DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0928]

Semiannual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the semiannual guidance document agenda. FDA committed to publishing, on a semiannual basis, possible guidance topics or documents for development or revision during the next year, and seeking public comment on additional ideas for new guidance documents or revisions of existing ones. This commitment was made in FDA's February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidances.

DATES: Submit comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For general information regarding FDA's GGP's contact: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

For information regarding specific topics or guidances, please see contact persons listed below.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing a semiannual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents.

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initiative, FDA is also seeking public comment on the clarity of its guidance documents.

The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by topic categories. The agency's contact persons are listed for each specific area.

II. Center for Biologics Evaluation and Research (CBER)

Title/Topic of Guidance	Contact
CATEGORY—COMPLIANCE AND INSPECTION	
Guidance for Reprocessing, Reworking, and Blending Practices for Biological Bulk Substances, Final Bulk, and Finished Products.	Stephen M. Ripley, Center for Biologics (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.
Compliance Program 7342.002, Inspection of Source Plasma Establishments.	Do.
Compliance Program, Inspection of Licensed Vaccine and Related Product Manufacturers.	Do.
Compliance Program 7341.002, Inspection of Tissue Banking Establishments.	Do.
Compliance Program 7341.003, Examination of Blood and Blood Components Offered for Import.	Do.
Compliance Program 7342.006, Inspection of Plasma Derivatives of Human Origin.	Do.
Compliance Program 7342.008, Inspection of Licensed Viral Marker Test Kits.	Do.
Guidance for the Design, Installation, and Operations of Water Systems.	Do.
Guidance on Heating, Ventilation, and Air Conditioning (HVAC) and the Monitoring of Environments for the Manufacture of Biological Substances and Products.	Do.
Guidance for the Validation of the Limulus Amebocyte Lystate Test as an End–Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices.	Do.
Guidance for Process Validation Considerations for Biological Drug Substances and Biological Drug Products.	Do.
Guidance on Lot Release for Licensed Biological Products Distributed into Foreign Markets.	Do.
CATEGORY—THERAPEUTICS	
Guidance for the Chemistry, Manufacturing and Control Information on Gene Therapy Products.	Do.

Title/Topic of Guidance	Contact
Guidance to Industry on Xenotransplantation.	Do.
Guidance in the Development of Products for Chronic Cutaneous Ulcers and Acute Burn Wounds.	Do.
Guidance on Recombinant Biologics Produced in Plants.	Do.
Guidance on the Development of Products for Systemic Lupus Erythematosus.	Do.
CATEGORY—BLOOD AND BLOOD COMPONENTS	Do.
Guidance for Collection, Testing and Release of Autologous Blood.	Do.
Guidance for Recommendations for Donor Testing By Automated Methods When Using Treponemal Based Screening Tests for Syphilis.	Do.
Guidance for Reviewer Guidance for a Pre–Market Notification Submission for Automated Blood Establishment Testing Instruments.	Do.
Guidance for HIV Reentry Algorithms for Deferred Blood and Plasma Donors.	Do.
Guidance for Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Xenograft Recipients and Their Close Contacts, Through Whole Blood, Blood Components, Source Plasma, and Source Leukocytes.	Do.
Guidance for Additional Recommendations for Donor Questioning Regarding Travel to Areas Endemic for Malaria.	Do.
CATEGORY—VACCINES	
Guidance for Immunization of Human Plasma Donors To Obtain Source Plasma for Preparation of Specific Immune Globulins.	Do.
Guidance on Assessment of the Reproductive Toxicity Potential of Preventative Vaccines for Infectious Diseases.	Do.
Guidance on the U.S. Minimum Standards (formerly U.S. Minimum Requirements) for Tetanus and Diphtheria Toxoid Containing Products.	Do.
CATEGORY—OTHER	
Guidance on the Development and Use of Comparability Protocols.	Do.

III. Center for Devices and Radiololgical Health (CDRH)

Title/Topic of Document	Contact
Preparation of IDE's for Spinal Systems.	Samie N. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3090.
Preclinical and Clinical Data and Labeling for Breast Prostheses.	Do.
Ultra High Molecular Weight Polyethylene (UHMWPE) Guidance.	John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2036.
Bone Cement Guidance.	Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2036.
Adhesion Prevention Guidance.	Dave B. Berkowitz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3090.
Neuroembolization Guidance.	Keith E. Foy, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3090.
Dura Substitutes Guidance.	Ann H. Costello, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1184.
Guidance on Labeling for Laboratory Tests.	Steve I. Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1905.
Over the Counter Luteunizing Hormone Assays.	Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1243.
Over the Counter Human Chorionic Gonadotropin Assays (Revision).	Do.
Quality Control Guidance (Revision).	Do.
Point of Care In Vitro Diagnostics.	Do.
Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer (Revision).	Do.

