SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information Required in a Premarket Notification Submission (21 CFR 807.87, 807.92, and 807.93) (OMB Control Number 0910–0281—Reinstatement)

Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), a premarket notification must be filed before the introduction or delivery for introduction of a device intended for human use. Under § 807.87 (21 CFR 807.87), premarket notifications are required to contain certain information, including the device name, establishment registration number, class of the device, the device's proposed labeling, action taken by the person required to register to comply with performance standards, and a 510(k) summary as described in § 807.92 (21 CFR 807.92) or a 510(k) statement as described in § 807.93 (21 CFR 807.93). In addition, § 807.87(i) requires that those filing premarket notification who claim substantial equivalence to certain devices as described in § 807.87(i), that are classified into class III, must submit to FDA a summary of safety and effectiveness problems and a citation to the information upon which the summary is based. The premarket notification submitter must also furnish FDA with a certification that a reasonable search has been conducted of all known information.

The information collected in the premarket notification is necessary to enhance FDA's ability to ensure that only premarket notification submissions for devices that are as safe and as effective as legally marketed predicate devices are cleared for marketing. In addition, FDA makes publicly available this information concerning devices for which a marketing order has been issued, in order to provide to the public the agency's basis for equivalence determinations.

Respondents to this collection of information are medical device manufacturers and distributors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.87(h) and 807.92 (simple 510(k) summaries)	2,592	1	2,592	8	20,736
807.87(h) and 807.92 (complex 510(k) summaries)	247	1	247	12	2,964
807.87(h) and 807.93 (510(k) statements)	2,896	1	2,896	1	2,896
807.87(i) and 807.94 (certifications)	208	1	208	40	8,320
Total					34,916

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

FDA bases these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in the table above.

Under § 807.93, anyone submitting a 510(k) statement must make that information available to anyone who requests it.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,896	10	28,960	0.5	14,480
Total					14,480

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

Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18595 Filed 7-15-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0129]

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 ''FDA Safety Alert/Public Health Advisory Readership Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, 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 April 21, 1997 (62 FR 19323), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910–

0341. The approval expires on June 30, 2000. 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.

Dated: July 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18594 Filed 7–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPD–845–PN]

RIN 0938–AH28

Medicare Program; Special Payment Limits for Home Oxygen

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed notice.

SUMMARY: This notice would establish special payment limits for home oxygen. Currently, payment under the Medicare program for home oxygen and other items of durable medical equipment is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Based on our experience and after consulting with representatives of home oxygen suppliers, we have determined that the Medicare fee schedule amounts for home oxygen are grossly excessive and are not inherently reasonable because they are excessively high relative to the payment amount for similar services by the Department of Veterans Affairs which uses a true competitive payment methodology. This notice would replace the use of the fee schedule amount and proposes that payment for home oxygen be equal to 80 percent of the lesser of the actual charge or a special payment limit set by HCFA, which would vary by locality. It is intended to prevent continuation of excessive payment. The special limit would be based on the average payment amount for home oxygen services by the Department of Veterans Affairs.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, by 5 p.m. on September 15, 1997.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–845–PN, P.O. Box 26676, Baltimore, MD 21207–0476.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–845–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: William J. Long (410) 786–5655.

SUPPLEMENTARY INFORMATION:

I. Background

A. Payment Under Reasonable Charges

Payment for durable medical equipment (DME) furnished under Part B of the Medicare program (Supplementary Medical Insurance) is made through contractors known as Medicare carriers. Before January 1, 1989, payment for DME was made on a reasonable charge basis by these carriers. The methodology used by the carriers to establish reasonable charges is set forth in sections 1833 and 1842(b) of the Social Security Act (the Act) and 42 CFR part 405, subpart E of our regulations. Reasonable charge determinations are generally based on customary and prevailing charges derived from historic charge data. The reasonable charge for an item of DME was generally set at the lowest of the following factors—

- The supplier's actual charge for the item.
- The supplier's customary charge.
- The prevailing charge in the locality for the item. (The prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality.)
- The inflation indexed charge (IIC). (The IIC is defined in § 405.509(a) as the lowest of the fee screens used to determine reasonable charges for services, supplies, and equipment paid on a reasonable charge basis (excluding physician services) that is in effect on December 31st of the previous fee screen year, updated by the inflation adjustment factor.)

B. Exception to the Reasonable Charge Payment Methodology—Special Reasonable Charge Limits

Section 1842(b)(3) of the Act requires that payments under Part B of the Medicare program that are made on a charge basis must be reasonable. Paragraphs (8) and (9) of section 1842(b) provide that we may establish a special reasonable charge for a category of service if, after appropriate consultation with representatives of affected parties, we determine that the standard rules for calculating reasonable charges result in grossly deficient or grossly excessive charges.

The applicable regulations are located at § 405.502(g) and require us to consider the available information that is relevant to the category of service and establish reasonable charge limits that are realistic and equitable. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly