regard to their immigration status. The TVPA also authorizes HHS to establish and strengthen programs to assist U.S. citizens and lawful permanent residents who have experienced sex trafficking or severe forms of trafficking in persons (22 U.S.C. 7105(f)(1)). Acting under a delegation of authority from the Secretary of HHS, ACF awards cooperative agreements to organizations to assist U.S. citizens and lawful permanent residents who have experienced human trafficking, the DVHT Program. The DVHT Program includes two distinct programs: the Domestic Victims of Human Trafficking Services and Outreach Program (DVHT–SO) and the Victims of Human Trafficking in Native Communities Demonstration Program (VHT–NC). Through the DVHT Program, grant recipients provide comprehensive case management to domestic survivors of human trafficking in traditional case management and Native community settings.

OTIP proposes to continue to collect information to measure grant project performance, provide technical assistance to grant recipients, assess program outcomes, inform 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, type of trafficking experienced, service location) and services provided, along with aggregate information on outreach activities conducted, subrecipients enrolled, and dollars spent per service. Minor nonsubstantive updates have been made to performance indicators under this collection to simplify response options or to bring the collection into alignment with OTIP's grant recipient reporting database, the Anti-Trafficking Information Management System (ATIMS). Additionally, certain data element response options that do not pertain to OTIP's domestic victim service programs were removed (*e.g.,* Refugee Cash Assistance, Refugee Medical Assistance, Refugee Social Services). Additionally, certain data elements have been simplified for respondent clarity.

Respondents: DVHT Program grant recipients and clients of those programs, specifically DVHT–SO and VHT–NC funding recipients.

Annual Burden Estimates

Based on review of performance data received pertaining to the number of clients served through DVHT programs and funding levels, the total number of respondents for each form has been lowered. The time to complete each form remains the same.

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 Program Entry	900	1	0.75	675	225
Client Case Closure	900	1	0.167	150.3	50.1
Barriers to Service Delivery and Monitoring	35	4	0.167	23.4	7.8
Client Service Use and Delivery	900	1	0.25	225	75
Client Outreach	35	4	0.3	42	14
Subrecipient Enrollment	35	3	0.167	17.5	5.8
Client Service Costs	35	1	0.75	26.25	8.75

Estimated Total Annual Burden Hours: 386.45.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 22 U.S.C. 7105

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–13455 Filed 7–16–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0476]

Submission for Office of Management and Budget Review; Generic Clearance for Disaster Information Collection Forms

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 Administration for Children and Families (ACF) is requesting a 3-year extension of the Generic Clearance for Disaster Information Collection Forms (Office of Management and Budget (OMB) #0970–0476) and the five forms currently approved for ACF programs. There are no changes requested to the umbrella generic and no substantial changes to the currently approved forms.

DATES: *Comments due* August 18, 2025. OMB must decide about 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.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The information collected through the forms approved under the umbrella Generic Clearance for Disaster Information Collection Forms is used to provide real-time updates during the response and

recovery phases of a disaster. Prior to the renewal process, the Office of Human Services Emergency Preparedness and Response (OHSEPR) revised the generic disaster information collection form approved under this generic: *Services for Planning Emergency Action and Response Form* (this submission will update the original title: *Administration for Children and Families Disaster Information Collection Form*). The *Services for Planning Emergency Action and Response Form* can be used as-is or tailored for a specific use by an ACF office or program. Each tailored form is submitted as an individual request under the umbrella generic.

The *Services for Planning Emergency Action and Response Form* has been tailored for each of the five following ACF offices or programs: The Children's Bureau, the Office of Family Violence Prevention and Services, the Office of Child Care, the Office of Head Start, and the Runaway and Homeless Youth (RHY) Program. It is possible that more program offices may request approval of a tailored version in the future.

The requested information is submitted by ACF award recipients, which includes states, tribes, and nongovernmental organizations.

Currently Approved Forms

Family Violence Prevention and Services Program. This form collects information on post-disaster impacts and disaster recovery, including requests for assistance from state administrators, tribes/tribal organizations, state coalitions, or resource centers comprising the Domestic Violence Resource Network; shelters that have been evacuated due to damage; shelter residents being served in alternate locations; reports of an increase in requests for assistance; capacity shortfalls; and reported increase in domestic violence post-disaster.

