is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Trafficking Victims Protection Act of 2000, as amended, authorizes the Secretary of Health and Human Services to establish a program to assist United States citizens and lawful permanent residents who are victims of severe forms of trafficking (22 U.S.C. 7105(f)). OTIP will award cooperative agreements to implement the DVHT program, which will include: (1) The Domestic Victims of Human Trafficking and Services Outreach Program, (2) Demonstration Grants to Strengthen the Response to Victims of Human Trafficking in Native Communities Program, and (3) the Strengthen the Health Care Response for Victims of Human Trafficking Program. Through the DVHT program, grantees will provide comprehensive case management to domestic survivors of severe forms of human trafficking in a traditional case management, Native community, or health care setting. The intent of the program is to connect survivors with the services they need to improve their lives and health outcomes.

OTIP proposes to collect information to measure grant project performance, provide technical assistance to grantees, assess program outcomes, improve program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (*e.g.,* age, sex, and country of origin); types of trafficking experienced (*e.g.,* sex, labor, or both); types of enrollment; types of services requested and provided, along with their cost; barriers to service delivery; subrecipients enrolled into the grantee's network; victim outreach activities; and the types of training provided to subrecipient organizations or other partners.

Respondents: Domestic Victims of Human Trafficking and Services Outreach Program grantees, Demonstration Grants to Strengthen the Response to Victims of Human Trafficking in Native Communities Program grantees, and the Strengthen the Health Care Response for Victims of Human Trafficking Program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Enrollment Form	1,908	1	1	1,908	636
Client Service Use and Delivery Form	1,908	3	.25	1,431	477
Client Case Closure Form	1,908	1	.167	319	106
Barriers to Service Delivery and Monitoring Form	36	15	.167	90	30
DVHT Spending Form	36	3	.75	81	27
Partnership Development and Expansion: Enrollment Form	25	1	.25	6	3
Partnership Development and Expansion: Exit Form	25	1	.083	2	1
Training Form	36	15	.5	270	90
Victim Outreach Reporting Form	36	15	.3	162	54

Estimated Total Annual Burden Hours: 1,424.

Authority: 22 U.S.C. 7105(f).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–01265 Filed 1–24–20; 8:45 am]

BILLING CODE 4184–47–P

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; 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 final guidance for industry entitled ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' This guidance is intended to help 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 treating specific hematologic malignancies. An analysis of marketing applications showed inconsistent quality of MRD data. Based on this analysis and discussion at various public workshops on MRD, FDA identified a need to provide guidance on the use of MRD as a biomarker in regulatory submissions. This guidance finalizes the draft guidance of the same title issued on October 16, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on January 27, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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.govinfo.gov/content/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 this 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 the 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 final guidance for industry entitled ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' This guidance is intended to help 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 treating specific hematologic malignancies.

This guidance finalizes the draft guidance of the same title issued on October 16, 2018 (83 FR 52225). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include editorial changes and clarifications throughout the document and the addition of definitions for individual-level and trial-level associations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment.'' 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.

II. Paperwork Reduction Act of 1995

This 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 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 guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: January 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01312 Filed 1–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4964]

Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled ''Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products; Draft Guidance for Industry; Availability'' that appeared in the **Federal Register** of December 20, 2019. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the notice published on December 20, 2019 (84 FR 70196). Submit either electronic or written comments on the draft guidance by March 19, 2020, 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 either electronic or written comments 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–2019–D–4964 for ''Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.'' 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.'' We will review this copy, including the claimed confidential information, in our 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.govinfo.gov/content/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 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 or 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. 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: Stephen Ripley, Center for Biologics Evaluation and Research, Food and