Dated: April 22, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0320]

Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases; Draft Guidance for Sponsor-Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' FDA is publishing this draft guidance to help sponsor-investigators (hereafter referred to as sponsors) with developing the nonclinical information that FDA recommends to support an investigational new drug application (IND) for certain individualized antisense oligonucleotide (ASO) drug products. ASO drug products that are the focus of this draft guidance are those being developed to treat rapidly progressing, severely debilitating or life-threatening (SDLT) disease attributable to a unique genetic variant or variants that may be amenable to RNA-directed treatment.

DATES: Submit either electronic or written comments on the draft guidance by June 28, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0320 for ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ronald Wange, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3342, Silver Spring, MD 20903, 301–796–1304.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' FDA is publishing this draft guidance, that, when finalized, will help sponsors with developing the nonclinical information that FDA recommends to support an IND for certain individualized ASO drug products. ASO drug products that are the focus of this draft guidance are those being developed to treat a rapidly progressing, SDLT disease attributable

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]

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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.