on regulatory considerations for use of MRD in drug and biological products in development for hematologic malignancies. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collection of information in 21 CFR part 312 for submitting INDs has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 for the submission of new drug applications has been approved under OMB control number 0910–0001. The collection of information in the draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf*) has been approved under OMB control number 0910–0429. The submission of special protocol assessments has been approved under OMB control number 0910–0470.

The submission of biologics license applications has been approved under OMB control number 0910–0338. The submission of investigational device exemptions has been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: October 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services.

Employee last name	Employee first name
Alvarez	Karl
Bush	Laina
Cash	Lester
Hoffman	Darrell
Kerr	Lawrence
Walker	Edwin

Dated: October 10, 2018.

Charles H. McEnerney III,

Director, Executive and Scientific Resources Division.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for Office of Management and Budget (OMB) Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: State Targeted Response to the Opioid Crisis Grant Program Mid-Year and End-Year Performance Reports—(OMB No. 0930–0378)—in Use Without OMB Approval

The Substance Abuse and Mental Health Services Administration (SAMHSA) is authorized under Section 1003 of the 21st Century Cures Act, as amended, to support a grant program, for up to 2 years, that addresses the supplemental activities pertaining to opioids currently undertaken by the state agency or territory and will support a comprehensive response to the opioid epidemic.

SAMHSA received approval from OMB in September 2017 to collect performance data from Opioid State Targeted Response (STR) grantees (OMB No. 0930–0378). However, SAMHSA omitted a data collection table (Table E) in the original OMB request. This data table is currently in use by Opioid STR grantees, who are reporting Table E data to SAMHSA on a semi-annual basis. In order to correct this violation, SAMHSA is now seeking OMB approval for a new data collection package that includes not only the instruments originally approved by OMB in September 2017, but also this additional data collection table. It is important for SAMHSA to continue to collect this information in order to assess the impact of funding from the Opioid STR program on increasing access to prevention strategies, as well as treatment and recovery services that address the opioid crisis. Additionally, this data will provide SAMHSA with critical information to effectively manage the Opioid STR program, to help states and territories adopt, or scale-up, effective practices and policies, and to help prepare to implement the new State Opioid Response grant program.

The primary purpose of the Opioid STR program is to address the opioid crisis by increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment and recovery activities for opioid use disorder (OUD) (including prescription opioids as well as illicit drugs such as heroin).

There are 57 (states and jurisdictions) award recipients in this program. All funded states and jurisdictions are asked to report on their implementation and performance through an online data collection system. Award recipients report performance on the following measures specific to this program: Number of people who receive OUD treatment, number of people who receive OUD recovery services, number of providers implementing medication-assisted treatment, and the number of OUD prevention and treatment providers trained, to include nurse practitioners, physician assistants, as well as physicians, nurses, counselors, social workers, case managers, etc. This information is collected at the mid-point and conclusion of each grant award year. Additionally, each award recipient