Office of Child Care. The baseline information includes the number of licensed, regulated, and license-exempt child care providers in the state; the number of children who are served by the ACF Office of Child Care's Child Care and Development Fund (CCDF); emergency contact information for the CCDF administrator, the licensing contacts, and resource and referral agencies; interruptions in systems that facilitate contacting the child care providers; contact person for state record-keeping systems; number of children served; and damage assessment plans of the licensing agency. The disaster impact information includes the number and type of child care providers closed, the number of closed providers that serve children who benefit from ACF CCDF, the number of children with CCDF subsidies affected by the closures, total child care capacity lost, whether the providers whose facilities have closed will be able to reopen, whether damaged facilities have been able to remain open, degree of disruption in services; state decision to implement temporary operating standards for child care providers; and requests for behavioral and mental health services for children, families, and staff. Post-disaster recovery questions include ability of child care providers to reopen, number of service slots lost due to closures, total number of child care providers that are open in the disaster impact zone; and staff shortages.

Family and Youth Services Bureau, Runaway and Homeless Youth Program. This form collects information on post-disaster impacts and disaster recovery, including requests from award recipients for technical assistance; a safety and accountability report for children and youth in RHY programs; reports of damage to RHY facilities; and a report of any children or youth that have been relocated due to damages to facilities.

Children's Bureau. This form requests information on any disaster-caused disruptions of the child abuse/neglect reporting and investigation system; reports of unaccompanied children needing protection, identification, and reunification with legal caregivers; actions taken by the Child Welfare Agency; impacts to Chafee Foster Care Independence Program providers; accountability and safety report for youth receiving services; reports on any increase in the number of child abuse or neglect reports in the affected areas; impacts to Safe and Stable Families or Community Based Child Abuse Prevention providers; whether families receiving in-home services are being supported; displaced or temporarily relocated foster families; coordination of needed services and supervision by the Child Welfare Agency; new or increased interstate challenges; and compromised program records.

Office of Head Start. Number of Head Start centers and service slots located in the disaster impact zone; number of centers and available service slots open and number closed post-disaster; number of Head Start centers with undetermined status; general access to services for children and families in the impacted areas; disruptions in transportation; ability of families to receive care elsewhere; number of Head Start centers closed post-disaster and number of service slots lost; and other program service interruptions.

Respondents: ACF Award Recipients and State Administrators.

ONGOING APPROVED INFORMATION COLLECTIONS

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Children's Bureau Disaster Information Collection Form	10	1	1	10
Family Violence Prevention and Services Program Disaster Information Collection Form	10	1	1	10
Office of Child Care Disaster Information Collection Form	7	1	2	14
Office of Head Start Disaster Information Collection Form	10	1	2	20
RHY Program Disaster Information Collection Form	10	1	1	10
Services for Planning Emergency Action and Response Form (Generic—Current)	400	1	0.1	40
Estimated Total Annual Burden Hours				104

BURDEN FOR POTENTIAL NEW INFORMATION COLLECTIONS

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Services for Planning Emergency Action and Response Form (Tailored or Generic)	60	1	1	60

Authority: 42 U.S.C. 68 Disaster Relief; 42 U.S.C. 5121; Pub. L. 113–5.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–13357 Filed 7–16–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1071]

Development of Cancer Drugs for Use in Novel Combination—Determining the Contribution of the Individual Drugs' Effects; 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 ''Development of Cancer Drugs for Use in Novel Combination—Determining the Contribution of the Individual Drugs' Effects.'' This draft guidance is intended for sponsors developing drugs for use in combination for the treatment of cancer and provides recommendations for characterizing the safety and effectiveness of individual drugs for use in a novel combination regimen in oncology (*i.e.,* demonstrating the contribution of each drug to the overall effect that is observed for the population). This guidance expands on the recommendations in the 2013 guidance for industry entitled ''*Codevelopment of Two or More New Investigational Drugs for Use in Combination.*'' This guidance does not address contribution of effect in settings where an investigational drug is being developed in combination with a drug approved for the same indication for the purposes of comparing the approved drug to the combination or to fixed combinations of previously approved drugs for the approved indication(s).

DATES: Submit either electronic or written comments on the draft guidance by September 15, 2025 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–2025–D–1071 for ''Development of Cancer Drugs for Use in Novel Combination—Determining the Contribution of the Individual Drugs' Effects.'' 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.