

**9. Who Should We Contact for Further Information and/or To Direct Comments to on the Issue of Limiting the Use of Wireless Phones While Driving Motor Vehicles Owned or Leased by the Federal Government?**

General Services Administration,  
Office of Governmentwide Policy,  
Federal Vehicle Policy Division (MTV),  
Washington, DC 20405, Telephone  
Number: 202-501-1777, E-mail  
Address: vehicle.policy@gsa.gov.

Dated: February 25, 2002.

**G. Martin Wagner,**

*Associate Administrator, Office of  
Governmentwide Policy.*

**Attachment A—Cellular Phone Safe Driving Tips**

Safe driving is your first priority. Always buckle up, keep your hands on the wheel and your eyes on the road.

Make sure that your phone is positioned where it is easy to see and easy to reach. Be familiar with the operation of your phone, so that you're comfortable using it on the road.

Use a hands-free microphone while driving. Make sure your phone is dealer-installed to get the best possible sound quality.

Use the speed dialing feature to program in frequently called numbers. Then you can make a call by touching only two or three buttons. Most phones will store up to 99 numbers.

When dialing manually without the speed dialing feature, dial only when stopped. If you can't stop, or pull over, dial a few digits, then survey traffic before completing the call. (Better yet, have a passenger dial.)

Never take notes while driving. Pull off the road to jot something down; if it's a phone number, many mobile phones have an electronic scratchpad that allows you to key in a new number while having a conversation.

Let your wireless network's voice mail pick up your calls when it's inconvenient or unsafe to answer the car phone. You can even use your voice mail to leave yourself reminders.

Be a cellular Samaritan. Dialing 9-1-1 is a free call for cellular subscribers; use it to report crimes in progress or other potential life-threatening emergencies, accidents or drunk driving.

*Source:* Department of Transportation, National Highway Traffic Safety Administration: An Investigation of the Safety Implications of Wireless Communications in Vehicles November 1997.

[FR Doc. 02-4880 Filed 2-28-02; 8:45 am]

BILLING CODE 6820-14-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Secretary's Advisory Committee on Regulatory Reform**

**AGENCY:** Office of the Assistant Secretary for Planning and Evaluation, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** Notice is hereby given of a public hearing by the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Regulatory Reform. As governed by the Federal Advisory Committee Act in accordance with Section 10(a)(2), the Secretary's Advisory Committee on Regulatory Reform is seeking guidance for the Department's efforts to streamline regulatory requirements. The Advisory Committee will advise and make recommendations for changes that would be beneficial in four broad areas: health care delivery, health systems operations, biomedical and health research, and the development of pharmaceuticals and other products. The Committee will review changes identified through regional public hearings, written comments from the public, and consultation with HHS staff.

All meetings and hearings of the Committee are open to the general public. During each meeting, invited witnesses will address how regulations affect health-related issues. Meeting agendas will also allow some time for public comment. Additional information on each meeting's agenda and list of participating witnesses will be posted on the Committee's Web site prior to the meetings, <http://www.regreform.hhs.gov>.

**DATES:** The second public hearing of the Secretary's Advisory Committee on Regulatory Reform will be held on Wednesday, March 20, 2002, from 8 a.m. to 5 p.m. and on Thursday, March 21, 2002, from 8 a.m. to 12 p.m.

**ADDRESSES:** The hearing will be held in Phoenix, AZ. Information about the exact location will be posted at the Web site address listed above and published in the **Federal Register** when the location has been confirmed.

**FOR FURTHER INFORMATION CONTACT:** Christy Schmidt, Executive Coordinator, Secretary's Advisory Committee on Regulatory Reform, Office of the Assistant Secretary for Planning and Evaluation, 200 Independence Avenue, SW., Room 344G, Washington, DC, 20201, (202) 401-5182.

