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

bear, including imposing administrative sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts; and

• keeps the Secretary of Health and Human Services and Congress fully and currently informed about problems and deficiencies in the administration of HHS programs and operations and about the need for and progress of corrective action.

In addition, OIG works with the Department of Justice (DOJ), on behalf of the Secretary, to operate the Health Care Fraud and Abuse Control Program. In accordance with authority enacted in its annual appropriations, OIG also provides protection services to the Secretary and conducts criminal investigations of violations of Federal child support provisions.

In support of its mission, OIG carries out and maintains an internal quality assurance system and a peer-review system with other Offices of Inspector General, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards, and other requirements are followed, are effective, and are functioning as intended in OIG operations.

Section Q, Office of Inspector General—Organization

There is at the head of OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. OIG consists of six organizational units:

1. Immediate Office of the Inspector General (QA)
2. Office of Management and Policy (QC)
3. Office of Evaluation and Inspections (QE)
4. Office of Counsel to the Inspector General (QG)
5. Office of Audit Services (QH)
6. Office of Investigations (QJ)

Section Q, Office of Inspector General—Functions

The component sections that follow describe the specific functions of the organization.

Section QA.00, Immediate Office of the Inspector General—Mission

The Immediate Office of the Inspector General is directly responsible for meeting the statutory mission of OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control reviews of OIG processes and products.

Section QA.10, Immediate Office of the Inspector General—Organization

The Immediate Office comprises the Inspector General, Principal Deputy Inspector General, Chief of Staff, several technical advisors, including the Chief Medical Officer, and staff.

Section QA.20, Immediate Office of the Inspector General—Functions

The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary. The Inspector General does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence conferred by the Inspector General Act, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of OIG and all mission-related authorities stated or implied in the law or delegated directly from the Secretary. The Inspector General provides executive leadership to the organization and exercises general supervision over the personnel and functions of its major components. The Inspector General determines the budget needs of OIG, sets OIG policies and priorities, oversees OIG operations, and provides reports to the Secretary and Congress. By statute, the Inspector General exercises general personnel authority, *e.g.,* selection, promotion, and assignment of employees, including members of the Senior Executive Service. The Inspector General delegates related authorities as appropriate. The Principal Deputy Inspector General assists the Inspector General in the management of OIG, and during the absence of the Inspector General, acts as the Inspector General. The Principal Deputy Inspector General supervises the Chief Counsel to the Inspector General, the Deputy Inspectors General, who head the major OIG components, as well as the Chief of Staff.

The Immediate Office interacts with the Department, Congress, and the public and leads OIG's congressional, media, and public affairs functions. The office also plans, conducts, and participates in a variety of interagency cooperative projects and undertakings relating to fraud and abuse with the DOJ, the Centers for Medicare & Medicaid Services (CMS), and other governmental agencies, and is responsible for the reporting and legislative functions required by the Inspector General Act.

Section QC.00, Office of Management and Policy—Mission

The Office of Management and Policy (OMP) provides management, guidance, and resources in support of OIG.

Section QC.10, Office of Management and Policy—Organization

OMP is directed by the Deputy Inspector General for Management and Policy, who, aided by Assistant Inspectors General, assures that OIG has the financial and administrative resources necessary to fulfill its mission. This office carries out its responsibilities through headquarters functions.

Section QC.20, Office of Management and Policy—Functions

The staffs within OMP are responsible for formulating and executing OIG's budget, developing policy, and managing information technology, human resources, executive resources, procurement activities, and physical space. OMP also executes and maintains an internal quality assurance system, which includes quality control reviews of its processes and products to ensure that OIG policies and procedures are followed and function as intended. OMP provides centralized services and management to deliver to OIG data, tools, skills, and support to use data and data analytics. Finally, OMP coordinates organizational performance management activities.

Section QE.00, Office of Evaluation and Inspections—Mission

The Office of Evaluation and Inspections (OEI) is responsible for conducting indepth evaluations of HHS programs, operations, and processes to identify vulnerabilities and recommend corrective action; to prevent and detect fraud and abuse; and to promote efficiency and effectiveness in HHS programs and operations. OEI conducts its work in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

Section QE.10, Office of Evaluation and Inspections—Organization

OEI is directed by the Deputy Inspector General for the Office of Evaluation and Inspections, who, aided by Assistant Inspectors General, is responsible for carrying out OIG's responsibilities to evaluate the effectiveness and efficiency of HHS programs and operations. The office is comprised of headquarters and regional functions.

