DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3090]

Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' This draft guidance is intended to assist sponsors planning to use minimal residual disease (MRD) as a biomarker in clinical trials conducted under an investigational new drug application (IND) or to support marketing approval of drugs and biological products for the treatment of specific hematologic malignancies.

DATES: Submit either electronic or written comments on the draft guidance by December 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–3090 for ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nicole Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2310, Silver Spring, MD 20993–0002, 240–402–0210; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' This draft guidance is intended to assist sponsors planning to use MRD as a biomarker in clinical trials conducted under an IND or to support marketing approval of drugs and biological products for the treatment of specific hematologic malignancies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA

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.

[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