

screenings overall. Of particular interest are adults aged 40–70 years of various races and ethnicities who are at high risk for lung cancer (i.e., long-term heavy smokers).

The proposed project will use focus groups to gather information about the target audiences' experiences and practices related to lung cancer screening and testing. If warranted from focus group data with adult consumers, follow-up personal interviews will be conducted with selected focus group participants, especially those reporting experience with screening tests, such as spiral computed tomography (CT).

A total of 16 focus groups will be conducted at professional focus group facilities with long term heavy smokers aged 40–70. The data will be collected from a convenience sample of adults who will be screened and recruited using lists maintained by the focus group facilities. Each focus group will include approximately nine participants and last two hours. If warranted, one-hour telephone follow-up interviews will be conducted with up to 16 participants within one month of the focus groups.

Four telephone focus groups will be conducted with primary care

physicians. The American Medical Association Physician Masterfile list will be used to recruit a random sample of physicians for participation in the focus groups. Potential participants (physicians) will be mailed a screening packet to complete and return. Each of the four focus groups will include approximately eight participants and last 75 minutes.

There are no costs to respondents except their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Patient Participants Screener	288	1	2/60	10
Patient Focus Group Participants	144	1	2	288
Patient Follow-up Interview In Depth Participants	16	1	1	16
Physician Participants Screener	96	1	5/60	8
Physician Focus Group Participants	32	1	1.15	40
Total	362	362

Dated: August 8, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion

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 for the aforementioned committee:

Time and Date: 11:30 a.m.–4:30 p.m., September 18, 2007.

Place: Grand Hyatt Washington, 1000 H. Street, NW., Burnham Room, Washington, DC 20001, Telephone: (202) 582–1234.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpreter, or have other special needs, please notify the contact person by 4:30 p.m., E.S.T. on September 7, 2007.

Purpose: The Committee advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other federal, state, local and private agencies and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and state and local public health agencies with respect to smoking and health activities.

Matters To Be Discussed: The agenda will focus on “Reducing Children’s Exposure to Second Hand Smoke.”

Agenda items are subject to change as priorities dictate.

Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the Internet at <http://www.cdc.gov/tobacco>.

Contact Person for More Information: Ms. Monica L. Swann, Management and Program Analyst, Office on Smoking and Health, CDC, 4770 Buford Highway, M/S K50, Atlanta, GA 30341, Telephone: (770) 488–5278.

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 CDC

and the Agency for Toxic Substances and Disease Registry.

Diane C. Allen,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 72 FR 38600–38601, dated July 13, 2007) is amended to reflect the reorganization of the Coordinating Office for Global Health, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows: Delete in their entirety the titles and functional statements for the

Coordinating Office for Global Health (CW), and insert the following:

Coordinating Office for Global Health (CW). The mission of the Coordinating Office for Global Health (COGH) is to work with partners in CDC and around the globe through technical assistance and health system development to promote improved health and health diplomacy, and protect citizens of the U.S. and the world.

To carry out its mission, working with and through global programs, COGH: (1) Serves as the principal Centers for Disease Control and Prevention (CDC) organization to develop and foster collaborations, partnerships, program integration, and resource leveraging among public and private organizations and to increase the CDC's global health impact in order to achieve global health goals; (2) coordinates review of current global health status and evolving issues; (3) provides strategic direction for CDC's global health policies and programs; (4) identifies and develops activities to ensure CDC's technical expertise is used to maximize global health impact; (5) stimulates global health research and program development based on assessments of current global health needs and available resources; (6) conducts and stimulates activities to strengthen global health capacity and systems through public health workforce, systems, and process development and improvements; (7) coordinates cross-cutting CDC global health activities and global health emergency response efforts; and (8) manages CDC global field operations through a system of regional and country directors.

Office of the Director (CWA). (1) Manages, directs, and evaluates the activities of COGH; (2) provides leadership in the formulation and implementation of CDC's global health strategies, policies, and goals; (3) advises the Director, CDC, on global health issues; (4) ensures coordination of the CDC response to global health emergencies; (5) leads the development of, and fosters strategic and working partnerships, in support of the global health goals; (6) coordinates CDC's legislative agenda and activities related to global health; (7) provides leadership in determining requirements for CDC's funding and staffing needs for global health programs; (8) manages the distribution of, and provides oversight for, CDC categorical global health program funding; (9) coordinates, in cooperation with the Office of Strategy and Innovation, the development, measurement, and assessment of progress toward CDC's global health goals, efforts to improve global health

