Organizations, State, Local or Tribal Government.

Respondents: 2,000.

Annual responses: 2,000.

Frequency of Response: Once per request.

Average minutes per response: 15.

Burden hours: 500.

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 Office of Management and Budget Control Number.

Dated: June 12, 2014.

Amy Borgstrom,

Associate Director of Policy.

[FR Doc. 2014–14225 Filed 6–17–14; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense is publishing this notice to announce that it is renewing the charter for the Missouri River (North Dakota) Task Force (''the Task Force'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: This committee's charter is being renewed under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b) (''the Sunshine Act''), and 41 CFR 102–3.50(d).

The Task Force is a nondiscretionary Federal advisory committee that shall provide independent advice and recommendations to the Secretary of the Army on plans and projects to reduce siltation of the Missouri River in the State of North Dakota and to meet the objectives of the Pick-Sloan Program. Specifically, the Task Force shall:

a. Prepare and approve, by a majority of the members, a plan for the use of the funds made available under the Missouri River Act, to promote conservation practices in the Missouri River watershed, control and remove the sediment from the Missouri River, protect recreation on the Missouri River from sedimentation, protect Indian and non-Indian historical and cultural sites along the Missouri River from erosion, and control erosion along the Missouri River;

b. Develop and recommend to the Secretary of the Army for implementation critical restoration projects meeting the goals of the plan; and

c. Determine if these projects primarily benefit the Federal Government.

The Task Force may, on an annual basis, revise the plan and shall provide the public with the opportunity to review and comment on any proposed revision.

The Task Force shall report to the Secretary of the Army and the U.S. Army Corps of Engineers.

The Secretary of the Army may act upon the Task Force's advice and recommendations.

The Department of Defense (DoD), through the Secretary of the Army, the Assistant Secretary of the Army for Civil Works, and the U.S. Army Corps of Engineers, shall provide support, as deemed necessary, for the performance of the Task Force's functions, and shall ensure compliance with the requirements of the FACA, the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended) (''the Sunshine Act''), governing Federal statutes and regulations, and established DoD policies and procedures.

Pursuant to Section 704 and 705 of the Missouri River Protection and Improvement Act of 2000 (''the Missouri River Act'') (Title VII of Pub. L. 106–541, the Water Resources Development Act of 2000), the Task Force shall be composed of not more than 20 members. Specifically, the Task Force membership shall be composed of:

a. The Secretary of the Army or designee, who shall serve as the Chair;

b. The Secretary of Agriculture or designee;

c. The Secretary of Energy or designee;

d. The Secretary of the Interior or designee; and

e. The Trust, which is composed of 16 members to be appointed by the Secretary of the Army, including:

i. Twelve members recommended by the Governor of North Dakota that represent, equally, the various interests of the public and include representatives of:

a. the North Dakota Department of Health,

b. the North Dakota Department of Parks and Recreation,

c. the North Dakota Department of Game and Fish,

d. the North Dakota State Water Commission,

e. the North Dakota Indian Affairs Commission,

f. agricultural groups,

g. environmental or conservation organizations,

h. the hydroelectric power industry,

i. recreations user groups,

j. local governments,

k. and other appropriate interests.

ii. Four members representing each of the four Indian tribes in the State of North Dakota. The members of the Trust shall be appointed by the Secretary of the Army as representative members to the Task Force, pursuant to 41 CFR 102–3.130(a). Those individuals who are full-time or permanent part-time Federal employees shall be appointed regular government employee (RGE) members, pursuant to 41 CFR 102–3.130(a).

All representative members of the Trust shall be appointed for a two-year term of service; and no member, unless authorized by the Secretary of Defense upon request of the Secretary of the Army, may serve more than two consecutive terms of service. In addition, all Task Force members shall, with the exception of reimbursement of official Task Force-related travel and per diem, serve without compensation.

The Department, when necessary and consistent with the Task Force's mission and DoD policies and procedures, may establish subcommittees, task forces, or working groups to support the Task Force. Establishment of subcommittees will be based upon a written determination, to include terms of reference, by the Secretary of Defense, the Deputy Secretary of Defense, or the Secretary of the Army, as the Task Force's Sponsor.

Such subcommittees shall not work independently of the chartered Task Force and shall report all of their recommendations and advice solely to the Task Force for full and open deliberation and discussion. Subcommittees, task forces, or working groups have no authority to make decisions and recommendations, verbally or in writing, on behalf of the Task Force. No subcommittee or any of its members can update or report, verbally or in writing, on behalf of the Task Force, directly to the DoD or any Federal officers or employees.

The Secretary of Defense or the Deputy Secretary of Defense may approve the appointment of subcommittee members for a two-year term of service with annual renewals; however, no member, unless authorized by the Secretary of Defense, may serve more than two consecutive terms of service. These individuals may come from the Task Force or may be new nominees, as recommended by the

Secretary of the Army and based upon the subject matters under consideration.

