

for Infectious Diseases, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 4770 Buford Highway, Mailstop F-22, Atlanta, GA 300341. Telephone: 770-488-3601. E-mail: [cxm6@cdc.gov](mailto:cxm6@cdc.gov).

For financial, grants management, or budget assistance, please contact the following: Jeff Napier, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2614. E-mail: [jln1@cdc.gov](mailto:jln1@cdc.gov).

#### VIII. Other Information

Other HHS funding opportunity announcements can be found on the HHS/CDC web site, Internet address: <http://www.cdc.gov> (Click on "Funding," then "Grants and Cooperative Agreements"), and on the HHS Office of Global Health Affairs Web site, Internet address: <http://www.globalhealth.gov> (Click on "What's new," then "Funding Opportunities.").

Dated: July 28, 2005.

**William P. Nichols,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention,  
U.S. Department of Health and Human  
Services.*

[FR Doc. 05-15271 Filed 8-2-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0290]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Importer's Entry Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on

information collection provisions for the Importer's Entry Notice.

**DATES:** Submit written or electronic comments on the collection of information by October 3, 2005.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Importer's Entry Notice (OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of goods to their final destinations; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Custom Service. FDA uses this information to make admissibility decisions about FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2004 was 6,626,827. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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

<sup>1</sup>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]

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## 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