treatment in accordance with these standards as a basis for CSAT certification. These standards address patient admission requirements, medical and counseling services, drug testing, and other requirements. The final rule also established an accreditation requirement. Each OTP is required to obtain and maintain accreditation from an accreditation organization approved by SAMHSA under 42 CFR part 8. Accreditation organizations that provide OTP accreditation under the final rule are required to apply for and obtain SAMHSA approval. Under 42 CFR 8.3(a)(3), each accreditation organization must develop a set of accreditation elements or standards together with a detailed discussion of how these elements will assure that each OTP surveyed by the accreditation organization is meeting each of the Federal opioid treatment standards. The Federal Guidelines for Opioid Treatment are intended to guide accreditation organizations in preparing their accreditation standards. In addition, the Guidelines provide useful elaborations on the regulatory standards set forth under 42 CFR part 8.

As such, the updated guidelines will assist both accreditation organizations and OTPs in complying with regulatory requirements. Prepared initially in 1997, the Federal Opioid Treatment Guidelines, originally titled Guidelines for the Accreditation of Opioid Treatment Programs, are being updated to reflect new information and research in the field of opioid assisted treatment. CSAT convened an expert panel to provide the draft guideline now being circulated for comment. CSAT is soliciting comments on the guideline from the public, and expects comments from OTPs, accreditation organizations, patients, the medical community and other interested parties. All comments submitted no later than 60 calendar days from the date of publication in the Federal Register will be considered.

Summer King, Statistician.

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DEPARTMENT OF HOMELAND SECURITY

[DOcket No. DHS–2013–0036]

Cooperative Research and Development Agreement (CRADA) Opportunity With the Department of Homeland Security for the Development of a Foot-and-Mouth Disease 3ABC ELISA Diagnostic Kit

AGENCY: Science and Technology Directorate, Plum Island Animal Disease Center, Department of Homeland Security.

ACTION: Notice of intent.

SUMMARY: The Department of Homeland Security Science and Technology Directorate (DHS S&T), through its Plum Island Animal Disease Center (PIADC), is seeking industry collaborators to aid DHS S&T in developing an ELISA diagnostic test that is capable of obtaining a U.S. regulatory license to detect antibodies to at least one of the Foot and Mouth Disease virus (FMDV) non-structural proteins (NSP): 3A, 3B, or 3C. This new FMDV 3ABC ELISA may be used in the event of a real or suspected outbreak of Foot-and-Mouth Disease (FMD) in order to differentiate infected from vaccinated, non-infected animals (DIVA).

The role of the industry collaborator(s) in this CRADA will be to develop and validate the FMDV 3ABC ELISA assay in collaboration with DHS S&T and the United States Department of Agriculture Animal and Plant Health Inspection Service Foreign Animal Disease Diagnostic Laboratory (USDA APHIS FADDL) at PIADC, and with other U.S. laboratories that are associated with USDA, such as the National Animal Health Laboratory Network (NAHLN). Components of a prototype assay, developed by USDA, Texas Veterinary Medical Diagnostic Laboratory, and a 3rd party fee-for-service contractor, will be made available to the industry collaborator(s).

The goal of the CRADA is to submit a data package to USDA APHIS Center for Veterinary Biologics (CVB) in order to obtain a U.S. regulatory license for use under the direction of USDA administrators of the FMDV 3ABC ELISA in the U.S. (See CVB Veterinary Services Memorandum No. 800.73 for “General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen.”) The assay must also successfully identify and test a reference panel of sera provided by OIE (World Organization for Animal Health) as tested in a U.S. Reference Laboratory, e.g., USDA APHIS FADDL.

DHS S&T is seeking CRADA collaborators that own or have access to the technological components for, have the technological expertise in, and have proven track records of success in the fields of diagnostic test kit research, development, and the obtaining of USDA licensure for the detection of antibodies to viral antigen(s). CRADA collaborators must indicate if they are currently or may be funded by the Federal government, and, if yes, they must include a discussion of how proposed CRADA work and Federal government-funded work would not be duplicative.

The proposed term of the CRADA can be up to thirty (30) months.

DATES: Submit comments on or before June 17, 2013.

ADDRESSES: Mail comments and requests to participate to Dr. Angela Ervin, (ATTN: Angela Ervin, 245 Murray Lane SW., Washington, DC 20528–0075). Submit electronic comments and other data to Angela.Ervin@hq.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Information on DHS CRADAs: Marlene Owens, (202) 254–6671.

SUPPLEMENTARY INFORMATION:

Assay Requirements

1. Ideally a competitive ELISA (an assay in which a molecule in the test sample competes against a reagent provided in the kit for binding to the target) for FMDV NSPs that will differentiate FMDV infected from FMDV vaccinated animals (DIVA) (specifically cattle) and can be made commercially by the CRADA partner or by another entity and upon request by USDA APHIS, be supplied to USDA APHIS FADDL and accredited state laboratories within the National Animal Health Laboratory Network.

2. The ideal assay will have the following characteristics:
   a. Diagnostic sensitivity of at least 96% for all seven major serotypes of FMDV, including detection of cattle antibodies to FMDV within 7 to 10 days post-infection.
   b. Diagnostic specificity of at least 96%, ideally >99% with respect to viruses that cause FMDV look-alike clinical signs, such as Vesicular Stomatitis Virus, Swine Vesicular Disease Virus, Bovine Rhinovirus, Seneca Valley Virus.
   c. Compatibility with serum samples from U.S. national cattle (beef and dairy) and domestic swine herds, and ideally with other species that are susceptible to FMDV, e.g., sheep, goats, feral swine, buffalo, deer, antelope, etc.
The submission must adhere to the requirements in USDA APHIS CVB Veterinary Services Memo No. 800.73 and other applicable CVB 9CFR requirements for diagnostic kits and reagents. The assay must also successfully identify samples in a reference panel of sera provided by OIE (World Organisation for Animal Health) as tested in a U.S. reference laboratory, e.g., USDA APHIS FADDL. Because these reference panels are provided on a yearly basis to FMD world reference laboratories, the testing and analysis of results may extend beyond the 30 month Period of Performance. Nevertheless, results should be made available within 2 months of the availability of reference panels.

Selection Criteria
The Plum Island Animal Disease Center (PIADC) reserves the right to select CRADA collaborators for all, some, or none of the proposals in response to this notice. PIADC will provide no funding for reimbursement of proposal development costs. Proposals (or any other material) submitted in response to this notice will not be returned. Proposals submitted are expected to be declassified.

PIADC will select proposals at its sole discretion on the basis of:
1. How well the proposal communicates the collaborators’ understanding of and ability to meet the CRADAs goals and proposed timeline.
2. How well the proposal addresses the following criteria:
   a. Capability of the collaborator to provide equipment and materials for proposed testing.
   b. Capability of the collaborator to meet the requirements for development, validation testing and analysis, and submission of supporting data and documents fulfilling the CVB requirements for licensure in the U.S.
   c. Preliminary data or results which support the assay requirements outlined above.

Participation in this CRADA does not imply the future purchase of any materials, equipment, or services from the collaborating entities, and non-Federal CRADA participants will not be excluded from any future PIADC procurements based solely on their participation in this CRADA.

Authority: CRADAs are authorized by the Federal Technology Transfer Act of 1980 as amended and codified by 15 U.S.C. 3710a. DHS, as an executive agency under 5 U.S.C. 105, is a Federal agency for the purposes of 15 U.S.C. 3710a and may enter into a CRADA. DHS delegated the authority to conduct CRADAs to the Science and Technology Directorate and its laboratories.