equity, fostering of excellence and innovation, and executive decision support; (10) coordinates, in cooperation with Office of the Chief of Public Health Practice and the Office of the Chief Science Officer, CDC's global health practice and science activities; (11) coordinates, in cooperation with the Office of Enterprise Communications, internal and external global health communications, media relations, issues management across CDC global programs, and develops and maintains the COGH intra-, extra-, and internet and web sites; (12) coordinates, in cooperation with the Office of Workforce and Career Development, efforts to ensure a competent and sustainable CDC and global health workforce through workforce and career development for CDC internationally assigned staff, both direct hires and locally employed staff, and assisting partner countries in their workforce and career development efforts; (13) convenes and supports the Global Health Leadership Board; (14) provides business services support for COGH and program services for global health programs; (15) develops and implements supplemental administrative policies and procedures that govern business administration, procurement practices, facilities management, time and attendance reporting, travel, records management, personnel and a wide scope of other business services; (16) plans, coordinates, tracks, and provides management advice and direction of fiscal management for the organization's annual budgets and spend plans; (17) provides consultation on human capital needs and facilitates hiring and training practices as described in the Office of Personnel Management and agency guidelines; (18) coordinates and manages all business services related to management, administration, and training for COGH; (19) working with and through global programs, coordinates issues related to telecommunications, office space and design, physical security, procurement of equipment, furniture, IT services, and facilities management; (20) provides assistance in formulating, developing, negotiating, managing, and administering various COGH contracts; and (21) maintains liaison with the other offices within COGH and other business services offices within CDC.

Global Program Services Office (CWA2). The mission of the Global Program Services Office (GPSO) is to support CDC-wide programs and staff through the efficient, professional and timely delivery of critical global health

mission-support services. To carry out its mission, GPSO performs the following functions: (1) Provides agency-wide support for global travel services; (2) provides agency-wide leadership and support in ensuring consistency for global assignments, systems, and operations; (3) provides a point of contact for overseas staff for deployment support, services, and entitlements; (4) administers the CDC Exchange Visitors Program and is responsible for agency-wide immigration-related activities; (5) provides leadership, expertise and technical assistance to CDC programs regarding extramural and procurement transactional functions; (6) provides a liaison with the Department of State for embassy related issues; (7) provides a liaison with the information technology office, global program offices, and overseas offices to advocate and coordinate global technology and systems; and (8) consults regularly with CDC Programs on strategic and operational issues regarding mission-support services provided by COGH-GPSO through a Governance Council and Customer Feedback Forum.

Global Operations Management Office (CWA23). (1) Advises the COGH Director and Chief Management Official on important issues related to assignments, systems, and operations for international activities impacting programmatic implementation; (2) services as the focal point for CDC services for international assignees; (3) coordinates the operational support services for CDC global programs; (4) coordinates development of policies for overseas services management, locally employed staff, and overseas travel; (5) coordinates and documents international services management policy agency-wide with the Department of Health and Human Services (DHHS) and with the Department of State (DOS), ascertaining the need for, and proposing administrative improvements and legislative requirements to improve operations and avoid management problems; (6) participates as a member of the government-wide working group for the interagency system for management of shared administrative support services (ICASS), overseas building operations and rightsizing liaison, capital security cost-sharing reconciliation, and property management (inventory, government-owned vehicles, furniture, furnishings, appliances, equipment); (7) in carrying out the above responsibilities, coordinates activities with coordinating center/offices/implementing programs,

DHHS, Office of Global Health Affairs, other governmental and non-governmental organizations, and other partners, as appropriate; (8) administers CDC Exchange Visitors Program and is responsible for agency-wide immigration-related activities; (9) coordinates processes for all overseas staff assignments including family support; (10) provided agency-wide passport, visa, and clearance services; (11) services as the CDC office responsible for obtaining DHHS and DOS clearances/approvals for all international TDY travel by CDC employees; (12) provides travel services to CDC employees traveling overseas including order issuance, country and DHHS clearances, as well as voucher preparation in support of the CDC global mission; (13) provides services to CDC employees stationed overseas who commence entitlement travel; (14) provides support and services to overseas assignees who are removed from their post for medical or security reasons; (15) provides reports to CDC programs regarding work volume, process timeliness, travel costs and customer satisfaction results; and (16) provides policy expertise to all employees performing international, entitlement or emergency travel.

