DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Partnerships To Advance the National Occupational Research Agenda (NORA)

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting: "Partnerships to Advance the National Occupational Research Agenda (NORA)".

Public Meeting Time and Date: 10 a.m.–3:30 p.m. EST, January 30, 2013.
Place: Patriots Plaza, 395 E Street SW., Conference Room 9000, Washington, DC 20201.

Purpose of the Meeting: The National Occupational Research Agenda (NORA) has been structured to engage partners with each other and/or with NIOSH to advance NORA priorities. The NORA Liaison Committee continues to be an opportunity for representatives from organizations with national scope to learn about NORA progress and to suggest possible partnerships based on their organization’s mission and contacts. This opportunity is now structured as a public meeting via the Internet to attract participation by a larger number of organizations and to further enhance the success of NORA. Some of the types of organizations of national scope that are especially encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome. This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the NORA Sector Councils on their progress, priorities, and implementation plans to date, likely including the NORA Agriculture, Forestry and Fishing; Healthcare; Mining; Oil and Gas Extraction; and Transportation, Warehousing and Utilities Sector Councils. An update will also be given on planning for the evaluation of the second decade of NORA. An additional NIOSH Program that is working on several NORA priorities may also provide an update. After each update, there will be time to discuss partnership opportunities.

Status: The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an email to noracoordinator@cdc.gov containing the participant’s name, organization name, contact telephone number on the day of the meeting, and preference for participation in-person or by Web meeting (requirements include computer, Internet connection, and telephone, preferably with ‘mute’ capability). An email confirming registration will include the details needed to participate in the Web meeting. Non-US citizens who do not register to attend in person on or before January 7, 2013, will not be granted access to the meeting site and will not be able to attend the meeting in-person due to mandatory security clearance procedures at the Patriots Plaza facility.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see http://www.cdc.gov/niosh/nora/about.html.

Since 2006, NORA has been structured according to industrial sectors. Ten major sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, ten NORA Sector Councils defined sector-specific strategic plans for conducting research and moving the results into widespread practice. To view the National Sector Agendas, see http://www.cdc.gov/niosh/nora/.

FOR FURTHER INFORMATION CONTACT: Sidney C. Soderholm, Ph.D., NORA Coordinator, Email

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### ESTIMATED ANNUALIZED BURDEN HOURS

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Ron A. Otten,
Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–27047 Filed 11–5–12; 8:45 am]
Federal employees will not be considered for membership. Members may be invited to serve up to four-year terms. Consideration is given to representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, and current curriculum vitae. Email addresses are requested if available. Nominations should be sent, in writing, and postmarked by November 30, 2012 to: Vernelia Johnson, Management and Program Analyst, Public Health Surveillance and Informatics Program Office, Centers for Disease Control and Prevention, Office of Surveillance, Epidemiology and Laboratory Services, 2500 Century Center Boulevard, Room 3017, Atlanta, Georgia 30345 or via email to hft9@cdc.gov. Telephone and facsimile submissions cannot be accepted.

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 the Agency for Toxic Substances and Disease Registry.

Dated: October 26, 2012.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Agencies Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Cover Sheet; Form FDA 3794

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 6, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and title “Generic Drug User Fee Cover Sheet; Form FDA 3794.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7720, ila.mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3501, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Cover Sheet; Form FDA 3794—(OMB Control Number 0910–New)

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Pub. L. 112–144, Title 111) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required by GDUFA are as follows: A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012, (also known as backlog applications); fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; fees for new ANDAs and prior approval supplements (PASs); and a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by the FDA to initiate the administrative screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and