TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
6	1	6	20	120

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

The Medical Devices Dispute Resolution Panel represents a new process for resolving scientific disputes. In arriving at the estimates in table 1 of this document for the burden imposed in connection with a request for review by the Medical Devices Dispute Resolution Panel, FDA considered the number and substance of similar appeals of various types made to FDA in recent years, knowledge of similar submissions, and discussions with manufacturers.

Dated: February 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–3319 Filed 2–7–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1604]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

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 March 12, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)(e).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

In the **Federal Register** of November 16, 2000 (65 FR 69314), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total Hours
809.10	20	1	20	100	2,000

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

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: February 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–3322 Filed 2–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration, DHHS.

[Document Identifier: HCFA–6401]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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 this 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: Extension of a currently approved collection; *Title of Information Collection:* Negative Case Action (NCA) Process/Annual Report; *Form No.:* HCFA–6401 (OMB# 0938–0300); *Use:* HCFA uses the NCA process to determine the accuracy of ineligible determinations focusing on the reason(s) for denial or the termination of assistance. The results of NCA reviews are used by the States and the Federal government to identify problem areas and plan corrective action initiatives to eliminate error causing situations; *Frequency:* Annually; *Affected Public:* State, local or tribal gov.; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 6770.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, HCFA–6401, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 23, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–3230 Filed 2–7–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0299]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

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 this 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:* A Project to Develop an Outcome-Based Continuous Quality Improvement System for PACE; *Form No.:* HCFA–R–0299 (OMB #0938–0791); *Use:* The purpose of this project is to develop an out-come based continuous quality improvement (OBCQI) approach for the PACE program by (a) developing and testing potential outcome measures, (b) testing risk adjustment methods so that each site's outcomes can be appropriately evaluated, and (c) designing an OBCQI approach to improve quality in a systematic, evolutionary manner. Findings from this project are intended to guide the possible implementation of a national approach for OBCQI, in which PACE sites will collect data that will be used to determine and profile participant outcomes for their site; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, Individuals or households; *Number of Respondents:* 8,298; *Total Annual Responses:* 93,970; *Total Annual Hours:* 21,692.04.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, HCFA-R–0299, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 18, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–3232 Filed 2–7–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10004]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

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 this 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