amendment is being made to cancel the entire session on October 7, 1999. This meeting will be open to the public. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail ''tituss@cder.fda.gov'', or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 26, 1999 (64 FR 46687), FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee would be held on October 7 and 8, 1999. On page 46687, beginning in the first column, the *Date and Time*, *Agenda*, and *Procedure* portions of this meeting are amended to read as follows:

Date and Time: The meeting will be held October 8, 1999, 8 a.m. to 4:30 p.m.

Agenda: On October 8, 1999, the committee will consider the safety and efficacy of new drug application 19–839/S–026, Zoloft®, (sertraline hydrochloride, Pfizer Pharmaceuticals) proposed to treat posttraumatic stress disorder.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 1, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Dated: September 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24597 Filed 9–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long–Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long–Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on October 14 and 15, 1999, 8:30 a.m. to 5 p.m.

Location: Parklawn Bldg., 5600 Fishers Lane, conference rm. K, Rockville, MD.

Contact Person: Ronald F. Coene, Food and Drug Administration, 5600 Fishers Lane, rm. 16–53, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will receive an update from the Department of Veterans Affairs on the Army Chemical Corps Vietnam Veterans Health Study and will continue their review of the Air Force Health Study-Cycle 5, draft report.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 7, 1999. Oral presentations from the public will be scheduled on October 15, 1999, between approximately ll a.m. to 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 7, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24598 Filed 9–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0296]

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 prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, part 1320. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result because beneficiaries may not receive timely, accurate, complete, and useful notices which will enable them to make informed consumer decisions, with a proper understanding of their rights to a Medicare initial determination, their appeal rights in the case of payment denial, and how these rights are waived if they refuse to allow their medical information to be sent to Medicare. This information collection standardizes the requirements set forth under 42 CFR 484.10, currently approved under OMB number 0938–0365.

HCFA is requesting OMB review and approval of this collection by close of business 09/30/1999, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by close of business 9/29/1999. 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: Home Health Advance Beneficiary Notices (HHABNs) and Supporting Regulations in 42 CFR 484.10;

Form No.: HCFA–R–0296 (OMB #0938–NEW);

Use: This program memorandum (PM) is intended to instruct Home Health Agencies (HHAs) with respect to their responsibility for providing proper written notice to beneficiaries in advance of furnishing what they believe to be noncovered care or of reducing or terminating ongoing care. These new instructions and notices apply where a physician has ordered home health care for a beneficiary but the HHA believes that Medicare will not pay for that care. They do not apply to situations where the physician will not order care, or where care is reduced or terminated in accordance with a physician's order. Medicare never pays for home health care that is not ordered by a physician. The instructions in the PM supersede current instructions in Medicare Intermediary Manual, Part 3 (MIM) § 3730.2 and in Home Health Agency Manual § 270. These new instructions are designed to ensure that beneficiaries receive timely, accurate, complete, and useful notices which will enable them to make informed consumer decisions, with a proper understanding of their rights to a Medicare initial determination, their appeal rights in the case of payment denial, and how these rights are waived if they refuse to allow their medical information to be sent to Medicare. It is essential that such notice be timely, readable and comprehensible, provide clear directions, and provide accurate and complete information about the services affected and the reason that Medicare denial of payment for those services is expected by the HHA. For this reason, new notices (the HHABNs) with very specific content and graphic design have been prepared and are attached as Exhibits 2–4 hereto, and must be used by all HHAs furnishing services to Medicare beneficiaries.

The model notices attached to the memorandum are designed to ensure HHAs inform beneficiaries in writing, in a timely fashion, about changes to their home health care, the fact that they may have to pay for care themselves if Medicare does not pay, the process they must follow in order to obtain an initial determination by Medicare and, if payment is denied, to file an appeal, and the fact that they waive those rights if they refuse to allow their medical information to be sent to Medicare. If the HHA expects payment for the home health services to be denied by Medicare, a beneficiary must be advised before home health care is initiated or continued, that in the HHA's opinion, payment probably will be required from him or her personally. These notices must be issued by the HHA each time, and as soon as the HHA makes the assessment that it believes Medicare payment will not be made. The HHABNs must be provided by HHAs according to these instructions in any case where a reduction or termination of services is to occur, or where services are to be denied before being initiated, except in any case in which a physician concurs in the reduction, termination, or denial of services. Failure to do so is a violation of the HHA Conditions of Participation in the Medicare Program, which are currently approved PRA requirements approved under OMB number 0938–0365, and may result in the HHA being held liable under the Limitation on Liability (LOL) provision.

These instructions for completion, provision, and effectuation of advance beneficiary notices by HHAs are to be used by RHHIs effective September 30, 1999. The model notices (HHABNs) must be used by providers and as required by the MIM, Part 3, § 3440 Establishing When Beneficiary is on Notice of Noncoverage.

