

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity, Comment Request

Proposed Project

Title: State Abstinence Education Program.

OMB No.: 0970-0381.

Description: Section 215 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) 42 U.S.C. 1305 extended funding through FY 2017 for the State Abstinence Program.

The Family and Youth Services Bureau (FYSB) is accepting applications

from States and Territories for the development and implementation of the State Abstinence Program. The purpose of this program is to support decisions to abstain from sexual activity by providing abstinence programming as defined by Section 510(b) of the Social Security Act (42 U.S.C. 710(b)) with a focus on those groups that are most likely to bear children out-of-wedlock, such as youth in or aging out of foster care and other vulnerable populations.

States are encouraged to develop flexible, medically accurate and effective abstinence-based plans responsive to their specific needs and inclusive of vulnerable populations. These plans must provide abstinence education, and at the option of the State, where appropriate, mentoring, counseling, and adult supervision to

promote abstinence from sexual activity, with a focus on those groups which are most likely to bear children out-of-wedlock. An expected outcome for all programs is to promote abstinence from sexual activity.

OMB approval is requested to solicit comments from the public on paperwork reduction as it relates to ACYF's receipt of the following documents from applicants and awardees:

State Plan.

Performance Progress Report.

Respondents: 50 States and 9 Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands and Palau.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Plan	59	1	40	2,360
Performance Progress Reports	59	2	30	3,540

Estimated Total Annual Burden Hours: 5,900.

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: Reports Clearance Officer, email address: infocollection@acf.hhs.gov. All request should be identified by the title of the information collection.

The Department specifically request 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 agencies estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden information to be collected; and (e) 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Bioequivalence Recommendations for Risperidone; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry on generic risperidone injection, entitled "Bioequivalence Recommendations for Risperidone." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for risperidone injection.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 31, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.