Title/Topic of Document	Contact
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology (Revision).	Do.
Criteria for a Streamline PMA for Early Detection of PSA.	Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1293.
Abbreviated 510(k) Submission for In Vitro Diagnostic Antinuclear Antibody (ANA) Immunological Test Systems.	Do.
Points to Consider for Cervical Cytology Devices (Revision).	Do.
Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVD's using Monoclonal Antibodies (Revision).	Do.
Review Criteria for Assessment of Antimicrobial Susceptibility Devices (Special Control).	Woody Dubois, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2096.
Premarket Approval Applications for In Vitro Diagnostics Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-associated Disease.	Do.
Oral Appliance For Snoring And Sleep Apnea.	Sandy L. Shire, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5283.
General Hospital IV Administration Sets.	Pat M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8879.
IV flushes.	Do.
Infrared Thermometers.	Do.
Jet Injectors.	Do.
Infection Control Expiration Dating of Medical Glove.	Chiu C. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8913.
Biological Indicators.	Do.
Chemical Indicators.	Do.
Renal Dialyzer Reprocessing.	Do.
Liquid Sterilizers and High Level Disinfectants.	Do.
General Purpose Washers/Disinfectants.	Do.
Heart Valve Guidance (Revision).	Thomas J. Callahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8252.
Cardiac Ablation: Atrial Fibrillation Clinical Study Design.	Dina J. Fleischer, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8517.
Cardiac Ablation: Pre-clinical Testing.	Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8517.
Cardiac Ablation: SVT Clinical Study Design.	Stuart M. Portnoy, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8517.
Cardiac Ablation: Atrial Flutter Clinical Study Design.	Jennifer L. Goode, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8517.
Percutaneous Transluminal Angioplasty (PTA) Catheters.	Christopher M. Sloan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8243.
Applications for Permanent Pacemaker Leads.	Lynette A. Gabriel, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8243.
Implantable Defibrillator Guidance Document.	Doris J. Terry, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8609.
Replacement Rechargeable Batteries 510(k)s.	Charles S. Ho, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8609.
Extracorporeal Membrane Oxygenators (ECMO).	Thinh Nguyen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8252.
Compressible Limb Sleeves.	Do.
Telemetry Guidance.	Do.
Electromagnetic Compatibility Guidance (Revision).	Do.
Roller Pump Special Control.	Do.
Arrhythmia Detector and Alarm including ST Segment Monitor and Alarm (Revision).	Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–8252.

Title/Topic of Document	Contact
External Cardiac Defibrillators (including AED's).	Do.
Multifunction Electrodes (a subset of the External Defibrillators).	Do.
510k Biopsy Devices Guidance (Revision).	Mary Beth Abt, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Irrigation Set Checklist (Revision).	Do.
Testicular Implant Guidance Document (Revision).	John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
Inflatable Penile Implant Guidance Document (Revision).	Do.
Content of PMA Application for Testicular Implants (Revised).	Do.
Content of PMN for Extracorpreal Shock Wave (Revised).	Do.
Lithrotriptor indicated for the fragmentation of kidney and ureteral calculi.	Do.
510(k) Enuresis Alarm Checklist (Revision).	Do.
510(k) Antimicrobial Foley Guidance (Revision).	Laura J. Byrd, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Electrical Surgical Unit Checklist (Revision).	Do.
510(k) Non-implantable Electrical Stim. Checklist (Revision).	Do.
Vesicoureteral Reflux Guidance Doc. (New).	Hector H. Herrera, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Urodynamic Systems Guidance Document (Revision).	Do.
BPH Guidance Document (Revision).	Mil J. Jevtich, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
Urethral Bulking Agent Guidance (Revision).	Rao Nimmagadda, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Condom Catheter Checklist (Revision).	Do.
External Penile Rigidity Device Guidance (New).	Jim Seiler, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Urine Drainage Bag Guidance (Revision).	Do.
Urethral Stent Guidance Document (Revision).	Do.
Artificial Urinary Sphincter Guidance (Revision).	Nicole L. Wolanski, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
510(k) Balloon Catheter Guidance Document (Revision).	Do.
510(k) Mechanical Lithrotriptor/Stone Dislodger (Revision).	Do.
510(k) Light Sources checklist (Revision).	Do.
510(k) Endoscope Guidance (Revision).	Mary Jo Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2194.
Thermal Endometrial Ablation Devices Submission Guidance for an IDE (Revision).	Veronica A. Price, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1180.
Guidance for Content of Premarket Notification for Conventional and High Permeability hemodialysers (Revision).	Carolyn Y. Neuland, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1220.
Guidance for Premarket Notification for Hemodialysis Delivery System (Revision).	Do.
Guidance for Industry and CDRH Rev. of Content of Premarket Notification for Perioneo–Venous Shunts (Revision).	Do.
Guidance for Content of Premarket Notification of Body Composition Analyzers (Revision).	Do.
Guidance of Content of Investigational Device Exemption (IDE) for Solutions for hypothermic flushing, transport and storage of organs and transplantation (Revision).	Do.
Guidance on Devices in Invitro Fertilization and other Assisted Reproduction procedures (Revision).	Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1220.
Guidance for Submission of Bone Sonometer Premarket Applications (PMS's) (Revision).	Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1212.
Guidance for Brachytherapy Source 510(k)s (Revision).	Do.
Guidance for Radiation Therapy Systems Software Testing (Revision).	Do.
Diagnostic Ultrasound Guidance (Revision).	Do.