Completion of Model Home Health Advance Beneficiary Notices (HHABNs) Model Notice Exhibit 1 of the PM is for instructional purposes only and includes guidance on the notice form. Model HHABNs, Exhibits 2–4, serve as notice to the beneficiary that the HHA believes that home health services are not covered in different situations. HHABN–1, Termination, is used when all home health services will be terminated. HHABN–2, Initiation, is used when the HHA expects that Medicare will not pay, even before services have been initiated. HHABN–3, Reduction, is used when ongoing home health services will be reduced (e.g., reduced in number, frequency, or for a particular subset of services, or otherwise). For any particular HHABN, the provider makes an original and two copies. (If you require a copy, one more will be made.) The provider gives, or where this is not possible mails, the original to the beneficiary (or the person acting on his or her behalf), sends the first copy to the beneficiary's physician, and keeps the second. When the beneficiary (or person acting on his or her behalf) is given a copy, he or she will return it to the provider with his or her signature and the date he or she signed the notice. If the beneficiary or the person acting on behalf of the beneficiary refused to sign the HHABN, the provider's copy should be annotated accordingly, indicating the circumstances and persons involved;

Frequency: On occasion;

Affected Public: Individuals or Households, Business or other for-profit, Not-for-profit institutions;

Number of Respondents: 188,326;

Total Annual Responses: 360,000;

Total Annual Hours: 60,000.

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, 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 designees referenced below, by close of business 09/29/1999:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

and

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: September 20, 1999.

John P. Burke III,

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

[FR Doc. 99–24845 Filed 9–20–99; 2:40 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of November 1999.

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: November 4, 1999; 8:30 a.m.–5:00 p.m.; November 5, 1999; 8:30 a.m.–4:00 p.m.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW, Washington, DC 20005.

The meeting is open to the public.

Purpose: The Advisory Committee shall (1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service (PHS) Act; and (2) prepare and submit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

Agenda: Introduction of the 23 new members. Discussion of history and current status of programs and activities authorized under section 747 of the PHS Act. Discussion of the intent of the programs; goals for improving access, diversity and supply; focus of programs; project requirements; funding priorities; outcomes data; and the peer review process. Strategic planning for the Committee.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Dr. Barbara Brookmyer, Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–1468, e-mail bbrookmyer@hrsa.gov.

Dated: September 15, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–24599 Filed 9–21–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Protection and Advocacy for Individuals With Mental Illness (PAIMI) Annual Program Performance Report (OMB No. 0930–0169, Revision)

The Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act, (42 U.S.C. Chapter 1114) authorized funds to support protection and advocacy services on behalf of individuals with mental illness and severe emotional disturbance who are at risk for abuse and neglect and other civil rights violations while under treatment in a residential facility. Under the PAIMI Act, formula grant awards are made to protection and advocacy (P&A) systems designated by the governors of the 50 states and 5 territories, and the District of Columbia to ensure that the rights of individuals with mental illness and severe emotional disturbance are not violated. The PAIMI Act requires P&A systems to file an annual report on their activities and accomplishments and to provide in the report information on such topics as, numbers of individuals served, types of complaints addressed, the number of intervention strategies used to resolve the presenting issues. The Act also requires that the P&A Advisory Council also submit an annual report that assesses the effectiveness of the services provided by P&A systems.

SAMHSA's Center for Mental Health Services (CMHS) is revising the PAIMI Annual Program Performance Report for the following reasons: (1) to make it consistent with the revised annual program report format used by the Administration on Developmental Disabilities, Administration on Children and Families; and, (2) to conform to the GPRA requirements that the reporting burden to the States be reduced. CMHS is making no revisions to the PAIMI Annual Advisory Council Report.

Revisions to the PAIMI Annual Program Performance Report include: (1) Deletion of financial expenditure and sub-contractor information, which P&A systems are required to submit annually to the SAMHSA Grants Management Office; (2) Deletion of items that are more appropriate for inclusion in the Guidance for Applicants (GFA), such as PAIMI program staff positions, by-laws and policies and procedures; (3) PAIMI staff, advisory council and governing board demographic information will be reduced to a comprehensive graph format; (4) All ''information not available'' statements will be deleted to ensure that P&A systems focus on gathering more accurate client data during the intake and referral process; (5) Sections such as, PAIMI program mechanisms for public comment, individual PAIMI clients, etc. will be reduced to a graph format similar to that approved by OMB for use by the Administration on Developmental Disabilities, Administration on Children and Families, which administers the Protection and Advocacy to the Developmentally Disabled (PADD) Program; (6) Case complaints and problems of the individuals served by the P&As will be modified to capture more accurate information on incidents of abuse, neglect and civil rights violations, such as the incidents of seclusion and restraint used in the emergency rooms of general hospitals on individuals with mental illness, co-occurring disorders and severe emotional disturbance, during transport