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Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave.,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 the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''In Vitro Release Test Studies for Topical Products Submitted in ANDAs.'' This draft guidance provides recommendations on IVRT studies for locally acting liquid-based and/or other semisolid topical products. This draft guidance is intended to assist applicants who are submitting ANDAs for such products, by providing recommendations for IVRT studies, which can be used to support a demonstration that two topical products are bioequivalent.

Once validated, an IVRT study may also be useful in controlling product quality and/or establishing acceptability of post-approval manufacturing changes. This draft guidance focuses on general considerations and recommendations for the method development, method validation, and conduct of IVRT studies that are submitted in ANDAs and intended to support a demonstration of bioequivalence.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''In Vitro Release Test Studies for Topical Products Submitted in ANDAs.'' 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 (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 for the submission of ANDAs have been approved under OMB control number 0910–0001. Applicant submission of controlled correspondence related to generic drug development and FDA approval is approved under OMB control number 0910–0797. The collections of information that support ''Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies'' have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 320 for ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' have been approved under OMB control number 0910–0014. The recordkeeping requirement for CGMP sample retention in 21 CFR 211.170 has been approved under OMB control number 0910–0139.

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: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23017 Filed 10–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Proposed Healthy People 2030 Objectives

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary of Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) solicits written comments on an additional objective proposed to be added to Healthy People 2030, and written comments from the public proposing additional new core, developmental, or research objectives to be included in Healthy People 2030. Public comment informed the development of Healthy People 2030. HHS will provide opportunities for public input periodically throughout the decade to ensure Healthy People 2030 reflects current public health priorities and public input. The updated set of Healthy People 2030 objectives will be incorporated on *https://health.gov/healthypeople.* This updated set will reflect further review and deliberation by federal Healthy People topic area workgroups, the Federal Interagency Workgroup on Healthy People 2030, and other federal subject matter experts.

DATES: Written comments will be accepted through 11:59 p.m. ET, December 2, 2022.

ADDRESSES: Written comments should be submitted by email to *HP2030Comment@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Dana Rosenberg, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Email: *HP2030@hhs.gov;* Phone: 240–453–6092.

SUPPLEMENTARY INFORMATION: Since 1980, Healthy People has provided a comprehensive set of national health promotion and disease prevention objectives with 10-year targets aimed at improving the health of all. Healthy People 2030 objectives present a picture of the nation's health at the beginning of the decade, establish national goals and targets to be achieved by the year 2030, and monitor progress over time. The U.S. Department of Health and Human Services (HHS) is soliciting the submission of written comments regarding one core objective proposed to be added to Healthy People 2030. The

public is also invited to submit proposals for additional new core, developmental, or research objectives that meet the criteria outlined below.

Healthy People 2030 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments are a cornerstone of Healthy People 2030. During the development of Healthy People 2030, HHS asked for the public's comments to help shape the initiative's framework (vision, mission, and overarching goals) and its objectives. HHS plans to periodically seek public comment to ensure Healthy People 2030 remains relevant and reflects emerging public health issues.

The public now is invited to comment on one new core objective proposed to be added to Healthy People 2030. This new objective was developed by federal subject matter experts, approved by the Healthy People Federal Interagency Workgroup and is presented for the public's review and comment. The objective is:

1. Social Determinants of Health-NEW–07: Increase the proportion of the voting age citizens who vote. Data Source: Current Population Survey (CPS), U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS).

The public is also invited to propose additional core, developmental, or research objectives for consideration that address critical public health issues. Proposed new objectives must meet all the objective selection criteria (see below).

Objective Selection Criteria

Core Objectives

Core objectives must meet the following 5 criteria to be included in Healthy People 2030. Core objectives should (1) have a reliable, nationally representative data source with baseline data no older than 2015; (2) have at least 2 additional data points beyond the baseline during the decade; (3) be of national importance; (4) have effective, evidence-based interventions available to achieve the objective; and (5) have data to help address disparities and achieve health equity.

Developmental Objectives

Developmental objectives will have the following characteristics: (1) represent high priority issues; (2) do not have reliable baseline data yet; and (3) have evidence-based interventions available.

Research Objectives

Research objectives will have the following characteristics: (1) represent key opportunities to make progress in areas with limited prior research, a high health or economic burden, or significant disparities between population groups; (2) may or may not have reliable baseline data; and (3) do not have evidence-based interventions available.

Written comments and evidence-based information should be submitted by email to *HP2030Comment@hhs.gov* by 11:59 p.m. ET on December 2, 2022. Comments received in response to this notice will be reviewed and considered by the Healthy People topic area workgroups, Federal Interagency Workgroup on Healthy People 2030, and other federal subject matter experts.

Paul Reed,

RDML, U.S. Public Health Service, Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2022–22983 Filed 10–21–22; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

The meetings 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: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: November 18, 2022.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 827–5467, *ganesan.ramesh@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Substance Use, Risks, Mechanisms, and Outcomes.

Date: November 18, 2022.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Izabella Zandberg, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–0359, *izabella.zandberg@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodegenerative Disorders.

Date: November 18, 2022.

Time: 11:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Roger Alan Bannister, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1010–D, Bethesda, MD 20892, (301) 435–1042, *bannisterra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Auditory System, Cognition and Memory.

Date: November 21, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pablo Miguel Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *pablo.blazquezgamez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–22–015: IND-enabling Studies of Somatic Genome Editing Therapeutic Leads.

Date: November 21–22, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christopher Payne, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3702, *christopher.payne@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell and Molecular Biology.

Date: November 21–22, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).