

(3) conduct and assist in research and control activities related to injury.

Matters to be Discussed: The BSC, NCIPC will discuss the recommendations provided by the expert panel on the Research Portfolio Reviews that have been conducted and to discuss research strategies needed to guide the Center's focus. There will be 15 minutes allotted for public comments at the end of the open session.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Dr. Arlene Greenspan, Designated Federal Officer, NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F-63, Atlanta, Georgia 30341, Telephone (770) 488-1430.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-2818 Filed 2-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Plan for States/Territories for FFY 2012-2013 (ACF-118).

OMB No.: 0970-0114.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101-508, Public Law 104-193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF-118, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the States' and Territories' child care programs. The ACF-118 is currently approved through April 30, 2012, making it available to States and Territories needing to submit Plan Amendments through the end of the FY 2011 Plan Period. However, on July 1,

2011, States and Territories will be required to submit their FY 2012-2013 Plans for approval by September 30, 2011. Consistent with the statute and regulations, ACF requests revision of the ACF-118 with minor corrections and modifications.

The Office of Child Care (OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB). The Tribal Plan (ACF-118a) will be addressed under a separate notice.

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

RESPONDENTS ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-118	56	0.50	162.50	4,550

Estimated Total Annual Burden Hours: 4,550.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: infocollection@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, Fax: 202-395-7285.

E-mail:

OIRA_SUBMISSION@OMB.EOP.GOV.

Attn: Desk Officer for the Administration for Children and Families.

Dated: February 2, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-2799 Filed 2-8-11; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Tribal Plan Preprint—ACF-118-A.

OMB No.: 0970-0198.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for Tribes (Indian Tribes, Tribal consortia and Tribal organizations) is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101-508, Pub. L. 104-193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF 118-A, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the Tribal child care program. The ACF 118-A is currently approved through September 30, 2011, making it available to Tribes needing to submit Plan Amendments through the end of the FY 2011 Plan Period. However, on July 1, 2011, Tribes will be required to submit their FY 2012-2013 Plans for approval by

September 30, 2011. Consistent with the statute and regulations, ACF requests revision of the ACF 118-A with minor corrections and modifications.

The Office of Child Care (OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The

revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	257	0.5	120	15,420
Estimated Total Annual Burden Hours				15,420

Additional Information:

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: infocollection@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, Fax: 202-395-7285, E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 2, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-2798 Filed 2-8-11; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-P-0394] (formerly Docket No. 2005P-0168)

Determination That DECASPRAY (Dexamethasone) Topical Aerosol, 0.04%, and AEROSEB-DEX (Dexamethasone) Topical Aerosol, 0.01%, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, and AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dexamethasone topical aerosol, 0.04% and 0.01%, if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for dexamethasone topical aerosol, 0.04% and 0.01%, future applicants are advised that they may not be able to obtain DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, or AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, for bioequivalence testing because the products have not been commercially available for a number of years. An ANDA applicant who is unable to obtain DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, or AEROSEB-DEX (dexamethasone) Topical Aerosol,

0.01%, for bioequivalence testing should contact the Office of Generic Drugs for a determination of what is necessary to show bioavailability and same therapeutic effect.

FOR FURTHER INFORMATION CONTACT:

Janice Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or