

average 29.5 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

I. Receipt of Applications

Applications must either be hand delivered or mailed to the address in Section E, The Application Process. The Administration for Native Americans cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ANA electronically will not be accepted regardless of date or time of submission and time of receipt. Videotapes and cassette tapes may not be included as part of a grant application for panel review.

Applications and related materials postmarked after the closing date will be classified as late.

1. Deadlines

- Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, ACYF/Office of Grants Management, 370 L'Enfant Promenade, SW, Mail Stop HHH 326-F, Washington, D.C. 20447-0002. Attention: Lois B. Hodge ANA No. 93612-992.

- Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

- Applications hand carried by applicants, applicant couriers, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date or postmarked on or before the deadline date, Monday through Friday (excluding Federal holidays), between the hours of 8:00 am and 4:30 p.m. at: U.S. Department of Health and Human Services, Administration for Children and Families, ACYF/Office of Grants Management, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, SW, Washington, D.C. 20024. (Applicants are cautioned that express/

overnight mail services do not always deliver as agreed.)

- ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

- No additional material will be accepted, or added to an application, unless it is postmarked by the deadline date.

2. Late applications

Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

3. Extension of deadlines

The Administration for Children and Families may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, or when there is a widespread disruption of the mails. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

(Catalog of Federal Domestic Assistance Program Numbers: 93.612 Native American Programs; and 93.587 Promoting the Survival and Continuing Vitality of Native American languages)

Dated: October 3, 2001.

Gary Mounts,

Acting Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1426]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Emergency Health Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 29, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Emergency Health Surveys

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: (1) Manufacturers to report medical-device-related deaths, serious injuries, and malfunctions; and (2) user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(b)(2) of the act (21 U.S.C. 393(b)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910-0281).

FDA is seeking OMB clearance to collect information via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(b)(2) of the act. Participation in these surveys will be voluntary. This request covers

emergency health surveys for general type medical facilities; specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.); and health professionals, but more typically risk managers working in medical facilities.

FDA will use the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 emergency health surveys per year with a sample of between 50 and 200 respondents per survey.

In the **Federal Register** of August 3, 2000 (65 FR 47734), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	10 (maximum)	2,000	2	4,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency of respondent was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times, depending on the medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, at a maximum it will take 2 hours for a respondent to gather the requested information and fill in the answers.

Dated: October 23, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-70]

Notice of Submission of Proposed Information Collection to OMB; Financial Statement of Corporate Applicant for Cooperative Housing Mortgage

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* November 29, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0058) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne.Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll- (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be

affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Financial Statement of Corporate Applicant for Cooperative Housing Mortgage.

OMB Approval Number: HUD-93232-A.

Description of The Need For The Information and Its Proposed Use: HUD insures mortgages covering property held by a non-profit cooperative ownership housing cooperation. The Department requires information on the applicant's financial and credit history to determine the capability and capacity of the borrower corporation and the individual members to meet the statutory requirement for repayment.

Frequency of Submission: Monthly.

Reporting Burden:

Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
1,500		1		2		3,000