Title/Topic of Document	Contact
Guidance for Manufacturing of Digital Mammography Devices (Revision).	William M. Sacks, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1212.
Guidance for Manufacturers of Bone Ultrasound Devices for Osteoporosis (Revision).	Do.
Guidance for Preparation of Bone Sonometer PMA Submissions (Revision).	Joe Arnaudo, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1212.
Guidance for Review of Bone Densitometer 510(k) Submissions (Revision).	Do.
Extended Wear Contact Lens Guidance, Including Clinical Studies.	Karen Warburton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1744.
Guidance on Post Market Studies for Extended Wear Contact Lenses.	Do.
Orthokeratology Contact Lens Clinical Study Guidance.	Eleanor M. Felton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1744.
Labeling Guidance for UV Absorbing Contact Lenses.	Do.
510k Guidance Document for Daily Wear Contacts (Revision).	Do.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Implantable Middle Ear Hearing Device.	Teri Cygnarowicz, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2080.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant for Children (Revision).	Do.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant for Adults (Revision).	Do.
Guidance for the Development of a Premarket Notification for a Disposable Sterile Ear, Nose and Throat Endoscope Sheath with Protective Barrier Claims (Revision).	Karen H. Baker, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2080.
Guidance for the Development of a Premarket Notification for Vocal Cord Medialization Devices.	Do.
Scanning Laser Ophthalmoscopes.	Everette T. Beers, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2018.
Electrosurgical Devices.	Do.
Microkeratomes.	Do.
Refractive Lasers (Revision).	Do.
Interocular Lenses Guidance Document (Revision).	Donna R. Lochner, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2053.
Refractive Implants Guidance Document.	Ashley A. Boulware, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2053.
Draft Guidance for Industry on the Custom Device Exemption of the Federal Food, Drug, and Cosmetic Act (Level 1).	Casper Uldrik, Office of Compliance, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–4692.
Draft Guidance for Industry on the Likelihood of Facilities Inspections When Modifying Devices Subject to PMA Approval (Level 1).	Do.
Draft Guidance for Industry on Quality System Regulation Information Required for Various Premarket Submissions. (Level 1).	Do.
Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers (Level 1).	Do.
Guidance to Industry on the information to be provided under 21 CFR 1020.30(g). (Level 1) This will be effective immediately based on the public health exemption, per Linda Kahan and Dr. Jacobson.	Do.
Guidance to Industry on the alternative use of the statement ''Rx only.'' (Level 1).	Do.
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 (Final).	Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3332.
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4.	Do.
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #5.	Do.
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #6.	Do.
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #7.	Do.

Title/Topic of Document	Contact
Mammography Quality Standards Act (MQSA) Inspections of Mobile Facilities Under the Final Regulations.	Walid G. Mourad, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3332.
MQSA Inspections of Digital Mammography Systems Under the Final Regulations.	Do.
Bayesian Statistics.	Laura Alonge, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2812.
Discrepant Resolution.	Do.
Diagnostic Devices (statistics).	Do.
Medical Device Reporting (MDR) Regulations: Reporting Adverse Events Associated with Medical Device Reprocessing or Medical Device Reuse.	Do.
MDR Guidance for Importers.	Do.
Non-diagnostic Devices (statistics) (Revision).	Do.
MDR Reporting for Endosseous Implants (Revision).	Do.
Guidance for Manufacturers for Preparation of Postmarket Surveillance Plans Required Under Section 522 of the Federal Food, Drug, and Cosmetic Act (Revision).	Do.

