the MA program for which limited data are currently available.

III. Collection of Information Requirements

This is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. In addition, this RFI does not commit the Government to any policy decision and CMS will follow established methods for proposing future policy changes, including the MA Advance Notice and Rate Announcement process. We note that not responding to this RFI does not preclude participation in any future procurement or rulemaking, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 22, 2024.

Dated: January 25, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–01832 Filed 1–25–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Office of Human Services Emergency Preparedness and Response Disaster Human Services Case Management Intake Assessment, Resource Referral, and Case Management Plan

AGENCY: Office of Human Services Emergency Preparedness and Response, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Human Services Emergency Preparedness and Response (OHSEPR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting an extension for approval of the following information collection: OHSEPR Disaster Human Services Case Management Intake Assessment, Resource Referral, and Case Management Plan; OMB No.: 0970–0619. This information collection was originally approved for 6 months through an emergency approval.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment 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 within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OHSEPR is seeking to continue data collection with all forms approved under OMB No. 0970–0619, which OMB recently approved through an emergency approval for 6 months. OHSEPR's Disaster Human Services Intake Assessment, Resource Referral, and Case Management Plan collection is part of a system of tools that OHSEPR utilizes to support disaster survivors during response missions. OHSEPR's case managers would use this collection during an intake assessment to identify a disaster survivor's unmet needs and to work with the survivor to develop a case management plan based on the survivor's responses.

Respondents: Disaster survivors.

ANNUAL BURDEN ESTIMATES

Data collection	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Disaster Human Services Case Management Intake Assessment—Survivor	9,000	1	1.5	13,500
Case Management Plan—Case Manager	180	50	1	9,000
Resource Referral Form—Case Manager	180	50	1	9,000
Case Record Notes—Case Manager	180	50	1	9,000
Survivor Satisfaction Survey—Survivor	9,000	1	.25	2,250
Estimated Total Annual Burden Hours:				42,750

Authority: The Disaster Human Services Case Management Program is authorized through appropriations language under the Children and Families Services account. It is operated by the ACF Office of Human Services

Emergency Preparedness and Response, which is the lead in HHS for human service preparation for, response to, and recovery from, natural disasters.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–01728 Filed 1–29–24; 8:45 am]

BILLING CODE 4184–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0404]

Considerations for the Development of Chimeric Antigen Receptor T Cell Products; 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 entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' The guidance is intended to assist sponsors, including industry and academic sponsors, developing ex vivo-manufactured CAR T cell products. The guidance provides CAR T cell specific recommendations regarding chemistry, manufacturing, and control (CMC), pharmacology and toxicology, and design of clinical studies for oncology indications (including hematologic malignancies and solid tumors). The guidance announced in this notice finalizes the draft guidance of the same title dated March 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 30, 2024.

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–2021–D–0404 for ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' 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, 240–402–7500.

- 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, 240–402–7500.

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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 document entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' The guidance is intended to assist sponsors, including industry and academic sponsors, developing ex vivo-manufactured CAR T cell products. The guidance provides CAR T cell specific recommendations regarding CMC, pharmacology and toxicology, and design of clinical studies for oncology indications (including hematologic malignancies and solid tumors). Recommendations