requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ORR UC Bureau is proposing two new forms: *Psychotropic Medication Informed Consent* (Form MMH–1) and *Psychotropic Medication Assent Notice* (Form MMH–2). The proposed information collection is necessary to allow the ORR UC Bureau to comply with a court order and improve processes for the administration of psychotropic medication. On June 29, 2018, Plaintiffs filed their Federal class action lawsuit in the Central District of California, western division, captioned *Lucas R. et al.* v. *Becerra et al.* (Case No. 2:18–CV–05741 DMG PLA), asserting claims under the Flores consent decree, the Trafficking Victims Protection Reauthorization Act, the Due Process clause, and the First Amendment. Plaintiffs allege violation of unaccompanied children rights in decisions regarding family reunification, placement in restrictive facilities, services for children with disabilities, administration of psychotropic medication, and access to legal assistance. On May 3, 2024, the Court granted final approval for the settlement agreements of the Plaintiffs' claims for disabilities, psychotropic medication, and legal assistance. As part of the settlement agreement for the psychotropic medication claim, ORR is required, whenever possible, to obtain informed consent for the administration of psychotropic medication and provide certain information to the authorized consenter. Additionally, ORR is required to provide a written notice and obtain informed assent or agreement from children aged 14 or older before administering psychotropic medication. The psychotropic medication settlement agreement must be fully implemented by August 3, 2026, but data collection must be implemented by February 3, 2025, to ensure compliance with the Agreement.

Respondents: Care provider grantees and contractors.

ANNUAL BURDEN ESTIMATES

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Psychotropic Medication Informed Consent (Form MMH–1)	300	2	1.50	900
Psychotropic Medication Assent Notice (Form MMH–2)	300	1	0.75	225

Estimated Total Annual Burden Hours: 1,125.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR part 410; *Flores* v. *Reno* Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996); *Lucas R. et al.* v. *Becerra et al.* (Case No. 2:18–CV–05741 DMG PLA) Psychotropic Medication Settlement Agreement.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–26690 Filed 11–14–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4624]

Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics; 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 ''Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics.'' FDA is publishing this draft guidance which, when finalized, will provide recommendations on approaches for the nonclinical safety evaluation of oligonucleotide-based therapeutics (ONTs) to support clinical development and marketing of these products. ONTs present unique challenges and opportunities in the nonclinical evaluation of safety that differ in many regards from those appropriate for small molecule drugs or therapeutic proteins.

DATES: Submit either electronic or written comments on the draft guidance by January 14, 2025 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–2024–D–4624 for ''Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics.'' 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 Safety Assessment of Oligonucleotide-Based Therapeutics.'' ONTs represent a rapidly evolving therapeutic modality, which is seeing application to a broad range of indications, including rare diseases, and have the potential to act on therapeutic targets that are not amenable to the action of small molecule drugs or therapeutic proteins. To further support the development of ONTs, FDA is publishing this draft guidance which, when finalized, will assist sponsors in optimizing the design of their nonclinical development package for ONTs.

The scope of the draft guidance includes single-stranded or double-stranded ONTs created synthetically or derived naturally, with native or modified backbone or nucleoside structures that increase or decrease expression and/or function of proteins. Examples of included oligonucleotides are antisense, small interfering RNA, microRNA, transfer RNAs, decoys, and aptamers. Immune stimulatory oligonucleotides (*e.g.,* CpG motifs acting via Toll-like receptors) are excluded, as are Center for Biologics Evaluation and Research-regulated ONTs (*e.g.,* DNA/RNA vaccines, messenger RNA, virally delivered ONTs, and RNA used for gene editing).

ONTs present unique opportunities and challenges in the nonclinical evaluation of safety that differ in many regards from that appropriate for small molecule drugs or therapeutic proteins. This draft guidance provides specific recommendations on approaches for the nonclinical safety evaluation of ONTs to support clinical development and marketing of these products. The draft guidance, when finalized, will provide recommendations on the nonclinical evaluation of oligonucleotides in multiple areas, including genotoxicity, safety pharmacology, general toxicity, carcinogenicity, and reproductive and developmental toxicity. These recommendations have been developed based on industry best practices and Agency experience to date with this category of drug products.

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 Safety Assessment of Oligonucleotide-Based Therapeutics.'' 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 collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 pertaining to protection of human subjects have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR 201.56 and 201.57 pertaining to content and format of labeling for human prescription drug and biological products have been approved under OMB control numbers 0910–0572. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 relating to the content and format of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the content and format of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the content and format of biologics license applications are approved under OMB control number 0910–0338. The collections of information for MEDWATCH Adverse Event and Product Experience Reporting system have been approved under OMB control number 0910–0291.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *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: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26682 Filed 11–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Novel Kinase Inhibitory Aplithianines

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing and/or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing and/or collaboration to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to these licensing or collaboration opportunities should be directed to: Taryn Dick, Ph.D., M.B.A., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *taryn.dick@nih.gov* or Phone: 301–631–3007.

SUPPLEMENTARY INFORMATION: Researchers at the NCI seek licensing and/or co-development research collaborations for a class of novel aplithianine-derived small molecule analogs that compete with ATP for binding on a range of clinically relevant kinases. In 2022, the NCI Molecular Targets Program (MTP) completed a screen of approximately 150,000 pre-fractionated natural products from the NCI Program for Natural Product Discovery (NPNPD). From this screen, a class of active compounds, named Aplithianines A & B (isolated from the marine organism Aplidium sp.), showed broad potential applicability to numerous kinases of importance, including but not limited to:

- Oncogenic gene fusion DNAJB1–PRKACA (PKADJ):
  - Implicated in an ultra-rare adolescent liver cancer.
- Wild type protein kinase A (PKA):
  - Implicated in Cushing's Disease.
- Protein kinase G (PKG):
  - Potential treatment of malaria.
- Ccdc2-like kinases (CLK) 1 and 2:
  - Implicated in gastric cancer.
- DYRK family of kinases:
  - Implicated in gastric or colon cancer as well as infections caused by a protozoa or parasites.

This technology describes the Original Family of compounds filed. Subsequent to this filing, two additional cohorts of related, but patentably distinct cohorts of compounds, have been filed. Both the Second and the Third Cohorts comprise the same chemical scaffold of the broadest generic formula of this Original Family but represent patentably distinct subgenus formulas.

BILLING CODE 4140–01–P