Annual reporting hours: 1,800 hours.

Estimated average hours per response: 100.

Number of respondents: 9.

Small businesses are not affected.

General description of report: This information collection is voluntary (12 U.S.C. 248 (a), 353–359, and 461) and is given confidential treatment (5 U.S.C. 552 (b) (4)).

Abstract: The FR 2436 collects derivatives market statistics from a sample of nine large U.S. dealers of over-the-counter (OTC) derivatives. Data are collected on notional amounts and gross market values of the volumes of broad categories of foreign exchange, interest rate, equity- and commodity-linked OTC derivatives instruments across a range of underlying currencies, interest rates, and equity markets.

This collection of information complements the ongoing triennial Survey of Foreign Exchange and Derivatives Market Activity (FR 3036). The FR 2436 collects similar data on the outstanding volume of derivatives, but not on derivatives turnover. As with the FR 3036, the Federal Reserve conducts this report in coordination with other central banks and forwards the aggregated data furnished by U.S. reporters to the Bank of International Settlements (BIS), which publishes global market statistics that are aggregations of national data.

4. *Report title:* Reports Related to Securities Issued by State Member Banks as Required by Regulation H.

Agency form number: Reg H–1.

OMB control number: 7100–0091.

Frequency: On occasion.

Reporters: State member banks.

Annual reporting hours: 2,085 hours.

Estimated average hours per response: 5.11.

Number of respondents: 24.

Small businesses are not affected.

General description of report: This information collection is mandatory (15 U.S.C. 781(i)) and is not given confidential treatment.

Abstract: The Federal Reserve's Regulation H requires certain state member banks to submit information relating to their securities to the Board of Governors of the Federal Reserve System on the same forms that bank holding companies and nonbank entities use to submit similar information to the Securities and Exchange Commission (SEC). The information is primarily used for public disclosure and is available to the public upon request.

Board of Governors of the Federal Reserve System, January 8, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–990 Filed 1–11–01; 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. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

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 5, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Ames National Corporation, Ames, Iowa; to retain 5.39 percent of investment in Mahaska Investment Company, Oskaloosa, Iowa, and obtain approval to acquire a total of 10 percent of the voting shares of Mahaska Investment Company, Oskalossa, Iowa, and its subsidiary banks, Mahaska State Bank, Oskaloosa, Iowa, and Pella State Bank, Pella, Iowa.

In connection with this application, Applicant also has applied to acquire Midwest Federal Savings & Loan Association of Eastern Iowa, Burlington, Iowa, Central Valley Bank, Ottumwa, Iowa, and thereby engage in operating savings associations, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, January 8, 2001.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 01–991 Filed 1–11–01; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Office of Communications; Cancellation of a Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The Department of Agriculture and the Department of Interior has cancelled the following Optional Form because of low usage: OF 289, Property Loss or Damage Report—Fire Suppression.

DATES: Effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: January 2, 2001.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 01–1104 Filed 1–11–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0490]

Determination of Regulatory Review Period for Purposes of Patent Extension; Synvisc Hylan G–F 20 (5,099,013)®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Synvisc Hylan G–F 20 (5,099,013)® 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 medical device.

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, 301–594–5645.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Synvisc Hylan G–F 20 (5,099,013)®. Synvisc Hylan G–F 20 (5,099,013)® is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (e.g., acetaminophen). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Synvisc Hylan G–F 20 (5,099,013)® (U.S. Patent No. 5,099,013) from Biomatrix, Inc., 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 medical device had undergone a regulatory review period and that the approval of Synvisc Hylan G–F 20 (5,099,013)® 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 Synvisc Hylan G–F 20 (5,099,013)® is 2,949 days. Of this time, 1,783 days occurred during the testing phase of the regulatory review period, while 1,166 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* July 14, 1989. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective July 14, 1989.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* May 31, 1994. FDA has verified the applicant's claim that the premarket approval application (PMA) for Synvisc Hylan G–F 20 (5,099,013)® (PMA P940015) was initially submitted May 31, 1994.

3. *The date the application was approved:* August 8, 1997. FDA has verified the applicant's claim that PMA P940015 was approved on August 8, 1997.

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 396 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 March 13, 2001. 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 July 11, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30. Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 2000.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug evaluation and Research.

[FR Doc. 01–974 Filed 1–11–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anti-Infective Drugs Advisory Committee. This meeting was announced in the **Federal Register** of December 27, 2000 (65 FR 81874). The amendment is being made to cancel the entire session on January 29, 2001. This meeting will be open to the public. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 27, 2000 (65 FR 81874), FDA announced that a meeting of the Anti-Infective Drugs Advisory Committee would be held on January 29 and 30, 2001. On page 81874, beginning in the first column, the *Date and Time*, *Location*, *Agenda*, and *Procedure* portions of this meeting are amended to read as follows: