

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](mailto: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, Washington, DC, Attn: Desk Officer for ACF, e-mail address: [lauren\\_wittenberg@omb.eop.gov](mailto:lauren_wittenberg@omb.eop.gov).

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.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "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" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 18, 2003 (68 FR 36676), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0513. The approval expires on July 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 4, 2003.  
**Jeffrey Shuren,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 03-20199 Filed 8-7-03; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 1993P-0174]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

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

**DATES:** Submit written comments on the collection of information by September 8, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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.

**Waiver From Labeling Requirements for New Animal Drugs Intended for Use in Liquid Medicated Animal Feed**

Proposed § 558.5(i) specifies procedures for obtaining a waiver from labeling requirements for certain drugs intended for use in animal feed or drinking water but not approved for use in liquid medicated feed. The request for waiver must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the product are such that diversion to use in liquid medicated feeds is unlikely. This information would be collected if the manufacturer or sponsor chose not to include the required warning "FOR USE IN \_\_\_\_\_ ONLY, NOT FOR USE IN LIQUID MEDICATED FEEDS" on its product label. The sponsor or manufacturers would then need to satisfy the requirements of the waiver section of the regulation. All other data collections are covered under OMB control number 0910-0032.

Medicated feed manufacturing facilities and sponsors of new animal drugs used in the manufacture of medicated feed.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Proposed 21 CFR Section	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
558.5(i)	1	1	1	5	5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived from data by our Division of Animal Feeds, Center for Veterinary Medicine, FDA. Only one respondent was used in these figures because although this particular waiver has been part of the regulations since 1973, it has never been utilized. We estimated it would take 5 hours to compile the required information because of the time necessary to explain why the drug would not be diverted to use in liquid feed.

Dated: August 4, 2003.  
**Jeffrey Shuren,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 03-20200 Filed 8-7-03; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0198]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Requirements for Medicated Feed Mill License**

**AGENCY:** Food and Drug Administration, HHS.