DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 4, 1999, 8 a.m. to 5 p.m., and on October 5, 1999, 8 a.m. to 12 m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 4, 1999, presentations and committee discussions will address issues related to the potential applicability of information from non-U.S. studies of prevention of perinatal human immunodeficiency virus transmission to U.S. clinical settings.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 27, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 4, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 27, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 4, 1999, from 2 p.m to 5 p.m., and on October 5, 1999, from 8 a.m. to 12 m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information relevant to pending investigational new drug applications and drug development plans (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 2, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–23465 Filed 9–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshops.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Devices and Radiological Health, and the Regional Small Business Assistance Offices in cooperation with the American Society for Quality, Association of Food and Drug Officials, BioFlorida, Inc., Health Industry Manufacturers Association, Medical Alley, New England Biomedical Discussion Group, Organization of Regulatory and Clinical Associates, Pharmaceutical Quality Institute, and the Regulatory Affairs Professionals Society is announcing a series of workshops on the FDA Quality System Inspection Technique (QSIT). Topics for discussion include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventative Action, Design Controls, Production and Process Controls, and Industry Perspective of QSIT. Through the workshops, FDA seeks to increase the medical device community's understanding of QSIT, and ensure that the device industry takes appropriate actions to establish effective quality systems, thus preventing regulatory problems when inspections occur.

Date and Time: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Location: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Registration: Send registration information as listed in the **SUPPLEMENTARY INFORMATION** section of this document, along with the correct payment amount, to the registrar for the site you wish to attend. Fees cover refreshments, organization and site costs, and materials. Space is limited, therefore interested parties are encouraged to register early. If you need special accommodations due to a disability, please inform the registrar for your site at least 7 days in advance of the workshop.

Contact: Herman B. Janiger, Northeast Regional Office (HFRNE–17), Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–340–7000, ext. 5528.

SUPPLEMENTARY INFORMATION: In the fall of 1999, FDA field offices will begin using the QSIT nationwide as the primary tool for medical device good manufacturing practice/quality system inspections. QSIT was developed using a collaborative effort with stakeholders and tested in three districts. The following workshops are scheduled to increase the medical community's understanding of QSIT:

TABLE 1.

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
EAST ELMHURST: Crowne Plaza, LaGuardia Airport, 104–04 Ditmars Blvd., East Elmhurst, NY 11369, 718–457–6300.	Tuesday, October 12, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, September 28, 1999, $170.	James Blanchard, Health Industry Manufacturers Association, 1200 G St. NW, suite 400, Washington, DC 20005, 202–434–7231, FAX 202–783–8750.	Herman B. Janiger, Small Business Representative, Northeast Regional Office, 718–340–7000, ext. 5528.
PRINCETON: Holiday Inn, US Route 1 & Ridge Rd., Princeton, NJ 08540, 609–452–2400 or 800–465–4329.	Thursday, October 14, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, September 30, 1999, $145.	Satish Laroia, Pharmaceutical Quality Institute, 33 Aspen Circle, Edison, NJ 08820, 973–890–1440, FAX 732–549–7487.	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
MINNEAPOLIS: Holiday Inn, Minneapolis West, 9970 Wayzata Blvd., Minneapolis, MN 55426, 612–593–1918 or 800–465–4329.	Thursday, October 21, 1999, 8:30 a.m. to 4:30 p.m.	Friday, October 15, 1999, $160 (member), $235 (nonmember).	Lisa Miller, Medical Alley, 1550 Utica Ave. South St., Louis Park, MN 612–542–3077, FAX 612–542–3088, or ''www.medicalalley.org''.	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
ORLANDO: Radisson Orlando Airport, 5555 Hazeltine National Dr., Orlando, FL 32812, 407–856–0100 or 800–333–3333.	Thursday, October 28, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, October 14, 1999, $90.	Larry M. Clark, BioFlorida, Inc., 15205 SW 78th CT, Miami, FL 33157, 305–971–1495, FAX 305–971–1496.	Barbara Ward-Groves, Small Business Representative, Southeast Regional Office, 404–253–2238.
CAMBRIDGE: Volpe National Transportation Systems, Center Auditorium, rm. 1–11, Bldg. 2, Kendall Sq., Cambridge, MA 02142–1093.	Tuesday, November 2, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, October 19, 1999, $50.	Terrence Sullivan, New England Biomedical Discussion Group, P.O. Box 1282, Attleboro Falls, MA 02763–0282, 508–643–0434, FAX 508–643–2237.	Herman B. Janiger, Small Business Representative, Northeast Regional Office, 718–340–7000, ext. 5528.
HOUSTON: Marriott West Loop, 1750 West Loop South, Houston, TX 77027, 713–960–0111 or 800–228–9290.	Thursday, November 4, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, October 21, 1999, $170.	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York, PA 17402, 717–757–2888, FAX 717–755–8089.	Brenda C. Baumert, Small Business Representative, Southwest Regional Office, 214–655–8100, ext. 133.
OAK BROOK: Marriott Oak Brook, 1401 West 22d St., Oak Brook, IL 60523, 630–573–8555 or 800–228–9290.	Wednesday, November 10, 1999, 8:30 a.m. to 4:30 p.m.	Wednesday, October 27, 1999, $80.	Susan B. Jacobs, American Society for Quality, 3516 North Wilshire Dr., Palatine, IL 60067, 847–359–4456, FAX 847–359–4512.	Marie T. Falcone, Small Business Representative, Central Regional Office, 215–597–2120, ext. 4003.
ATLANTA: Sheraton Colony Sq., 188 14th St. NE., Atlanta, GA 30361, 404–892–6000.	Tuesday, November 16, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, November 2, 1999, $170.	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York, PA 17402, 717–757–2888, FAX 717–755–8089.	Barbara Ward-Groves, Small Business Representative, Southeast Regional Office, 404–253–2238.
FOSTER CITY: Crowne Plaza Hotel, 1221 Chess Dr., Foster City, CA 94404, 650–570–5700.	Thursday, November 18, 1999, 8:30 a.m. to 4:30 p.m.	Thursday, November 4, 1999, $120.	Courtney Ford, Regulatory Affairs Professionals Society, 12300 Twinbrook Pkwy., suite 350, Rockville, MD 20852–1606, 301–770–2920, FAX 301–770–2924.	Acting Small Business Representative, Pacific Regional Office, 510–637–3980.
BELLEVUE: Rockwell Institute, 13218 North East 20th St., Bellevue, WA 90005, 425–747–7272.	Tuesday, November 23, 1999, 8:30 a.m. to 4:30 p.m.	Sunday, November 7, 1999, $100.	Jaimee Hansen, Organization of Regulatory & Clinical Associates, P.O. Box 3490, Redmond, WA 98073–3490, 425–487–7179, FAX 425–487–8666.	Acting Small Business Representative, Pacific Regional Office, 510–637–3980.

