

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response: participants + staff	Total burden hours
Mother/Father Elig. Checklist	96,000	1	0.03 + 0.06	8,640
Consent Form	24,000	1	0.08 + 0.12	4,800
Baseline Info Form	24,000	1	0.25 + 0.33	13,920
Contact Info Form	24,000	1	0.03 + 0.06	2,160

Estimated Total Annual Burden Hours: 29,520.

Additional Information: Copies of the proposed collection may be obtained 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. E-mail address: grjohnson@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: Katherine_T_Astrich@omb.eop.gov.

Dated: December 20, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04-28212 Filed 12-23-04; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families (ACF)

Notice of Public Comment on the Proposed Adoption of ANA Program Policies and Procedures

AGENCY: Administration for Native Americans (ANA).

SUMMARY: Pursuant to section 814 of the Native American Programs Act of 1974; as amended, 42 U.S.C., 2991b-1, the Administration for Native Americans (ANA) herein describes its proposed interpretive rules, general statement of policy and rules of agency procedure or practice in relation to the Social and Economic Development Strategies

(SEDS), Language Preservation and Maintenance (hereinafter referred to as Native Language), and Environmental Regulatory Enhancement (hereinafter referred to as Environmental) programs. Under the statute, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules, statements of general policy, and rule of agency procedure or practice and to give notice of the final adoption of such changes at least 30 days before the changes become effective. The notice also provides additional information about ANA's plan for administering the programs.

DATES: The deadline for receipt of comments is 30 days from date of publication in the **Federal Register**.

ADDRESSES: Comments in response to this notice should be addressed to Sheila Cooper, Director of Programs Operations, Administration for Native Americans, 370 L'Enfant Promenade, SW., Mail Stop: Aerospace 8-West, Washington, DC 20447. Delays may occur in mail delivery to Federal offices; therefore, a copy of comments should be faxed to: (202) 690-7441. Comments will be available for inspection by members of the public at the Administration for Native Americans, Aerospace Center, 901 D Street SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Sheila Cooper, toll free at (877) 922-9262.

SUPPLEMENTARY INFORMATION: Section 814 of the Native American Programs Act of 1974 (the Act), as amended, requires ANA to provide notice of its proposed interpretive rules, statements of policy and rule of agency organization, procedure or practice. These proposed clarifications, modifications and new text will appear in the three ANA FY 2005 program announcements: SEDS, Native Language and Environmental. This notice serves to fulfill this requirement.

Additional Information

I. ANA Application Format

ANA has revised Part Two, "Application Review Criteria" of the FY 2005 Program Announcement, specifically the Application Submission Requirements. Previously, ANA required applicants to include and count the Objective Work Plan (OWP) form (OMB Control Number 0980-0204), and the Federal and non-Federal share line-item budget and budget justification narrative in the page limitation. In FY 2005, ANA has removed the OWP and the line-item budget and budget justification narrative from the page limitation. With the exemption of the OWP and the budget section from the page limitation, ANA has reduced in the FY 2005 program announcements the Application Submission Requirements to 40 pages. The exemption of the OWP and the budget from the page limitation will enable applicants applying for multi-year awards to provide more information on the proposed project. (Legal authority: Section 803 (a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

II. Required Forms

The Grant Application Data Summary (GADS) form (OMB Clearance Number 0970 0261 exp. 03/31/2007) is a new ANA form. The Commissioner for the Administration for Native Americans is required to collect and disseminate information related to the social and economic conditions of Native Americans for inclusion in its annual report to Congress. The data collected on the GADS is required to assist in gathering that data. The information is also used to ensure that ANA obtains the proper number of reviewers to review each category of grant applications. Although not included in prior announcements, GADS received OMB approval after the publication of the FY 2004 announcement. It will be included in this announcement and future announcements to be submitted as a part of the application package.

(Legal authority: Section 803B of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b-2.)

