emergency. The guidance announced in this notice supersedes the guidance of the same title dated April 2020 and updated in May 2020, and provides recommendations and additional information related to the August 23, 2020, EUA for COVID–19 convalescent plasma for the treatment of hospitalized patients with COVID–19.[1] Accordingly, FDA is replacing the May 2020 guidance to provide recommendations to healthcare providers for administering COVID–19 convalescent plasma under the EUA. The new guidance also provides recommendations to blood establishments on collection of COVID–19 convalescent plasma under the EUA, including on donor eligibility and qualification, testing plasma for anti-SARS-CoV2 antibodies, and labeling.

In addition, the guidance describes FDA's interim compliance and enforcement policy regarding the IND requirements for the use of investigational convalescent plasma. Following issuance of the EUA for COVID–19 convalescent plasma on August 23, 2020, FDA has received numerous inquiries from blood establishments and healthcare providers regarding investigational convalescent plasma that was collected prior to the EUA and that remains in inventory. FDA understands that investigational convalescent plasma collected prior to the EUA may not meet the Conditions of Authorization set forth in the EUA. FDA also understands that it will take time for blood establishments to develop the necessary operating procedures to manufacture COVID–19 convalescent plasma pursuant to the Conditions of Authorization in the EUA. In addition, the Agency is aware that enrollment into the National Expanded Access Treatment Protocol sponsored by the Mayo Clinical was discontinued as of August 28, 2020.

Considering these issues and recognizing the immediate need for convalescent plasma to treat hospitalized patients with COVID–19, the guidance explains that FDA intends to exercise enforcement discretion with respect to the IND requirements for the collection, shipment, and administration of investigational convalescent plasma for a period of 90 days following the issuance of the guidance document provided certain circumstances are present. The guidance outlines these circumstances and explains that during this period of enforcement discretion and beyond, FDA will continue to work with any investigators who wish to submit INDs for the study of investigational convalescent plasma and that ongoing clinical trials of investigational convalescent plasma should not be amended because of this enforcement discretion policy. The guidance also provides recommendations for healthcare providers who wish to administer and study convalescent plasma under an IND.

In light of this public health emergency, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

In the **Federal Register** of May 26, 2020 (85 FR 31513), FDA announced the availability of a guidance of the same title. Elsewhere in this issue of the **Federal Register**, FDA is announcing the withdrawal of the guidance of the same title that was announced on May 26, 2020.

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 investigational COVID–19 convalescent plasma. 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 in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 606.121 and 21 CFR part 630 have been approved under OMB control number 0910–0116; and the collections of information in Form FDA 3926 have been approved under OMB control number 0910–0814.

III. Electronic Access

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

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20800 Filed 9–18–20; 8:45 am]

BILLING CODE 4164–01–P

[1] Emergency Use Authorization for COVID–19 Convalescent Plasma available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1825]

Investigational COVID–19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a final guidance for industry entitled ''Investigational COVID–19 Convalescent Plasma,'' which was issued in April 2020 and updated in May 2020. FDA is withdrawing the guidance because the Agency is issuing a new guidance for industry of the same title.

DATES: The withdrawal is applicable September 21, 2020.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled ''Investigational COVID–19 Convalescent Plasma'' (May 2020 guidance) dated April 2020 and updated May 2020. The availability of this guidance was announced in the **Federal Register** of May 26, 2020, (85 FR 31513) and was posted on FDA's website on May 1, 2020.

On August 23, 2020, the Agency issued an emergency use authorization (EUA) (available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs*) for COVID–19 convalescent plasma for the

treatment of hospitalized patients with COVID–19. Given the issuance of this EUA, FDA is issuing a new guidance of the same title that provides recommendations and additional information related to the EUA for the use of COVID–19 convalescent plasma to treat hospitalized patients with COVID–19. The new guidance supersedes the May 2020 guidance. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the new guidance.

Dated: September 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20801 Filed 9–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: STI National Strategic Plan 2021–2025 Available for Public Comment

AGENCY: Office of the Secretary, Department of Health and Human Services.

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 Sexually Transmitted Infections National Strategic Plan 2021–2025 (STI Plan) available for public comment. The draft STI Plan may be reviewed at *www.hhs.gov/STI.*

DATES: All comments must be received by 5:00 p.m. ET on October 1, 2020 to ensure consideration.

