DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreement for Prevention Research Centers, Program Announcement #98028 meeting.

Times and Dates: 8:30–8:50 a.m., August 4, 1998 (Open). 9 a.m.–4:30 p.m., August 4, 1998 (Closed). 9 a.m.–4:40 p.m., August 5, 1998 (Closed).

Place: National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, Building 12, Room 1307 (Library), Atlanta, Georgia 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #98028.

Contact Person for More Information: John R. Lehnnherr, Chief, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 11 Corporate Square Boulevard, m/s E07, Atlanta, Georgia 30329, telephone 404/639–8025.

Dated: July 10, 1998.

Nancy C. Hirsch,

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

[FR Doc. 98–18937 Filed 7–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Workshop on Toxoplasmosis; Meeting

The National Center for Infectious Diseases (NCID), Division of Parasitic Diseases (DPD) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: National Workshop on Toxoplasmosis: Preventing Congenital Toxoplasmosis.

Times and Dates: 8:30 a.m.–6 p.m., September 9, 1998.; 8:30 a.m.–3 p.m., September 10, 1998.

Place: CDC, 1600 Clifton Road, Auditorium A, Atlanta, GA 30333.

Status: Open to the public, limited only by the space available.

Purpose: The purpose of this working meeting is to define the key strategies to reduce the burden of congenital toxoplasmosis in the United States.

Matters to be Discussed: Participants will include representatives from public, private, and foreign organizations. They will (1) define approaches to reduce the prevalence of congenital toxoplasmosis, (2) identify data needs to evaluate and/or implement these strategies, and (3) identify critical next steps.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person For More Information: Vance Dietz, Epidemiology Branch, DPD, NCID, CDC, M/S F–22, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 770/488–7771, fax 770/488–7761, e-mail vxd0@cdc.gov.

Dated: July 10, 1998.

Nancy C. Hirsch,

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

[FR Doc. 98–18938 Filed 7–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 63 FR 31785–31786, June 10, 1998) is amended to reflect the establishment of the Office of Global Health within the Office of the Director, Centers for Disease Control and Prevention (CDC), and the abolishment of the International Health Program Office.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title, mission, and functional statement for the *International Health Program Office (CG).*

After the title and functional statement for the *Division of Media Relations (CAA33), Office of Communication (CAA,* insert the following:

Office of Global Health (CAB). Under the direction of the Associate Director for Global Health, the Office of Global Health (OGH) provides leadership, policy guidance, coordination, technical expertise, and services to promote the agency's global health initiatives. In carrying out this mission, OGH: (1) Advises the CDC Director on global health issues relevant to the agency; (2) assesses evolving global health issues and, in cooperation with Ministries of Health and other appropriate institutions, identifies and develops activities to which the application of CDC's technical expertise would be of maximum public health benefit; (3) collaborates with CDC Centers/Institute/Offices (CIO's), other federal agencies, countries, and organizations, as appropriate, to assist CIO's in the development of appropriate policy for global health initiatives for which they have responsibility; (4) coordinates plans for the allocation of global health resources and assists in the development of external funding sources for programs and projects; (5) coordinates cross-cutting CDC global health enterprises; (6) provides leadership in the development and implementation of the CDC Global Health Strategic Plan and guides CDC's efforts to enhance institutional global health capacity; (7) coordinates international collaboration with external partners, including administration, budgets, and technical assistance to assure that agency obligations are met; (8) provides for the enhancement of internal and external global health partnerships; (9) coordinates the recruitment and orientation of CDC assignees to other agencies or countries; (10) stimulates research and program development through the dissemination of information acquired through on-going global health initiatives; (11) provides global health expertise to CIO international projects, as appropriate and requested by CIO's; (12) coordinates bilateral health agreements between CDC and foreign governments; (13) administers the Exchange Visitors Program; (14) in carrying out the above responsibilities, coordinates activities with CDC/CIO's, the Office of Public Health and Science's Office of International and Refugee Health, the Department of Health and Human

Services' Office of International Affairs, other government and nongovernment organizations, and academic institutions, as appropriate.

Office of the Director (CAB1). (1) Manages, directs, and coordinates the activities of the OGH; (2) provides leadership in developing OGH policy, program planning, implementation, and evaluation; (3) coordinates the management of legislated international ceiling exempt positions; (4) coordinates the CDC cable clearance function; (5) provides for the orientation and scheduling of foreign visitors to CDC; (6) provides CDC support services related to international travel, such as the acquisition of passports, visas, and international clearances; (7) maintains international travel database and develops related reports; (8) serves as the CDC focal point for information regarding CDC's overseas assignees.

Dated: July 7, 1998.

Claire V. Broome, M.D.,

Acting Director.

[FR Doc. 98–18935 Filed 7–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0494]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for domestic manufacturers and initial importers of devices to register their establishments and list their devices.

DATES: Submit written comments on the collection of information by September 14, 1998.

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: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301827–1223

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. ''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, 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 Device Registration and Listing—21 CFR 807

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with FDA. This is accomplished by completing FDA Form 2891, ''Initial Registration of Device Establishment'' and FDA Form 2892, ''Medical Device Listing.'' In addition, each year active, registered establishments must notify FDA of changes to the current registration and device listing for the establishment. Annual changes to current registration information are pre-printed on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA's Center for Devices and Radiological Health (CDRH), even if no changes have occurred. Changes to listing information are submitted on Form 2892. Refurbishers/reconditioners are not required to register or list; however, FDA will accept voluntary registration and listings from firms that wish to be registered with FDA.

In addition, under § 807.31 (21 CFR 807.31), each owner or operator is required to maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements above, the owner or operator must be prepared to submit to FDA upon specific request all labeling and advertising mentioned above (§ 807.31(e)).

The information collected through these provisions is used by FDA to identify firms subject to FDA's regulations and is used to identify geographic distribution in order to effectively allocate FDA's field resources for these inspections and to identify the class of the device which determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection will be domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

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