Interested parties may obtain a copy of the solicitation by writing to Ms. Patricia Walker at the address indicated in the **FOR FURTHER INFORMATION CONTACT** paragraph.

Dated: August 3, 1998.

Allan J. Zaic,

Assistant Commissioner, Office of Transportation and Property Management.

[FR Doc. 98–21131 Filed 8–6–98; 8:45 am]

BILLING CODE 6820–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Secretary.

ACTION: Revised notice of meeting.

The Advisory Committee on Blood Safety and Availability will meet on August 27, 1998, from 8:00 a.m. to 5:00 p.m. and on August 28, 1998 from 8:00 a.m. to 3:00 p.m. The meeting will take place in the Ticonderoga Room of the Hyatt Regency Hotel on Capitol Hill, 400 New Jersey, N.W., Washington, D.C. 20001. The meeting will be entirely open to the public.

The agenda of this meeting has been revised as follows: on August 27, 1998 the Committee will consider potential barriers to the evolution from human- to recombinant-based blood products. The focus of this discussion will be on blood products used by patients with bleeding disorders. The discussion will be limited to this topic so that the Committee can discuss, on August 28, 1998 what, if any, additional recommendations it may wish to make regarding the transmissible spongiform encephalopathies and blood safety.

Public comment on the first topic will be solicited at or about 1:00 p.m. on August 28, 1998; public comment on the second topic will be solicited at or about 11:00 a.m. on August 28, 1998. Public comment will be limited to three minutes per speaker. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business August 14, 1998.

FOR FURTHER INFORMATION CONTACT: Stephen D. Nightingale, M.D., Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Safety, Department of Health and Human Services, 200 Independence Avenue S.W., Washington, D.C. 20201. Phone (202) 690–5560 FAX (202) 690–6584 e-mail SNIGHTIN@osophs.dhhs.gov.

Dated: July 27, 1998.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 98–21236 Filed 8–6–98; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Early Head Start Evaluation.

OMB No: 0970–0143.

Description: The Head Start Reauthorization Act of 1994 established a special initiative creating funding for services for families with infants and toddlers. In response the Administration on Children, Youth and Families (ACYF) designed the Early Head Start (EHS) program. In September 1995, ACYF awarded grants to 68 local programs to serve families with infants and toddlers. ACYF has subsequently awarded grants to an additional 107 local programs, for a total of 175 EHS programs.

EHS programs are designed to produce outcomes in four domains: (1) child development, (2) family development, (3) staff development, and (4) community development. The Reauthorization required that this new initiative be evaluated. To study the effect of the initiative, ACYF awarded a contract through a competitive procurement to Mathematical Policy Research, Inc. (MPR) with a subcontract to Columbia University's Center for Young Children and Families. The evaluation will be carried out from October 1, 1995 through September 30, 2000. Data collection activities that are the subject of this Federal Register notice are intended for the third and final phase of the EHS evaluation.

The sample for the child and family assessments will be approximately 3,000 families who include a pregnant woman or a child under 12 months of age, in 17 EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The sample for the child care assessments will include the primary child care provider for the focal child in each of the 3,000 study sample families. The surveys and assessments will be conducted through computer-assisted telephone and personal interviewing, pencil and paper self-administered questionnaires, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to identify the features and evaluate the effectiveness of the EHS program.

Respondents: Applicants to the Early Head Start program and child care providers for Early Head Start families and control group families.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
36-Month Parent Interview, Child Assessment, and Videotaping Protocol	576	1	2.0	1,152
Child Care Provider Interview:				
Child Care Centers—				
Center Directors	161	1	.25	40
Direct Provider	161	1	.17	27
Classroom Staff	161	1	.17	27
Family Child Care Providers	40	1	.5	20
Family Provider Assistants	9	1	.17	1
Relative Care Providers	113	1	.5	57
Relative Provider Assistants	25	1	.17	4
Child Care Provider Observation Protocol:				
Child Care Centers—				
Family Child Care Providers	161	1	2	321
Relative Care Providers	40	1	2	79

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
.....	113	1	2	227
Staff Questionnaire	190	1	1	190
Estimated Total Annual Burden Hours:	.....	.....	.....	2,146

Additional Information: Copies of the proposed collection of information can be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource management, 370 L'Enfant Promenade, S.W., Washington, DC 20047, Attn.: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: August 3, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–21111 Filed 8–6–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0515]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Amendments to Humanitarian Use Device (HUD) Requirements

Section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)) was created as an incentive for the development of HUD's for use in the treatment or diagnosis of diseases or conditions affecting fewer than 4,000 individuals in the United States. FDA is issuing this rule to amend the existing regulations governing HUD's, found in part 814 (21 CFR part 814), to conform to the amendments made by the Food and Drug Administration Modernization Act of 1997 (FDAMA) to section 520(m) of the act.

In the **Federal Register** of April 17, 1998 (63 FR 19185), the agency requested comments on the proposed collection of information amending the regulations governing HUD's. FDA received one comment concerning the information collection provisions of the rule. A summary of the comment and FDA's response is provided as follows.

The comment objected to the annual reporting requirement and suggested that FDA determine the appropriate reporting period at the time of product approval rather than always requiring reporting on an annual basis.

FDA has modified the rule in response to this comment. Under the final rule of June 26, 1996 (61 FR 33232), a humanitarian device exemption (HDE) holder was required to obtain approval of an extension request every 18 months in order to continue marketing the HUD. FDAMA eliminated this requirement but provided that FDA may require the holder to demonstrate continued compliance with the HDE requirements if the agency believes that such demonstration is needed to protect the public health or has reason to believe that the criteria for the exemption are no longer met.

FDA included a provision for annual reporting in the proposed rule because the agency believed that annual reporting would be the most appropriate mechanism for the agency to monitor whether there is reason to question the continued exemption of the device from the act's effectiveness requirements. Upon reconsideration, FDA has determined that the reporting frequency necessary to protect the public health may vary depending upon the device, its intended use, the affected patient population, and experience with the device after it is marketed. Therefore, § 814.126(b)(1) has been modified in the final rule to state that the frequency of the reports will be specified in the approval order for the HDE. Ordinarily, FDA does not expect to require periodic reports to be submitted more frequently than annually. FDA does believe, however, that it may be appropriate to require reports on certain HDE's less frequently and that in many cases the frequency of required reports will decrease after the device has been marketed for a period of time.

FDA estimates that, due to the nature of some of the devices, initially 15 HDE holders per year will be required to submit annual reports. As the agency and industry gain experience with HDE's, FDA believes the number of HDE holders who will be required to submit annual reports will decrease. FDA believes that much of the information will already be in the HDE holder's possession, and the agency estimates that the reports will take an average of 120 hours per response.

The same comment also objected to the ''requirement'' that an ''HDE holder maintain records in perpetuity * * *'' and suggested that a more appropriate timeframe would be 3-calendar years after the manufacturer ceases distribution of the product in question.

Section 814.126(b)(2) of the HDE regulation specifies the types of records that should be maintained by the HDE holder, but does not specify the