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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collection of information for ''Current Good Manufacturing Practices for Finished Pharmaceuticals and Medical Gases'' has been approved under OMB control number 0910–0139. The collection of information for ''Postmarketing Adverse Drug Experience Reporting'' has been approved under OMB control number 0910–0230. The collection of information for ''MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based)'' has been approved under OMB control number 0910–0291. The collection of information for ''Format and Content Requirements for Over-the-Counter Drug Product Labeling'' has been approved under OMB control number 0910–0340. The collection of information for ''FDA Adverse Event and Products Experience Reports; Electronic Submissions'' has been approved under OMB control number 0910–0645. The collection of information for ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' has been approved under OMB control number 0910–0800.

IV. 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: March 17, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05959 Filed 3–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Public Comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act

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

ACTION: Request for public comment.

SUMMARY: The Office of the Assistant Secretary for Health in the Department of Health and Human Services seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

Congress passed the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) in June 2019. Section 209 of this legislation states that the Secretary of Health and Human Services shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply. The legislation poses four specific questions regarding the adequacy of the national blood supply. HHS welcomes any public feedback related to how these questions should be addressed and/or potential solutions. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be assured consideration, electronic or written/paper comments must be submitted no later than midnight Eastern Standard Time (EST) on April 22, 2020.

ADDRESSES: Individuals are encouraged to submit responses electronically to *ACBTSA@hhs.gov*. Please indicate ''RFI RESPONSE'' in the subject line of your email. Written responses should be addressed to: U.S. Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Room L600, Washington, DC 20024 Attn: ACBTSA–PAHPAIA Sec. 209. Mailed paper submissions and electronic submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, (202) 795–7608.

SUPPLEMENTARY INFORMATION:

(1) Challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate);

(2) Ensuring the adequacy of the blood supply in the case of public health emergencies;

(3) Implementation of the transfusion transmission monitoring system; and

(4) Other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply.

Dated: March 11, 2020.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–06047 Filed 3–20–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[OIG–1810–N]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This notice replaces all language in Part Q (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG), (published March 15, 2016).

SUPPLEMENTARY INFORMATION: The Statement of Organization, Functions, and Delegations of Authority conforms to and carries out the statutory requirements for operating OIG. The organizational changes reflected in this notice are primarily to realign the functions within OIG to better reflect the current work environment and priorities and to more clearly delineate responsibilities for the various activities within OIG's offices.

OIG was established by law as an independent and objective oversight unit of the Department to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations. In furtherance of this mission, the organization:

- Conducts and supervises audits, investigations, evaluations, and inspections relating to HHS programs and operations;
- identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence;
- leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations;
- detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to