ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application	200	1	24	4,800
Estimated Total Annual Burden Hours				4,800

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication

Dated: September 4, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–22852 Filed 9–9–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Withdrawal of Guidances on Estrogen and Estrogen/Progestin-Containing Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two guidances: A draft entitled''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescibing Information for Healthcare Providers and Patient Labeling'' and a final ''Guidance for Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women.'' These guidances are under agency review for change.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Dan Shames, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260

SUPPLEMENTARY INFORMATION: FDA is announcing the withdrawal of two guidances on estrogen and estrogen/progestin drug products. The two guidances being withdrawn are the draft guidance ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescibing Information for Healthcare Providers and Patient Labeling'' (labeling guidance) and the final ''Guidance for Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women'' (combination guidance). The draft labeling guidance was made available for comment in the **Federal Register** of September 27, 1999 (64 FR 52100); the final combination guidance was made available in March 1995. Both guidances are undergoing review for change as a result of the results from the National Institutes of Health (NIH) Women's Health Initiative trial.[1]

Interested persons may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**). 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. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain CDER guidance documents at *http://www.fda.gov/cder/guidance/index.htm*.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22900 Filed 9–9–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

[1] The results of the NIH Women's Health Initiative trial were reported in the *Journal of the American Medical Association*, 2002;288:321–333.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Private Health Insurance Coverage of Immunosuppressive Drugs Survey—NEW

Public Law 106–310, section 2101(b) of Title XXI of the Children's Health Act of 2000, states that the Secretary of Health and Human Services shall provide for a study to determine the costs of immunosuppressive drugs provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs.

The Health Resources and Services Administration (HRSA) has determined the extent of government insurance coverage for immunosuppressive drugs given to children pursuant to organ transplantation. However, HRSA still does not know the extent of private health insurance coverage for immunosuppressive drugs. Analysis of the Organ Procurement and Transplantation Network (OPTN) database revealed that approximately 45% of pediatric organ transplant recipients list their primary insurer as being private health insurance—this category being the largest insurer of pediatric organ transplant recipients. Little is known about co-payments, limitation on drug usage, *etc.,* in this category of patients.

In order to fulfill the requirements of Section 2101(b), the Division of Transplantation in the Office of Special Programs, HRSA, contracted with the EMMES Corporation to study the costs of immunosuppressive drugs and to conduct a survey to send to approximately 600 families of post-transplant liver and kidney patients who list private health insurance as their primary provider at the time of transplantation. Data collected and analyzed will be reported to Congress. The report will contain information about the extent to which private health insurance covers the cost of immunosuppressive drugs given pursuant to organ transplants and provide recommendations from the Secretary of Health and Human Services about the findings. Once information has been collected and the report to Congress submitted, the information will be incorporated into private databases maintained by the EMMES

Corporation which are closely protected and not available to the public. Analytical requests can be made on the data, but requests are subject to an advisory board and the release in any type of personally-identifiable data or standard analytical file will not be available to the public. The Federal government will not have access to any of the personally-identifiable data. All these measures will assure patient privacy.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Respondents	Number of respondents	Responses per respondents	Hours per response	Total hour burden
Guardians patients	600	1	.75	450
Transplant Centers	143	1	2.5	357.50
Total	743			807.50

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 3, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–22901 Filed 9–9–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Refugee Resettlement Program; Final Notice of Availability of Formula Allocation Funding for FY 2002 Targeted Assistance Grants for Services to Refugees in Local Areas of High Need

AGENCY: Office of Refugee Resettlement (ORR), ACF, HHS.

ACTION: Final notice of availability of formula allocation funding for FY 2002 targeted assistance grants to States for services to refugees [1] in local areas of high need.

SUMMARY: This notice announces the availability of funds and award procedures for FY 2002 targeted assistance grants for services to refugees under the Refugee Resettlement Program (RRP). The purpose of these grants is to provide services in localities with large refugee populations, high refugee concentrations, and high use of public assistance by refugees, and where specific needs exist for supplementation of currently available resources.

The final notice reflects adjustments in final allocations to States as a result of additional arrival data. A notice of proposed allocations of targeted assistance funds was published for public comment in the **Federal Register** on May 28, 2002 (67 FR 36905).

DATES: The closing date for submission of applications is October 10, 2002. Refer to the section of this notice entitled Additional Information for more information on submitting applications. For more information on application procedures, States should contact their ORR State Analyst.

[1] Eligibility for targeted assistance includes refugees, asylees, Cuban and Haitian entrants, certain Amerasians from Vietnam who are admitted to the U.S. as immigrants, certain Amerasians from Vietnam who are U.S. citizens, and victims of a severe form of trafficking who receive certification or eligibility letters from ORR. (See section II of this notice on ''Authorization,'' and refer to 45 CFR 400.43 and the ORR State Letter #01–13 on the Trafficking Victims Protection Act dated May 3, 2001.) The term ''refugee,'' used in this notice for convenience, is intended to encompass such additional persons who are eligible to participate in refugee program services, including the targeted assistance program.