

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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:**

Lauren Milligan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3159, Silver Spring, MD 20903-0002, 301-796-5008, or [OCP@fda.hhs.gov](mailto:OCP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Clinical Drug Interaction Studies With Combined Oral Contraceptives.” COCs can effectively prevent pregnancy; however, the use of concomitant medications could result in DDIs that affect the safety and/or efficacy of COCs. For example, the induction of drug metabolizing enzymes could cause lower levels of progestin and/or estrogen and compromise the efficacy of COCs, while inhibition of metabolizing enzymes could cause higher levels of these hormones and increase the risk of safety events such as venous thromboembolism.

This draft guidance discusses when DDI studies with COCs should be conducted. It also provides recommendations on the design and conduct of such studies, including but not limited to the study population, the choice of COC, study design, pharmacokinetic sampling schedule, and pharmacodynamic assessments. This guidance discusses the interpretation of results from clinical DDI studies with COCs and whether it is possible to extrapolate the results of such studies to other COCs. Based on the study results, specific recommendations for labeling are provided. Decision trees regarding whether a DDI study with a COC is recommended based on the metabolizing enzyme inhibition or induction potential of the investigational drug are also included.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Clinical Drug Interaction Studies With Combined Oral Contraceptives.” 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 submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014; 0910–0001; and 0910–0338, respectively. In addition, the submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572.

**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: November 13, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–25744 Filed 11–20–20; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Request for Information (RFI): Vaccines National Strategic Plan Available for Public Comment**

**AGENCY:** Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft Vaccines National Strategic Plan 2021–2025 (Vaccine Plan) available for public comment. The draft Vaccine Plan may be reviewed at [www.hhs.gov/oidp](http://www.hhs.gov/oidp).

**DATES:** All comments must be received by 5:00 p.m. ET on December 3, 2020 to be considered.

**ADDRESSES:** All comments must be submitted electronically to [NVP.RFI@hhs.gov](mailto:NVP.RFI@hhs.gov) to be considered.

**FOR FURTHER INFORMATION CONTACT:** David Kim, OI DP, [David.Kim@hhs.gov](mailto:David.Kim@hhs.gov), 202–795–7636.

**SUPPLEMENTARY INFORMATION:** The development of a National Vaccine Plan was mandated by Congress as a mechanism for the Director of the National Vaccine Program (as delegated by the Assistant Secretary for Health) to communicate priorities for achieving the Program’s responsibilities of ensuring adequate supply of and access to vaccines and ensuring the effective and optimal use of vaccines. The most recent Plan, released in 2010, provided a comprehensive 10-year national strategy for enhancing all aspects of the plan, including vaccine research and development, supply, financing, distribution, and safety; informed decision-making by consumers and health care providers; vaccine-preventable disease surveillance; vaccine effectiveness and use monitoring; and global cooperation ([http://www.hhs.gov/nvpo/vacc\\_plan/index.html](http://www.hhs.gov/nvpo/vacc_plan/index.html)). The 2010 Plan and the associated implementation plan ([https://www.hhs.gov/sites/default/files/nvpo/vacc\\_plan/2010-2015-Plan/implementationplan.pdf](https://www.hhs.gov/sites/default/files/nvpo/vacc_plan/2010-2015-Plan/implementationplan.pdf)) have played an important role in guiding strategies and allocations of resources with respect to vaccines and vaccination. However, since the publication of the 2010 Plan, there have been many changes in the vaccine landscape.

With U.S. vaccination rates above 90% for many childhood vaccines, most individuals have not witnessed firsthand the devastating illnesses against which vaccines offer protection, such as polio or diphtheria. According to a recent study, routine childhood immunizations among U.S. children born in 2009 will prevent 20 million cases of disease and 42,000 premature deaths, with a net savings of \$13.5 billion in direct costs and \$68.8 billion in total societal costs.<sup>1</sup> In contrast, adult vaccination coverage rates have remained persistently low, with only modest gains for certain populations in the past few years.<sup>2</sup> As a result, the standards for adult immunization practice were updated in 2014 to promote integration of vaccines into routine clinical care for adults.<sup>3</sup>

<sup>1</sup> Zhou F. *et al.* Economic evaluation of the routine childhood immunization program in the United States, 2009. *Pediatrics*. 2014; 133: 1–9.

<sup>2</sup> <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html>.

<sup>3</sup> National Vaccine Advisory Committee. Recommendations from the National Vaccine

Despite the widespread availability of effective vaccines, vaccine-preventable diseases (VPDs) remain a significant public health challenge. In particular, rates of non-medical exemptions for childhood vaccines are increasing,<sup>4</sup> and there have been recent measles outbreaks in the U.S.<sup>5</sup> and globally, due to growing vaccine hesitancy and coverage levels below the threshold needed for herd immunity. With an estimated cost of \$20,000 per case of measles to the public sector in 2016,<sup>6</sup> the economic consequences of this and other VPDs, as well as the health consequences, are significant. Furthermore, few adults in any age group are fully vaccinated as recommended by the Advisory Committee on Immunization Practices.<sup>2</sup> Large disparities in vaccine coverage by race/ethnicity persist, with African Americans, Hispanics, and Asian Americans lagging behind whites in nearly all vaccination coverage rates.<sup>7</sup> VPDs such as pertussis and hepatitis B continue to take a heavy toll on public health,<sup>8</sup> with 18,975 cases of pertussis and 3,409 (22,000 estimated) cases of hepatitis B infections reported in the United States in 2017.<sup>9</sup> <sup>10</sup> In light of these challenges, strengthening the vaccine and immunization enterprise is a priority for HHS.

To respond to the public health challenges of VPDs, OIDP in collaboration with other federal partners is leading the development of the Vaccines National Strategic Plan (Vaccine Plan). This updated plan will recommend vaccine strategies across the lifespan and guide priority actions for the period 2021–2025. While COVID–19 and coronavirus vaccine development are currently changing the landscape of the vaccine enterprise, the Vaccine Plan

Advisory Committee: Standards for adult immunization practice. *Public Health Rep.* 2014;129:115–23.

<sup>4</sup> Omer, S. *et al.* Nonmedical exemptions to school immunization requirements: Secular trends and association of state policies with pertussis incidence. *JAMA.* 2006;296(14):1757–1763.

<sup>5</sup> <https://www.cdc.gov/measles/cases-outbreaks.html>.

<sup>6</sup> Lo NC, Hotez P.J. Public Health and Economic Consequences of Vaccine Hesitancy for Measles in the United States. *JAMA Pediatr.* 2017;171(9):887–892. doi:10.1001/jamapediatrics.2017.1695.

<sup>7</sup> Lu P.J. *et al.* Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S. *Am J. Prev Med.* 2015;49(6 Suppl 4):S412–S425. doi:10.1016/j.amepre.2015.03.005.

<sup>8</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf>.

<sup>9</sup> <https://www.chop.edu/centers-programs/vaccine-education-center/global-immunization/diseases-and-vaccines-world-view>.

<sup>10</sup> Schillie *et al.* Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR.* 2018;67(1):1–31.

has a broad focus on the entire vaccine enterprise and is not focused specifically on any one vaccine or the pandemic response. HHS, through OIDP, seeks input regarding the draft of the Vaccine Plan from subject matter experts and nonfederal partners and stakeholders such as health care providers, national professional organizations, health departments, school administrators, community-based and faith-based organizations, manufacturers, researchers, advocates, and persons affected by VPDs.

The following are the Vaccine Plan's vision and goals. *Vision:* United States will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination over the lifespan. *Goals:*

1. Foster innovation in vaccine development and related technologies.
2. Maintain the highest possible levels of vaccine safety.
3. Increase knowledge of and confidence in routinely recommended.
4. Increase access to and use of all routinely recommended vaccines.
5. Protect the health of the American public by supporting global immunization efforts.

#### Information Needs

The draft Vaccine Plan may be reviewed at [www.hhs.gov/oidp](http://www.hhs.gov/oidp).

OIDP seeks to obtain feedback from external stakeholders on the following:

1. Do the draft Vaccine Plan's goals, objectives, and strategies appropriately address the vaccine landscape?
2. Are there any critical gaps in the Vaccine Plan's goals, objectives, and strategies? If so, please specify the gaps.
3. Do any of the Vaccine Plan's goals, objectives and strategies cause concern? If so, please specify the goal, objective or strategy, and describe the concern regarding it.

Please be succinct and limit your comments to a maximum of seven pages.

**Authority:** 42 U.S.C. Section 300aa–3.

Dated: November 17, 2020.

#### B. Kaye Hayes,

*Acting Director, Office of Infectious Disease and HIV/AIDS Policy.*

[FR Doc. 2020–25842 Filed 11–20–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Mental Health Services Research Special Emphasis Panel.

*Date:* December 17, 2020.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MSB 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, [nick.gaiano@nih.gov](mailto:nick.gaiano@nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 17, 2020.

#### Patricia B. Hansberger,

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020–25749 Filed 11–20–20; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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.,