

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 01-5841 Filed 3-8-01; 8:45 am]

BILLING CODE 6718-02-P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-1361-DR]

Washington; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Washington (FEMA-1361-DR), dated March 1, 2001, and related determinations.

EFFECTIVE DATE: March 1, 2001.

FOR FURTHER INFORMATION CONTACT:

Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3772.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 1, 2001, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, as follows:

I have determined that the damage in certain areas of the State of Washington, resulting from an earthquake on February 28, 2001 and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 (Stafford Act). I, therefore, declare that such a major disaster exists in the State of Washington.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance, Public Assistance, and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint William Lokey of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Washington to have been affected adversely by this declared major disaster:

King, Kitsap, Lewis, Mason, Pierce, and Thurston Counties for Individual Assistance and Public Assistance.

All counties within the State of Washington are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

John W. Magaw,

Acting Deputy Director.

[FR Doc. 01-5845 Filed 3-8-01; 8:45 am]

BILLING CODE 6718-02-P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System

TIME AND DATE: 10:00 a.m., Wednesday, March 14, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: March 6, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01-5951 Filed 3-6-01; 4:14 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: AFIA IDA In-depth Participant Interview.

OMB No.: New Collection.

Description: Part of a Congressionally mandated evaluation of demonstrations carried out under AFIA to address the effects on savings behavior, differential savings rates, homeownership, education and self-employment. To identify lessons to be learned and whether the program should be made permanent.

Respondents: AFIA, IDA Demonstration Participants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
In-depth Interview	540	1	2/3	360

Estimated Total Annual Burden Hours: 360.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 1, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01-5777 Filed 3-8-01; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E-1071]

Determination of Regulatory Review Period for Purposes of Patent Extension; Provigil

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Provigil 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 which 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.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

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 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 Provigil (modafinil). Provigil is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Provigil (U.S. Patent No. 4,177,290) from Cephalon, and the Patent and Trademark Office requested

FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 1999, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Provigil represented the first permitted commercial marketing or use of the product. Later, 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 Provigil is 1,975 days. Of this time, 1,250 days occurred during the testing phase of the regulatory review period, while 725 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:* July 30, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 30, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* December 30, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Provigil (NDA 20-717) was initially submitted on December 30, 1996.

3. *The date the application was approved:* December 24, 1998. FDA has verified the applicant's claim that NDA 20-717 was approved on December 24, 1998.

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 985 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 comments and ask for a redetermination by May 8, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the