for the evaluation of topical microbicides through late preclinical, phase I and phase II safety and phase II efficacy clinical trials.

Technology Sought

EpiBr now seeks potential collaborators having licensed or patented agents for use as vaginal and/or rectal microbicides which:

(1) Have laboratory or animal model evidence of anti-HIV activity;

(2) Have been formulated for vaginal or rectal application;

(3) Are not entering phase III clinical trial in the next 12 months;

(4) Have sufficient preclinical data to submit an IND application within approximately six months following submission of proposal; and

(5) Have manufacturing arrangements for production of clinical trial-grade product (and applicator if necessary) under Good Manufacturing Process (c-GMP) standards.

NCHSTP and Collaborator Responsibilities

The NCHSTP anticipates that its role may include, but not be limited to, the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Planning and conducting preclinical (in-vitro and in-vivo) research studies of the agent and interpreting results;

(3) Publishing research results;

(4) Depending on the results of these preclinical investigations, NCHSTP may elect to conduct additional research with macaques to evaluate safety and/or efficacy proof-of-concept; and

(5) Depending on the results of preclinical and/or macaque studies and FDA approval, NCHSTP may elect to conduct phase I/II clinical trials of the agent.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Participating in the planning of research studies, interpretation of research results, and as appropriate, joint publication of conclusions;

(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and

(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

Selection Criteria

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on vaginal and/or rectal commensal microbial organisms; and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: December 11, 2003.

Joseph R. Carter,

Deputy Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 03–31186 Filed 12–17–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Information Hotline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that we have revised the Advisory Committee Information Hotline (the hotline). The hotline provides the public with access to the most current information available on FDA advisory committee meetings. This notice supersedes all previously published announcements of FDA's Advisory Committee Information Hotline.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Committee Management Officer (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: The Advisory Committee Information Hotline can be accessed by dialing 1–800–741–8138 or 301–443–0572. The advisory committee meeting information and information updates can also be accessed via FDA's Advisory Committee calendar at *http://www.fda.gov/oc/advisory/accalendar/accalendar.html*.

Each advisory committee is assigned a 10-digit number. This 10-digit number will appear in each individual notice of meeting. The public can obtain information about a particular advisory committee meeting by using the committee's 10-digit number. Information on the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made. The following is a list of each advisory committee's 10-digit number to be used when accessing the hotline.

ADVISORY COMMITTEE	NUMBER
OFFICE OF THE COMMISSIONER	
Science Board to the FDA	3014512603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	3014512388
Biological Response Modifiers Advisory Committee	3014512389
Blood Products Advisory Committee	3014519516
Transmissible Spongiform Encephalopathies Advisory Committee	3014512392
Vaccines and Related Biological Products Advisory Committee	3014512391
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Life Support Drugs Advisory Committee	3014512529
Anti-Infective Drugs Advisory Committee (Peds SubC)	3014512530
Antiviral Drugs Advisory Committee	3014512531
Arthritis Advisory Committee	3014512532
Cardiovascular and Renal Drugs Advisory Committee	3014512533

ADVISORY COMMITTEE	NUMBER
Dermatologic and Ophthalmic Drugs Advisory Committee	3014512534
Drug Safety and Risk Management Advisory Committee (Drug Abuse Subcommittee)	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee	3014512536
Gastrointestinal Drugs Advisory Committee	3014512538
Nonprescription Drugs Advisory Committee	3014512541
Oncologic Drugs Advisory Committee	3014512542
Peripheral and Central Nervous System Drugs Advisory Committee	3014512543
Pharmaceutical Science, Advisory Committee for	3014512539
Psychopharmacologic Drugs Advisory Committee	3014512544
Pulmonary-Allergy Drugs Advisory Committee	3014512545
Reproductive Health Drugs, Advisory Committee for	3014512537
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee (full committee and subcommittees)	3014510564
Additives and Ingredients Subcommittee	
Biotechnology Subcommittee	
Contaminants and Natural Toxicants Subcommittee	
Dietary Supplements Subcommittee	
Infant Formula Subcommittee	
Nutrition Subcommittee	
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Device Good Manufacturing Practice Advisory Committee	3014512398
Medical Devices Advisory Committee (comprised of 18 panels)	N/A
Anesthesiology and Respiratory Therapy Devices Panel	3014512624
Circulatory System Devices Panel	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	3014512514
Dental Products Panel	3014512518
Ear, Nose, and Throat Devices Panel	3014512522
Gastroenterology-Urology Devices Panel	3014512523
General and Plastic Surgery Devices Panel	3014512519
General Hospital and Personal Use Devices Panel	3014512520
Hematology and Pathology Devices Panel	3014512515
Immunology Devices Panel	3014512516
Medical Devices Dispute Resolution Panel	3014510232
Microbiology Devices Panel	3014512517
Molecular and Clinical Genetics Panel	3014510231
Neurological Devices Panel	3014512513
Obstetrics-Gynecology Devices	3014512524
Ophthalmic Devices Panel	3014512396
Orthopaedic and Rehabilitation Devices Panel	3014512521
Radiological Devices Panel	3014512526
National Mammography Quality Assurance Advisory Committee	3014512397
Technical Electronic Product Radiation Safety Standards Committee	3014512399
CENTER FOR VETERINARY MEDICINE	
Veterinary Medicine Advisory Committee	3014512548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	
Science Advisory Board to NCTR	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants.	3014512560

The hotline will provide the most recent information available on upcoming advisory committee meetings, guidance for making an oral presentation during the open public hearing portion of a meeting, and procedures on obtaining copies of transcripts of advisory committee meetings. Because the hotline will communicate the most current information available about any particular advisory committee meeting, this system will provide interested parties with timely and equal access to such information. The hotline should also conserve agency resources by reducing the current volume of inquiries individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 10, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–31157 Filed 12–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0371]

Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Human Dura Mater.'' This guidance document describes a means