

a sponsor of investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator once every three years. All comparisons are done with the intention of ensuring protocol, patient and drug compliance for patient and drug compliance for patient safety and protections.

Frequency of Response: Daily.

Affected Public: State or local governments, businesses or other for-profit. Federal agencies or employees, non-profit institutions, and small business or organizations.

Type of Respondents: Investigators, pharmacist, nurses, pharmacy technicians, data manager. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows:

Federal Burden: 1700 audits are conducted of clinical research sites, a minimum of three Drug Accountability Forms are reviewed at the audit. Each form requires ½ hour to review.

Number of Respondents: 1700.

Number of Responses per Respondent: 3.

Average Burden per Response: 0.5 hours.

Annual Burden Hours: 2,250 hours.

Clinical Trial Site Burden: The annual respondents' burden for record keeping is estimated to require 6,240 hours. The record keeping burden represents an average time required for multiple entries (6 minutes or 0.1 hour per entry) on the drug accountability form, the average number of forms maintained by each record keeper and the number of record keepers.

Drug Accountability Forms

Number of Record Keepers: 3990.

Number of Responses per Respondent: 16.

Average Burden per Response: 0.1 (6 minutes).

Annual Burden Hours: 6,240 hours.

There are no Capital Costs, Operating Costs, and Maintenance Cost to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response times, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301-496-5725 or e-mail your request, including your address to: Hallch@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved collection, OMB Number 1660-0011, FEMA Form 22-13.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revised information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning an information collection system for disaster program accounts and debts receivable. The automated portion of the system is an accounts receivable system and is complimented by a manual technique that collects personal financial data directly from individual debtors by their completion of FEMA Form 22-13.

SUPPLEMENTARY INFORMATION: When errors in payments occur or reviews and audits determine that overpayments were made in various disaster entitlements, FEMA's Disaster Finance Branch (DFB), Office of the Chief Financial Officer (CFO) records pertinent receivable data, including individuals' personal data, within an automated, commercial, off-the-shelf (COTS) accounts receivable system—ACCPAC. Using various screens, a receivable is established to bill, monitor payments and produce reports. If, for lack of payment, an account receivable becomes a debt, ACCPAC continues as the receivable billing and collection system, but additional personal financial information is gathered and used to determine an ability to pay in setting requirements of installment payment agreements. DHS debt collection regulations, 6 CFR part 11, require FEMA to maintain current credit data on FEMA's debtors. To determine debtors' financial condition, this includes the individual debtors' own financial statements, executed under penalty for false claim, concerning their assets and liabilities and their income and expenses. FEMA Form 22-13 is the vehicle used to collect such data directly from the individual debtor.

FEMA uses this data to understand the debtors' financial conditions to accurately determine their ability to pay debts, to set arrangements for installment payments of debts, or to compromise/terminate debt collection. This data is also used to locate debtors' assets should it become necessary when referring debts to the Treasury Department for collection.

Collection of Information

Title: Debt Collection Financial System.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660-0011.

Form Numbers: FEMA Form 22-13, Debt Collection Financial Statement.

Abstract: FEMA may request debtors to provide personal financial information on FEMA Form 22-13 concerning their current financial position. With this information, FEMA evaluates whether to allow debtors to pay the FEMA debts under installment repayment agreements and if so, under

what terms. FEMA also uses this data to determine whether to compromise, suspend, or completely terminate collection efforts on respondent's debts. This data is also used to locate the debtor's assets if the debts are sent for judicial enforcement.

Affected Public: Individuals or Households.

Estimated Total Annual Burden Hours: 750 hours.

ANNUAL HOUR BURDEN

Data collection activity/instrument	Number of respondents (A)	Frequency of responses (B)	Hour burden per response (C)	Annual responses (D) = (A × B)	Total annual burden hours (C × D)
FEMA Form 22-13, Debt Collection Financial Statement ..	1,000	1	.75	1,000	750
Total	1,000	1	.75	1,000	750

Estimated Cost: There are no costs to the respondents resulting from the collection of information since debtor-respondents provide the necessary data either from memory or from their own records that they already maintain. Cost to the respondents for the hour burdens is \$10,597.50.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. Comments must be submitted on or before December 31, 2007.

ADDRESSES: Interested persons should submit written comments to, Office of Management, Records Management Division, Federal Emergency Management Agency, 500 C Street, SW., Room 609, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Michael Komack, Policy Analyst, Financial Policy Branch, Office of the CFO, 202 646-4164 for additional information. You may contact the

Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646-3347 or e-mail address: *FEMA-Information-Collections@dhs.gov*.

Dated: October 23, 2007.

John A. Sharets-Sullivan,
Director, Office of Records Management, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-3279-EM]

California; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of California (FEMA-3279-EM), dated October 23, 2007, and related determinations.

DATES: *Effective Date:* October 24, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the

State of California is hereby amended to include Individual Assistance, limited to the Individuals and Households Program under section 408 of the Stafford Act, 42 U.S.C. 5174 for the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of October 23, 2007.

The counties of Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara, and Ventura for Individual Assistance, limited to the Individuals and Households Program under section 408 of the Stafford Act, 42 U.S.C. 5174, (already designated for emergency protective measures [Category B], including direct Federal assistance, under the Public Assistance program.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,
Administrator, Federal Emergency Management Agency.

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