

Type of respondents	Number of respondents	Number of responses per respondent	Average burden (in hrs)	Total burden (in hrs)
NBCCEDP grantee .....	68	1	22	1,496

Dated: October 30, 2008.  
**Maryam I. Daneshvar,**  
*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Objective Work Plan (OWP), Objective Progress Report (OPR) and Project Abstract.

*OMB No.:* 0980-0204.

*Description:* Content changes are being made to the OPR ONLY. The information in the OPR is being collected on a quarterly basis to monitor the performance of grantees and better gauge grantee progress. The standardized format will allow ANA to

report results across all its program areas and flag grantees that may need additional training and/or technical assistance to successfully implement their projects.

Following are content changes being made within specific sections of the OPR form:

*OBJECTIVE WORK PLAN UPDATE Section:* Adding 1st through 4th Quarter (Q1,Q2,Q3,Q4) results for Activities within each Objective. The grantee can continue to add to this form each quarter (rather than on to a new form), reflecting cumulative results throughout the project period rather than just the quarter.

*FINANCIAL Section:* Add 2 Questions: (1) Provide details on any income generated as a result of ANA project activities; (2) Provide details on any changes made to the budget during the reporting period.

*NATIVE AMERICAN YOUTH AND ELDER OPPORTUNITIES Section:* Add Question: (1) Request details on any intergenerational activities between grandparents and their grandchildren.

*Finally, add a new section (last section) to the form:* PROJECT SUSTAINABILITY: (1) Request details on the grantee's intention to continue the project benefits and/or services after the project period has ended.

End of Content Changes to the OPR. No changes are being made to the OWP or to the Project Abstract (below).

The information collected by the OWP is needed to properly administer and monitor the Administration for Native Americans (ANA) programs within the Administration for Children and Families (ACF). The OWP assists applicants in describing their projects' objectives and activities, and also assists independent panel reviewers, ANA staff and the ANA Commissioner during the review and funding decision process.

The Project Abstract provides crucial information in a concise format that is utilized by applicants, independent reviewers, ANA staff and the ANA Commissioner.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities

*Annual Burden Estimates.*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP .....	500	1	3	1,500
OPR .....	275	4	1	1,100
Project Abstract .....	500	1	0.50	250

*Estimated Total Annual Burden Hours:* 2,850.

In compliance with the requirements of Section 506(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: [infocollection@acf.hhs.gov](mailto:infocollection@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: November 3, 2008.

**Janean Chambers,**  
*Reports Clearance Officer.*  
 [FR Doc. E8-26519 Filed 11-5-08; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Notice of Partially Closed Meeting; National Commission on Children and Disasters**

**AGENCY:** Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**DATES:** The open session of the meeting will be held on Thursday, November 20, 2008, from 10:45 a.m. to 5:30 p.m. and Friday, November 21, 2008, from 8:30 a.m. to 1:30 p.m. The closed session of the meeting will be held on Thursday, November 20, 2008, from 8:30 a.m. to 10:30 a.m. The portion of the meeting that will be closed to the public shall be

so in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended.

**ADDRESSES:** The meeting will be held at the Administration for Children and Families, 901 D Street, SW., Washington, DC 20447. Seating is limited. To attend, please register by 5 p.m. EST, November 17, 2008. To register, please e-mail [carol.apelt@acf.hhs.gov](mailto:carol.apelt@acf.hhs.gov) with "Meeting Registration" in the subject line, or call Carol Apelt at (202) 205-4618. Registration must include your name, affiliation, and phone number. If you require a sign language interpreter or other special assistance, please contact Carol Apelt as soon as possible and no later than 5 p.m. EST, November 14, 2008.

*Agenda:* As pertaining to man-made and natural disaster situations, the Commission will hear presentations on and discuss: (1) Medical countermeasures; (2) case management; (3) shelter design and transition to permanent housing; (4) acute medical care; (5) other matters as may reasonably come before the Commission and plans for future work of the Commission.

*Additional Information:* Contact Roberta Lavin, Office of Human Services Emergency Preparedness and Response, e-mail [roberta.lavin@acf.hhs.gov](mailto:roberta.lavin@acf.hhs.gov) or (202) 401-9306.

**SUPPLEMENTARY INFORMATION:** The National Commission on Children and Disasters is an independent Presidential Commission that shall independently conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission shall then submit a report to the President and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies.

Dated: October 31, 2008.

**Daniel C. Schneider,**

*Acting Assistant Secretary for Children and Families.*

[FR Doc. E8-26418 Filed 11-5-08; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0567]

#### Designating Additions to the Current List of Tropical Diseases in the Food and Drug Administration Amendments Act; Public Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on adding additional diseases to the list of tropical diseases recognized under the Food and Drug Administration Amendments Act (FDAAA), which adds a new section to the Federal Food, Drug, and Cosmetic Act (the act). The new section authorizes FDA to award priority review vouchers to sponsors of certain tropical disease product applications that meet the criteria specified by the act. The new section lists diseases considered to be "tropical diseases" for the purposes of this legislation, and provides for expansion of the list to include diseases meeting certain criteria. This public meeting is being held to obtain comments from the public on the criteria that should be used to determine whether an infectious disease should be added to the list, and to elicit suggestions for adding specific diseases.

**DATES:** The public hearing will be held on December 12, 2008, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early. Submit written or electronic requests for oral presentations and comments by November 17, 2008. Written or electronic comments will be accepted after the hearing until February 6, 2009.

**ADDRESSES:** The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center at 429 L'Enfant Plaza, SW, Washington, DC 20594. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the hearing.

**FOR FURTHER INFORMATION CONTACT:** Jeff O'Neill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-0777, FAX: 301-847-8753, e-mail: [jeff.o'neill@fda.hhs.gov](mailto:jeff.o'neill@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The new section, section 524 of the act (21 U.S.C. 360n), is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Section 524 provides a means by which the holder of an application for a tropical disease product may be eligible to receive a priority review voucher upon approval of that application. This voucher entitles the sponsor to be granted a priority review for a subsequent application of a drug or biologic, submitted under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (42 U.S.C. 262), of the sponsor's choosing that would not otherwise be eligible for a priority review. FDA is committed to a goal of reviewing and taking an action within 6 months of receipt on 90% of applications that have been granted a priority review (see <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>).

To be granted a priority review voucher, the tropical disease application must meet all of the following criteria:

- The application must be a human drug application as defined in section 735(1) of the act (21 U.S.C. 379g(1)).
- The application must be for the prevention or treatment of a tropical disease.
- The tropical disease application must be eligible for priority review.
- The tropical disease application must be for "a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health service Act."

After being granted a priority review voucher, the owner of the voucher may transfer it to another sponsor. The sponsor intending to redeem a priority review voucher must notify the agency at least 365 days prior to submission of the application for which the voucher is to be redeemed. This notification constitutes a legally binding agreement to pay a supplemental user fee that is mandated by the act to be applied to an application using a priority review voucher.