

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 97N-0182]

**Agency Information Collection Activities; Announcement of OMB Approval**

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

**ACTION:** Notice.

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

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 19, 1997 (62 FR 49244), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0206. The approval expires on November 30, 2000.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-33375 Filed 12-22-97; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 97N-0495]

**Agency Information Collection Activities; Announcement of OMB Approval**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled

"Medical Devices, Investigational Device Exemptions, Treatment Use" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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

**SUPPLEMENTARY INFORMATION:** On August 25, 1997, the agency submitted the proposed information collection to OMB for review and clearance under section 3507 of the PRA (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 0910-0348. The approval expires on October 31, 2000.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-33481 Filed 12-22-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 97N-0264]

**Agency Information Collection Activities; Announcement of OMB Approval**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Information Required in a Premarket Notification Submission (21 CFR 807.87, 807.92, and 807.93) (OMB Control Number 0910-0281—Reinstatement)" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 16, 1997 (62 FR 38098), the agency announced that the proposed information collection had

been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0281. The approval expires on September 30, 2000.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-33484 Filed 12-22-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 97N-0022]

**Agency Information Collection Activities; Announcement of OMB Approval**

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

**ACTION:** Notice.

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

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 17, 1997 (62 FR 48870), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0048. The approval expires on November 30, 2000.

Dated: December 16, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-33485 Filed 12-22-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

[Document Identifier: HCFA-6401]

**Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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:* Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Negative Case Action Review Process (NCA)/Annual Report and Supporting Regulations 42 CFR 431.800; *Form No.:* HCF-6401 OMB #0938-0300; *Use:* HCFA uses the NCA reviews to assure that beneficiaries are not being denied medical assistance that they are eligible for and that recipients are being given adequate and

timely notice of termination. The results of NCA reviews are used by states and the Federal Government to identify problem areas and plan corrective action initiatives. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 6,770.

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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, *Attention:* Allison Eyd, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 6, 1997.

**John P. Burke III,**

*HCFA Reports Clearance Officer, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 97-33399 Filed 12-22-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish periodic

summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

*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.

*Proposed Project: Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title IV (OMB No. 0915-0206)—Extension, No Change—*The HRSA HIV-AIDS Bureau proposes to continue to collect aggregated data from 44 grantees and their 90 local service providers that are funded under Section 2671 of the Public Health Service Act (42 USC 300ff-71). Data are collected from grantees and providers on the organizational structures, service delivery approaches, numbers and demographic characteristics of clients served, service utilization, and activities related to outreach, prevention, and education. The data collection strategy includes six tables that the grantees and their local service providers use to submit information annually about program and client characteristics. The data collected are used within and outside the HIV-AIDS Bureau and HRSA to inform the administration and Congress about the Title IV program and are used by grantees and the HIV-AIDS Bureau for other planning and policy efforts. No changes to the data tables are planned. Burden estimates are as follows:

Type of form	Number of Respondents	Responses per respondent	Average hours per response	Total burden hours
Designation of Local Reporting Entities .....	44	1	.25	11
Local Network Profile .....	134	1	.5	67
Service Mix Profile .....	134	1	2.8	375
Demographic and Clinical Status .....	134	1	33.0	4,422
Service Utilization Summary .....	134	1	20.0	2,680
Prevention and Education Activities .....	134	1	4.0	536
Total .....	134	.....	.....	8,091