IV. Center for Drugs Evaluation and Research (CDER)

Title/Topic of Document	Contact
CATEGORY—ADVERTISING	
Accelerated Approval Products: Submission of Promotional Materials.	Nancy E. Derr, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5400.
Advertising and Labeling of Treatment IND Protocols.	Do.
Anti–Infective Human Drug and Biological Products Advertising and Promotional Labeling.	Do.
Comparative Claims in Advertising and Labeling.	Do.
Continuing Medical Education.	Do.
Fair Balance.	Do.
Health Related Quality of Life Claims.	Do.
Informercials.	Do.
Promotion of Investigational Products.	Do.
Promotion of Medical Products on the Internet.	Do.
Promotion at International Meetings.	Do.
Proprietary (Brand) Name & Established (Generic) Name Placement, Size, & Prominence in Advertising and Promotional Labeling.	Do.
Providing Electronic Submissions to the Division of Drug Marketing, Advertising, and Communications.	Do.
CATEGORY—BIOPHARMACEUTICS	
Food–Effect Bioavailability and Bioequivalence Studies.	Do.
Oral Inhalation Drug Products; In Vivo Bioavailability and Bioequivalence.	Do.
Pharmacokinetics Metrics for Bioavailability/Bioequivalence.	Do.
CATEGORY—CHEMISTRY	
BAC PAC II—Bulk Actives Postapproval Changes (Re: Postapproval Changes from the Final Intermediate to the Drug Substance).	Do.
Comparability Protocol for Making Changes to Chemistry, Manufacturing, and Controls for Drug and Biological Products.	Do.
Drug Master Files; General Content and Format.	Do.
Drug Master Files for Bulk Antibiotic Drug Substances.	Do.
Formal Meetings Between CDER/CBER and Sponsors on Chemistry, Manufacturing and Controls Information for IND Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products.	Do.
ISPE for SUPAC TDS.	Do.
ISPE for SUPAC SS.	Do.
Methods Validation for the Assay of Drugs And/or Metabolites in Human Biological Matrices.	Do.
Post Approval Changes for Sterile Aqueous Solutions.	Do.
Proprietary Drug Names.	Do.
Provides Recommendation Regarding Submission of Information for Drug Products Containing Cyclodextrin.	Do.
Recombinant DNA Growth Hormone Drug Products.	Do.

Title/Topic of Document	Contact
Recombinant DNA Human Insulin Drug Products.	Do.
Revision to the SUPAC IR Guidance Document That Published in November 1995.	Do.
Submission of Documentation for Antibiotics and Other Cellular Metabolites Produced by Microorganisms Modified by the Use of Recombinant DNA Technology.	Do.
Submission of CMC Information for Synthetic Peptide Substances.	Do.
Submission of CMC and Biopharm Information for Liposomal and Lipid-Complexed Drug Products.	Do.
Submission of Chemistry, Manufacturing, and Controls Documentation for Inhalation Drug Products: MDI's and DPI's.	Do.
Submission of CMC Information on Chiral Drugs.	Do.
Submitting Manufacturing and Quality Control Information with INDs, NDAs, ANDA's, and AADA's.	Do.
SUPAC TDS.	Do.
CATEGORY—CLINICAL/ANTIMICROBIAL	
Acute Bacterial Arthritis; Developing Antimicrobials for Treatment.	Do.
Agents to Treat Opportunistic Infections Related to AIDS; Developing Antimicrobials for Treatment.	Do.
Agents Used in Surgical Prophylaxis, Developing Antimicrobials for Treatment.	Do.
Agents to Treat Sepsis/Septic Shock; Developing Antimicrobials for Treatment.	Do.
Antifungal Agents; Developing Antimicrobials for Treatment.	Do.
Antimycobacterial Agents; Developing Antimicrobials for Treatment.	Do.
Antiparasitic Agents; Developing Antimicrobials for Treatment.	Do.
Antiviral Agents; Developing Antimicrobials for Treatment.	Do.
Catheter–Related Infections.	Do.
Complicated Intra–Abdominal Infections; Developing Antimicrobials for Treatment.	Do.
Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements.	Do.
Dermatologic Surgical Scrubs, Etc., Developing Antimicrobials for Treatment.	Do.
Endocarditis; Developing Antimicrobials for Treatment.	Do.
Gynecologic Infections (Except Sexually Transmitted Disease and Pelvic Inflammatory Disease); Developing Antimicrobials for Treatment.	Do.
Helicobacter Pylori Infections; Developing Antimicrobials for Treatment.	Do.
Immunologic/Transplant Agents; Developing Antimicrobials for Treatment.	Do.
Nongonoccocal Urethritis/Cervicitis; Developing Antimicrobials for Treatment.	Do.
Osteomyelitis (Acute and Chronic); Developing Antimicrobials for Treatment.	Do.
Pelvic Inflammatory Disease; Developing Antimicrobials for Treatment.	Do.
Uncomplicated Intra–Abdominal Infections; Developing Antimicrobials for Treatment.	Do.
CATEGORY—CLINICAL/MEDICAL	
Clinical Development for Drugs to Treat Urinary Incontinence.	Do.
Clinical Development Programs for MDI and DPI Drug Products Revised.	Do.
Clinical Evaluation of Drugs for the Treatment of Acute Coronary Syndrome.	Do.
Clinical Evaluation of Drugs for the Treatment of Heart Failure.	Do.
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis.	Do.
Clinical Development of Drugs for the Treatment of Allergic Rhinitis Revised.	Do.
Clinical Evaluation of Drugs for Ulcerative Colitis.	Do.
Clinical Evaluation of Weight–Control Drugs Revised.	Do.
Clinical Development of Products for the Treatment of Chronic Cutaneous Ulcers and Acute Burn Wounds.	Do.
Clinical Evaluation of Lipid–Altering Agents Revised.	Do.
Clinical Evaluation of Estrogen—and Estrogen/Progestin–Containing Drug Products Used for Hormone Replacement Therapy in Postmenopausal Women.	Do.
Clinical Evaluation of Motility Modifying Drugs.	Do.
Clinical Evaluation of Drugs for Crohn's Disease.	Do.

