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]

BILLING CODE 4160–01–F

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 3collection 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]

BILLING CODE 4160–01–F

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 PO_2 and/or oxygen saturation tests.

2. The most recent arterial blood gas PO_2 and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR

within two days prior to discharge from an inpatient facility to home.

3. The most recent arterial blood gas PO_2 and/or oxygen saturation test performed at rest, during exercise, or during sleep.

4. Name and address of the physician/provider performing the most recent arterial blood gas PO_2 and/or oxygen saturation test.

5. If ordering portable oxygen, information regarding the patient's mobility within the home.

6. Identification of the highest oxygen flow rate (in liters per minute) prescribed.

7. If the prescribed liters per minute (LPM), as identified in item 6, are greater than 4 LPM, provide the results and date of the most recent arterial blood gas PO_2 and/or oxygen saturation test taken on 4 LPM.

If the PO_2 = 56–59, or the oxygen saturation = 89%, then evidence of the beneficiary meeting at least one of the following criteria must be provided.

8. The patient having dependent edema due to congestive heart failure.

9. The patient having cor pulmonale or pulmonary hypertension, as documented by P pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement.

10. The patient having a hematocrit greater than 56%.

Form HCFA–484 obtains all pertinent information and promotes national consistency in coverage determinations; *Frequency:* Other (as needed); *Affected Public:* Individuals/households, business or other for profit, and not for profit institutions; *Number of Respondents:* 300,000; *Total Annual Responses:* 300,000; *Total Annual Hours Requested:* 50,000.

To obtain copies of the supporting statement, and any related forms referenced above, 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 Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 2, 1997.

John P. Burke III,

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

[FR Doc. 97–32100 Filed 12–8–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of National Cancer Institute Director's Consumer Liaison Group Meeting

Notice is hereby given that the National Cancer Institute will hold its first public meeting of the Director's Consumer Liaison Group, beginning at 9:00 a.m. on December 17, 1997 and ending at 3:00 p.m. on December 18, 1997 at the Pooks Hill Marriott, Bethesda, MD. Seating is limited and will be on a first-come, first-served basis.

The National Cancer Institute (NCI), the federal government's primary agency for cancer research, is bringing together fifteen (15) consumer-advocates to create a two-way street that enables them to interact directly with the scientific community at NCI on a wide range of programs and issues. The 15-member DCLG is made up of people involved in cancer advocacy and who reflect the breadth and diversity among those whose lives are touched by cancer. The DCLG will also help NCI to widen the pool of qualified consumer-advocates who can be called upon to serve on NCI advisory committees and other groups.

The members are (in alphabetical order):

Paula E. *Bowen*, Brooklyn, N.Y.
Susan Lowell *Butler*, Alexandria, Va.
Manuel H. *Castillo*, Dayton, Ohio
Kerry J. *Dewey*, Missoula, Mont.
M. Venus *Gines*, Lithonia, Ga.
Felicia Schanche *Hodge*, Berkeley, Calif.
Michael *Katz*, New York, N.Y.
Susan A. *Leigh*, Tucson, Ariz.
Ruth Chiang *Lin*, Short Hills, N.J.
Gena H. *Love*, Albuquerque, N.M.
Susan *McCarthy*, Vancouver, Wash.
Daniel M. *Moore*, Jr., Decatur, Ill.
Lillouise *Rogers*, Chicago, Ill.
Susan K. *Stewart*, Highland Park, Ill.
Brad *Zebrack*, Ann Arbor, Mich.

The majority of the newly appointed DCLG members are cancer survivors, but family members of cancer patients and health professionals involved in cancer advocacy are represented. The cancer experience of the group includes prostate, breast, kidney, ovarian, cervical, lung, bladder, and brain cancer, Hodgkin's disease, leukemia, sarcoma, and myeloma. The group represents Asian American, Native American, Hispanic, African American, and non-Hispanic white persons, the young and old, men and women, the medically underserved, and people from all geographic areas of the country, both rural and urban. The constituencies represented by the members include advocacy organizations that represent both specific cancers and all cancers. DCLG members will serve three-year terms. The three-fold purpose of the DCLG will be to:

- Serve as a primary forum for discussing issues and concerns and exchanging viewpoints that are important to the broad development of NCI program and research priorities.
- Help develop and establish processes, mechanisms, and criteria for identifying appropriate consumer advocates to serve on a variety of NCI program and policy advisory committees.
- Establish and maintain strong collaborations between NCI and the cancer advocacy community.

One purpose of this first meeting is to decide how the group will do its work. For example, how it will select a chair and identify members who will serve in the future. The DCLG will also discuss how it will communicate internally and with the broad advocacy community it represents. In addition, the group will begin discussion on several key issues for the Institute. The most pressing issues faced by cancer patients today, as described in the candidates' applications, include: Access to and availability of reliable cancer information; access to effective, high-quality treatment, including clinical trials; increased rehabilitation, psychosocial support, and other survivor concerns; and participation in setting research priorities. NCI may also begin issues to the attention of the group.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other special accommodations, should contact Elaine C. Lee, in the Office of Liaison Activities, National Cancer Institute, Building 31, Room 10A06; or by calling telephone No. 301 594–3194 or sending a fax to 301 480–7558. For additional information, contact Ms. Lee at the above address.