ADDRESSES: Submit written requests for single copies of the guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' Traditionally, FDA has required that regulatory submissions, such as investigational new drug applications and NDA's, be submitted as paper documents. The regulations in part 314 (21 CFR part 314), for example, set forth the requirements and procedures for submitting applications to obtain approval for the marketing of new drugs to FDA. These regulations require the submission of three copies of an application for marketing approval: (1) A complete archival copy, (2) a review copy, and (3) a field copy (§ 314.50(k)).

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures regulation that provides for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public docket number 92S–0251 so the agency can maintain a list of the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997). The agency unit(s) that are prepared to receive electronic submissions are to identify themselves in that docket. The regulation states that persons should consult with the intended agency receiving unit for details on how to proceed with the electronic submission. The guidance is intended to reduce the need on the part of sponsors to consult CDER for details on archiving electronic submissions. The guidance specifically addresses the NDA and includes subsections on how to submit case report forms and case report tabulations in electronic format to CDER for the archive. Conforming to the guidance in this document will help ensure that submissions provided to CDER in electronic format can be accessed, handled, reviewed, and maintained efficiently.

The guidance is the first in a series that will be issued on archiving electronic submissions to CDER. As a result, it is not all inclusive. CDER anticipates that, as this effort proceeds, sponsors, investigators, and CDER staff may develop alternative and more effective procedures for submitting electronic applications for the archive. For this reason, the guidance will be updated periodically.

The guidance represents the agency's current thinking on electronic submissions for the archive for NDA's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of the guidance also is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: September 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25126 Filed 9–17–97; 4:58 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–304A]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Form No.:* HCFA–304A; *Use:* In response to a need for improved data exchange between drug labelers and States, HCFA, in conjunction with outside consultants, developed the Reconciliation of State Invoice (ROSI), form HCFA–304, and the Prior Quarter Adjustment Statement (PQAS), form HCFA–304A. The ROSI is to be used by Drug Labelers when responding to State invoices of current quarter utilization data only and functions as a reconciliation report to assure accurate rebate payments. The PQAS is used by labelers to report only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between Drug labelers and States. *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 365; *Total Annual Responses:* 1,460; *Total Annual Hours:* 132,120.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, nformation Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 15, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards Health Care Financing Administration.

[FR Doc. 97–25218 Filed 9–22–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Division of Intramural Research; Proposed Data Collection Available for Public Comment and Recommendation

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the NIEHS Project Clearance Liaison, at (919) 541–5047.

Comments are invited 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) ways to enhance 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.

This notice regards a request for OMB processing for a proposed study: The Johnston County ADHD Study: Environmental, Reproductive and Familial Risk Factors for Attention Deficit/Hyperactivity Disorder in accordance with 5 CFR 1320.13 of the OMB guidelines. We received emergency OMB clearance in June 1997 for conducting a pilot study for this study which is being conducted June 1997–November 1997. The OMB clearance for the pilot study expires in November 1997. We are now applying for clearance for the full study which we anticipate beginning in January 1998.

New—Proposed Project: The Johnston County ADHD Study: Environmental, Reproductive and Familial Risk Factors for Attention-Deficit/Hyperactivity Disorder. For the proposed study we plan to collect questionnaire data from 350 teachers and 2400 parents. Data will be collected over two years. Teachers will use a brief symptom checklist to screen all the children in their class; about 8,000 children will be screened in all. We will conduct telephone interviews with the mothers or guardians of children identified as possible cases and a 15% random sample of control children. If children meet DSM–IV criteria for ADHD after both screens, they will be considered cases. The primary hypotheses of the study are that preterm delivery and other reproductive risk factors increase risk of ADHD and childhood lead exposure (measured in shed baby teeth) increases risk of ADHD. In year two of the study we will use cheek swabs to collect DNA from 1,200 mothers, 1,200 children, 1,200 siblings and 1,200 fathers to study possible genetic or familial risk factors for ADHD. The data collected in this study will allow us to describe the prevalence of Attention Deficit/Hyperactivity Disorder in Johnston County, how prevalence varies by demographic profile, and to identify environmental, reproductive and familial risk factors for the disorder.

Type respondent	Estimated number of respondents	Estimated number of responses	Average # responses per respondent	Average burden hours per response	Total burden hours
Teachers	350	10,150	29	.18	1827
Mother/guardian	2400	13,200	5.5	.32	4224
Father	1,200	1,000	1	.17	204
Study child	1,200	1,000	1	.17	204
Sibling	1,200	1,200	1	.17	204

Total Burden: 6,663 hours.

Total Burden per Year: 3,331.5 hours.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Andrew Rowland, Senior Staff Fellow, NIEHS, DIR/EDMP/Epidemiology Branch, PO Box 12233, RTP, NC 27709, or call non-toll free number (919) 541–7886.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before November 21, 1997.

Dated: September 10, 1997.

Charles Leasure,

Associate Director for Management, NIEHS.

[FR Doc. 97–25150 Filed 9–19–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMNET OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Center for Research Resources Initial Review Group and the Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities, National Center for Research