Dated: November 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30609 Filed 11–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0373]

Agency Information Collection Activities; Announcement of OMB Approval; FDA Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled '' FDA Recall Regulations'' 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 14, 1998 (63 FR 49130), 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 0910–0249. The approval expires on October 31, 2001.

Dated: November 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30610 Filed 11–16–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form #HCFA–R–0264–a,b,c,d,e]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), is publishing the following summary of a proposed collection 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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, part 1320 and is essential to the mission of the Agency. The Agency cannot reasonably comply with the normal clearance procedures because of a statutory deadline imposed by section 4319 of the Balanced Budget Act of 1997. Without this information, HCFA would not be able to properly implement all of the requirements set forth in the statute prior to the statute's sunset provision, causing a statutorily ordered deadline to be missed. Also, an unanticipated event has occurred, which may contribute to the missing of the statutory deadline. In particular, HCFA inadvertently referenced the incorrect statutory section in the location of the previous notice justifying the need for emergency clearance, published in the **Federal Register** on October 16, 1998, at 63 FR 55631. While the correct section of statute mandating the collection was denoted elsewhere in the notice, a commentor pointed out that the statutory citation specifically justifying the need for emergency clearance was incorrect. Therefore, HCFA is correcting its oversight by republishing its request for OMB review and approval of this collection. Lastly, emergency clearance is requested because public harm will likely result if the normal clearance procedures are followed. Studies by the Government Accounting Office and the Office of the Inspector General have found that Medicare payments for items of durable medical equipment are far greater than prices paid by other insurers and are sometimes greater than prices available to the general public at retail outlets. And, the payments provided under Medicare fee schedules often represent unreasonably high markups from actual prices paid by suppliers. The use of the standard OMB approval process will cause the nonfulfillment the statutory requirements set forth in section 4319 of the Balanced Budget Act of 1997 that seek to address these issues, resulting in public harm by allowing the unnecessary loss of public Medicare trust fund dollars.

HCFA is requesting OMB review and approval of this collection within six working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below within five working days.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection;

Title of Information Collection: Collection of DMEPOS Supplier Data in Support of the Medicare DMEPOS Competitive Bidding Demonstration using form (HCFA–R–0264) and Supporting Statute Section 4319 of the Balanced Budget Act of 1997;

Form No.: HCFA–R–0264;

Use: Section 4319 of the Balanced Budget Act (BBA) mandates HCFA to implement demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of Part B items and services, except for physician's services. The first of these demonstration projects implements competitive bidding of categories of

durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Under the law, suppliers can receive payments from Medicare for items and services covered by the demonstration only if their bids are competitive in terms of quality and price. Each demonstration project may be conducted in up to three metropolitan areas for a three year period. Authority for the demonstration expires on December 31, 2002. The schedule for the demonstration anticipates about a six month period required between mailing the bidding forms to potential bidders and the start of payments for DMEPOS under the demonstration. HCFA intends to operate the demonstration in two rounds, the first of two years, and the second of one year. HCFA has announced that it intends to operate its first demonstration in Polk County, Florida, which is the Lakeland-Winter Haven Metropolitan Area.

There are five forms that are required for the demonstration. The first, HCFA–R–0264A, will be filled out by suppliers to describe the attributes of their organization, including quality of services and financial data. Form HCFA–R–0264B will be filled out by suppliers for each of the categories of DMEPOS for which they bid, and includes information about their supply of that category of equipment or supplies, and the prices that they bid for each item in that category. Form HCFA–R–0264C will be used by site inspectors who gather information at the facilities of bidders. Form HCFA–R–0264D is used to gather data by telephone from referral sources of business for the bidding suppliers, and form HCFA–R–0264E is used to gather data by telephone from banks and other financial institutions for financial and business references.

The competitive bidding demonstration for DMEPOS has the following objectives:

- Test the policies and implementation methods of competitive bidding to determine whether or not it should be expanded as a Medicare Program.
- Reduce the price that Medicare pays for medical equipment and supplies.
- Limit beneficiary out-of-pocket expenditures for copayments.
- Improve beneficiary access to high quality medical equipment and supplies.
- Prevent business transactions with suppliers who engage in fraudulent practices.

HCFA plans to mail the bidding package, including the referenced forms A and B, to potential bidders at the first demonstration sites in Polk County, Florida on November 16, 1998, and to request bidder submissions by December 16, 1998. The remaining forms C, D and E will be used for inspections and reference checking in the three months following the bid submissions. These forms will be used by HCFA or its agents to gather information regarding bidders who have made financially attractive bids and are being evaluated for quality, financial stability, and other attributes for consideration as demonstration suppliers.

Frequency: Two times at each demonstration site;

Affected Public: Business or other for-profit, and not-for-profit institutions;

Number of Respondents: 2,040;

Total Annual Responses: 2,040;

Total Annual Hours: 25,260

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, and HCFA form number(s) referenced above, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designee referenced below, within five working days:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, Fax Number: (410) 786–0262, Attn: John Burke

or

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: November 10, 1998.

John P. Burke III,

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

[FR Doc. 98–30661 Filed 11–16–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December, 1998.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 2, 1998; 9 a.m.–5 p.m.

Place: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, December 2, from 9 a.m. to 5 p.m. Agenda items will include, but not be limited to: a report on the Anthrax Vaccine Expert Committee, a presentation on options for coverage of the Hepatitis A vaccine, an update on the Vaccine Safety Action Plan, reports from the Department of Justice, the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on December 2. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Melissa Palmer, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign up in Conference Rooms G and H on December 2. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Melissa Palmer at the address mentioned above.

Agenda items are subject to change as priorities dictate.

Dated: November 10, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–30676 Filed 11–16–98; 8:45 am]

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