

Dated: November 4, 1998.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

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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.*

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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 commenter 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 of 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