**SUPPLEMENTARY INFORMATION:** Anyone planning to attend the meeting who requires special disability-related

arrangements such as sign-language interpretation should provide notice of their need by Friday, March 15th. Please make any request to Michael Starkweather—phone: 301-628-3141; fax: 301-628-3101; e-mail: [mstarkweather@s-3.com](mailto:mstarkweather@s-3.com).

On June 8, 2001, HHS Secretary Thompson announced a Department-wide initiative to reduce regulatory burdens in health care, to improve patient care, and to respond to the concerns of health care providers and industry, State and local Governments, and individual Americans who are affected by HHS rules. Common sense approaches and careful balancing of needs can help improve patient care. As part of this initiative, the Department is establishing the Secretary's Advisory Committee on Regulatory Reform to provide findings and recommendations regarding potential regulatory changes. These changes would enable HHS programs to reduce burdens and costs associated with departmental regulations and paperwork, while at the same time maintaining or enhancing the effectiveness, efficiency, impact, and access of HHS programs.

Dated: February 25, 2002.

**William Raub,**

*Deputy Assistant Secretary for Planning and Evaluation.*

[FR Doc. 02-4916 Filed 2-28-02; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration on Aging**

**[Program Announcement No. AoA-02-02]**

**Fiscal Year 2002 Program Announcement; Availability of Funds and Notice Regarding Applications**

**AGENCY:** Administration on Aging, HHS.

**ACTION:** Announcement of availability of funds and request for applications for the Alzheimer Disease Demonstration Grants to States Program.

**SUMMARY:** The Administration on Aging announces that under this program announcement it will hold a competition for grant awards for five (5) to seven (7) projects at a federal share of approximately \$225,000-\$350,000 per year for a project period of three years.

**Purpose of Grant Awards**

The purpose of these projects is to:  
1. Develop models of home and community based care for persons with Alzheimer's disease and their families, and

2. Improve the existing home and community based care system to better respond to the needs of persons with dementia and their families.

#### Eligibility for Grant Awards and Other Requirements

Eligibility for grant awards is limited to state agencies. The twenty-five states currently funded under the Alzheimer's Demonstration Program are not eligible. Only one application per state will be accepted. Applicants must provide a letter from their state's Governor designating the applicant agency as the sole applicant for the state.

Grantees are required to provide a 25% non-federal match during the first year, 35% during the second year, and 45% during the third year of the grant.

**DATES:** The deadline date for the submission of applications is April 24, 2002.

**ADDRESSES:** Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Center for Policy and Planning Development, 330 Independence Ave., SW, Room 4270, Washington, DC 20201, by calling 202/401-4547, or online at <http://www.aoa.gov/egrants>.

Applications may be mailed or hand-delivered to the AoA Office of Grants Management at the same address. Instructions for electronic submission of grant applications are available at <http://www.aoa.gov/egrants>.

Dated: February 25, 2002.

**Josefina G. Carbonell,**

*Assistant Secretary for Aging.*

[FR Doc. 02-4917 Filed 2-28-02; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00E-1233]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for HECTOROL 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 Commissioner of Patents and

Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (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 Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner 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 drug 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 drug product HECTOROL (doxercalciferol). HECTOROL is indicated for the reduction of elevated iPTH levels in the management of secondary hyperparathyroidism in patients undergoing chronic renal dialysis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HECTOROL (U.S. Patent No. 4,555,364) from The Wisconsin

Alumni Research Foundation, 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 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of HECTOROL 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 HECTOROL is 4,072 days. Of this time, 3,614 days occurred during the testing phase of the regulatory review period, while 458 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* April 17, 1988. The applicant claims April 16, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 17, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* March 9, 1998. The applicant claims March 7, 1998, as the date the new drug application (NDA) for HECTOROL (NDA 20-862) was initially submitted. However, FDA records indicate that NDA 20-862 was submitted on March 9, 1998.

3. *The date the application was approved:* June 9, 1999. FDA has verified the applicant's claim that NDA 20-862 was approved on June 9, 1999.

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 1,824 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 30, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by