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. 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 December 18, 1998.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Union Planters Corporation, and its wholly owned subsidiary, Union Planters Holding Corporation, both of Memphis, Tennessee; to acquire 100 percent of the voting shares of First Mutual Bancorp, Inc., Decatur, Illinois, and thereby indirectly acquire First Mutual Bank, S.B., Decatur, Illinois.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Woodlands Bancorp, Inc., Homer, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of First Woodlands Bank, Homer, Louisiana;

Board of Governors of the Federal Reserve System, November 19, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31427 Filed 11–24–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 9, 1998.

A. Federal Reserve Bank of San Francisco (Maria Villanueva, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Philippine National Bank, Metro Manila, The Philippines, and Century Holding Corporation, Beverly Hills, California; to acquire PNB Remittance Centers, Inc., Los Angeles, California, and thereby engage in money remittance activities; *Philippine Commercial International Bank*, 77 Fed. Res. Bull. 270 (1991); *Bergen Bank A/S*, 76 Fed. Res. Bull. 457 (1990); and *Norwest Corporation*, 81 Fed. Res. Bull. 974 (1995).

Board of Governors of the Federal Reserve System, November 19, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31426 Filed 11–24–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0396]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed in this document has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by December 28, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Title: Medical Devices; Reports of Corrections and Removals.

Description: FDA issued a direct final rule to amend the reporting and recordkeeping requirements for corrections and removals under part 806 (21 CFR part 806) to eliminate those requirements for distributors of medical devices. This amendment implements changes made by the Food and Drug Administration Modernization Act of 1997 (FDAMA) to section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)). FDAMA did not amend section 519(f) of the act with respect to manufacturers and importers. Manufacturers and importers continue to be subject to the requirements of part 806.

Description of Respondents: Business or other for profit organizations.

In the **Federal Register** of August 7, 1998 (63 FR 42229), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	440	1	440	10	4,400

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements in part 806 prior to the direct final rule (63 FR 42229) have been approved by OMB and assigned control number 0910–0359. When preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under 21 CFR part 7 (the agency's recall provisions). During that period of time, no reports of corrections or removals were submitted by distributors. For that reason, FDA did not include distributors among the respondents estimated in the collection burden for the requirements previously approved by OMB. Because distributors were not included in that earlier estimate and because FDAMA now has eliminated requirements for distributor reporting, FDA has determined that estimates of the reporting burden for §§ 806.10 and 806.20 should remain the same.

Dated: November 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31411 Filed 11–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0791]

Determination of Regulatory Review Period for Purposes of Patent Extension; Tisseel VH Kit

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Tisseel VH Kit 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 biological 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: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 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 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 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 Tisseel VH Kit. Tisseel VH Kit is indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of splenic injuries due to blunt or penetrating trauma to the abdomen, when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery is ineffective or impractical, and also as an adjunct for the closure of colostomies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Tisseel VH Kit (U.S. Patent No. 4,362,567) from Immuno Aktiengesellschaft fur chemsih-medizinshe Produkte, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 7, 1998, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Tisseel VH Kit 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 Tisseel VH Kit is 5,065 days. Of this time, 1,203 days occurred during the testing phase of the regulatory review