Title/Topic of Document	Contact
Clinical Development of Drugs for the Treatment of Chronic Sinusitis (Other than Antimicrobials).	Do.
Clinical Evaluation of Potential ECG Effects of New Antihistamines Revised.	Do.
Content and Format of the Clinical Studies Section of Labeling for Human Drugs and Biologics.	Do.
Content and Format for Submission of Carcinogenicity Protocols for Evaluation.	Do.
Content and Format of the Adverse Reactions Section of the Labeling.	Do.
Data Monitoring and Interim Analysis of Clinical Studies Performed Under an IND.	Do.
Design and Endpoint Issues Related to Treatment Trials for Female Sexual Disfunction.	Do.
Developing Clinical Programs for Developing Drugs, Devices and Biological Products for the Treatment of Systemic Lupus Erythematosus.	Do.
Evaluation of New Treatments for Diabetes Mellitus.	Do.
Evaluation of Growth Effects of Orally Inhaled and Intranasal Corticosteroids in Asthma and Allergic Rhinitis.	Do.
H.Pylori Ulcer.	Do.
NSAID Ulcer.	Do.
Performance of Clinical Trials for Gastroduodenal Ulcer Disease.	Do.
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products.	Do.
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis Revised.	Do.
Preclinical Development of Inhalation Drugs for Indications in Children 2 Years of Age or Less.	Do.
Psoriasis Therapies.	Do.
Safety Review of Clinical Data; Reviewer Guidance.	Do.
Ulcers Not Due to H.Pylori or NSAID.	Do.
Ulcers Without Consideration of Pathogenesis.	Do.
Vaginal Contraceptive Drug Development Revised.	Do.
CATEGORY—CLINICAL/PHARMACOLOGY	
Clinical Pharmacology and Biopharmaceutic Data for Human Drug Products.	Do.
Failed Bioequivalence.	Do.
Format and Content of the Clinical Pharmacology Section of Prescription Drug Product Labeling.	Do.
General Considerations for Pediatric Pharmacokinetic Studies.	Do.
Immediate Release to Modified Release Dosage Forms.	Do.
In Vitro Drug Metabolism/Drug Interaction.	Do.
Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.	Do.
Pharmacokinetics and Pharmacodynamics.	Do.
Special Initiative: Narrow Therapeutic Index (Range).	Do.
Submission of Expanded Synopses for Clinical Pharmacology and Biopharmaceutics Studies.	Do.
CATEGORY—COMPLIANCE	
Civil Money Penalty Cases Under PDMA.	Do.
Development, Implementation, and Maintenance of a Sample Security and Audit System under the Prescription Drug and Marketing Act of 1987.	Do.
First Party Audit.	Do.
Information Required for Pre–Approval GMP Inspections.	Do.
Maintaining Adequate and Accurate Records During Clinical Investigations.	Do.
National Drug Code Number and Drug Product Labels.	Do.
Sterile Drug Products Produced by Aseptic Processing Revised.	Do.
Submission to an IND of Investigator Information for Non–US Studies.	Do.
Waiver of Informed Consent Requirements for Emergency Care Research.	Do.
CATEGORY—ELECTRONIC SUBMISSIONS	
Electronic Submission of Adverse Reaction Data via Physical Media.	Do.
Preparing Data for Electronic Submissions of ANDA's.	Do.
Standards for Electronic Safety Data Submissions.	Do.
CATEGORY—GENERICS	
Botanical Drug Products.	Do.
Changes in Labeling of ANDA's Subsequent to Revisions in the RLD Labeling.	Do.

