[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used to Detect and Measure Botulinum Neurotoxin

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used to detect and measure botulinum neurotoxin (BoNT). Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods that are used to detect the presence of BoNT and measure potency of BoNT preparations.

DATES:

Receipt of information: Deadline is July 11, 2018.

ADDRESSES: Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (984) 287-3118.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use. As part of this activity, NICEATM supports efforts to develop, validate, and implement alternative approaches for biologics tests, including those used to detect the presence of BoNT and measure potency of BoNT preparations. Tests to detect and measure BoNT are required by multiple federal agencies for regulatory and other decision contexts. Currently, the standard test for these endpoints is a mouse lethality assay that can use large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to detect the presence of BoNT and measure potency of BoNT preparations. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo test methods currently used by federal agencies for regulatory and other decision contexts. NICEATM also requests available data from in vivo BoNT tests used for similar applications as the proposed alternative, such as distinguishing between BoNT serotypes in biological matrix samples or measuring the potency of therapeutic BoNT preparations.

Respondents to this request for information should include their name, affiliation

(if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is July 11, 2018. Responses to this notice will be posted at: https://ntp.niehs.nih.gov/go/bont. Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods.

Information about NICEATM and ICCVAM can be found at http://ntp.niehs.nih.gov/go/niceatm and http://ntp.niehs.nih.gov/go/iccvam.

Dated: June 6, 2018.

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Brian R. Berridge,

Associate Director,

National Toxicology Program.

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