Extramural and Procurement Services Office (CWA24). (1) Working with and through global programs, provides support in the development and implementation of Funding Opportunity Announcements and Request for Financial Assistance; (2) as an extension of program, provides leadership in establishing and implementing the Objective Review Panel Process leading to funding determinations; (3) monitors and evaluate the business services components of recipient organizations achievement of goals and objectives; (4) manages the credit card processes for CDC programs with an overseas presence; (5) coordinates and approves individual international credit card transactions for CDC programs with an overseas presence; (6) manages the procurement processes from request to implementation; (7) participates in strategic planning development and implementation of CDC program support goals; and (8) provides routine and continuous feedback to recipients of Extramural and Program Support services and their managers regarding services provided.

Division of Global Preparedness and Program Coordination (CWE). The Division of Global Preparedness and Program Coordination supports CDC global programs for global health preparedness and global health protection and promotion through

leadership and coordination for global health programs. This includes agency-level oversight for CDC's system of international offices, and cross-cutting situational awareness for health status, program status, and partnership issues in all geographic regions of the world. To carry out its mission, the division performs the following functions: (1) Fosters collaborations, partnerships, integration, and resource leveraging to increase CDC's impact and achieve global health goals; (2) manages and supports all CDC global health field operations using CDC Country Director or Country Representative structures where there are multiple CDC programs in a country; (3) provides, in cooperation and coordination with GPSO, support for all CDC global health field operations; (4) coordinates management and oversight of critical global health preparedness and emergency response activities across CDC, including situational awareness and partnership management at the global and regional level; (5) coordinates with and responds to requests from a wide array of internal CDC and external partners and stakeholders; and (6) provides stewardship and leadership support to global health preparedness programs housed in the division.

Office of the Director (CWE1). (1) Provides leadership, oversight and overall direction for the activities of the division; (2) provides leadership and guidance on policy, program planning and evaluation, program management, and operations; (3) plans, allocates, and monitors resources; (4) provides leadership and management oversight in carrying out CDC global field programs; (5) provides liaison with other CDC organizations, other Federal agencies, national ministries of health, international organizations, non-governmental organizations, private sector, and others with whom CDC cooperates in global health programs and activities; (6) in collaboration with the COGH Science Officer, and the Associate Directors of Science from the CDC global programs, promotes high standards in science and ethics among CDC's international activities; and (7) in collaboration with the COGH Strategy and Innovation Officer, translates strategy and innovation concepts and initiatives out to the network of CDC international offices.

Global Disease Detection and Emergency Response Branch (CWEB). The Global Disease Detection and Emergency Response Branch provides leadership and works with partners around the globe to increase preparedness to prevent and control naturally-occurring and man-made

threats to health. Specifically, it: (1) Administers CDC's Global Disease Detection program through coordination with relevant implementing programs; (2) coordinates global aspects of CDC's terrorism preparedness and emergency response activities in collaboration with CDC's Coordinating Office for Terrorism Preparedness and Emergency Response; (3) plans, supports, and coordinates international influenza pandemic preparedness in collaboration with relevant partners in CDC and DHHS; (4) provides leadership and support for the CDC global emergency preparedness and response program designed to prevent, if possible, and to prepare for, detect and respond to biological, chemical, radiological incidents, naturally occurring or man-made, of international interest; (5) works cooperatively with all CDC and U.S. government organizations involved in global emergency preparedness and response as well as with World Health Organization and other international organizations and partner countries; (6) assists in developing country-level epidemiologic, laboratory, and other capacity to ensure country emergency preparedness and response to outbreaks and incidents of local importance and of international interest; and (7) maintains staff in the Director's Emergency Operations Center to serve as a central focus for CDC's global outbreak/incident response activities.

Geographic and Program Coordination Branch (CWE2). (1) Directs and manages human and financial resources in consolidated CDC country offices; (2) provides leadership, support and coordination for the agency-wide responsibilities of CDC country offices; (3) provides core support and coordination to CDC country offices through regional liaison teams, in cooperation with the GPSO; (4) facilitates new opportunities for international activities of the national centers' programs, and provides technical and management support for existing activities; (5) promotes partnerships and coordination in strategic areas with key country, regional, international and U.S. Government institutions; (6) provides leadership on cross-cutting global health issues; and (7) coordinates country-based assessments, planning and performance monitoring and evaluation.