III. Evaluation Criteria

(a) ANA has modified five evaluation criteria titles and adjusted the point values and weight of three criteria. In ANA's FY 2004 grant competitions, ANA did not rate applications on how closely they followed the prescribed format. This year, ANA is proposing to revise the Evaluation Criteria to provide for the award of points in rating applications based on whether the applicant complied with the requirements in the announcement with regard to the organization of the application. ANA will maintain six evaluation criteria and the titles and merit weight apply to all three ANA program areas. Criterion One was retitled from "Project Introduction and Summary/Abstract" to "Introduction and Project Summary/Application Format" and modified to add points for the Application Format to clarify the importance of adhering to the application requirements. Criterion Two was retitled from "Objectives and Need for Assistance" to "Need for Assistance". Criterion Three was retitled for clarity from "Approach" to "Project Approach". Criterion Four was retitled from "Organizational Profiles" to "Organizational Capacity" and the point value was reduced to allow for the increase in weight and points awarded under Criterion One. Criterion Five was retitled for clarity from "Results or Benefits Expected" to "Project Impact/Evaluation" and the point value was reduced to allow for the increase in weight and points awarded under Criterion Six. For FY 2005 program announcements the titles and assigned point criteria values are: Criterion One—Introduction and Project Summary/Application Format (10 pts.); Criterion Two—Need for Assistance (20 pts.); Criterion Three—Project Approach (25 pts.); Criterion Four—Organizational Capacity (15 pts.); Criterion Five—Project Impact/Evaluation (15 pts.); Criterion Six—Budget and Budget Justification/Cost Effectiveness (15 pts.). (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

(b) In the FY 2004 Program Announcement within the ANA Criterion Five, ANA used the term "Performance" Indicator. In the FY 2005 Program Announcement this term will be changed to "Impact" Indicator to be consistent with the Native American Programs Act of 1974, as amended. (Legal authority: Section 803(a) and (d)

and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

(c) Standard and Required Impact Indicators: As ANA continues to improve its competitive grant program ANA has modified (through addition or deletion) its collection of impact indicators under each of its programs (SEDS, Native Language and Environmental). The modified impact indicators will continue to be used to inform Congress and the public on the effectiveness, success and impact that ANA programs have in Native American communities and on behalf of Native American families. Two impact indicators will be required across all three program areas to serve as a common baseline of data that is required to be reported in ANA's legislation to demonstrate the diversity of projects and to monitor the impact of projects on the community. The FY 2005 program announcements still require five impact indicators to be submitted by the applicant under Criterion Five. ANA has standardized for consistency and program performance data collection two of the required impact indicators across all three program areas (SEDS, Native Language and Environmental). The two standard required impact indicators are: (1) number of partnerships formed and (2) the amount of dollars leveraged beyond the required NFS match. In addition to the two standard required impact indicators, an applicant must also submit three additional indicators either selected from a suggested list in each program announcement or applicant project-specific impact indicators. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

The optional impact indicators for SEDS are: (1) Number of infrastructures and administrative systems, including policies and procedures developed and implemented; (2) number of codes or ordinances developed and implemented; (3) number of people to successfully complete a workshop/training; (4) number of children, youth, families or elders assisted or participating; (5) number of volunteer hours; (6) number of faith-based or community-based partnerships; (7) number of jobs created; (8) number of community-based small businesses established or expanded; (9) identification of Tribal or Village government business, industry, energy or financial codes or ordinances that were adopted or enacted; and (10) number of micro-businesses started. The

optional impact indicators for Language, Category I are: (1) Number of surveys completed; (2) percent and number of community members assessed; (3) the rate of language loss or gain; (4) number of elders consulted; (5) number of language experts consulted; (6) number of community goals developed to preserve the native language; and (7) number of infrastructure and administrative systems, including policies and procedures developed and implemented. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

The optional impact indicators for Language, Category II are: (1) Number of people involved in establishment or operation of project; (2) number of training classes or workshops held to teach language; (3) number and type of materials developed; (4) number of media products developed; (5) number of translations achieved; (6) number of individuals who increased in ability to speak the language; (7) number of participants who achieve fluency; (8) number of settings the language is spoken in; and (9) number of infrastructure and administrative systems, including policies and procedures developed and implemented. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

