Initial inspections of newly registered establishments,

Initial inspections of new facilities, and

Initial inspections under new management and/or ownership.

e. Non-QS/GMP inspections other than:

Government Wide Quality Assurance (GWQAP) inspections with short deadlines,

Immediate and urgent responses to complaints,

Immediate and urgent followup to information from any source, and

Immediate hazard to health recall followup inspections.

f. Recall followup inspections at manufacturers/initial importers/U.S. designated agent.

2. Eligibility Criteria:

a. GMP inspections of firms with nonviolative histories (inspections classified as no action indicated (NAI) or voluntary action indicated (VAI)). For VAI, adequate corrections of conditions observed and listed on FDA–483 during the previous inspection were verified and did not lead to any further agency action.

b. To remain eligible for preannounced inspections, firms must have a history of having individuals and/or documents identified in previous preannounced inspections reasonably available at the time of inspection.

C. Procedures

1. The investigator or coordination group designated to conduct the inspection will contact or, if unavailable at the time of call, leave word for the most responsible individual at the facility.

2. Changes in dates should be kept to a minimum. If a change is made, a new date should be provided as soon as possible that will facilitate the inspection and accommodate the investigator's schedule.

3. Preannouncements are normally limited to the investigator (or lead investigator or coordinating group for a team inspection) informing the firm of an upcoming inspection. Usually it will be appropriate to inform the firm as to the purpose, estimated duration, and the number of agency personnel expected to take part in the inspection. The products or processes to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection.

4. When known, specific records/personnel will be requested at the time the inspection is scheduled.

II. FDA–483 Annotations

A. Basic Premise

1. For inspections in all program areas, the investigator will annotate the FDA–483 at the time of issuance to acknowledge an establishment's promised or completed corrective action. The firm should review the annotations on this issued FDA–483 to ensure that there are no misunderstandings about promised corrective actions.

2. A reportable item will not be deleted from the FDA–483 because the establishment has promised or completed a corrective action. The investigator will continue to have the latitude to delete the observation if the establishment's response to the observation clearly shows that the observation is in error or to clarify the observation based on additional information provided.

3. FDA investigators will continue to report only significant observations on the FDA–483 and to discuss these and other less significant observations with the establishment's management.

B. Procedures

1. Investigators and analysts will discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA–483 is issued. This discussion will include those observations that may be written on the FDA–483 and oral observations. Industry should use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made as soon as possible during the inspection. Investigators are encouraged to verify the establishment's completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

2. Where practical, FDA–483 observations should include the number of records of a given type examined, for example, ''Two out of 50 records examined were * * *.''

3. If the establishment has promised and/or completed a corrective action to an FDA–483 observation prior to the completion of the inspection, all copies of the FDA–483 should be annotated (either following each observation or at the end of the FDA–483) with one or more of the following comments, as appropriate:

Item # _____ reported corrected but not verified.

Item # _____ corrected and verified.

Correction of items_____, _____ and promised by 00/00/98.

No comment at this time.

4. If an observation made during a prior inspection is noted as not being corrected or is a reoccurring observation, it is appropriate to note this on the FDA–483.

5. All corrective action taken by the establishment and verified by FDA should be discussed in detail in the establishment inspection report and reported using the Compliance Achievement Reporting Systems (CARS).

III. Postinspection Notification

A. Basic Premise

1. FDA will issue postinspection notification to establishments regarding their compliance status for all inspections except foreign drug establishments. Foreign drug establishments have traditionally and will continue to receive correspondence from FDA upon evaluation and closure of each inspection.

2. The two new categories under which firms will receive postinspection notification are:

a. NAI situations where no FDA–483 was issued or only limited, less significant deficiencies were reported.

b. VAI situations where an FDA–483 was issued but all profile classes were found acceptable. In this circumstance, no further action is contemplated based on the inspection.

3. The postinspection notification letters that are issued under this pilot program will be mailed under the signature of the district director, in that district in which the establishment is located, or the Director of the Center of Compliance, as appropriate.

4. For those inspections where further action is being considered, FDA's existing modes of notification will continue to be used.

Dated: November 5, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30608 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–0335]

Agency Information Collection Activities; Announcement of OMB Approval; Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled '' Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies'' 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 25, 1998 (63 FR 51357), 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 0910–0119. The approval expires on October 31, 2001.

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]

BILLING CODE 4160–01–F

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