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