TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801	3,406	1,089	3,709,134	.14	519,279

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15371 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0564]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Temporary Marketing Permit Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 26, 2005 (70 FR 43159). The document announced Office of Management Budget approval for State petitions for exemption from preemption. The document was published with an incorrect title and an incorrect docket number. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–14697, appearing on page 43159 in the **Federal Register** of Tuesday, July 26, 2005, the following corrections are made:

1. On page 43159, in the third column, in the heading of the document, ''[Docket No. 2004N–0565]'' is corrected to read ''[Docket No. 2004N–0564]''.

2. On page 43159, in the third column, in the heading of the document, ''Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Petitions for Exemption From Preemption'' is corrected to read ''Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Temporary Marketing Permit Applications''.

3. On page 43159, in the third column, in the **SUMMARY** section of the document, beginning in the fourth line, ''State Petitions for Exemption From Preemption'' is corrected to read ''Temporary Marketing Permit Applications''.

Dated: July 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15369 Filed 8–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0299]

Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension of the Emergency Use Authorization (EUA) (the Authorization) for Anthrax Vaccine Adsorbed (AVA), issued on January 27, 2005, for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by the Department of Defense (DoD) to be at heightened risk of exposure due to attack with anthrax. The FDA Commissioner is extending the term of this Authorization on the request of DoD.

DATES: The extension of the Authorization was effective as of July 22, 2005.

ADDRESSES: Submit written requests for single copies of the extension of the Authorization to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris D. Lushniak, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows the FDA Commissioner, by delegation from the Secretary of Health and Human Services (the Secretary), to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. As a result of an October 27, 2004, order by the U.S. District Court for the District of Columbia, the use of AVA by DoD for the prevention of inhalation anthrax is deemed an unapproved use of an approved product for purposes of section 564(a)(2) of the act.

On December 10, 2004, under section 564(b)(1)(B) of the act, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On December 22, 2004, DoD requested an EUA for AVA for protection against inhalation anthrax. DoD asked for a 6-month authorization and indicated that, if necessary, it might ask for an extension of the duration of the EUA.

Under section 564(b) of the act, and on the basis of the Deputy Secretary of Defense's determination of a significant potential for a military emergency, on January 14, 2005, the Secretary of Health and Human Services, Tommy G. Thompson, declared an emergency justifying the authorization of the emergency use of AVA. Notice of the determination of the Deputy Secretary of Defense and the declaration of the Secretary of Health and Human Services