Section QE.20, Office of Evaluation and Inspections—Functions

OEI is responsible for conducting evaluations of HHS programs; conducting data and trend analysis; and recommending changes in programs, procedures, policies, regulations, and legislation. OEI develops evaluation policies, procedures, techniques, and guidelines to be followed by all OEI staff in conducting evaluations. The office maintains an internal quality assurance program. OEI also oversees the activities of State Medicaid Fraud Control Units (MFCUs) to ensure the MFCUs' compliance with Federal grant regulations, administrative rules, and performance standards for the purpose of certifying or recertifying the MFCUs annually. The office also maintains automated data and management information systems used by all OEI employees, a quality assurance/peer-review program, and policy and procedure manuals.

Section QG.00, Office of Counsel to the Inspector General—Mission

In accordance with section 3(g) of the Inspector General Act (5 U.S.C. App. § 3(g)), the Office of Counsel to the Inspector General (OCIG) provides all legal advice to OIG and represents OIG in administrative litigation. OCIG proposes and litigates civil money penalty (CMP) and program exclusion cases within the jurisdiction of OIG. It coordinates False Claims Act matters involving HHS programs and resolves voluntary disclosure cases. OCIG develops guidance to assist providers in establishing compliance programs; monitors ongoing compliance of providers subject to integrity agreements; and promotes industry awareness through advisory opinions, fraud alerts, and special advisory bulletins.

Section QG.10, Office of Counsel to the Inspector General—Organization

OCIG is directed by the Chief Counsel to the Inspector General, who also serves as OIG's Deputy Ethics Counselor and is aided by Assistant Inspectors General. The office carries out its responsibilities through headquarters functions.

Section QG.20, Office of Counsel to the Inspector General—Functions

OCIG provides legal advice to OIG on issues that arise in the exercise of OIG's responsibilities under the Inspector General Act of 1978, as amended. Such issues include the scope and exercise of the Inspector General's authorities and responsibilities; investigative techniques and procedures (including criminal procedure); the sufficiency and impact of legislative proposals affecting OIG and HHS; and the conduct and resolution of investigations, audits, and inspections. The office evaluates the legal sufficiency of OIG findings and recommendations and develops formal legal opinions to support these findings and recommendations. The office also provides legal advice on OIG internal administration and operations, including appropriations, procurement, delegations of authority, OIG regulations, personnel matters, disclosure of information under the Freedom of Information Act (FOIA), and safeguarding information under the Privacy Act. Additionally, OCIG coordinates OIG's regulatory review functions required by the Inspector General Act and responses to all requests made under FOIA. The office is responsible for the clearance and enforcement of OIG subpoenas.

The office represents OIG in administrative litigation and related appeals. This includes representing OIG in personnel and Equal Employment Opportunity matters; coordinating OIG's representation in Federal tort actions involving OIG employees; and representing OIG in bid protests before the Government Accountability Office and the U.S. Court of Federal Claims.

OCIG also determines whether to propose or implement administrative sanctions, including CMPs and assessments within OIG's jurisdiction. The office effectuates mandatory and permissive exclusions from participation in Federal health care programs under the Social Security Act; decides on all requests for reinstatement from, or waiver of, exclusions; and participates in developing standards governing the imposition of these exclusion authorities. The office also oversees OIG's suspension and debarment referral program. The office litigates and resolves all appealed or contested exclusions from participation in Federal health care programs under the Social Security Act. In conjunction with DOJ, the office represents HHS in all False Claims Act cases, including qui tam cases, and is responsible for final approval of civil False Claims Act settlements for the Department, including the resolution of the program exclusion authorities that have been delegated to OIG.

In conjunction with the Office of Investigations, OCIG coordinates resolution of all voluntary and mandatory disclosure under OIG's Provider Self-Disclosure Protocol, the contractor self-disclosure requirement and otherwise. OCIG develops and monitors corporate and individual integrity agreements adopted in connection with settlement agreements, conducts onsite reviews, and develops audit and investigative review standards for monitoring such integrity agreements in conjunction with other OIG components. The office also resolves breaches of integrity agreements through the development of corrective action plans and the imposition of sanctions.

OCIG, through the Whistleblower Protection Coordinator, provides education to agency employees about prohibitions against whistleblower retaliation, and the rights and remedies available for such matters.

Finally, OCIG issues advisory opinions to the health care industry and members of the public on whether a current or proposed activity would constitute grounds for the imposition of a sanction under the anti-kickback statute, the CMP law, or the program exclusion authorities. The office develops procedures for submitting and processing requests for advisory opinions and for determining the fees that will be imposed. It solicits and responds to proposals for new regulatory safe harbors to the anti-kickback statute, modifications to existing safe harbors, and new fraud alerts. OCIG consults with DOJ on proposed advisory opinions and safe harbors before issuance or publication. The office provides legal advice to the components of OIG, other HHS offices, and DOJ concerning matters involving the interpretation of the anti-kickback statute and other legal authorities, and assists those components or offices in analyzing the applicability of the anti-kickback statute to particular practices or activities under review.

