

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

1. *Community West Bancshares*, Goleta, California; to become a bank holding company by acquiring 100 percent of the voting shares of Goleta National Bank, Goleta, California.

Board of Governors of the Federal Reserve System, November 13, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97-30280 Filed 11-18-97; 8:45 am]

BILLING CODE 6210-01-F

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. 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 15, 1997.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. *Compass Bancshares, Inc., and Compass Banks of Texas, Inc.*, both of Birmingham, Alabama, and *Compass Bancorporation of Texas, Inc.*,

Wilmington, Delaware; to merge with Fidelity Resources Company, University Park, Texas, and Fidelity Resources Company of Delaware, Wilmington, Delaware, and thereby indirectly acquire Fidelity Bank, National Association, University Park, Texas.

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

1. *Richmond Mutual Bancorporation, Inc., and First Mutual of Richmond, Inc.*, both of Richmond, Indiana; to become bank holding companies by acquiring 100 percent of the voting shares of First Bank of Richmond, Richmond, Indiana.

C. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Sundance Bankshares, Inc.*, Sundance, Wyoming; to become a bank holding company by acquiring 100 percent of the voting shares of Sundance State Bank, Sundance, Wyoming.

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

1. *Eggemeyer Advisory Corp., and Castle Creek Capital LLC, Castle Creek Capital Partners Fund - I, LP*, all of La Jolla, California; to acquire up to 24.9 percent of the voting shares of Regency Bancorp, Fresno, California, and thereby indirectly acquire Regency Bank, Fresno, California.

In connection with this application, Applicants have also applied to acquire Regency Investment Advisors, Fresno, California, and thereby engage in financial and investment advisory activities, pursuant to § 225.28(b)(6) of the Board's Regulation Y.

2. *InterWest Bancorp, Inc.*, Oak Harbor, Washington; to merge with Puget Sound Bancorp, Inc., Port Orchard, Washington, and thereby indirectly acquire First National Bank of Port Orchard, Port Orchard, Washington.

Board of Governors of the Federal Reserve System, November 14, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97-30374 Filed 11-18-97; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97C-0466]

Archer Daniels Midland Co.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Archer Daniels Midland Co. has filed a petition proposing that the color additive regulations be amended to provide for the safe use of astaxanthin from *Phaffia rhodozyma* as a color additive in salmonid fish feeds.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3076.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0252) has been filed by Archer Daniels Midland Co., P.O. Box 1470, Decatur, IL 62525. The petition proposes to amend the color additive regulations to provide for the safe use of astaxanthin from *P. rhodozyma* as a color additive in salmonid fish feeds.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: October 31, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97-30336 Filed 11-18-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F-0467]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: NOTICE.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of benzenesulfonic acid, 4-chloro-5-methyl-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazo-4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food.

DATES: Written comments on petitioner's environmental assessment by December 19, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4566) has been filed by Ciba Specialty Chemicals Corp., 335 Water St., Newport, DE 19804. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of benzenesulfonic acid, 4-chloro-5-methyl-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazo-4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 3, 1997.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 97-30406 Filed 11-18-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0460]

Ventritex, Inc.; Premarket Approval of the TVL® Lead System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Ventritex, Inc., Sunnyvale, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the TVL® Lead System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 10, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 19, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Doris J. Terry, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609.

SUPPLEMENTARY INFORMATION: On June 30, 1995, Ventritex, Inc., Sunnyvale, CA 94086-6527, submitted to CDRH an application for premarket approval of the TVL® Lead System. The TVL® Lead System is indicated for use with commercially available pulse generators with which it has been tested. The TVL® Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tachyarrhythmias. In addition, the TVL® Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy backup in the event that the arrhythmia accelerates.

In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Advisory Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially

duplicates information previously reviewed by this panel. On May 10, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before December 19, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).