The workshops, scheduled above, will help to implement the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and

ensuring access to needed scientific and technical expertise. These workshops also comply with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that requires outreach activities by Government agencies directed to small businesses.

This notice announcing the workshops and a registration form may also be accessed at the CDRH website at ''http://www.fda.gov/cdrh/fedregin.html''.

The following information is requested for registration:

REGISTRATION FORM

Quality System Inspection Technique (QSIT)

Regional Medical Device Workshop

Instructions: To register, complete this form and mail with registration fee to the Registrar for the workshop you wish to attend.

Date,_____

Location,_____

Fee enclosed,_____

Name,_____

Title,_____

Company,_____

Address,_____

Telephone,_____

Fax,_____

E-mail_____

Dated: September 2, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23633 Filed 9–7–99; 4:16 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–13]

Agency Information Collection Activities; Submission For OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Conditions of Coverage for Organ Procurement Organizations (OPOs) and Supporting Regulations in 42 CFR, Section 486.301–325;

Form No.: HCFA–R–13;

Use: An Organ Procurement Organization (OPO) is an entity that performs or coordinates the performance of retrieving, preserving and transporting organs and maintains a system of locating prospective recipients for available organs. OPOs are required to submit accurate data to HCFA concerning population and information on donors and organs on an annual basis in order to assure maximum effectiveness in the procurement and distribution of organs. This information collection lays out the conditions for coverage for OPOs;

Frequency: Annually;

Affected Public: Not-for-profit institutions;

Number of Respondents: 62;

Total Annual Responses: 62;

Total Annual Hours Requested: 1.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–23603 Filed 9–9–99; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–281]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The HCFA–R–281 will be used to evaluate the effects of the ''Medicare and You Handbook: 2000'' to determine that beneficiaries not only received it and are aware of the information, but whether they understand the information and are able to use it in making informed choices about their Medicare plan. Without this information, HCFA would not be able to obtain the information necessary to determine whether these goals have been met. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the possibility of beneficiaries not being properly informed/educated as to the importance of their Medicare plan choices.

HCFA is requesting OMB review and approval of this collection by 9/10/99, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below, by 9/9/99. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Survey of Medicare Beneficiaries for the National ''Medicare and You Handbook: 2000'' Evaluation;

Form No.: HCFA–R–281 (OMB #0938–0771);

Use: As part of the National Medicare Education Program (NMEP), HCFA plans a national mailing of the Medicare & You 2000 handbook to the entire Medicare population in September 1999. To evaluate the effects of the handbook, HCFA needs to know not only that beneficiaries received it and are aware of the information, but whether they understand the information and are able to use it in