unit cost of materials, per unit cost of labor, per unit cost of design, test and certification, etc. Data from each manufacturer will be held confidential by the CPA and coded to remove corporate identifiers. The goal is to assess the cost of change to the industry rather than to an individual product within a given manufacturers’ broad product line.

Candidate companies will be evaluated based on their capability and willingness to work cooperatively to achieve the stated goals. Candidates selected will be required to enter into a Letter of Agreement spelling out the level of participation expected of each partner and the handling of data generated from the partnership. This announcement does not obligate NIOSH to enter into an agreement with any respondents. NIOSH reserves the right to establish a partnership based on the engineering analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.

NIOSH recognizes this opportunity will raise many questions for prospective partners. In order to give all involved the greatest opportunity to understand the process and project expectations, the NTEA–AMD, our collaborative partner and host standards setting body, has agreed to provide a meeting room for us to hold an informational meeting to present a broad overview of the effort and answer any resulting questions.

In order to provide us with the best opportunity to meet the needs of all prospective partners at each of these meetings; we request that all interested parties contact Jim Green, NIOSH Project Officer, by e-mail at JGreen@cdc.gov; or telephone (304) 285–5837, by Thursday, March 17, 2011.

CONTACT PERSON FOR MORE INFORMATION:
Jim Green, NIOSH Project Officer, e-mail: JGreen@cdc.gov; telephone (304) 285–5837.

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: March 7, 2011.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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


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 aforementioned meeting:

Time and Date: 11 a.m.–5 p.m., April 21, 2011 (Closed).

Place: Teleconference.

Status: 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 Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to Be Discussed: The meeting will include the initial review, discussion, and evaluation of “Pilot for State-Specific Cross-Sectional Surveillance of Persons with Rare Disorders and Longitudinal Assessment of Outcomes, FOA DD11–004, and Pilot Longitudinal Data Collection to Inform Public Health—Fragile X Syndrome, FOA DD11–007.”

Contact Person for More Information:
Donald Blackman, PhD, Scientific Review Officer, Extramural Research Program Office, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, Georgia 30341. Telephone: (770) 488–6423. E-mail: MED1@CDC.GOV.

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Dated: March 7, 2011.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Family History and Diamond Blackfan Anemia, DD11–010, Initial Review

Correction: This notice was published in the Federal Register on January 21, 2011, Volume 76, Number 14, Page 3909. The date for the aforementioned meeting has been changed to the following:

DATES: April 27, 2011 (Closed).

Contact Person for More Information:
Michael Dalmat, Dr.P.H., Scientific Review Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, Georgia 30341. Telephone: (770) 488–6423. E-mail: MED1@CDC.GOV.

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Dated: March 7, 2011.
Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity to Partner; Testing of Patient Litters and Patient Restraints to Proposed Test Standard

AGENCY: NIOSH, Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

**ACTION:** Notice of informational meeting and opportunity to partner.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH), CDC, HHS, in collaboration with the National Truck Equipment Association, Ambulance Manufacturers Division (NTEA–AMD) has developed a series of proposed ambulance component test standards. One such standard, AMD STANDARD 004—Method for Conducting Litter and Litter Retention System Dynamic Test—Proposed (draft), seeks to improve patient and litter retention during crash conditions. As a part of the standard development process, NIOSH will be conducting a series of tests to evaluate existing, redesigned, and/or new litters to validate the test methods proposed. It is anticipated testing will be conducted in up to three phases over approximately 15 months. NIOSH will contract with an independent test facility and provide funding for all testing, instrumentation, data collection, and data analysis. Prospective industry partners will provide the test assets: Litters and litter retention devices. This project has three key goals: (1) To validate test and data collection methodologies proposed in AMD 004 (draft) to support standard development; (2) to support and facilitate the transition of the industry from the current litter design parameters to those proposed in SAE J2917 Surface Vehicle Recommended Practice, Occupant Restraint and Equipment Mounting Integrity—Frontal Impact System-Level Ambulance Patient Compartment, published May 2010, and SAE J2956 Surface Vehicle Recommended Practice, Occupant Restraint and Equipment Mounting Integrity—Side Impact System-Level Ambulance Patient Compartment (draft); and, (3) to develop the design and production “cost-of-change” to meet the proposed design parameters.

**DATES AND TIMES:** March 23, 2011, 1 p.m.—5 p.m., Eastern Standard Time (EST). March 24, 2011, 8 a.m.—12 noon, EST, by appointment. NIOSH is available to meet with individual companies for those interested in further discussion. We anticipate offering the prospective partners the opportunity to meet for 30 minutes, to ask specific questions pertinent to their situation.

**ADDRESSES:** Homewood Suites Indianapolis-Downtown, 211 South Meridian Street, Indianapolis, Indiana 46225, Telephone (317) 636–7992. (Coincident with the 2011 Fire Department Instructors Conference (FDIC)).

**Letters of Interest:** Interested manufacturers should submit a letter of interest with information about their capabilities and level of proposed participation to Jim Green at JGreen@cdc.gov. Letters of interest must be received by April 25, 2011.

**SUPPLEMENTARY INFORMATION:** NIOSH proposes a series of up to 48 tests to better understand the capabilities and limitations of currently available litters, investigate redesign or new design options, and validate the proposed test standard. As a byproduct of this effort, it is expected that NIOSH and its partners will be able to demonstrate that litters provided by partners meet the design parameters specified in AMD 004 (draft) and test requirements outlined in SAE J2917 and SAE 2956 (draft), respectively.

Prospective partners will be existing litter manufacturers nationally or internationally. A prospective partner need not be selling to the United States market at the time of this announcement.

Prospective partners will be required to provide test assets (litters and mounting systems) free of charge in exchange for their participation in this collaborative standards development and validation effort. In return, NIOSH will cover all costs associated with testing. This includes the cost of the sled buck design and manufacture, rental of appropriate test manikins, instrumentation related to the litter, manikin, and sled buck; test execution, test data analysis, and cost data analysis.

Given the nature of the proposed change, coupled with the cost for each unit, NIOSH anticipates the need to partner with more than one manufacturer. Therefore no one manufacturer should expect to be asked to contribute all needed test assets. In phase 1, test assets are expected to come from those in the existing product line per mutual agreement with NIOSH. In phases 2 and 3, test assets are expected to be introduced as either redesigns of existing products or new products entirely based on the results of phase 1 testing. The cost of product redesign and manufacture for phase 2 and 3 testing would be borne by the manufacturer partner(s).

Each partner will be invited to participate at the site of testing (a third party independent test facility) during the testing of their partners. However, at no time will representatives from two different manufacturers be present at the same time or on the same date. As a participant, each partner will be provided with a copy of all digital video and instrumented data for use in future product development. NIOSH will retain a copy of all data but will code, to the extent possible, to prevent release of vendor specific product data. Partners will retain ownership of each test asset and will be asked to retrieve test assets once each test has been completed. All shipping and/or disposal costs of test assets to and from the independent test facility will be borne by the manufacturer partner(s).

Recognizing any change in standard or test requirement may have a coincident cost; NIOSH will also be seeking to quantify the cost of change—that is, the cost of redesigning and manufacturing to meet the proposed new test standards. In this instance, NIOSH has a separate effort in place with an independent Certified Public Accountant (CPA). Any participant or partner in this effort would be required to work with the CPA in parallel with the test program outlined above. Specifically, the partner would be required to provide the underlying cost data for each product evaluated in the test program. This would include the costs for a current or comparable pre-test or pre-standard litter and its companion post standard or post redesign equivalent. Prospective partners should be aware it may be possible to consider a few products within their existing product line (e.g.; entry level, mid level, and high end products). These costs may include: Per unit cost of materials, per unit cost of labor, per unit cost of design, test and certification, etc. Data from each manufacturer will be held confidential by the CPA and coded to remove corporate identifiers. The goal is to assess the cost of change to the industry rather than to an individual product within a given manufacturers’ broad product line.

Candidate companies will be evaluated based on their capability and willingness to work cooperatively to achieve the stated goals. Candidates selected will be required to enter into a Letter of Agreement spelling out the level of participation expected of each partner and the handling of data generated from the partnership. This announcement does not obligate NIOSH to enter into an agreement with any respondents. NIOSH reserves the right to establish a partnership based on the engineering analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.
NIOH recognizes this opportunity will raise many questions for prospective partners. In order to give all involved the greatest opportunity to understand the process and project expectations, the NTEA-AMD, our collaborative partner and host standards setting body, has agreed to provide a meeting room for us to hold an informational meeting to present a broad overview of the effort and answer any resulting questions.

To provide us with the best opportunity to meet the needs of all prospective partners at each of these meetings, we request that all interested parties contact Jim Green, NIOSH Project Officer, by email at JGreen@cdc.gov; or telephone (304) 285–5857, by Thursday, March 17, 2011.

CONTACT PERSON FOR MORE INFORMATION: Jim Green, NIOSH Project Officer, e-mail: JGreen@cdc.gov; telephone (304) 285–5857.

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Dated: March 7, 2011.
Tanja Popovic,
Deputy Associate Director for Science, Centers for Disease Control and Prevention.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 28, 2010 (75 FR 81616), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0375. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: March 8, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0116]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

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, 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 these topics: (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 Labeling Regulations—(OMB Control Number 0910–0485)—(Extension)

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the labeling of a medical device so that it is not misbranded and subject to a