Subcommittee members, if not full-time or permanent part-time Federal employees, shall be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Those individuals who are full-time or permanent part-time Federal employees will be appointed, pursuant to 41 CFR 102–3.130(a), to serve as RGE members.

With the exception of reimbursement for official Task Force-related travel and per diem, subcommittee members shall serve without compensation.

All subcommittees operate under the provisions of FACA, the Sunshine Act, governing Federal statutes and regulations, and established DoD policies and procedures.

The Designated Federal Officer (DFO), pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures.

In addition, the DFO is required to be in attendance at all meetings of the Task Force and any subcommittees, for the entire duration of each and every meeting; however, in the absence of the DFO, a properly approved Alternate DFO, duly appointed to the Task Force according to established DoD policies and procedures, shall attend the entire duration of all meetings of the Task Force or its subcommittees.

The DFO or the Alternate DFO, shall call all meetings of the Task Force and its subcommittees; prepare and approve all meeting agendas; and adjourn any meeting when the DFO, or the Alternate DFO, determines adjournment to be in the public interest or required by governing regulations or DoD policies and procedures.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Missouri River (North Dakota) Task Force membership about the Task Force's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of Missouri River (North Dakota) Task Force.

All written statements shall be submitted to the DFO for the Missouri River (North Dakota) Task Force, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Missouri River (North Dakota) Task Force DFO can be obtained from the GSA's FACA Database—*http://www.facadatabase.gov/.* The DFO, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Missouri River (North Dakota) Task Force. The DFO, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: June 12, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–14165 Filed 6–17–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Agency Evaluation of Non-United States Food and Drug Administration; Approved Laboratory Developed Tests Demonstration Project

AGENCY: Department of Defense.

ACTION: Notice of Demonstration.

SUMMARY: This notice is to advise interested parties of a Military Health System (MHS) demonstration project under the authority of Title 10, United States Code, Section 1092, entitled Defense Health Agency (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project. The demonstration project is intended to further evaluate whether it is feasible for the Department of Defense (DoD) to review LDTs not yet examined by the FDA to determine if they meet TRICARE's requirements for safety and effectiveness according to the hierarchy of reliable evidence (32 CFR 199.4(g)(15)(i)(C) and 32 CFR 199.2(b)), or TRICARE's rare disease policy (32 CFR 199.4(g)(15)(ii)) in the case of LDTs used in the diagnosis or medical management of a rare disease (32 CFR 199.2(b)), and allow those that do to be covered as a benefit under the TRICARE Program. The demonstration project will evaluate feasible alternatives to support modifications to 32 CFR 199.4(g)(15)(i)(A) to allow coverage for non-FDA approved LDTs that otherwise meet the TRICARE requirements for safety and effectiveness. The Department currently has an ongoing demonstration project to test this same provision for LDTs with a Center for Medicare and Medicaid Services (CMS) national or local coverage determination that were submitted by laboratories for consideration for coverage under TRICARE. However, this new demonstration is being conducted in order to be able to evaluate the feasibility of establishing a cost-effective and efficient way to review an expanded pool of non-FDA approved LDTs prioritized based on their potential high utilization and clinical utility within the TRICARE population. This new demonstration project will also extend coverage for prenatal and preconception cystic fibrosis carrier screening, when provided in accordance with the American College of Obstetricians and Gynecologists guidelines in order to allow DoD to establish whether there is a benefit to offering such testing to TRICARE beneficiaries.

DATES: This demonstration will be effective July 18, 2014. This demonstration will remain in effect for three years.

ADDRESSES: Defense Health Agency, Attn: Clinical Support Division, 7700 Arlington Blvd., Falls Church, VA 22040.

FOR FURTHER INFORMATION CONTACT: Jim Black, Clinical Support Division, Defense Health Agency, Telephone (703) 681–0068.

SUPPLEMENTARY INFORMATION:

A. Background

1. LDTs

According to 32 CFR 199.4(g)(15)(i)(A), TRICARE may not cost-share medical devices including LDTs if the tests are non-FDA cleared or approved; that is, they have not received FDA medical device 510(k) clearance or premarket approval. For purposes of this demonstration, LDTs that are not FDA cleared or approved will hereinafter be referred to as non-FDA approved for brevity purposes. Under the current regulation cited above, LDTs that have been identified as non-FDA approved are summarily denied.

An LDT is an in vitro diagnostic (IVD) that is designed, manufactured, and used within a single laboratory. In the past, these tests were relatively simple tests used within a single laboratory, usually at a local large hospital or academic medical center, to diagnose rare diseases or for other uses to meet the needs of a local patient population. The FDA has exercised enforcement discretion in that the agency has generally not enforced applicable provisions under the Federal Food, Drug, and Cosmetic Act (FFDCA) and its regulations with respect to LDTs.

The 1976 Medical Device Amendments modified the FFDCA to provide for a comprehensive system for the regulation of medical devices. The term ''device'' is defined broadly in 21 U.S.C. 321(h) to include: ''an