requires CSE programs to transmit child support case information on standard interstate forms when referring cases to other states for processing. The forms are expiring and we are taking the opportunity to make small revisions that have been requested by states.

Respondents: State agencies administering the child support enforcement program under title IV–D of the Social Security Act.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal 1	54	19,278	.25	260,253
Transmittal 2	54	14,458	.08	62,459
Transmittal 3	54	964	.08	4,164
Uniform Petition	54	9,639	.08	41,640
General Testimony	54	11,567	.33	206,124
Affidavit—Paternity	54	4,819	.17	44,238
Locate Data Sheet	54	375	.08	1,620
Notice of Controlling Order	54	964	.08	4,164
Registration Statement	54	8,675	.08	37,476

Estimated Total Annual Burden Hours: 662,138

It 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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-Mail address: *rsargis@acf.hhs.gov.* 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: December 10, 2003

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–31380 Filed 12–18–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Administration for Native Americans Consultant and Evaluator Qualifications Form.

OMB No. New Collection.

Description: The Administration for Native Americans (ANA) Consultant and Evaluator Qualifications Form is used to collect information from prospective panel reviewers in compliance with 42 USC Section 2991d–1. The form will allow the Commissioner of ANA to select qualified people to review grant applications for: Social and Economic Development Strategies (SEDS), Language Preservation and Environmental Mitigation. The panel review process is a legislative mandate in the ANA grant funding process.

Respondents are drawn from the public with a legislatively required preference being given to those who are Native American, Native Alaskan, Native Hawaiian and other Pacific Islanders. These project evaluation panels review and rank applications.

Respondents: Tribal members, the public.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Consultant and Evaluator Qualifications Form	300	1	28	8,400

Estimated Total Annual Burden Hours: 8,400

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.* 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: December 15, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–31381 Filed 12–18–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N–1449]

Agency Information Collection Activities; Comment Request; Guidance for Industry—Changes to an Approved New Drug Application or Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in a guidance for industry entitled ''Changes to an Approved NDA or ANDA.''

DATES: Submit written or electronic comments on the collection of information by February 17, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Division of Dockets Management, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry—Changes to an Approved NDA or ANDA (OMB Control Number 0910–0431)—Extension

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pubic Law 105–115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs), to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 116 of the Modernization Act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

The guidance provides recommendations to holders of approved NDAs and ANDAs who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in the following areas: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Some of the basic elements of section 506A of the act are as follows:

A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (sections 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when ''validating the effects of the change'' (section 506A(c)(1) of the act).

A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include the following possibilities: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a