dust. Once these discoveries are made, they need to be documented and shared throughout the industry.

The diffusion of this innovation will occur much more rapidly and efficiently if this proposed study takes place. Effective strategies for using PDM information will be well documented and quickly shared throughout the coal industry. The alternative is to wait for the miners at each of the 482 actively producing coal mines in the U.S. to go through their own trial and error process of discovering how PDMs can and cannot be used to reduce dust exposure. The proposed study will help to significantly reduce the incidence of lung disease among coal miners, leading to improvements in their longevity and quality of life.

The information for this study will be collected by conducting one-on-one structured interviews with approximately 20 miners at each of 5 mines located throughout the major coal producing regions of the U.S.

This survey will last 2 years. There will be no cost to respondents except their time to participate. The total estimated annualized burden hours are 25.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Coal Miners	50	1	30/60

Dated: August 18, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–16895 Filed 8–24–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0296]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information requiring the sponsor of any drug, biologic, or device marketing application to certify to the absence of clinical investigators and/or disclose those financial interests as required, when covered clinical studies are submitted to FDA in support of product marketing.

DATES: Submit written or electronic comments on the collection of information by October 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Financial Disclosure by Clinical Investigators (OMB Control Number 0910–0396)—Extension

Respondents are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic and medical device firms. The applicant will incur reporting costs in order to comply with the final rule. Applicants will be required to submit, for example, the complete list of clinical investigators for each covered study, not employed by the applicant and/or sponsor of the covered study, and either certify to the absence of certain financial arrangements with clinical investigators or disclose the nature of those arrangements to FDA and the steps taken by the applicant or sponsor to minimize the potential for bias. The clinical investigator will have to supply information regarding financial interests or payments held in the sponsor of the covered study. FDA has said that it has no preference as to how this information is collected from investigators and that sponsors/applicants have the flexibility to collect the information in the most efficient and least burdensome manner that will be effective. FDA estimated

that the total reporting costs of sponsors would be less than $450,000 annually. Costs could also occur after a marketing application is submitted if FDA determines that the financial interests of an investigator raise significant questions about the integrity of the data.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
54.4(a)(1) and (a)(2)	1,000	1	1,000	5	5,000
54.4(a)(3)	100	1	100	20	2,000
54.4	46,000	.25	11,500	.1	11,500
Total					18,500

[1]There are no capital cost or operating and maintenance costs associated with this collection of information.

The sponsors of covered studies will be required to maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices. Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours
54.6	1,000	1	1,000	.25	250
Total					250

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16915 Filed 8–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0264]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Ribonucleic Acid Preanalytical Systems (Ribonucleic Acid Collection, Stabilization and Purification Systems for Real Time Polymerase Chain Reaction Used in Molecular Diagnostic Testing); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT–PCR used in Molecular Diagnostic Testing).'' This guidance document describes a means by which Ribonucleic Acid (RNA) preanalytical systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify RNA preanalytical systems into class II (special controls). This guidance document is immediately in effect as the special control for RNA preanalytical systems but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT–PCR used in Molecular Diagnostic Testing)'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying RNA preanalytical systems into class II (special controls) under