Description: OPR information is collected to provide the Administration for Native Americans with programmatic progress reports on discretionary grant projects to meet ANA's legislatively required evaluation of grantee locally-determined grant objectives. This collection also complies with Department of Health and Human Services regulations and policies requiring grantees to submit progress reports and agencies to perform grant oversight.

The information is collected in a narrative format without the use of a government form. Grantees compose a narrative explaining the status of the funded, grantee-identified project objective(s). Project objectives are listed on an Objective Work Plan (OWP) which is approved and funded for each grant. An enclosure with every grant award provides instructions on completing and submitting the OPR.

Native American Program Specialists use the OPR information to perform legislatively required Federal program oversight such as evaluate project and grantee performance, identify project outcomes suitable for use in program evaluation and Government Performance and Results Act (GPRA) analysis, and to identify grantees and projects that require more detailed Federal training and/or technical assistance. OPRs are used in ANA competitive grant programs such as Social and Economic Development Strategies (SEDS), Native American Languages Preservation, Environmental Regulatory Enhancement, etc.

The Administration for Native Americans simplified the way OPR information is collected. Until June 1999, OPRs were transcribed onto a government designed form where every project objective was listed; grantees often worked to fill in space under each objective to accommodate the volume of information they believed was required. Grantees now use their letterhead and present the level of detail they deem appropriate.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Objective Progress Report (OPR):	300.0	2.0	1.5	900.0

Estimated Total Annual Burden Hours: 900.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

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.

Dated: October 7, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–26727 Filed 10–13–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: Program Narrative Objective Work Plan (OWP).

OMB No.: 0980–0204.

Description: Program Narrative (OWP) information is collected as part of a competitive, discretionary grant application submitted to the Administration for Native Americans (ANA). Included with the OWP are standard, government-wide Federal assistance application forms (e.g., SF–424, 424A, 424B, Non-Constructions Assurances, and various OMB certifications). The OWP provides information used by legislatively mandated project evaluation panels to compete and rank applications. ANA uses the OWP information to perform legislatively mandated project evaluations supporting the basis for recommendations to award or not award ANA grants. After funding, the OWP is used to reflect funded objectives and to administer and monitor ANA grants.

OWP information presents the grant applicants' locally-determined project objectives and plan to achieve those objectives. Economic development projects may attach a business plan. OWP information is presented as narrative and transcribed onto a government form titled, ''ANA Objective Work Plan''. In the past, ANA used two forms to collect the program narrative; i.e., ''Program Narrative Objective Work Plan'' and ''Program Narrative Approach.'' The new, single form combines the two old forms and eliminates some information items.

Instructions for completing the OWP are provided in the ''Administration for Native Americans Application Packet for Financial Assistance.'' Instructions for compiling a complete application are provided in the packet. The OWP and instruction packet are used in all ANA competitive discretionary grant programs such as Social and Economic Development Strategies (SEDS), Native American Languages Preservation, Environmental Regulatory Enhancement, etc.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Program Narrative Objective Work Plan (OWP):	650	1	28	18,200

Estimated Total Annual Burden Hours: 18,200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

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 suggestion submitted within 60 days of this publication.

Dated: October 7, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–26728 Filed 10–13–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4054]

Draft Guidance for Industry on Intraocular Lens; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Intraocular Lens Guidance Document.'' This draft guidance is not final nor is it in effect at this time. This draft guidance describes preclinical and clinical requirements that may be used in support of investigational device exemptions, premarket approval applications, and product development protocols. This draft guidance describes for industry and FDA reviewers the type of information needed to support investigational and marketing applications for intraocular lenses.

DATES: Written comments concerning this guidance must be received by January 12, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Intraocular Lens Guidance Document'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to this draft guidance.

FOR FURTHER INFORMATION CONTACT: Donna R. Lochner, Center for Devices and Radiological Health (HFZ–463), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Intracular Lens Guidance Document.'' This draft guidance provides detailed information about the type of preclinical testing needed to support both a clinical investigation and marketing applications for new intraocular lenses and modifications to intraocular lenses. This draft guidance also provides the basic principles that should be applied in the conduct of a clinical study for new or modified intraocular lenses. Earlier revisions of this draft guidance have been discussed in numerous forums since April of 1997, and industry, clinicians, and other interested parties have participated. These forums have included at least three Ophthalmic Device Panel meetings at which this draft guidance, or parts of the guidance, have been discussed. These Panel discussions began before 1997, and most recently they occurred in October 1997. Both written and verbal comments have been received and discussed thoroughly in these forums.

Although this draft guidance, to a large extent, describes review elements that have been in existence since almost the inception of FDA's review of intraocular lenses, it has been refined and improved through the interactive discussions with the industry, clinicians, panel members, and other interested parties. FDA has made available to all interested parties a summary of all written comments received, and on each version of the guidance FDA has noted the changes from the previous version. This information is available for this most recent release and for previous revisions. Interested persons may obtain this information through the contact person at the address and phone number given above.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on submissions for intraocular lenses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is