ADDRESSES: All comments must be submitted electronically to *STDPlan@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Carol Jimenez, OIDP, *Carol.Jimenez@hhs.gov,* 202–401–5131.

SUPPLEMENTARY INFORMATION: Persistent rises in the rates of sexually transmitted infections (STIs) in the United States constitute an epidemic and public health crisis with profound implications for all Americans. In recent decades, rates of chlamydia, gonorrhea, syphilis, congenital syphilis, and human papillomavirus have increased significantly. The rate of chlamydia, the most prevalent STI, increased by greater than 200% from 2011 to 2018.[1] In just over a decade, the rate of gonorrhea rose by greater than 80% from a historic low. The rates of primary and secondary syphilis and of congenital syphilis increased every year since 2001 and 2012, respectively.[2] Human papillomavirus (HPV), the most common STI, accounts for 14 million new STI infections each year.[3] Left untreated, STIs can lead to significant health consequences.

To spur action to reduce STI rates and their adverse public health impact, OASH through OIDP, in collaboration with federal partners throughout HHS and other departments, led and coordinated development of the inaugural STI Plan. Opportunities for public input were provided, and public comments received were reviewed, and analyzed and helped inform the components of the STI Plan.

The STI Plan is intended to serve as a roadmap for all stakeholders at all levels to guide development of policies, initiatives, and actions for STI prevention and control. The STI Plan focuses on four of the STIs that have the greatest impact on the health of the nation: chlamydia, gonorrhea, syphilis, and HPV. However, most of its components are also applicable to other prevalent STIs.

The STI Plan presents a strategic framework for integrating and leveraging synergistic policies, programs, and resources. It sets forth a vision and goals for the nation, with objectives and strategies for each goal. The objectives and strategies offered in this plan are interrelated and may be used to make progress toward more than one goal. The STI Plan identifies priority populations (*i.e.,* those populations disproportionately impacted by STIs based on national data) to guide national efforts to realize the highest impact on reducing STIs. The STI Plan also includes indicators to measure progress and quantitative targets for each indicator. Although it is a 5-year plan, it sets 10-year quantitative targets for each indicator—reflecting the reality that it will take more than 5 years to reverse, not just slow, the upward trajectory of rising STI rates, and to eliminate the epidemic. The order in which the goals, objectives, strategies, and indicators are presented is not associated with any prioritization.

The following are the STI Plan's vision and goals. *Vision:* The United States will be a place where sexually transmitted infections are prevented and where every person has high-quality STI prevention, care, and treatment while living free from stigma and discrimination. This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, disability, geographic location, or socioeconomic circumstance. *Goals:*

1. Prevent new STIs
2. Improve the health of people by reducing adverse outcomes of STIs
3. Accelerate progress in STI research, technology, and innovation
4. Reduce STI-related health disparities and health inequities
5. Achieve integrated, coordinated efforts that address the STI epidemic

A roadmap for stakeholders at all levels and sectors, the STI Plan envisions a whole-of-nation response to preventing and controlling STIs in the United States. The STI Plan assumes the active participation of state, local, and tribal health departments and organizations, health plans and health care providers, schools and other academic institutions, community- and faith-based organizations, scientists, researchers, and the public in this effort. The priority populations, indicators, and quantitative targets, especially the methods used to determine them, are intended to help focus efforts and limited resources to realize the most impact. Stakeholders are encouraged to focus on activities that resonate the most with the needs of the populations they serve and services they provide, and, using the STI Plan as a framework, develop their own plans to reverse the rise of STIs and improve the health of their communities, states, tribal nations, and the nation.

Information Needs

The draft STI Plan may be reviewed at: *www.hhs.gov/STI.*

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

1. Do the draft plan's goals, objectives, and strategies appropriately address the STI epidemic?

2. Are there any critical gaps in the STI Plan's goals, objectives, and strategies? If so, please specify the gaps.

3. Do any of the STI 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: 77 FR 15761 (March 16, 2012).

Dated: September 15, 2020.

B. Kaye Hayes,

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

Footnotes

1. Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2018.* U.S. Department of Health and Human Services; 2019. Accessed June 22, 2020. *https://www.cdc.gov/std/*