

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 May 19, 1997.

**A. Federal Reserve Bank of Philadelphia** (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:  
1. *Susquehanna Bancshares, Inc.*, Lititz, Pennsylvania; to acquire 100 percent of the voting shares of Founders Bank, Bryn Mawr, Pennsylvania.

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

1. *First Robinson Financial Corporation*, Robinson, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of First Robinson Savings Bank, National Association, Robinson, Illinois, the successor to the charter of First Robinsin Savings & Loan, F.A., Robinson, Illinois, which will convert from a mutual to a stock savings and loan association, and then to a national bank.

Board of Governors of the Federal Reserve System, April 21, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97-10691 Filed 4-24-97; 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 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. Once the notice has been accepted for processing, it will also 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 May 9, 1997.

**A. Federal Reserve Bank of Minneapolis** (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480-2171:

1. *Norwest Corporation*, Minneapolis, Minnesota; to acquire IMS Mortgage Company, Cedar Rapids, Iowa, and thereby engage in residential mortgage lending activities, pursuant to § 225.28(b)(1) of the Board's Regulation Y. The co-venturers will be Norwest Ventures, Inc., Des Moines, Iowa, and East Brook Corporation of Iowa, d/b/a/ Skogman Realty, Cedar Rapids, Iowa.

Board of Governors of the Federal Reserve System, April 21, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97-10690 Filed 4-24-97; 8:45 am]

BILLING CODE 6210-01-F

## FEDERAL RESERVE SYSTEM

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Board of Governors of the Federal Reserve System.

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** 62 FR 18629-30, April 16, 1997.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** 11:00 a.m., Monday, April 21, 1997.

**CHANGES IN THE MEETING:** Addition of the following closed items to the meeting: (1) Proposed amendments to the Voluntary Guide to Conduct for Senior Federal Reserve System Officials; and (2) Status Report of the Committee on the Federal Reserve in the Payments Mechanism (Alternative Roles for the Federal Reserve in the Retail Payments System).

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: April 22, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97-10824 Filed 4-23-97; 10:30 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0137]

### Cellpro, Inc.; Premarket Approval of CEPRATE® SC Stem Cell Concentration System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by CellPro, Inc., Bothell, WA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CEPRATE® SC Stem Cell Concentration System (CEPRATE® SC System). FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of December 6, 1996, of the approval of the application.

**DATES:** Petitions for administrative review by May 27, 1997.Q02

**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:** Keith O. Webber, Center for Biologics Evaluation and Research (HFM-594), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5103.

**SUPPLEMENTARY INFORMATION:** On January 3, 1994, CellPro, Inc., Bothell, WA 98021, submitted to CBER an application for premarket approval of the CEPRATE® SC System. The device is indicated for the processing of autologous bone marrow to obtain a cell population enriched with cells displaying the CD34 surface marker (CD34+). Such cells are intended for hematopoietic support after myeloablative chemotherapy. Infusion of CD34+ enriched cell populations results in a lower incidence of dimethyl sulfoxide infusion-associated complications compared with infusion of unselected bone marrow cells. The CEPRATE® SC System consists of an instrument and a single-use, sterile, prepackaged kit containing disposable components which includes: (1) An avidin column, (2) a precolumn, (3) a tubing set, (4) a vial of anti-CD34+ biotinylated monoclonal antibody, (5) a blood filter, and (6) wash and culture media. The CEPRATE® SC System concentrates CD34+ cells using a

proprietary, continuous flow immunoadsorption technique. Bone marrow cells are harvested, fractionated for recovery of the buffy-coat and incubated with biotinylated murine anti-CD34 monoclonal antibody which selectively binds CD34+ cells. After incubation, the cells are washed to remove excess, unbound antibody and then processed through the CEPRATE® SC System. After processing through the CEPRATE® SC System, the CD34+ enriched population of autologous bone marrow cells are reinfused into the patient.

On December 6, 1996, CBER approved the application by a letter to the applicant from the Director of the Office of Therapeutics Research and Review, CBER.

In the December 6, 1996, approval letter the expiration dating period for the anti-human CD34 biotinylated antibody (murine) was approved at 18 months when stored at -70 °C. An expiration dating period for all other components of the CEPRATE® SC Disposables Kit was approved for 12 months when stored at the appropriate temperatures. FDA received a submission from CellPro, Inc., dated December 12, 1996, in support of extending the expiration dating period for the remaining components of the CEPRATE® SC System from 12 months to 18 months. On February 19, 1997, FDA approved the 18-month expiration dating period for all components of the CEPRATE® SC System except for the Roswell Park Memorial Institute cell culture medium, which has an approved expiration dating period of 16 months.

FDA has determined that the sale, distribution, and use of the CEPRATE® SC System is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)). FDA has also determined that to ensure the safe and effective use of the device, the CEPRATE® SC System is further restricted within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as: (1) The labeling specifies the requirements that apply to the training of practitioners who may use the device; and (2) the sale, distribution, and use must not violate section 502(q) and (r) of the act (21 U.S.C. 352(q) and (r)).

A summary of the safety and effectiveness data on which CBER 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 CBER'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 CBER'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 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 May 27, 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 Biologics Evaluation and Research (21 CFR 5.53).

Dated: April 17, 1997.

**Kathryn C. Zoon,**

*Director, Center for Biologics Evaluation and Research.*

[FR Doc. 97-10720 Filed 4-24-97; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of the Committee:* Veterinary Medicine Advisory Committee.

*General Function of the Committee:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

*Date and Time:* The meeting will be held on May 13 and 14, 1997, 8:30 a.m. to 4:30 p.m. Open public hearing portions are scheduled from 2:30 p.m. to 3:30 p.m. on May 13, 1997, and from 1 p.m. to 2 p.m. on May 14, 1997.

*Location:* Holiday Inn—Gaithersburg, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Jacquelyn L. Pace, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-5920, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On May 13, 1997, the committee will discuss veterinary medical issues related to the quality standards for the manufacture of animal drugs, such as current good manufacturing practices. On May 14, 1997, the committee will discuss topics concerned with the Animal Drug Use Clarification Act, specifically, the part of the regulation that permits extralabel use where a drug is clinically ineffective.

*Procedure:* The meeting is open to the public. Interested persons may present data, information, or views, orally, or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 7, 1997. Those desiring to make formal presentations should notify the contact person before May 7, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of