to a unique genetic variant or variants that may be amenable to RNA-directed treatment.

The draft guidance addresses the nonclinical information that FDA recommends to support an IND for the development of an antisense oligonucleotide from a well-characterized chemical class, for which there is substantial nonclinical information and clinical experience that is publicly available or to which the sponsor has a right of reference. The draft guidance discusses the importance of sponsors providing convincing in vitro and/or in vivo proof of concept data as part of any such IND submission. The draft guidance describes recommended nonclinical safety studies that should be submitted with such IND submissions, the duration and timing of general toxicity studies, first-in-human dose selection, and dose escalation, each within the context stipulated above. Finally, the draft guidance describes certain factors, present in the context of an IND for an individualized investigational antisense oligonucleotide developed to treat a rapidly progressing SDLT disease, that support differences in the nonclinical safety package recommended in this context from that generally recommended for non-SDLT diseases, for modalities other than antisense oligonucleotides, and for use in larger patient populations.

The draft guidance is intended to help sponsors of such development programs, who may be relatively unfamiliar with FDA regulations, processes, and practices, seek feedback from FDA on their development programs and make regulatory submissions related to these development programs. The draft guidance is expected to facilitate the preparation of adequate pre-IND and IND submissions for review by the Agency that will enable prompt initiation of the clinical trial.

This draft guidance represents the second in a series of guidances FDA intends to publish to advise and help sponsors developing individualized ASO drug products for individuals who have SDLT diseases or conditions and no approved products available to them to treat their disease.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA.

- The following collections of information in 21 CFR part 312 (IND regulations) have been approved under OMB control number 0910–0014: (1) Submissions of IND applications, amendments, safety reports, and investigator brochures and (2) requests for pre-IND meetings.
- The collections of information in 21 CFR parts 50 and 56 for obtaining informed consent for prospective patients have been approved under OMB control number 0910–0130.
- The collections of information for paper submissions of Form FDA 3500A (Mandatory Reporting) have been approved under OMB control number 0910–0291.
- The collections of information in the final guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants'' have been approved under OMB control number 0910–0429.
- The collections of information relating to electronic submissions of Form FDA 3500 used for voluntary reporting (not mandated by law or regulation) by healthcare professionals, including safety reporting submissions relating to bioavailability and bioequivalence studies under 21 CFR 320.31(d)(3), have been approved under OMB control number 0910–0645.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08675 Filed 4–26–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Developing the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The development of a national strategy on vector-borne diseases including tickborne diseases was mandated by Congress. To inform development of the national strategy to address vector-borne diseases, HHS is issuing this Request for Information (RFI). The RFI solicits specific input regarding strategic goals, benchmarks, gaps, duplicative federally funded programs, and opportunities to enhance coordination data collection, research, and the development of diagnostics, treatments, vaccines and other related activities across HHS and other federal departments. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be considered, public comments must be received electronically no later than midnight eastern standard time (EST) on June 11, 2021.

ADDRESSES: Public comments should be submitted online at *http://www.regulations.gov.* All submissions must be submitted to the Docket named HHS–OASH–2021–0001 to ''Request for Information (RFI) from Non-Federal Stakeholders: Developing the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans.'' Comments submitted electronically, including attachments, will be posted to the docket unchanged and available to view by the public. Evidence and information supporting your comment can be submitted as attachments. Please provide your contact information or organization name on the web-based form for possible follow up from HHS. There is a 5,000 character limit on comments and maximum number (10) of attached files and maximum size (10 MB) of each attached file.

FOR FURTHER INFORMATION CONTACT: Dr. Kristen Honey, Chief Data Scientist, Senior Advisor, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, *vectorbornedisease@hhs.gov,* (202) 853–7680.

SUPPLEMENTARY INFORMATION: The development of a national strategy on vector-borne diseases including tickborne diseases was mandated by Congress through Section 404 of H.R. 1865, the Further Consolidated Appropriations Act. Section 404 is Section 317u of the Public Service Act and is named the Kay Hagan Tick Act (Act), in honor of Senator Kay Hagan, who died from complications of having tickborne Powassan virus disease. The Act requires HHS to develop a national strategy to address vector-borne diseases including tickborne diseases (National Strategy). Preparation of the National Strategy builds upon an inter-departmental effort to develop A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans, released in September 2020.[1]

Vector-borne diseases, including diseases caused by mosquitoes, ticks, and fleas, pose an increasing threat to our nation's health. From 2004 to 2018, U.S. cases doubled and nine new pathogens—including chikungunya and Zika viruses—were introduced or discovered.[2] [3] Tickborne diseases account for nearly 80% of all U.S. vector-borne disease cases, with approximately 476,000 Americans diagnosed and treated for Lyme disease annually.[2] [4] When not diagnosed and treated early, consequences of Lyme disease can include death due to acute carditis as well as late manifestations that can be difficult to treat and costly.[5]

Local health departments and vector control organizations are the nation's first defense against vector-borne disease outbreaks. Yet some evidence indicates they lack the tools, resources, and training to prevent these outbreaks. For example, an assessment of mosquito control competency at the local-level found that during the 2016–2017 Zika emergency response 84% lacked one or more core vector control competencies.[6] In parallel, widespread and growing insecticide-resistance threatens the ability of standard pest control measures to control these disease vectors. Additional capacity is needed at state and local levels for vector tracking, testing, and control as well as the prevention of vector-borne disease transmission. Currently no effective population-level interventions that address tickborne diseases exist. No human vaccines against any vector-borne diseases endemic to the continental United States are widely available. Additionally, evidence-based community interventions (*e.g.,* acaricide spraying, animal host vaccination) have not been studied sufficiently to support their use as effective measures to prevent vector-borne disease.

Recognizing the numerous public health challenges and stakeholders involved in the prevention of vector-borne diseases, OASH is working closely with a range of federal partners to lead the development of the National Strategy. This five-year strategy will establish goals to address vector-borne diseases including improving surveillance, diagnosis, prevention, treatment, and research. It will also identify strategies and benchmarks to measure and drive progress toward achieving the goals. To develop this plan, OASH seeks input from subject matter experts, non-federal stakeholders, and other members of the public. Examples of these stakeholders may include health care providers, national professional organizations, state and local health departments, community-based and faith-based organizations, manufacturers, researchers, advocates, and persons affected by vector-borne diseases.

This RFI seeks public input on strengthening and improving the nation's response to vector-borne diseases in a number of areas. Responses may address one or more of the areas below:

1. What do you recommend as the top priorities to address vector-borne diseases in the United States during the next five years? Why are these the most important priorities?
2. What goals, objectives, and strategies would you propose for each of your top priority areas?
3. Do you have recommendations on specific research or programmatic efforts to improve surveillance, diagnosis, prevention, and treatment of vector-borne diseases?
4. Any additional topics you wish to provide input on.

The information received will inform the development of the National Strategy to address vector-borne diseases.

Kristen Honey,

Chief Data Scientist, Senior Advisor, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Endnotes

[1] *A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans,* Centers for Disease Control and Prevention, 28 Sept. 2020, *www.cdc.gov/ncezid/dvbd/pdf/Brochure_National_Framework_VBDs-P.pdf.*

[2] Centers for Disease Control and Prevention. 2019. National notifiable diseases surveillance system, 2018 annual tables of infectious disease data. Centers for Disease Control and Prevention. *https://www.cdc.gov/nndss/infectious-tables.html.*

[3] Rosenberg, R., N.P. Lindsey, M. Fischer, C.J. Gregory, A.F. Hinckley, P.S. Mead, G. Paz-Bailey, S.H. Waterman, N.A. Drexler, G.J. Kersh, et al. 2018. Vital signs: Trends in reported vectorborne disease cases—United States and territories, 2004–2016. MMWR. Morb. Mortal. Wkly. Rep. 67: 496–501. *https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm.*

[4] Centers for Disease Control and Prevention. 2018. Lyme Disease. *https://www.cdc.gov/lyme/stats/humancases.html.*

[5] Marx et al. Ann Intern Med. 2020;172(3):222–224. DOI: 10.7326/L19–0483.

[5] National Association of County and City Health Officials. 2017. NACCHO report: Vector control assessment in Zika virus priority jurisdictions. Washington, DC: National Association of County and City Health Officials; *http://nacchopreparedness.org/naccho-report-vector-control-assessment-in-zika-virus-priority-jurisdictions.*

[FR Doc. 2021–08167 Filed 4–26–21; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Career Development for Clinicians/Health Professionals AGCD–3 Clinical and Patient-oriented career awards.

Date: June 1–2, 2021.

Time: 10:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 496–9374, *grimaldim2@mail.nih.gov.*