Division of Global Public Health Capacity Development (CWF). The Division of Global Public Health Capacity Development contributes to improving the health of the people of the United States and other nations by partnering with ministries of health, educational institutions, Federal

agencies, and international organizations to strengthen capacity of countries around the world to improve public health. To carry out its mission, the division performs the following functions: (1) Works with partners to build strong, transparent, and sustained public health systems through training, consultation, capacity building, and technical assistance in applied epidemiology, public health surveillance, evaluation, and laboratory systems; and promotes organizational excellence in public health through strengthening leadership and management capacity; (2) assists in developing and implementing COGH policy on public health system strengthening and sustainability; and (3) collaborates with other ODC organizations, Federal agencies, international agencies, partner countries, and non-governmental organizations assisting ministries of health to build public health capacity in other areas of public health.

Office of the Director (CWF1). (1) Provides leadership, overall direction, and evaluation for the division; (2) formulates and implements CDC's strategy for developing global public health capacity in applied epidemiology, public health systems, laboratory operations and management, and leadership; (3) provides leadership and guidance on policy, program planning, program management, and operations; (4) plans, allocates, and monitors resources; (5) provides leadership in assisting national ministries of health, international agencies, and non-governmental organizations in the delivery of epidemiologic services and the development of international epidemiologic networks; (6) provides liaison with other CDC organizations, other Federal agencies, national ministries of health, and international organizations; and (7) provides consultations with partners and stakeholders including nongovernmental organizations and the private sector on program development and overall public health systems and sub-systems.

Sustainable Management Development Program (CWF12). (1) Partners with ministries of health, educational institutions, and non-governmental organizations in developing countries, to promote organizational excellence in public health through strengthening leadership and management capacity; (2) works with partners to build capacity for public health leadership and management development through a multi-phased approach including

situational analysis, capacity development, technical assistance, and sustainability; (3) develops strategic institutional partnerships for public health leadership and management capacity-building efforts; (4) develops faculty to enhance in-country leadership and management training capacity through the Management for International Public Health course and in-country training-of-trainers; (5) provides support to training faculty in partner institutions to conduct performance needs assessments; develops locally appropriate curricula; and designs in-country leadership and management workshops that provide participants with practical skills needed to manage public health teams, programs, and organizations; and (6) works with partner institutions to ensure the long-term sustainability of global public health leadership and management development programs.

Capacity Development Branch (CWF3). (1) With partners, designs and conducts evidence-based instruction in public health disciplines needed to strengthen their public health systems, including instructional design, epidemiology, surveillance, laboratory operations and management, communications, and economic evaluation; (2) working with the technical program components, provides consultation to ministries of health in development of surveillance systems (e.g. Integrated Disease Surveillance, injury, chronic diseases, infectious diseases, etc.); (3) creates and maintains computer-based and distance-based learning methods, and develops the capacity of partners to create, evaluate, and share their own; (4) develops and evaluates competency-based training materials; (5) maintains a divisional training material library and Web site; and (6) collaborates within CDC and with national or international organizations in development of competency-based training materials, evaluation of training, and design of surveillance systems needed to accomplish the mission.

Program Development Branch (CWF4). (1) Assists partners in assessing their needs for health systems strengthening; (2) plans, directs, supports, and coordinates field epidemiology and laboratory training programs, Data for Decision Making Projects, and other partnerships with ministries of health; (3) provides leadership and management oversight in assisting ministries of health in capacity building by training epidemiologists and other health professionals through the development of competency-based, residency-style, applied training

programs; (4) provides leadership and expertise in assisting national ministries of health to utilize trained public health workers for developing health policy, and implementing and evaluating health programs; (5) assigns and manages expert consultants as long-term, in-country advisors to ministry of health programs; and (6) collaborates within CDC, with other Federal agencies, and with national and international organizations in support of partner programs.

Dated: August 3, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 07-3953 Filed 8-13-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D-0077 (formerly 98D-0077)]

Clinical Development Programs for Human Drugs, Biological Products, and Medical Devices for the Treatment and Prevention of Osteoarthritis; Request for Assistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) seeks additional information on issues related to clinical development programs for human drugs, biological products, and medical devices for the treatment and prevention of osteoarthritis (OA). We will take such information into account as we work to finalize our draft guidance issued in July 1999. Once finalized, the guidance will aid sponsors and other interested parties in developing new products to treat OA.

Before the agency can issue such guidance, a critical appraisal of certain fundamentals of the science related to OA is needed. FDA is inviting any interested party, or parties, to conduct and manage the coordination of this critical appraisal. FDA believes that the party, or parties', first step in conducting the critical appraisal would be to hold a public meeting to discuss issues related to OA assessment and trial design. FDA intends to submit to the docket all the information received in response to this notice so that interested parties may be fully informed and to facilitate participation in and coordination of these activities.