DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Emergency Contingency Fund for Temporary Assistance for Needy Families (TANF) Programs OFA–100.

OMB No.: 0970–0366.

Description

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Recovery Act), which establishes the Emergency Contingency Fund for State TANF Programs (Emergency Fund) as section 403(c) of the Social Security Act (the Act). This legislation provides up to $5 billion to help States, Territories, and Tribes in fiscal year (FY) 2009 and FY 2010 that have an increase in assistance caseloads and basic assistance expenditures, or in expenditures related to short-term benefits or subsidized employment. The Recovery Act made additional changes to TANF extending supplemental grants through FY 2010, expanding flexibility in the use of TANF funds carried over from one fiscal year to the next, and adding a hold-harmless provision to the caseload reduction credit for States and Territories serving more TANF families.

The Emergency Fund is intended to build upon and renew the principles of work and responsibility that underlie successful welfare reform initiatives. The Emergency Fund provides resources to States, Territories, and Tribes to support work and families during this difficult economic period.

On July 20, 2009 we issued a Program Instruction accompanied by the Emergency Fund Request Form (OFA–100), and instructions for jurisdictions to complete the OFA–100 to apply for emergency funds.

Failure to collect this data would compromise ACF's ability to monitor caseload and expenditure data that must increase in order for jurisdictions to receive awards under the Emergency Fund.

Documentation maintenance on financial reporting for the Emergency Fund is governed by 45 CFR 92.20 and 45 CFR 92.42.

ACF is planning to extend the information collection with the adjustment to the Estimated Annual Burden shown in the table below. Based on our projections for a lower Estimated Annual Burden, we have revised the Number of Responses per Respondent to 1 from its previous number of 5. Because the Number of Responses per Respondent has been revised, the Estimated Total Burden Hours is now 2,232, down from its previous number of 11,160.

Respondents

State, Territory, and Tribal agencies administering the Temporary Assistance for Needy Families (TANF) Program that are applying for the Emergency Fund.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF Emergency Fund Request Form, OFA–100	93	1	24	2,232

Estimated Total Annual Burden Hours: 2,232.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–3873 Filed 2–17–12; 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 Projects

Title: TANF Quarterly Financial Report, ACF–196.

OMB No.: 0970–0247.

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for renewal of approval to use the Administration for Children and Families' (ACF) 196 form for periodic financial reporting under the Temporary Assistance for Needy Families (TANF) program. Approval of this information collection expires on April 30, 2012. States participating in the TANF program are required by statute to report financial data on a quarterly basis. This form meets the legal standard and provides essential data on the use of Federal funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions required by Congress. Financial reporting under the TANF program is governed by 45 CFR part 265.

Respondents: TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196T	51	4	2	408
ACF–196	51	4	8	1,632

Estimated Total Annual Burden Hours: 2,040.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–3895 Filed 2–17–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0170]

Determination That REQUIP XL (Ropinerole Hydrochloride) Extended-Release Tablets, 3 Milligrams, 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 REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ropinerole hydrochloride extended-release tablets, 3 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6370, 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 (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 suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are the subject of NDA 22–008, held by GlaxoSmithKline, and initially approved on June 13, 2008. REQUIP XL is indicated for the treatment of treatment of signs and symptoms of idiopathic Parkinson's disease.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. GlaxoSmithKline has never marketed REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 1, 2009 (Docket No. FDA–2009–P–0170), under 21 CFR 10.30, requesting that the Agency determine whether REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were withdrawn from sale for reasons of safety or effectiveness.