Title/Topic of Document	Contact
Clindamycin Intravenous Labeling.	Do.
OGD's Policy on Inactive Ingredients.	Do.
Submitting Documentation to Abbreviated Drug Applications for Degredation Products in Drug Products.	Do.
Variation in Drug Product That May Be Included in a Single Application.	Do.
CATEGORY—LABELING	
Content and Format for ''Geriatric Use'' Supplemental Applications.	Do.
Labeling Guidance for Combined Oral Contraceptives—Physician Labeling and Instructions for Use Revised.	Do.
Topical Corticosteroid Class Labeling.	Do.
CATEGORY—OTC	
Eye Allergy Relief/Allergic Conjunctivitis.	Do.
Labeling of OTC Human Drug Products.	Do.
Labeling Comprehension Studies for OTC Drug Products.	Do.
Manufacturing Issues/Policy for Ophthalmic Drug Products.	Do.
Points to Consider—OTC Actual Use Studies.	Do.
Post Cataract Inflammation Studies.	Do.
Removal of a Preservative to Create a ''Preservative Free'' Ophthalmic Solution.	Do.
The Small Entity Compliance Guidance On: Regulations for the Labeling of Over-the-counter Human Drugs.	Do.
Uveitis Studies.	Do.
CATEGORY—PHARMACOLOGY/TOXICOLOGY	
Evaluation of Preclinical Reproductive Toxicology Data.	Do.
Immunotoxicology.	Do.
Photo Safety Testing.	Do.
Statistical Aspects of Design, Analysis, and Interpretation of Animal Carcinogenicity Studies.	Do.
Testing for Photocarcinogenesis.	Do.
CATEGORY—PROCEDURAL	
Available Therapy Guidance (As Defined by CDER and CBER).	Do.
Appeal of Center Regulatory and Scientific Decisions.	Do.
Applications Pursuant to 505 (B)(2).	Do.
Clarify Requirements for Submission of Supplements.	Do.
Formal Meetings Between CDER and Sponsors and Applicants for PDUFA Products.	Do.
Health Care Economic Information.	Do.
Meetings Between CDER and External Constituents on Non-PDUFA Products.	Do.
New Drug Evaluation: Refusal to File.	Do.
Qualifying for Pediatric Exclusivity Revised.	Do.
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of FDAMA.	Do.
Special Protocols for the Content and Review of Applications.	Do.
Submission of Debarment Certification Statements and Other Information under the Generic Drug Enforcement Act of 1992.	Do.
Submitting Requests for Waiver or Deferral under the Pediatric Study Requirements.	Do.
CATEGORY—USER FEES	
Assessment of Product, Establishment, and Application Fees.	Do.
User Fee Waivers and Reductions.	Do.

V. Center for Food Safety and Applied Nutrition (CFSAN)

Title/Topic of Document	Contact
CATEGORY—ENVIRONMENTAL	
Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition.	Buzz L. Hoffman, Office of Premarket Approval (HFS–246), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3012.
CATEGORY—ANTIMICROBIAL FOOD ADDITIVES	
Antimicrobial Food Additives.	Mark A. Hepp, Office of Premarket Approval (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098
CATEGORY—PREMARKET NOTIFICATION FOR FOOD CONTACT SUBSTANCES	

Title/Topic of Document	Contact
Draft Guidance for Preparing a Premarket Notification for Food Contact Substances.	Mitch A. Cheeseman, Office of Premarket Approval (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083
CATEGORY—DIETARY SUPPLEMENTS	
Dietary Supplements: Questions and Answers.	Ellen M. Anderson, Office of Food Labeling (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5562
Dietary Supplements: Identity Testing Guidelines.	Karen F. Strauss, Office of Special Nutritionals (HFS–456), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–205–4168

