

1. *Susquehanna Bancshares*, Litiz, Pennsylvania; to acquire 100 percent of the voting shares of First Capitol Bank, York, Pennsylvania.

C. Federal Reserve Bank of Richmond (A. Linwood Gill III, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Mid-Atlantic Community BankGroup, Inc.*, Gloucester, Virginia; to merge with United Community Bankshares, Inc., Franklin, Virginia, and thereby indirectly acquire The Bank of Sussex and Surry, Wakefield, Virginia, and The Bank of Franklin, Franklin, Virginia.

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

1. *First Citizens Bancshares, Inc.*, Dyersburg, Tennessee; to merge with First Volunteer Corporation, Union City, Tennessee, and thereby indirectly acquire First Volunteer Bank, Union City, Tennessee.

Board of Governors of the Federal Reserve System, September 24, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-26074 Filed 9-29-98; 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 October 23, 1998.

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

1. *Decatur Bancshares, Inc.*, Decatur, Arkansas; to acquire Grand Federal Savings Bank, Grove, Oklahoma, and thereby engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, September 24, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-26073 Filed 9-29-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 8:15 a.m.-6:15 p.m., October 21, 1998. 8 a.m.-4:30 p.m., October 22, 1998.

Place: Atlanta Marriott North Central, 2000 Century Boulevard, N.E., Atlanta, Georgia 30345-3377.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise, the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The agenda will include an update on the Food and Drug Administration; National Immunization Program; update on the Vaccine Injury Compensation Program; update on the National Vaccine Program; review of changes in the revised draft rabies recommendation; consider for approval or modification the draft recommendations for use of Lyme disease vaccine; progress on The Guide to Community Preventive Services chapter on methods to raise vaccination coverage levels

among children, adolescents, and adults; approval of changes in the harmonized immunization schedule; approval of the Notice to Readers for hepatitis B and for DTaP; consolidate resolutions currently included in the Vaccines for Children (VFC) Program; resolution to include rotavirus in the VFC Program; discuss the present ACIP general recommendations; computerization of ACIP recommendations; pneumococcal conjugate vaccine; update on U.S. influenza activity; update on ACIP prevention and control guidelines; influenza outbreak aboard a cruise ship in 1997; influenza outbreak among tour group passengers in Alaska in 1998; 1997-98 Aviron live attenuated influenza vaccine trial; 1997-98 vaccine cost effectiveness study of healthy adult workers; update on implementation of the sequential IPV/OPV schedule; revised recommendation for vaccination of children against hepatitis A; and the Infectious Disease Society of America efforts on vaccine safety. Other matters of relevance among the Committee's objectives may be discussed.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Gloria A. Kovach, Committee Management Specialist, CDC, 1600 Clifton Road, NE, Mailstop D50, Atlanta, Georgia 30333, telephone 404/639-7250.

Dated: September 24, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-26128 Filed 9-29-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 78G-0195]

Valley Forest Resources, Inc.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP MF-3714) proposing to affirm that the use of ground whole aspen and ground aspen parts as a feedstuff for livestock are generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 28, 1978 (43 FR 32864), FDA announced that a petition (GRASP MF-

3714) had been jointly filed by Aspen Fiber Corp., P.O. Box 14, Marcell, MN 56657, and Fiber For, Inc., R.D. No. 4, Box 207, Prior Lake, MN 55372. This petition proposed to amend the GRAS regulations in 21 CFR part 582 to affirm that ground whole aspen and ground aspen parts used as a feedstuff for livestock are GRAS.

FDA spoke with a member of the Minnesota Office of Economic Opportunity, Minnesota Department of Economic Security, and a former employee of the Aspen Fiber Corp. Through these sources, FDA determined that Aspen Fiber Corp. has merged with Valley Forest Resources, Inc., HC 1 Box 76, Marcell, MN 56657. Valley Forest Resources agreed, by letter of April 2, 1998, to the withdrawal of the petition. FDA attempted to contact Fiber For, Inc., by letter of January 28, 1998, but that letter was returned as undeliverable. FDA has been unable to locate the firm through directory assistance or the Internet.

The petition is withdrawn based on the letter from Valley Forest Resources, Inc., without prejudice to future filing.

Dated: September 17, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-26085 Filed 9-29-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98P-0425, 98P-0506, and 98P-0621]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of petitions requesting exemption from the premarket notification requirements for certain class II devices. FDA is publishing this notice in order to obtain comments on these petitions in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by October 30, 1998.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101-629)), devices are to be classified into Class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) generally referred to as preamendment devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendment devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is

“substantially equivalent” within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added a new section 510(m)(1) of the act which requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.” That guidance can be obtained through the World Wide Web on the CDRH Home Page at “<http://www.fda.gov/cdrh>” or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify “159” when prompted for the document shelf number.

III. List of Petitions

FDA has received the following petitions requesting an exemption from premarket notification for class II devices: