

Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–RFA–OH–22–003, Occupational Safety and Health Training Project Grants.*

*Date: February 1–2, 2022.*

*Time: 1:00 p.m.–4:00 p.m., EST.*

*Place: Video-Assisted Meeting.*

*Agenda: To review and evaluate grant applications.*

*For Further Information Contact:*

Marilyn Ridenour, B.S.N., M.P.H., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, Telephone: (304) 285–5879; Email: [MRidenour@cdc.gov](mailto:MRidenour@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2021–26575 Filed 12–7–21; 8:45 am]

**BILLING CODE 4163–18–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2021–D–1140]

**Investigational New Drug Application Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations; Draft Guidance for Sponsor-Investigators; Availability**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 sponsor-investigators entitled “IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations.” FDA is publishing this draft guidance to provide sponsor-investigators (hereafter referred to as sponsors) who are interested in developing individualized antisense oligonucleotide (ASO) drug products for a rapidly progressive, severely debilitating, or life-threatening (SDLT) genetic disease (caused by a unique genetic variant or variants), with clinical recommendations for submission of investigational new drug applications (INDs). These recommendations specifically address the following clinical considerations: Ethical and human subject protection, diagnostic and genetic, dosing, administration, safety, and assessment of clinical response to treatment.

**DATES:** Submit either electronic or written comments on the draft guidance by February 7, 2022 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–1140 for “IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations.” 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:** Hobart Rogers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Rm 3114, Silver Spring, MD 20903-0002, 301-796-2213.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for sponsor-investigators entitled "IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations." FDA is publishing this draft guidance to provide sponsor-investigators (hereafter referred to as sponsors) who are interested in developing individualized ASO drug products for a rapidly progressive SDLT genetic disease (caused by a unique genetic variant or variants), with clinical recommendations for submission of INDs. These recommendations specifically address the following clinical considerations: Ethical and human subject protection, diagnostic and genetic, dosing, administration, safety, and assessment of clinical response to treatment.

This draft guidance describes clinical considerations and, when applicable, important information to include in IND submissions for such ASO drug products for a small number of participants (typically one to two) with SDLT diseases. In general, ASO drug products referred to in this draft guidance belong to a well-characterized chemical class and for which there is considerable nonclinical and clinical experience that is publicly available or to which the sponsor has a right of reference. The draft guidance discusses considerations and information to

submit in an IND regarding: (1) Confirmation of the participant's genetic diagnosis and genetic variant(s) targeted by the ASO drug product, (2) the requirements and procedures for informed consent of the participant, (3) appropriate and safe dosing and administration procedures that are detailed and supported by relevant nonclinical evidence, (4) the nature and schedule of the specific safety assessments (adverse events and laboratory testing) to be conducted, and (5) methods for continuous clinical monitoring (e.g., via clinical outcome assessments, pharmacodynamic biomarkers) of the participant to evaluate and document their clinical response(s) and to allow for an informed benefit-risk determination. This draft guidance is expected to facilitate the preparation of adequate and complete IND submissions for investigational ASO drug products for participants with SDLT diseases targeted by the specified ASO drug product.

This draft guidance represents one guidance in a series of guidances that FDA intends to publish to advise and help sponsors planning to use individualized ASO drug products for SDLT diseases caused by unique genetic variant(s) and for whom there are no alternative therapies available 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 "IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Clinical Recommendations." 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**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. 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.

##### **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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 1, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2021-D-1139]

#### **Investigational New Drug Application Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Chemistry, Manufacturing, and Controls Recommendations, Guidance for Sponsor-Investigators; Draft Guidance for Industry; 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 "IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases: Chemistry, Manufacturing, and Controls Recommendations." This draft guidance provides FDA's recommendations on the chemistry, manufacturing, and controls (CMC) information needed to support an investigational new drug application (IND) submitted by a sponsor-investigator developing an individualized antisense oligonucleotide (ASO) drug product for a severely debilitating or life-threatening (SDLT) disease caused by a unique genetic variant affecting a small number of individuals (typically one or two).

**DATES:** Submit either electronic or written comments on the draft guidance by February 7, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.