program staff and grants officials in assessing the adequacy of applicant's proposals to accomplish project objectives and determine whether the business aspects of grants applications reflect program needs and grants policies. Federal agencies will not be required to collect all of the information included in the proposed data set. The agency will identify the data that must be provided by applicants through instructions that will accompany the application forms.

Frequency: Recording, Reporting, and on Occasion;

Affected Public: Federal, State, local, or tribal governments, business or other for profit, not for profit institutions;

Annual Number of Respondents: 459,425;

Total Annual Responses: 459,425;

Average Burden Per Response: 40 hours;

Total Annual Hours: 19,037,350;

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/oirm/infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *naomi.cook@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be mailed directly to the Desk Officer at the address below: OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, Attention: (OMB#OS–4040–0001), New Executive Office Building, Room 10235, Washington DC 20201.

Dated: January 26, 2005.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 05–1962 Filed 2–1–05; 8:45 am]

BILLING CODE 4168–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0990–New]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), 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.

Type of Information Collection Request: New Collection, Regular;

Title of Information Collection: Office for Human Research Protections, Fellowship Program;

Form/OMB No.: OS–0990–New;

Use: The Office for Human Research Protections (OHRP) developed the Fellowship Program to provide individuals who are interested in learning about OHRP's regulatory processes and programs with an opportunity to expand their knowledge and experience regarding the complexities of the ethical and regulatory issues relating to human subject protections in biomedical and behavioral research.

Frequency: Reporting,

Affected Public: Business or other for-profit;

Annual Number of Respondents: 25;

Total Annual Responses: 25;

Average Burden Per Response: 1 hour;

Total Annual Hours: 50;

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/oirm/infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *naomi.cook@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the OS Paperwork Clearance Officer designated at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0990–New), Room 531–H, 200 Independence Avenue, SW., Washington DC 20201.

Dated: January 21, 2005.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 05–1963 Filed 2–1–05; 8:45 am]

BILLING CODE 4168–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services is issuing this notice pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act to justify the emergency use of Anthrax Vaccine Adsorbed (AVA) for prevention of inhalation anthrax. The Secretary provides notice of the determination of the Department of Defense that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. The determination of the Department of Defense was effective as of December 10, 2004. The Secretary also provides notice that, on the basis of such determination, he has declared an emergency justifying the authorization of the emergency use of AVA.

DATES: This Notice and the referenced declaration are effective as of January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness, (202) 205–2882.

SUPPLEMENTARY INFORMATION:

I. Background

AVA was first licensed by the National Institutes of Health in November 1970. Upon the delegation of vaccine regulation to FDA in 1972, FDA undertook a comprehensive review of the safety, effectiveness, and labeling of all vaccines. *See* 21 CFR 601.25. Under this review, independent advisory panels evaluated the safety and effectiveness data of vaccines to assure that they met appropriate standards. The advisory panel that reviewed AVA concluded that it is safe, effective, and not misbranded, and FDA issued a proposal to adopt the panel's recommendation (the Bacterial Vaccines

and Toxoids Efficacy Review). 50 FR 51002 (Dec. 13, 1985).

In March 2003, six plaintiffs, known as John and Jane Doe 1 through 6, filed suit in the United States District Court for the District of Columbia (the Court) seeking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense, and to declare AVA an investigational drug when used for protection against inhalation anthrax. On December 22, 2003, the Court issued a preliminary injunction barring inoculations under the AVIP in the absence of informed consent or a Presidential waiver of the informed consent requirement.

In the **Federal Register** of January 5, 2004 (69 FR 255), FDA published a final rule and final order in response to the report and recommendations of the independent advisory panel that reviewed the safety and effectiveness data pertaining to AVA. Following FDA's issuance of the final rule and final order, the Court lifted the preliminary injunction on January 7, 2004, except as it applied to the six Doe plaintiffs.

On October 27, 2004, the Court issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. The Court also enjoined operation of the AVIP for inoculation using AVA to prevent inhalation anthrax. On December 29, 2004, FDA reopened the comment period on the Bacterial Vaccine and Toxoids Efficacy Review for 90 days. As a result of the Court's October 27, 2004, order, the use of AVA for the prevention of inhalation anthrax under the AVIP is deemed an unapproved use of an approved product.

II. Determination of the Department of Defense

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb–3(b)(1)(B), the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax.

By letter dated December 22, 2004, the Assistant Secretary of Defense for Health Affairs (Assistant Secretary) requested that the Food and Drug Administration issue an Emergency Use Authorization for the use of AVA for protection against inhalation anthrax. The letter of the Assistant Secretary states that the Deputy Secretary of Defense has assigned authority from the Secretary of Defense to make the statutory determination under section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act.

III. Declaration of the Secretary of Health and Human Services

On December 10, 2004, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. Pursuant to 21 U.S.C. 360bbb–3(b) and on the basis of such determination, I hereby declare an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed subject to the conditions described in the authorization issued under 21 U.S.C. 360bbb(a). Notice of the authorization issued under 21 U.S.C. 360bbb(a) is provided elsewhere in this issue of the **Federal Register**.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–2027 Filed 1–31–05; 11:39 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grants for Battered Women's Shelters.

OMB No.: New collection.

Description: This information collection is authorized under Title III of the Child Abuse Amendments of 1984, Public Law 98–457, as amended. In response to the program announcement, the respondents must submit information about their services program and their eligibility. Information that is collected is used to award grants under the Grants for Battered Women's Shelters program.

Respondents: State agencies administering the Family Violence Prevention and Services program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State FVPSA Agencies	53	1	6	318
Estimated Total Annual Burden Hours				318

Additional Information: Copies of the proposed collection may be obtained 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. E-mail address: *grjohnson@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 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, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: January 26, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–1895 Filed 2–1–05; 8:45 am]

BILLING CODE 4184–01–M