DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Extension to HS Transportation Requirement.

OMB No.: 0970–0260.

Description: The Office of Head Start is proposing to renew authority to collect information regarding the Head Start transportation requirement without changes. The transportation requirement provides the requirement that each child be seated in a child restraint system while the vehicle is in motion, and the requirement that each bus have at least one bus monitor on board at all times. Waivers would be granted when the Head Start or Early Head Start grantee demonstrates that compliance with the requirement(s) for which the waiver is being sought will result in a significant disruption to the Head Start program or the Early Head Start program and that waiving the requirement(s) is in the best interest of the children involved.

Respondents: Head Start and Early Head Start program grants recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form	1,670	1	1	1,670

Estimated Total Annual Burden Hours: 1,670.

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*. 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: January 5, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–98 Filed 1–7–09; 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: Cross-Site Evaluation of the Infant Adoption Awareness Training Program for Projects Initially Funded in Fiscal Year 2006–NEW.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Childrens Bureau (CB), will conduct the Cross-Site Evaluation of the Infant Adoption Awareness Training Program (IAATP). Title XII, Subtitle A, of the Childrens Health Act of 2000 (CHA) authorizes the Department of Health and Human Services to make Infant Adoption Awareness Training grants available to national, regional, and local adoption organizations for the purposes of developing and implementing programs that train the staff of public and non-profit private health service organizations to provide adoption information and referrals to pregnant women on an equal basis with all other courses of action included in non-directive counseling of pregnant women. Participants in the training include individuals who provide pregnancy or adoption information and those who will provide such services after receiving the training, with Title X (relating to voluntary family planning projects), Section 330 (relating to community health centers, migrant health centers, and centers serving homeless individuals and residents of public housing), and CHA-funded school-based health centers, receiving priority to receive the training. A total of six organizations were awarded IAATP funding in 2006.

Section 1201(a)(2)(A) of the IAATP legislation requires grantees to develop and deliver trainings that are consistent with the Best Practice Guidelines for Infant Adoption Awareness Training. The IAATP guidelines address training goals, basic skills, curriculum and training structure. A complete description of the guidelines is available at *http://www.acf.hhs.gov/programs/cb/programs_fund/discretionary/iaatp.htm.*

In addition, grantees are required to conduct local evaluation of program outcomes and participate in the national evaluation of the extent to which IAATP training objectives are met. The Infant Adoption Awareness Training Program: Trainee Survey is the primary data collection instrument for the national cross-site evaluation. Respondents will complete the survey prior to receiving training and approximately 90 days after the training to assess the extent to which trainees demonstrate sustained gains in their knowledge about adoption, and to determine the impact of the training on their subsequent work with pregnant women.

1. Do health care workers who participate in the IAATP training: Demonstrate enhanced knowledge, attitudes, skills, and behaviors with respect to adoption counseling following completion of the program? Provide adoption information to pregnant women on an equal basis with other pregnancy planning options? Demonstrate enhanced awareness of community adoption-related resources and refer expectant mothers to them as needed?

2. Are trainees more confident about discussing all three pregnancy planning options (parenting, abortion, and adoption) in a non-directive counseling

style than they were prior to participating in the training? Cross-site evaluation data will be collected on an annual basis throughout the five-year funding period. Pre-test and follow-up versions of the survey are expected to require approximately 10 to 15 minutes to complete. Estimated response time for the follow-up survey includes time for respondents to access the Web-based survey, complete the survey online, and electronically submit the survey. Respondents will not need to implement a recordkeeping system or compile source data in order to complete the survey. Where possible, fields in the follow-up version of the survey will be pre-filled with static data from the respondents pre-test (*e.g.*, demographics, agency type) in order to further expedite completion of the survey and minimize respondent burden.

Respondents: Infant Adoption Awareness Program Trainees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IAATP: Trainee Survey Pre-Test Administration	1,200	1	0.15	180
IAATP: Trainee Survey Follow-Up Administration	1,200	1	0.10	120

Estimated Total Annual Burden Hours: 300.

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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: October 1, 2008.

Janean Chambers,

Reports Clearance Officer.

Editorial Note: This document was received at the Office of the Federal Register on January 5, 2009.

[FR Doc. E9–100 Filed 1–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0464] (formerly Docket No. 2005N–0403)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 9, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(OMB Control Number 0910–0045—Amendment)

Description of Respondents: Respondents to this collection of information are foreign and domestic owners and operators of establishments that engage in the manufacture, preparation, propagation, compounding, or processing (which includes, among other things, repackaging and relabeling) of a drug or drugs[1] and that are not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act (the act) or subpart B of part 207 (21 CFR part 207) (registrants).

A. Reporting Burden

The draft guidance describes how to electronically create and submit Structured Product Labeling (SPL) files using defined code sets and codes for establishment registration and drug listing information (including labeling). Most information is already required to be submitted under section 510 of the act, section 351 of the Public Health Service Act, and part 207.

Drug establishment registration and drug listing information and updates to such information, required under part 207, and certain additional recommended information are currently submitted in paper form using Form FDA 2656 (Registration of Drug

[1] Means both human, including biological products, and animal drugs.