Board of Governors of the Federal Reserve System, January 21, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–1917 Filed 1–26–00; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 22, 2000.

A. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervision) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Ohio Legacy Corp., Wooster, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of Ohio Legacy Bank, National Association, Wooster, Ohio.

B. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1413:

1. The Leaders Group, Inc., Oak Brook, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of The Leaders Bank (in organization), Oak Brook, Illinois.

2. Woodland Financial Group L.L.C., Oak Brook, Illinois; to become a bank holding company by acquiring 40 percent of the voting shares of The Leaders Group, Inc., Oak Brook, Illinois, and thereby indirectly acquire The Leaders Bank (in organization), Oak Brook, Illinois.

C. Federal Reserve Bank of San Francisco (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105–1579:

1. Scottsdale Bancorp, Woodbury, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Scottsdale Community Bank (in organization), Scottsdale, Arizona.

Board of Governors of the Federal Reserve System, January 21, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–1918 Filed 1–26–00; 8:45 am]

BILLING CODE 6210–01–P

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: Notice of Meeting on February 10–11, 2000.

Board Meeting Summary: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will hold a meeting on Thursday, February 10, and Friday, February 11, from 9:00 to 4:30 P.M. room 7C13, the Elmer Staats Briefing Room, of the General Accounting Office building, 441 G St., N.W., Washington, D.C.

The purpose of the meeting is to discuss:

- The process for developing Technical Bulletins.
- National Defense PP&E.
- Major Acquisition Programs.
- Amendments to Direct Loans and Loan Guarantee Accounting.
- Other topics as needed.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G St., N.W., Room 6814, Washington, D.C. 20548, or call (202) 512–0730.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: January 24, 2000.

Wendy M. Comes,

Executive Director.

[FR Doc. 00–1981 Filed 1–26–00; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency information collection activities; proposed collections; comment request

The Department of Health and Human Services; Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project 1. HHS Acquisition Regulations—HHSAR Subpart 315 Solicitations and Receipt of Proposals and Quotations—0990–0139—Extension with no change—Subpart 315.4 is needed to ensure consistency in all Departmental solicitations and to ensure that all solicitations describe all of the information which an offeror would need to submit an acceptable proposal. Respondents: State and local government, Businesses or other for-profit organizations, non-profit institutions, small businesses; Total Number of Respondents: 6,645; Frequency of Response: one time; Average Burden per Response: 2 hours; Estimated Annual Burden 13,290 hours.

Send comments to Cynthia Agnes Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW.,

Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: January 18, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 00–1884 Filed 1–26–00 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

NAME: National Committee on Vital and Health Statistics (NCVHS).

TIME AND DATE: 1:30–3:30 EST, February 2, 2000.

PLACE: Conference Call, Participants Dial-in Number: 1–888–422–7105, Participants Code: 348362.

STATUS: Open.

PURPOSE: During this conference call, the Committee will discuss the Notice of Proposed Rule Making (NPRM) issued by HHS on Standards for Privacy of Individually Identifiable Health Information and review draft comments on the NPRM developed by the Subcommittee on Privacy.

NOTICE: This conference call is open to the public using the participants' dial-in telephone number and participants' code, but access may be limited by the number of available telephone lines.

CONTACT PERSON FOR MORE INFORMATION: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Gail Horlick, M.S.W., J.D., Lead Staff Person for the NCVHS Subcommittee on Privacy and Confidentiality, Program Analyst, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–62, Atlanta, Georgia 30333, telephone (404)–639–8345; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: http://www.ncvhs.hhs.gov/, where further information will be posted when available.

Dated: January 19, 2000.

James Scanlon,

Director, Division of Data Policy Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–1885 Filed 1–26–00; 8:45 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0852]

Determination of Regulatory Review Period for Purposes of Patent Extension; Maxalt®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Maxalt® 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: Written comments and petitions should be directed 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, 301–594–5645.

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 Maxalt® (rizatriptan benzoate). Maxalt® is indicated for the acute treatment of migraine attacks, with or without aura in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Maxalt® (U.S. Patent No. 5,298,520) from Merck & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Maxalt® 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 Maxalt® is 2,099 days. Of this time, 1,734 days occurred during the testing phase of the regulatory review period, while 365 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:* October 1, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 1, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* June 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Maxalt® (NDA 20–864) was initially submitted on June 30, 1997.

3. *The date the application was approved:* June 29, 1998. FDA has