

**B. Federal Reserve Bank of San Francisco** (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. *Western Alliance Bancorporation*, Las Vegas, Nevada; to merge with Intermountain First Bancorp, Las Vegas, Nevada, and thereby indirectly acquire voting shares of Nevada First Bank, Las Vegas, Nevada.

Board of Governors of the Federal Reserve System, January 27, 2006.

**Robert deV. Frierson**,

*Deputy Secretary of the Board.*

[FR Doc. E6-1325 Filed 1-31-06; 8:45 am]

**BILLING CODE 6210-01-S**

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## GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0277]

### Office of Citizen Services and Communications; Information Collection; Market Research Collection

**AGENCY:** Office of Citizen Services and Communications, General Services Administration (GSA).

**ACTION:** Notice of request for comments regarding a renewal to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration has submitted to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding Market Research for the Office of Citizen Services and Communications. A request for public comments was published at 70 FR 69154, November 14, 2005. No comments were received.

This information collection will be used to determine the utility and ease of use of GSA's Web site, <http://www.gsa.gov>. The respondents include individuals and representatives from businesses currently holding GSA contracts.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

**DATES:** Submit comments on or before: March 3, 2006.

**FOR FURTHER INFORMATION CONTACT:** Ms. Jocelyn Johnson, Office of Citizen Services and Communications, at telephone (202) 208-0043, or via e-mail to [jocelyn.johnson@gsa.gov](mailto:jocelyn.johnson@gsa.gov).

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Ms. Jeanette Thornton, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090-0277, Market Research Collection for the Office of Citizen Services and Communications, in all correspondence.

### SUPPLEMENTARY INFORMATION:

#### A. Purpose

The General Services Administration will be requesting the Office of Management and Budget (OMB) to review and approve information collection 3090-0277 concerning Market Research Collection for the Office of Citizen Services and Communications. The purpose of this information collection is to inform GSA on how to best provide service and relevance to the American public via GSA's Web site <http://www.gsa.gov>. The information collected from an online survey, focus groups, and Web site usability testing will be used to refine the <http://www.gsa.gov> Web site. The questions to be asked are non-invasive and do not address or probe sensitive issues. It is important for the GSA to gain information from the many diffuse groups it serves; therefore, the GSA will be questioning individuals and households, and businesses and other for-profit groups.

#### B. Annual Reporting Burden

*Respondents:* 190.

*Responses Per Respondent:* 1.

*Total Responses:* 190.

*Hours Per Response:* 72.6 minutes.

*Total Burden Hours:* 230.

**Obtaining Copies of Proposals:** Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208-7312. Please cite OMB Control No. 3090-0277, Market Research Collection for the Office of Citizen Services and Communications, in all correspondence.

Dated: January 23, 2006.

**Michael W. Carleton**,

*Chief Information Officer.*

[FR Doc. E6-1217 Filed 1-31-06; 8:45 am]

**BILLING CODE 6820-CX-S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Termination, By Expiration, of Declaration of Emergency Justifying Emergency Use Authorization of Anthrax Vaccine Adsorbed

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this notice, under the Federal Food, Drug, and Cosmetic Act (the act), of the termination, by expiration, of the declaration of emergency justifying emergency use authorization of Anthrax Vaccine Adsorbed (AVA) that was issued by the former Secretary of Health and Human Services Secretary Tommy G. Thompson (the former HHS Secretary) on January 14, 2005. The declaration of emergency terminated by expiration on January 14, 2006, which is the end of the 1-year period that began on the date that the declaration was made. Under the act, advance notice of the termination of the declaration was provided to the Department of Defense.

**DATES:** The Notice is effective as of February 1, 2006.

**FOR FURTHER INFORMATION CONTACT:** Boris 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

On December 10, 2004, the Deputy Secretary of Defense determined, under section 564(b)(1)(B) of the act (21 U.S.C. 360bbb-3(b)(1)(B)), that there was a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On the basis of such determination and under section 564(b)(1) of the act, the former HHS Secretary declared an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed. A notice of the determination of the Deputy Secretary of Defense and the declaration of the former HHS Secretary was published in the **Federal**

Register of February 2, 2005 (70 FR 5452).

## II. Advance Notice of Termination

Under section 564(b)(3) of the act, the FDA Commissioner provided advance notice of the termination of the former HHS Secretary's declaration of emergency to the Department of Defense.

The January 2006 letter notifying the Department of Defense of the termination of the declaration of emergency follows:

William Winkenwerder, Jr., M.D.,  
Assistant Secretary of Defense for Health Affairs,

The Pentagon,  
Washington, D.C. 20301-1200  
Dear Dr. Winkenwerder:

This letter is to provide advance notice of the termination of the above-referenced declaration of emergency that was issued by Secretary of Health and Human Services Tommy G. Thompson on January 14, 2005, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3.

In accordance with section 564(b)(2)(A)(ii) of the Act, the declaration of emergency will terminate by expiration on January 14, 2006, which is the end of the one year period that began on the date that the declaration was made. This advance notice of termination will be published in the **Federal Register**, pursuant to section 564(b)(4) of the Act. Sincerely,

Andrew C. von Eschenbach, M.D.  
Acting Commissioner of Food and Drugs

Dated: January 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-1311 Filed 1-31-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004E-0445]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; HUMIRA

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for HUMIRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of

Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product HUMIRA (adalimumab). HUMIRA is indicated for reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Subsequent to this approval, the Patent and

Trademark Office received a patent term restoration application for HUMIRA (U.S. Patent No. 6,090,382) from Abbott Biotechnology Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of HUMIRA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HUMIRA is 1,722 days. Of this time, 1,443 days occurred during the testing phase of the regulatory review period, while 279 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 16, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 16, 1998.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 28, 2002. FDA has verified the applicant's claim that the product license application (BLA) for HUMIRA (BLA 125057) was initially submitted on March 28, 2002.

3. *The date the application was approved:* December 31, 2002. FDA has verified the applicant's claim that BLA 125057 was approved on December 31, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 326 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence