cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental new drug application (sNDA 021945/S–023#) for MAKENA (hydroxyprogesterone caproate injection, 250 milligrams per milliliter) manufactured by AMAG Pharmaceuticals. In 2011, MAKENA received approval under the accelerated approval pathway (21 CFR part 314, subpart H, and section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. MAKENA was shown in the preapproval clinical trial to reduce the proportion of women who delivered at less than 37 weeks gestation, a surrogate endpoint that FDA determined was reasonably likely to predict a clinical benefit of preterm birth prevention, such as improved neonatal mortality and morbidity. As required under 21 CFR 314.510, the Applicant conducted a postapproval confirmatory clinical trial to verify and describe clinical benefit. AMAG Pharmaceuticals has disclosed that this completed confirmatory trial did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints of reducing the risk of recurrent preterm birth or improving neonatal mortality and morbidity. The committee will consider the trial's findings and the sNDA in the context of AMAG Pharmaceuticals' confirmatory study obligation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 15, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 4, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 7, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20656 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI) From Non-Federal Stakeholders: Developing the 2020 National Vaccine Plan

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 development of a National Vaccine Plan (NVP) 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 NVP, 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*). To help inform the development of the National Vaccine Plan 2020, HHS is issuing a Request for Information (RFI). The RFI will solicit specific information regarding the priorities, goals, and objectives in the next iteration of the NVP, remaining gaps, and stakeholder perspectives for the 2020–2025 timeframe.

DATES: To be considered, comments must be received electronically at the email address provided below, no later than 5:00 p.m. ET on October 24, 2019.

ADDRESSES: Responses must be submitted electronically, and should be addressed to *NVP.RFI@hhs.gov.* Mailed paper submissions and submissions received after the deadline will not be reviewed.

SUPPLEMENTARY INFORMATION: 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.[1] In contrast, adult vaccination coverage rates have remained persistently low, with only modest gains for certain populations in the past few years.[2] As a result, the standards for adult immunization practice were updated in 2014 to promote integration of vaccines into routine clinical care for adults.[3]

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,[4] and there have been recent measles outbreaks in the U.S.[5] 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,[6] 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. 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.[7] VPDs such as pertussis and hepatitis B continue to take a heavy toll on public health,[8] with 18,975 cases of pertussis and 3,409 (22,000 estimated) cases of hepatitis B infections reported in the United States in 2017.[9] [10] In light of these challenges, strengthening the vaccine and immunization enterprise is a priority for HHS.

The 2010 National Vaccine Plan (*https://www.hhs.gov/sites/default/files/nvpo/vacc_plan/2010-Plan/nationalvaccineplan.pdf*) and the associated implementation plan (*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 National Vaccine Plan, there have been many changes in the vaccine landscape.

To respond to the public health challenges of VPDs, OIDP in collaboration with other federal partners is leading the development of the 2020 National Vaccine Plan. This updated plan will recommend vaccine strategies across the lifespan and guide priority actions for the period 2020–2025. To develop this plan, HHS, through OIDP, seeks input 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.

This request for information seeks public input on strengthening and improving the nation's response to VPDs and strategies to address infectious diseases through vaccination. The 2020 National Vaccine Program requests information in five broad areas. Responders may address one or more of the areas below:

1. Priorities for the 2020 National Vaccine Plan during 2020–2025. What do you recommend as the top priorities for vaccines and immunizations in the United States? Why are these priorities most important to you? [Provide up to 2 pages to answer these questions]

2. What changes should be made to the 2010 National Vaccine Plan to make it more current and useful? This could include changes to the goals, objectives, strategies, activities, indicators, and other areas of the plan. Which components of the 2010 National Vaccine Plan worked well and should be maintained? [Provide up to 2 pages to answer these questions]

3. What are the goals, objectives, and strategies for each of your top priority areas? Are there any goals in the current strategy that should be discarded or revised? Which ones and why? [Provide up to 2 pages to answer these questions]

4. What indicators can be used to measure your top priorities and goals? Are there any indicators in the 2010 National Vaccine Plan or the National Adult Immunization Plan (*https://www.hhs.gov/sites/default/files/nvpo/national-adult-immunization-plan/naip.pdf*) that should continue to be used? If so, which ones, and why? [Provide up to 2 pages to answer these questions]

5. Identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the 2020 National Vaccine Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles that you or your organization might have in the 2020 National Vaccine Plan. [Provide up to 2 pages to answer these questions].

The information received will inform the development of the 2020 National Vaccine Plan.

Dated: September 9, 2019.

Tammy R. Beckham,

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

[FR Doc. 2019–20415 Filed 9–23–19; 8:45 am]

BILLING CODE 4150–28–P

[1] Zhou F et al. Economic evaluation of the routine childhood immunization program in the United States, 2009. Pediatrics. 2014; 133: 1–9.

[2] *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html.*

[3] National Vaccine Advisory Committee. Recommendations from the National Vaccine Advisory Committee: standards for adult immunization practice. Public Health Rep. 2014;129:115–23.

[4] 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.

[5] *https://www.cdc.gov/measles/cases-outbreaks.html.*

[6] Lo NC, Hotez PJ. 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.

[7] Lu PJ 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.

[8] *https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.*

[9] *https://www.chop.edu/centers-programs/vaccine-education-center/global-immunization/diseases-and-vaccines-world-view.*

[10] *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.

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(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: October 18, 2019.

Time: 9:00 a.m. to 2:40 p.m.

Agenda: Discussion of Patient Safety, Quality Improvement Assessment, and Medical Research Scholars Program.

Place: National Institutes of Health, Building 1, Wilson Hall, One Center Drive, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, Office of the Director, National Institutes of Health, One Center Drive, Building 1, Bethesda, MD 20892, 301–496–4272, *woodgs@nih.gov.*