The optional impact indicators for Environmental are: (1) Number of environmental regulations, codes or ordinances created; (2) number of people to successfully complete a workshop/training; (3) number of workshops/trainings provided; (4) types of capacity building systems created and implemented to support environmental program functions; (5) identification of Tribal or Village government regulations, codes or ordinances that were enacted and adopted; (6) number of regulations, codes or ordinances successfully enforced; and (7) number of infrastructure and administrative systems, including policies and procedures developed and implemented. ANA may add/delete optional impact indicators to program announcements as necessary to support ANA initiatives. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

(d) ANA corrected the timeframe for use of research data in an application from 48 to 36 months under the Language, Category II program.

IV. ANA Funding Restrictions

In ANA's effort to streamline its program announcements and to clarify Funding Restriction Policies for applicants, ANA has relocated general policy statements from the criterion section of the program announcement text to the Funding Restrictions Policies section. Formerly listed under "ANA Administrative Policies", the bullet point on funding requests for feasibility studies, business plans, marketing plans or written materials and the bullet point on proposals from consortia of Tribes were moved to the section entitled "ANA Funding Restrictions". These restrictions are already reflected in the ANA eligibility restrictions at 45 CFR 1336.33(b) (2) and (b) (6). The bullet point on the social service delivery programs was inadvertently omitted from previous announcements, but ANA is statutorily required to address these programs. The restriction already appears in the ANA eligibility regulation at 45 CFR 1336.33(b) (3). ANA will include the following funding restrictions in all program announcements in compliance with sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336:

- Projects that request funds for feasibility studies, business plans, marketing plans or written materials, such as manuals, that are not an essential part of the applicant's project or SEDS long-range development plan. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)

- The support of ongoing social service delivery programs or the expansion, or continuation, of existing social service delivery programs. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)

- Proposals from consortia of Tribes that are not specific to support from and roles of member Tribes. An application from a consortium must have goals and objectives that will create positive impacts and outcomes in the communities of its members. ANA will not fund activities by a consortium of Tribes that duplicates activities for which member Tribes also receive funding from ANA. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)

V. Initial Screening

Prior to competitive panel review, all applications are pre-screened for completeness. Previously, each application submitted to ANA in response to a program announcement was pre-screened to ensure that (a) The application was received by the program announcement closing date; (b) the application was submitted in accordance with Section IV, "Application and Submission Information"; (c) the applicant is eligible for funding in accordance with Section III, "Eligibility Information"; (d) the applicant submitted the proper supporting documentation such as proof of non-profit status, resolutions, and required government forms; (e) an authorized representative has signed the application; and (f) the applicant has a DUNS number. An application that does not meet (a) through (f) immediately above is determined to be incomplete and is excluded from the competitive review process.

In an effort to ensure consistency with the way ACF evaluates competitive discretionary grant applications, ACF has changed its policy to include only two enforceable screen-out criteria: timeliness and compliance with stated funding limitations. Additionally, ACF has approved ANA's request to include two additional screen-out criteria: inclusion of a signed and dated resolution by the governing body and, for applicants that are not Tribes or Alaska Native Village governments, submission of a resolution and proof that a majority of the governing board of directors is representative of the community to be served.

Consequently, ANA will screen applications for completeness prior to the competitive panel review using the following elements: (a) The application is received by ANA on or before the published program announcement closing date; (b) the Federal request does not exceed the ceiling award amount as published in the program announcement; (c) the application includes a signed and dated resolution of the governing body; and (d) if the applicant is not a Tribe or Alaska Native village government, the native non-profit organization submits a resolution and proof that a majority of the governing board of directors is representative of the community to be served. An application that does not contain these elements will be considered incomplete and excluded from the competitive review process.