Section QH.00, Office of Audit Services—Mission

The Office of Audit Services (OAS) is responsible for protecting the integrity of HHS operations and programs by conducting audits that identify and report ways to improve the economy, efficiency, and effectiveness of operations and services to beneficiaries of HHS programs and to help reduce fraud, waste, abuse, and mismanagement. OAS conducts audits and oversees audit work performed by others. It conducts its work in accordance with Government Auditing Standards and follows applicable legal, regulatory, and administrative requirements.

Section QH.10, Office of Audit Services—Organization

OAS is directed by the Deputy Inspector General for Audit Services,

who, aided by Assistant Inspectors General, performs the functions designated in section 3(d)(1)(A) of the Inspector General Act for the position of Assistant Inspector General for Auditing. The office comprises headquarters and regional functions and includes a designated Whistleblower Protection Ombudsman, and the functions thereof, as required by law (section 3(d)(1)(C) of the Inspector General Act).

Section QH.20, Office of Audit Services—Functions

OAS establishes audit priorities; performs audits; oversees the progress of audits; coordinates with stakeholders on bodies of work; recommends changes in program policies, regulations, and legislation to prevent fraud, waste, and abuse and improve programs and operations; and reports on the impact of audit work. The office develops audit policies, procedures, techniques, and guidelines to be followed by all OAS staff in conducting audits. OAS maintains an internal quality assurance program, conducts peer reviews of other OIGs, and maintains automated data and management information systems used by all OAS employees. The office also provides oversight for audits of State and local governments, universities, and nonprofit organizations conducted by non-Federal auditors.

Section QJ.00, Office of Investigations—Mission

The Office of Investigations (OI) is granted full statutory law enforcement authority under the Homeland Security Act of 2003 (Pub. L. 107–296). OI is responsible for protecting the integrity of the programs administered and/or funded by HHS by conducting criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and employees. The office serves as OIG's liaison to DOJ on all matters relating to investigations of HHS programs and personnel and reports to the Attorney General when there are reasonable grounds to believe Federal criminal law has been violated. OI serves as a liaison to CMS, State licensing boards, and other outside organizations and entities with regard to exclusion, compliance, and enforcement activities.

Section QJ.10, Office of Investigations—Organization

OI is directed by the Deputy Inspector General for Investigations, aided by Assistant Inspectors General, and performs the functions designated in the law (section 3(d)(1)(B) of the Inspector General Act) for the position of Assistant Inspector General for Investigations. The office is comprised of headquarters and regional functions.

Section QJ.20, Office of Investigations—Functions

OI conducts criminal, civil, and administrative investigations of allegations of fraud, waste, abuse, mismanagement, and violations of standards of conduct within the jurisdiction of OIG. OI establishes investigative priorities, evaluates the progress of investigations, and reports findings to the Inspector General. The office develops and implements investigative techniques, programs, guidelines, and policies; manages OI's quality assurance/peer-review program, and conducts peer reviews of other OIGs. OI also carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively and are functioning as intended. OI implements policies and procedures and plans, develops, implements, and evaluates all levels of training for OI employees. The staff provides for the personal protection of the Secretary and other Department officials, as needed, and all emergency operations preparedness and response. OI coordinates the adoption of advanced digital forensic acquisition and examination and information security technologies to assist in the investigation, prevention, and detection of fraud and abuse; maintains an automated data and management information system used by all OI employees; provides technical expertise on computer applications for investigations; and coordinates and approves investigative computer matches with other agencies. In addition, the office operates a toll-free hotline to permit individuals to report suspected fraud, waste, and abuse within HHS programs.

Dated: March 17, 2020.

Christi A. Grimm,

Principal Deputy Inspector General.

[FR Doc. 2020–06046 Filed 3–20–20; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 24, 2020, 10:00 a.m. to March 24, 2020, 01:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 25, 2020, 85 FR 10708.

The format of the Special Emphasis Panel; Member Conflicts: Sensory Processes and Pain has been changed to a Virtual Meeting. The meeting date, time and location remain the same. The meeting is closed to the public.

Dated: March 17, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05968 Filed 3–20–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 27, 2020, 01:00 p.m. to March 27, 2020, 05:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 which was published in the **Federal Register** on March 04, 2020, 85 FR 12799.

The format of the Special Emphasis Panel; Member Conflict: Sleep, Stress, Motion, and Taste has been changed to a Telephone Assisted Meeting. The meeting date, time and location remain the same. The meeting is closed to the public.

Dated: March 17, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05967 Filed 3–20–20; 8:45 am]

BILLING CODE 4140–01–P