

programs provide to enrolled children and their families.

Respondents: Head Start and Early Head Start grantees.

Annual Burden Estimates

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Standard | 2590 | 16 | 41.8 | 1,732,192 |

Estimated Total Annual Burden Hours: 1,732,192.

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: rsargis@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, Attn: Desk Officer for ACF, e-mail address: lauren_wittenberg@omb.eop.gov.

Dated: August 4, 2003.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Family and Child Experience Survey (FACES) and Quality Research Centers.

OMB No.: Revision of a currently approved collection (OMB No. 0970-0151).

Description: The Administration for Children and Families (AFC) of the Department of Health and Human Services is requesting comments on plans to collect data on a new cohort for the Head Start Family and Child Experience Survey (FACES). This study is being conducted under contract with Westat, Inc. (with Xtria, LCC and The CDM Group as their subcontractors) (contract #GS23F8144H; order #03Y00318101D) to collect information on Head Start performance measures.

FACES will involve four waves of data collection. The first wave will occur in Fall 2003. Data will be collected on a sample of approximately 2,721 children and families from about 378 classrooms across 66 programs. Data collection will include assessments of Head Start children, interviews with their parents, and ratings by their Head Start teachers. Further, site visitors will interview Head Start teachers and make observations of the types and quality of classroom activities.

The second wave, which will be a repeat of the Fall 2003 data collection, will occur in Spring 2004 when the sample children are at the end of their first year of Head Start.

The third wave will occur in Spring 2005, and will involve follow-up with children who at this time are either completing a second year in Head Start, or completing kindergarten. For those children who are still attending Head Start, data collection will follow the same procedures as in Spring 2004. For those children attending kindergarten, data collection will include assessments of Head Start children, an "update" survey of the information collected from

the parent interview, and ratings of the children's academic progress and school adjustment by kindergarten teachers.

The fourth wave of data collection will occur in Spring 2006. Children who attended kindergarten the previous year will not be included in this wave. The procedures for this effort will be the same as for kindergartners in Spring 2005.

For the Head Start Quality Centers, 100 children in eight sites will be followed during each of two program years, 2003-2004 and 2004-2005. FACES procedures will be carried out, including child assessments, parent and teacher interviews, and observations of types and quality of classroom activities.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures, and by the 1994 reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649(d)), which requires periodic assessments of Head Start's quality and effectiveness.

Respondents: Federal Government, Individuals or Households, and Not-for-profit institutions.

Annual Burden Estimates:

ESTIMATED RESPONSE BURDEN FOR RESPONDENTS TO THE HEAD START FAMILY AND CHILD EXPERIENCE SURVEY (FACES 2003)—FALL 2003, SPRING 2004, SPRING 2005, SPRING 2006

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Year 1 (2003): | | | | |
| Head Start Parent Interview | 2,721 | 1 | 1.00 | 2,721 |
| Head Start Child Assessment | 2,721 | 1 | 0.66 | 1,796 |
| Teacher Child Rating | 378 | 7 | 0.25 | 662 |
| Program Director Interview | 66 | 1 | 1.00 | 66 |
| Center Director Interview | 171 | 1 | 1.00 | 171 |

ESTIMATED RESPONSE BURDEN FOR RESPONDENTS TO THE HEAD START FAMILY AND CHILD EXPERIENCE SURVEY (FACES 2003)—FALL 2003, SPRING 2004, SPRING 2005, SPRING 2006—Continued

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Education Coordinator Interview | 171 | 1 | 0.75 | 128 |
| Teacher Interview | 378 | 1 | 1.00 | 378 |
| Year 2 (2004): | | | | |
| Head Start Parent Interview | 2,313 | 1 | 0.75 | 1,735 |
| Head Start Child Assessment | 2,313 | 1 | 0.66 | 1,527 |
| Teacher Child Rating | 378 | 6 | 0.25 | 567 |
| Family Service Coordinator Interview | 171 | 1 | 0.75 | 128 |
| Year 3 (2005): | | | | |
| Head Start Parent Interview | 818 | 1 | 0.75 | 614 |
| Head Start Child Assessment | 818 | 1 | 0.66 | 540 |
| Teacher Child Rating | 121 | 7 | 0.25 | 212 |
| Kindergarten Parent Interview | 1,082 | 1 | 0.75 | 812 |
| Kindergarten Child Assessment | 1,082 | 1 | 0.75 | 812 |
| Kindergarten Teacher Questionnaire | 1,082 | 1 | 0.50 | 541 |
| Year 4 (2006): | | | | |
| Kindergarten Parent Interview | 695 | 1 | 0.75 | 521 |
| Kindergarten Child Assessment | 695 | 1 | 0.75 | 521 |
| Kindergarten Teacher Questionnaire | 695 | 1 | 0.50 | 348 |

Estimated Total Burden Hours (FACES): 14,800.

ESTIMATED RESPONSE BURDEN FOR RESPONDENTS TO THE HEAD START QUALITY RESEARCH CENTERS (FACES QRC 2003)—FALL 2003, SPRING 2004, FALL 2004, SPRING 2005

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Year 1 (2003): | | | | |
| Head Start Parent Interview | 800 | 1 | 1.00 | 800 |
| Head Start Child Assessment | 800 | 1 | 0.66 | 528 |
| Teacher Child Rating | 80 | 10 | 0.25 | 200 |
| Teacher Interview | 80 | 1 | 1.00 | 80 |
| Year 2 (2004): | | | | |
| Head Start Parent Interview | 1,480 | 1 | 1.00 | 1,480 |
| Head Start Child Assessment | 1,480 | 1 | 0.66 | 977 |
| Teacher Child Rating | 160 | 8 | 0.25 | 320 |
| Year 3 (2005): | | | | |
| Head Start Parent Interview | 680 | 1 | 1.00 | 680 |
| Head Start Child Assessment | 680 | 1 | 0.66 | 449 |
| Teacher Child Rating | 180 | 6 | 0.25 | 270 |

Estimated Total Burden Hours (QRC): 5,784.

Estimated Annualized Burden for both FACES and Quality Research Centers is 6861 hours. This annual burden was calculated by dividing total burden hours by three years.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: rsargis@acf.hhs.gov.

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Dated: August 4, 2003.
Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N-0417]

Agency Information Collection Activities; Announcement of OMB Approval; Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

AGENCY: Food and Drug Administration, HHS.