they are willing to speak with Flores counsel.

3. *Authorization for Release of Records (Form A–5):* This instrument is used by attorneys, legal service providers, child advocates, government agencies, and other stakeholders to request UAC case file records. In most cases, requesters are required to obtain the signature of the subject of the record request (UAC or their parent/legal guardian or sponsor) and a witness.

4. *Program Level Event (PLE) Report (Form A–9):* This instrument is used by ORR care provider programs to inform ORR of events that may affect the entire care provider facility, such as an active shooter or natural disaster. An updated PLE Report is required for events that occur over multiple days or if the situation changes regarding the event.

5. *Emergency Significant Incident Report (SIR) and Addendum (Forms A–10A & A–10B):* This instrument is used by ORR care provider programs to inform ORR of urgent situations in which there is an immediate threat to a child's safety and well-being that require instantaneous action. In some cases, an Emergency SIR Addendum may be required to provide additional information obtained after the initial report.

6. *Significant Incident Report (SIR) and Addendum (Forms A–10C & A–10D):* This instrument is used by ORR care provider programs to inform ORR of situations that affect, but do not immediately threaten, the safety and well-being of a child. In some cases, an SIR Addendum may be required to provide additional information obtained after the initial report.

7. *Sexual Abuse Significant Incident Report (SA/SIR) and Addendum (Forms A–10E & A–10F):* This instrument is used by ORR care provider programs to inform ORR of allegations of sexual harassment, sexual abuse, and inappropriate sexual behavior. In some cases, an SA/SIR Addendum may be required to provide additional information obtained after the initial report.

8. *Hotline Alert (A–12):* This instrument is used by ORR's National Call Center to inform ORR of allegations sexual harassment, sexual abuse, inappropriate sexual behavior, and physical abuse that occurred while the UAC was in ORR custody.

ORR no longer plans to implement the UAC Satisfaction Survey (Form A–11 & A–11s) or the UAC Satisfaction Survey Aggregate Data instruments, which were included in the 60-Day **Federal Register** Notice (85 FR 21240) for this information collection. ORR is removing these two instruments from this information collection request.

Respondents: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual burden minutes
Care Provider Facility Tour Request (Form A–1A)	200	1	10	2,000
Notice to UAC for Flores Visits (Forms A–4 & A–4s)	20	1	15	300
Authorization for Release of Records (Form A–5)	4,000	1	10	40,000
Program Level Event (Form A–9)	1,500	1	20	30,000
Emergency Significant Incident Report (Form A–10A)	1,640	1	20	32,800
Emergency Significant Incident Report Addendum (Form A–10B)	1,360	1	15	20,400
Significant Incident Report (Form A–10C)	80,340	1	20	1,606,800
Significant Incident Report Addendum (Form A–10D)	25,630	1	15	384,450
Sexual Abuse Significant Incident Report (Form A–10E)	5,980	1	20	119,600
Sexual Abuse Significant Incident Report Addendum (Form A–10F)	4,190	1	15	62,850
Hotline Alert (Form A–12)	80	1	15	1,200
Estimated Annual Burden Total	.....	.....	.....	2,300,400

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement,* No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–24006 Filed 10–28–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2583]

Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products; 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 final guidance for industry entitled ''Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products.'' The document provides guidance about the nonclinical information FDA recommends to support development and approval of orally inhaled nicotine-containing drug products, including electronic nicotine delivery systems intended for smoking cessation and related chronic indications. This guidance finalizes the draft guidance of the same name issued August 6, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 29, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–2583 for ''Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products.'' 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Alina Salvatore, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20903–0002, 240–402–0379.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products.'' The recommended nonclinical assessment as outlined in the guidance addresses safety of novel chemicals of the drug product formulation, novel chemicals generated from any chemical of the drug product formulation by the delivery system, and novel impurities. As used in the guidance, the phrase novel chemicals of the drug product formulation refers to active and inactive ingredients intentionally added to the drug product that have not been approved in drugs at an equal or greater dose, for an equal or greater duration of use, or by a relevant route of administration sufficient to characterize toxicity via local and systemic exposure. FDA expects that in many cases use of the delivery system will generate novel chemicals (*e.g.,* heat-generated products).

Orally inhaled nicotine-containing drug products developed for smoking cessation and related chronic indications are expected to involve continuous use or chronic intermittent use resulting in 6 months or more exposure over a lifetime. Because of the duration of use, the nonclinical assessment for marketing approval should include general toxicity studies, developmental and reproductive toxicity studies, an assessment of carcinogenic potential, and supporting toxicokinetic and pharmacokinetic studies.

FDA is aware of the serious risk associated with smoking and is committed to facilitating the development of therapies to support smoking-cessation efforts. This guidance focuses on novel chemicals of the drug product formulation, heat-generated products, and impurities that are generally not well characterized. Orally inhaled nicotine-containing tobacco products, including electronic nicotine delivery systems currently marketed in the United States, have already been associated with toxicity concerns. An adequate nonclinical assessment, as described in this guidance, can address the potential toxicity of chemicals from orally inhaled nicotine-containing drug products. As noted in the guidance, sponsors can use an alternative approach if that approach provides adequate safety information.

This guidance finalizes the draft guidance of the same name issued August 6, 2018 (83 FR 38315). Changes from the draft to the final include the following:

- More information to guide the nonclinical development of an active ingredient in addition to nicotine
- Clarification on absorption, distribution, metabolism, and excretion studies, consistent with previous reference to the International Council for Harmonisation guidance for industry entitled ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals'' (January 2010)
- Reference to the draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA [Prescription Drug User Fee Amendments] Products'' (December 2017), which describes the process through which sponsors can request meetings
- Clarification on how sponsors can compare the exposure to nicotine in an approved drug by providing

pharmacokinetic information (*e.g.,* C_{max}, T_{max}, area under the curve) from the proposed drug product

- An example of how systemic toxicity could be addressed by a nonclinical toxicity study conducted with a noninhalation route of exposure
- Clarification that local effects in oral or respiratory tract tissues are best addressed with a nonclinical inhalation study

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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 resulting from special protocol assessments have been approved under OMB control number 0910–0470.

III. Electronic Access

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

Dated: October 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23999 Filed 10–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute Of Allergy And Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel NIAID Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV–2) and Coronavirus Disease 2019 (COVID–19) (R01, R21 Clinical Trial Not Allowed).

Date: November 20, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G62, Bethesda, MD 20892, (240) 669–5069. *lrust@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 23, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–23965 Filed 10–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director, National Institutes of Health Notice of Meeting

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

The meeting will be held as a virtual meeting and will be open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

Name of Committee: Council of Councils.

Open: November 13, 2020.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: Presentation and discussion of the draft NIH-Wide Strategic Plan (2021–2025).

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Council of Councils, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, *GriederF@mail.nih.gov,* 301–435–0744.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 26, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–23996 Filed 10–28–20; 8:45 am]

BILLING CODE 4140–01–P