ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Classifying Resubmissions in Response to Action Letters.'' In the Prescription Drug User Fee Act of 1992 (PDUFA), FDA committed to certain user fee performance goals, including the goal of responding to an applicant's resubmission of an original NDA or LA in 6 months or less. In her letter to Congress regarding the reauthorization of PDUFA in November 1997 as part of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Secretary of Health and Human Services committed FDA to recognizing two classes of resubmissions: Class 1 and Class 2. This guidance describes the classification of resubmissions as Class 1 or Class 2 based on the information submitted by the applicant in response to the action letter. In addition, the guidance specifies the percentages of resubmissions in each class that will be reviewed and acted upon within a certain time period from the date the resubmission is received by FDA, based on the fiscal year in which the resubmission is received.

This guidance is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance is issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on classifying resubmissions in response to action letters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12830 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0282]

Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' This guidance describes how to submit a complete response if an investigational new drug application is placed on clinical hold.

DATES: Written comments may be submitted on this guidance document by August 12, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm; or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD. 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the addresses that follow.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Robert A. Yetter, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' Section 117 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), signed into law by President Clinton on November 21, 1997, provides that a written request that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. In addition, the agency committed to user fee performance goals incorporating the same response time. This guidance describes how sponsors should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to response.

This guidance document is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance for industry is a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on submitting complete responses to clinical holds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

The guidance and comments received in the Dockets Management Branch (address above) are available for public examination between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12831 Filed 5–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–229]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary of proposed collections for public comment. 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; *Title of Information Collection:* Development of an Assessment System for post Acute Care; *Form No.:* HCFA–R–229, OMB #0938–0720; *Use:* The Minimum Data Set- Post Acute Care (MDS–PAC) will be used to establish patient case mix groups including classes of patients in the rehabilitation facility for the payment system. It will also provide data and seek input from the rehabilitation industry for HCFA to formulate policy and promulgate regulations. *Frequency:* On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit; *Number of Respondents:* 10,465; *Total Annual Responses:* 10,465; *Total Annual Hours:* 23,301.

To obtain copies of the supporting statement for the proposed paperwork collections 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 5, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 98–12766 Filed 5–13–98; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–250 through HCFA–254]

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

AGENCY: Health Care Financing Administration, HHS

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, is publishing the following summary of proposed collections 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 before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. This is necessary to collect information from beneficiaries on health insurance coverage that is primary to Medicare. Collection of this information allows HCFA to identify those Medicare beneficiaries who have other group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. The annual savings from the Medicare Secondary Payer (MSP) program are more than $3 billion per year. Emergency approval is needed to prevent a disruption in the information collection and to continue the savings to the Medicare Trust Fund. We cannot reasonably comply with the normal clearance procedures because public harm is likely to result because eligible individuals may not receive the health insurance protections under the statute.

HCFA is requesting OMB review and approval of this collection 15 working days after the publication of this **Federal Register** notice, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below 14 working days after the publication of this notice. 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 Request: Reinstatement, without change, of a previously approved collection for which approval has expired;

Title of Information Collection: Medicare Secondary Payer Information Collection and Supporting Regulations in 42 CFR 489.20;

Form Number: HCFA–250 through HCFA–2545 (OMB approval #: 0938–0214);

Use: Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. HCFA contracts with health insuring organizations, herein referred to as intermediaries and carriers, to process Medicare claims. HCFA charges its Medicare intermediaries and carriers with various tasks to detect MSP cases; develops and disseminates tools to enable them to