VI. Administrative Policies

In ANA's effort to streamline its program announcements and to clarify administrative policies for applicants, ANA has relocated general policy statements from the Criterion section of the program announcement text to the Administrative Policies section. ANA has also clarified administrative policies that have historically prompted numerous questions and created application and project development inconsistencies. For example, ANA removed "Organizational Capacity" and reworded the first bullet below for clarity. The second bullet below clarifies the administrative policy on the funding of projects versus programs to include the term "short-term" to communicate that projects will not be awarded for longer than three years in most program areas. The third and fourth bullets were moved from Definitions to Administrative Policies to establish the policy to determine project progress before additional funding is committed. For the purposes of clarity, the fifth bullet combined and reworded the requirement for community involvement under the definition for "Community Involvement" with a similar paragraph under "Need for Assistance". The sixth bullet supports the needs of ANA and was reworded for clarity. The seventh bullet was also reworded for clarity. The policy on the treatment of multiple applications and applications from Tribal components has been reworded for clarity and broken into two separate points to ensure application to both Tribes and non-profit organizations. The revised policy is contained in the eighth and ninth bullet points of the list below. The ninth bullet corrects the inadvertent omission of the categories that apply to the board of directors for non-profit applicants. ANA will now include the following administrative policies in each program announcement (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, and 45 U.S.C. 2991b and 2991b-3):

Applicants must comply with the following administrative policies:

- All funded applications will be reviewed to ensure that the applicant has provided a positive statement to give credit to ANA on all material developed using ANA funds.

- ANA funds short-term projects, not programs. Proposed projects must have definitive goals and objectives that will be achieved by the end of the project period. All projects funded by ANA must be completed, or self-sustaining or

supported by other-than-ANA funding at the end of the project period.

- Before funding the second or third year of a multi-year grant, ANA will require verification and support documentation from the grantee that objectives and outcomes proposed in the preceding year were accomplished and that the non-Federal share was met.

- ANA reviews the quarterly and annual reports of grantees to determine if the grantee is meeting its goals, objectives and activities identified in the Objective Work Plan (OWP).

- Applications from national and regional organizations must clearly demonstrate a need for the project, explain how the project originated, discuss the community-based delivery strategy of the project, identify and describe the intended beneficiaries, describe and relate the actual project benefits to the community and organization and describe a community-based delivery system. National and regional organizations must describe their membership, define how the organization operates and demonstrate Native community and/or Tribal government support for the project. The type of community to be served will determine the type of documentation necessary to support the project.

- Applicants proposing an Economic Development project must address the project's viability. A business plan, if applicable, must be included to describe the project's feasibility, cash flow and approach for the implementation and marketing of the business.

- ANA will review proposed projects to ensure applicants have considered all resources available to the community to support the project.

- ANA will not accept applications from Tribal components that are Tribally authorized divisions unless the ANA application includes a Tribal resolution.

- ANA will only accept one application per eligible entity. The first application received by ANA will be the application considered for competition unless ANA is notified in writing which application should be considered for competitive review.

- If the applicant, other than a Tribe or an Alaska Native Village government, is proposing a project benefiting Native Americans, Alaska Natives, or both, the applicant must provide assurance that its duly elected or appointed board of directors is representative of the community to be served. Applicants must provide information that at least a majority of the individuals serving on a non-profit applicant's board fall into one or more of the following categories: (1) A current or past member of the

community to be served; (2) a prospective participant or beneficiary of the project to be funded; or (3) have a cultural relationship with the community to be served. (Legal authority: 45 CFR 1336.33(a).)

VII. Funding Thresholds

This is a clarification to the ANA Environmental Regulatory Enhancement program announcement funding threshold. The funding threshold for the Environmental Regulatory Enhancement program will be \$50,000.00 (floor amount) to \$250,000.00 (ceiling amount) per budget period. Applications exceeding the \$250,000.00 threshold will be considered non-responsive and will not be considered for funding under this announcement. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

VIII. Definitions

The following definitions will be used in the appropriate program-specific FY 2005 program announcements. ANA has clarified many areas that applicants have historically found difficult to understand and that have previously prompted numerous questions and created application and project development inconsistencies. The ANA program announcements will now include additional definitions for the following terms:

Consortium/Tribal Village: A group of Tribes or Villages that join together for long-term purposes or for the purpose of an ANA grant.

