

Fee category	Fee rates for FY 1997
Supplements requiring clinical data	\$128,423
Establishments	\$141,966
Products	\$18,591

VI. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under the PDUFA that is submitted after December 31, 1997, must be accompanied by the appropriate application fee established in the new fee schedule. FDA will bill applicants who submitted application fees between October 1, 1997, and December 31, 1997, based on the adjusted rate schedule.

B. Establishment and Product Fees

By December 31, 1997, FDA will issue invoices for establishments and product fees for FY 1998 under the new fee schedules. Payment will be due by January 31, 1998. FDA will issue invoices in October 1998 for any products and establishments subject to fees for FY 1998 that qualify for fees after the December 1997 billing.

Dated: December 3, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-32164 Filed 12-8-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0151]

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 "Applications for Exemption from Preemptions of Medical Device Requirements" 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 May 16, 1997 (62 FR 27059), 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 0910-0129. The approval expires on July 31, 2000.

Dated: December 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-32166 Filed 12-8-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0266]

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 "Administrative Detention and Banned Medical Devices" 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 38095), 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 0910-0114. The

approval expires on September 30, 2000.

Dated: November 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-32167 Filed 12-8-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-484]

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: Extension of a currently approved collection without change;
Title of Information Collection: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations 42 CFR 410.38 and 42 CFR 424.5; **Form Number:** HCFA-484 (OMB approval #0938-0534); **Use:** To determine oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD-9) and:

1. Results and date of the most recent arterial blood gas PO₂ and/or oxygen saturation tests.

2. The most recent arterial blood gas PO₂ and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR