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This draft guidance refers to previously approved collections of information found in FDA regulations.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 The collection of information in the draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (available at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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,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.

[FR Doc. 2018–22436 Filed 10–15–18; 8:45 am]

BILLING CODE 4164–01–P

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.

[FR Doc. 2018–22491 Filed 10–15–18; 8:45 am]

BILLING CODE 4151–17–P

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

describes the purposes for which the grant funds received were expended and the activities implemented under this program.

ANNUALIZED ESTIMATED BURDEN HOURS FOR THE PROGRESS REPORT

Respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
State and Jurisdictions	57	2	114	8.5	969

Written comments and recommendations concerning the proposed information collection should be sent by November 15, 2018 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2018–22446 Filed 10–15–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA Inc. (Yorktown, VA) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA Inc. (Yorktown, VA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA Inc. (Yorktown, VA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 23, 2017.

DATES: Intertek USA Inc. (Yorktown, VA) was approved and accredited as a commercial gauger and laboratory as of August 23, 2017. The next triennial inspection date will be scheduled for August 2020.

FOR FURTHER INFORMATION CONTACT: Melanie Glass, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA, Inc., 109–B Freedom Blvd., Yorktown, VA 23692, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Intertek USA Inc. (Yorktown, VA) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank Gauging.
5	Metering.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurement.

Intertek USA Inc. (Yorktown, VA) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–09	D4953	Standard Test Method for Vapor Pressure of Gasoline and Gasoline-Oxgenate Blends (Dry Method).
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.