Impact Indicators: Measurement descriptions used to identify the outcomes or results of the project. Outcomes or results must be quantifiable, measurable, verifiable and related to the outcome of the project to determine that the project has achieved its desired objective and can be independently verified through ANA monitoring and evaluation.

Objective Work Plan (OWP): The project plan the applicant will use in meeting the results and benefits expected for the project. The results and benefits are directly related to the Impact Indicators. The OWP provides detailed descriptions of how, when, where, by whom and why activities are proposed for the project and is complemented and condensed in the OWP. ANA will require separate OWPs for each year of the project. (Form OMB# 0980-0204 exp 10/31/2006.)

Minor Renovation or Alteration: Work required to change the interior arrangements or other physical characteristics of an existing facility, or

install equipment so that it may be more effectively used for the project. Minor alteration and renovation may include work referred to as improvements, conversion, rehabilitation, remodeling or modernization, but is distinguished from construction and major renovations. A minor alteration and/or renovation must be incidental and essential for the project ("incidental" meaning the total alteration and renovation budget must not exceed the lesser of \$150,000 or 25 percent of total direct costs approved for the entire project period).

Total Approved Project Costs: The sum of the Federal request plus the non-Federal share. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

IX. Application Review Information

To ensure that grantees fulfill their obligations to ANA, ANA is including a review of grantees' past performance when considering the applicant for a new or ongoing award under all three program areas. The inclusion of this item in the application consideration process will assist ANA in making its funding decisions on whether or not to award to a particular grant applicant. Factors that may impact a grantee's past performance are their timeliness to report submission requirements, timely use and proper expenditure of the grant award funds and the administrative ease of closing out the grantee at the end of the award period.

The following statement is included under the Application Consideration for the Review and Selection Process:

Application Consideration: The Commissioner's funding decision is based on an analysis of the application by the review panel, panel review scores and recommendations; an analysis by ANA staff; review of previous ANA grantee's past performance; comments from State and Federal agencies having contract and grant performance-related information; and other interested parties.

X. Native Language Program Area

The title for Native Language Category I grants has been changed from "Native Language Category I Planning" to "Native Language Category I Assessment". The change clarifies the purpose of the 12-month Category I grant. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

The FY 2005 Native Language Program Announcement expands the Category I—Program Area of Interest and the necessary assessment data to be collected. ANA recommends each applicant consider the Program Area of Interest in the development of a project. The Program Area of Interest under Category I is “A project for data collection and compilation that surveys the current language status through a “formal” method (e.g., work performed by a linguist and/or a language survey conducted by community members) or an “informal” method (e.g., a community consensus of the language status based on elders, Tribal scholars and/or other community members) with the development of long-range language preservation goals and uses elders in the development of these goals. This assessment data should capture, at a minimum, the following data: number of speakers; age of speakers; gender of speakers; level(s) of fluency; number of first language speakers (native language as the first language acquired); number of second language speakers (native language as the second language acquired); where native language is used (e.g., home, court system, religious ceremonies, church, media, school, governance or cultural activities); source of data (formal and/or informal); and rate of language loss or gain. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3.)

Dated: December 17, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans

[FR Doc. 04–28216 Filed 12–23–04; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0497]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Pharmacogenomics Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Industry on Pharmacogenomics Data Submissions” has been approved by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of August 11, 2004 (69 FR 48876), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0557. The approval expires on December 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28134 Filed 12–23–04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0166]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Feeding Practices Study II

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Infant Feeding Practices Study II” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 1, 2004 (69 FR 58915), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0558. The approval expires on December 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28136 Filed 12–23–04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0541]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exports; Notification and Recordkeeping Requirements

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 notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

DATES: Submit written or electronic comments on the collection of information by February 25, 2005.

ADDRESSES: Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments 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:

Jonna Capezuto, Office of Management Programs (HFA–250), Food and Drug