VI. Center for Veterinary Medicine (CVM)

Title/Topic of Document	Contact
CATEGORY—FOOD ADDITIVES	
Data Requirements for Demonstrating a Food Additive Can Contro *Salmonella* in Feed.	George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6651.
Data Requirements for Demonstrating a Food Additive Binds Mycotoxins.	Do.
CATEGORY—MICROBIAL PRODUCTS IN FEEDS	
Compliance Policy Guide about Microbial Products.	Do.
CATEGORY—HUMAN FOOD SAFETY	
Disposition of Animals Used in Research and in the Manufacture of Biomedical Products.	Linda R. Tollefson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6644.
Threshold Assessment Guidance.	Devaraya R. Jagannath, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6982.
Tolerance Guidance.	Steven Brynes, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6975.
Risk Analysis Guidance.	Kevin J. Greenlees, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977.
Animal Drug Availability Act Import Tolerance Policy.	Do.
Microbiological Testing of Antimicrobial Drug Residues in Food Guidance.	Do.
CATEGORY—SUBSTANTIAL EVIDENCE	
One v. Multiple Adequate and Well-controlled Studies/Field Studies.	Claire M. Lathers, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620.
Use of Published Studies.	Do.
Dose or Dose Range Characterization.	Do.
CATEGORY—MANUFACTURING CHEMISTRY	
Stability Guidance.	William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966.
Guidance on Chemistry and Manufacturing Changes and Good Manufacturing Practices Requirements for Minor Use/Minor Species Drug Products.	Do.
Guidance on Chemistry and Manufacturing and Controls Changes to an Approved NADA or ANADA.	Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.
Stability Testing of New Drug Substances and Products in the Veterinary Field.	William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966.
Stability Testing of New Dosage Forms in the Veterinary Field.	Do.
Stability Testing for Medicated Premixes.	Do.
Stability Testing: Photostability Testing of New Drug Substances and Products in the Veterinary Field.	Do.
Guidance for Industry, BACPAC I: Intermediates in Drug Substance Synthesis - Bulk Actives Postapproval Changes: Chemistry, Manufacturing and Controls Documentation.	David R. Newkirk, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967.
CATEGORY—TARGET ANIMAL SAFETY AND EFFECTIVENESS STUDIES FOR PRODUCTION DRUGS	

Title/Topic of Document	Contact
Anticoccidials in Poultry Guidance.	Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0233.
CATEGORY—TARGET ANIMAL SAFETY AND EFFECTIVENESS STUDIES FOR THERAPEUTIC DRUG USES	
Non–Steroidal Anti-inflammatory Drug Guidance.	Elizabeth Reese, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0132.
Competitive Exclusion Guidance.	Steven D. Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7580.
Minor Species Simulated Pharmacokinetic Submissions.	Marilyn Martinez, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577.
CATEGORY—OTHER PRE–MARKETING	
Bioequivalence of Continual Release Drugs Such as Implant Drugs.	Marilyn Martinez, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577.
Correlation of In-vitro Dissolution and In-vivo Bioavailability.	Do.
FOI Summary Guidance.	Steven Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7580.
CATEGORY—STATISTICS	
Add Log C I Guidance to Bioequivalence Guidance.	Anna Nevius, Center for Veterinary Medicine (HFV–124), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855,301–827–0218.
Principles of Statistical Analysis relevant to Regulatory Studies.	Do.
CATEGORY—ELECTRONIC SUBMISSIONS	
Submitting a Notice of Final Animal Disposition of Animals not Intended for Slaughter in Electronic Format to the CVM via E–Mail.	Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.
Submitting a Notice of Intent to Slaughter for Human Purposes in Electronic Format to the CVM and USDA via E–Mail.	Do.
Submitting a Request for Meeting or Teleconference in Electronic Format to the CVM via E–Mail.	Do.
Submitting a Protocol in Electronic Format to the CVM via E–Mail.	Do.
CATEGORY—ANALYTICAL METHODS	
Guidance Document on the Validation of Analytical Procedures for Medicated Feeds.	Mary Leadbetter, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6964.
Guidance Document on Analytical Method Documents for Medicated Feeds.	Do.
Guidance Document on Protocols for Conduct of Method Transfer Trials for Medicated Feed Assays.	Do.

VII. Office of Regulatory Affairs (ORA)

Title/Topic of Document	Contact
CATEGORY—COMPLIANCE POLICY GUIDES	
Compliance Policy Guide, Chapter 5, Sec.540.400, Shrimp—Fresh or Frozen, Raw, Headless, Peeled or Breaded—Adulteration Involving Decomposition (CPG 7108.11).	MaryLynn A. Datoc, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0413.
Compliance Policy Guide, Chapter 5, 540.650, Sale—Cured, Air–Dried, Uneviscerated Fish (e.g.,''Kapchunka'')(CPG 7108.17).	Do.
Compliance Policy Guide (NEW) Regulation of Somatic Cell and Tissue–Based Products.	JoAnne C. Marrone, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1242.
CATEGORY—COMPLIANCE PROGRAMS: BIORESEARCH MONITORING	
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A: EPA Data Audit Inspections.	James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.
Compliance Program7348.809: Bioresearch Monitoring; Institutional Review Board.	Do.
Exception for Informed Consent Requirements for Emergency Research.	Do.
CATEGORY—INSPECTION GUIDES	

Title/Topic of Document	Contact
Guide to Inspections of Source Plasma Establishments.	Elizabeth A. Waltrip, Division of Emergency and Investigational Operations (HFC–132), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5662.
Guide to Inspections of Aseptic Processing and Packaging (Food).	Jody Robinson, Division of Emergency and Investigational Operations (HFC–132), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7691.
CATEGORY—REGULATORY PROCEDURES MANUAL	
Regulatory Procedures Manual (Revision), Chapter 10, Subchapter: Application Integrity Policy.	Sharon Sheehan, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0412.
CATEGORY—LABORATORY PROCEDURES MANUAL	
Chapter 1, Sample Accountability.	Jim Yager, Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1025.
Chapter 2, Sample Analysis.	Do.
Chapter 3, Laboratory Reporting.	Do.
Chapter 4, Sample Disposition.	Do.
Chapter 21, Guidance on the Review of Analytical Data Generated by Private Laboratories.	Leonard Valenti, Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–7103.

Dated: November 4, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–29699 Filed 11–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3027–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—December 8, 1999

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations to the agency about clinical coverage issues. The Committee will hear reports from recent meetings of MCAC medical specialty panels. The Committee will also consider how to provide guidance to, and substantive coordination among, MCAC panels. For example, the Committee will consider the levels of evidence, types of information needed, and the nature of issues that will be considered by the medical specialty panels at future public meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10 (a)(1) and (a)(2)).

DATES:

The Meeting: December 8, 1999, from 8 a.m. until 4 p.m., E.D.T.

Deadline for Presentations and Comments: Submit formal presentations and written comments to the **FOR FURTHER INFORMATION CONTACT** by November 18, 1999, 5 p.m., E.S.T.

Special Accomodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must notify the Executive Secretary by November 18, 1999, 5 p.m., E.D.T.

ADDRESSES:

The Meeting: The meeting will be held at the Health Care Financing Administration, Main Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

Presentations and Comments: Submit formal presentations and written comments to Sharon K. Lappalainen, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3–02–01; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

SUPPLEMENTARY INFORMATION:

On August 13, 1999, we published a notice (64 FR 44231) to establish the Medicare Coverage Advisory Committee (MCAC) to provide advice and recommendations to us about clinical coverage issues. This notice announces the following public meeting of the MCAC:

Current Members of the Committee

Thomas V. Holohan, M.A., M.D., (FACP); Leslie P. Francis, JD, Ph.D.; John H. Ferguson, M.D.; Robert L. Murray, Ph.D.; Alan M. Garber, M.D., Ph.D.; Michael D. Maves, M.D., M.B.A.; David M. Eddy, M.D., Ph.D.; Frank J. Papatheofanis, M.D., Ph.D.; Harold C. Sox, M.D.; Ronald M. Davis, M.D.; Daisy Alford-Smith, Ph.D.; Joe W. Johnson, D.C.; Robert H. Brook, M.D., Sc.D.; Linda A. Bergthold, Ph.D.; and Randel E. Richner, M.P.H.

Meeting Topic

The Committee will hear reports from recent meetings of MCAC medical specialty panels. The Committee will also consider how to provide guidance to, and substantive coordination among, MCAC panels. For example, the Committee will consider the levels of evidence, types of information needed, and the nature of issues that will be considered by the medical specialty panels at future public meetings.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 90 minutes on the day of the meeting. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the **FOR FURTHER INFORMATION CONTACT**, and submit the following by the Deadline for Presentations and Comments date listed in the Dates section of this notice: a brief statement of the general nature of the information you wish to present, the