

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting Notice

Deletion of Agenda Items From July 14th Meeting

The following items have been deleted from the list of agenda items

scheduled for consideration at the July 14, 1999, Open Meeting and previously listed in the Commission's Notice of July 7, 1999. Items 1 and 2 have been adopted by the Commission.

| Item No. | Bureau | Subject |
|----------|------------------------------|--|
| 1 | Common Carrier | Title: 1998 Biennial Regulatory Review—Streamlined Contributor Reporting Requirements Associated with Administration of Telecommunications Relay Services, North American Numbering Plan, Local Number Portability, and Universal Service Support Mechanisms (CC Docket No. 98-171). Summary: The Commission will consider a Report and Order that would simplify reporting requirements for contributors to the numbering administration, local number portability, Telecommunications Relay Services, and universal service support mechanisms. |
| 2 | Common Carrier | Title: Comprehensive Review of the Accounting Requirements and ARMIS Reporting Requirements for Incumbent Local Exchange Carriers: Phase I. Summary: The Commission will consider a Notice of Proposed Rulemaking that commences Phase I of a comprehensive review of its accounting and reporting requirements. |
| 3 | Wireless Telecommunications. | Title: Amendment of the Commission's Rules regarding the 37.0-38.6 GHz and 38.6-40.0 GHz Bands (ET Docket No. 95-183, RM-8553); and Implementations of Section 309(j) of the Communications Act—Competitive Bidding, 37.0-38.6 GHz 38.6-40.0 GHz Bands (PP Docket No. 93-253). Summary: The Commission will consider a Memorandum Opinion and Order addressing petitions for reconsideration regarding licensing and service rules in the 39 GHz service. |

Federal Communications Commission.
Magalie Romas Salas,
Secretary.
[FR Doc. 99-18506 Filed 7-15-99; 3:35 pm]
BILLING CODE 6712-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Disease Control and Prevention (CDC)

Agency for Toxic Substances and Disease Registry (ATSDR)

The Research Agenda Subcommittee of the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Conference Call Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following conference call meeting.

Name: Research Agenda Subcommittee of the Board of Scientific Counselors, ATSDR.
Time and Date: 1:30p.m.-3p.m., July 30, 1999.

Place: The Conference Call will originate from the Agency for Toxic Substances and Disease Registry, in Atlanta, Georgia. Please see "Supplementary Information" for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports. (There will be 10 telephone ports available.)

Purpose: This subcommittee will advise the Board of Scientific Counselors and the

Agency on areas of emphasis and focus for the ATSDR five-year environmental public health research agenda. The subcommittee will report jointly to the Board of Scientific Counselors and the ATSDR Associate Administrator for Science.

Matters to be Discussed: The conference call agenda is to establish a plan of action for the beginning and intermediate phase of developing the ATSDR five-year environmental public health research agenda.

Supplementary Information: This conference call is scheduled to begin at 1:30 p.m., EDT. To participate in the conference call, please dial 1-800-713-1971 and enter conference code 950512. You will then be automatically connected to the call.

For Further Information Contact: Robert F. Spengler, Sc.D., Executive Secretary, BSC, ATSDR, M/S E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, Telephone 404/639-0708, e-mail: rys2@cdc.gov.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: July 12, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-18294 Filed 7-16-99; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notices of Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Study Protocol Peer Review Meeting: Evaluation of Factors Affecting Disease Transmission in Commercial Aircraft Cabins.

Time and Date: 9 a.m.-3 p.m., August 3, 1999.

Place: NIOSH, Alice Hamilton Laboratory, Conference Room C, 5555 Ridge Avenue, Cincinnati, Ohio 45213, telephone 515/841-4106.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

Purpose: The purpose of this meeting is to obtain expert input regarding technical and scientific aspects of the study "Evaluation of Factors Affecting Disease Transmission in Commercial Aircraft Cabins" being conducted at NIOSH. Designated reviewers will individually critique the study protocol and provide comments on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other government agencies and the public are invited.

Matters to be Discussed: The agenda will include opening remarks/introductions, project overview, individual comments from formal reviewers, and a general discussion.

Contact Person for More Information: Ms. Jennifer Topmiller, Engineering Control Technology Branch, Division of Physical

Sciences and Engineering, NIOSH, CDC, 4676 Columbia Parkway, M/S R-5, Cincinnati, Ohio 45226, telephone 513/841-4292.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 9, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99-18293 Filed 7-16-99; 8:45 am]

BILLING CODE 4160-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2097]

Agency Information Collection

Activities: Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Humanitarian Use Devices, 21 CFR part 814 subpart H.

DATES: Submit written comments on the collection of information by September 17, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-26; Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Humanitarian Use Devices—21 CFR Part 814—Subpart H (OMB No. 0910-0332—Extension)

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814 subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnosis a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnosis the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection herein will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making these determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of Respondents: Businesses or others for-profit.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMANITARIAN DEVICE EXEMPTION SPONSORS¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 814.102 | 20 | 1 | 20 | 40 | 800 |
| 814.104(b) and 814.104(c) | 15 | 1 | 15 | 320 | 4,800 |
| 814.106 | 15 | 4 | 60 | 50 | 3,000 |
| 814.108 | 12 | 1 | 12 | 80 | 960 |
| 814.116(d)(3) | 1 | 1 | 1 | 1 | 1 |
| 814.124(a) | 5 | 1 | 5 | 1 | 5 |
| 814.124(b) | 1 | 1 | 1 | 2 | 2 |
| 814.126(b)(1) | 15 | 1 | 15 | 120 | 1,800 |