ACCME) that any speaker who makes a presentation at a program designated for AMA Physician's Recognition Award (PRA) Category 1 or 2 credit must disclose any financial interest or other relationship (i.e., grants, research support, consultant, honoraria) that speakers may have with the manufacturer(s) of any commercial product(s) that may be discussed in the educational presentation.

The ACCME does not imply that such financial interests or relationships are inherently improper or that such interest or relationships would prevent the speaker from making a presentation. However, it is imperative that such financial interests or relationships be identified by the speaker so that participants at the CME activity may have these facts fully disclosed prior to the presentation, and may form their own judgments about the presentation.

In keeping with this policy, the speaker is required to sign the following disclosure statement.

FULL DISCLOSURE STATEMENT (Please sign A or B, whichever is applicable)

Title of CME Activity: _____

Name of Speaker: _____

- A. I, the undersigned, declare that I do not have a financial interest or other relationship with any manufacturer(s) of any commercial product(s).

Signature

Date

- B. I, the undersigned, declare that I have a financial interest or other relationship with a manufacturer of a commercial product(s). This financial interest or relationship is specified below (please print).

Company: _____

Company: _____

Company: _____

Signature

Date

TRAVEL FORM

International Workshop on Diagnostics for Transmissible Spongiform Encephalopathies (TSEs)

September 20-22, 2000

Please fill in the information below and return to Amy Hartlaub, Courtesy Associates,
by fax at 202-331-0111.

The information you include on this form will allow us to provide you with the most convenient,
most economical travel possible. Once you receive a proposed itinerary from Courtesy Travel,
if you have questions, please call Courtesy Travel Service at 202-331-2000 or 800-458-5966
and ask for Jack Harrington.

Name _____ Social Security # _____

Title _____

Affiliation _____

Address _____

Fax #: _____ Telephone #: _____

E-Mail _____

PLEASE PROVIDE YOUR FULL STREET ADDRESS (NO P.O. BOXES) FOR CORRESPONDENCE
AND TICKET DELIVERY IF DIFFERENT FROM ABOVE. IF USING HOME ADDRESS PLEASE
PROVIDE HOME TELEPHONE NUMBER.

TRAVEL ARRANGEMENTS

INBOUND

Origin: City/Airport _____ Date _____

Approx. time of (choose one) departure _____ or arrival _____

RETURN

Destination city _____

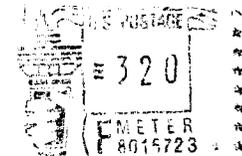
Date _____ Approx. time of departure _____

Flight/Seating preference? If so, please state. _____

Special requirements for flight or meeting functions (e.g., seating preference, special meal, wheelchair):

N.W.

C 20036



Jane Henney, MD
Commissioner
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

