Address: 3405 NW. 72nd Ave., Bldg. A, Ste. 101, Miami, FL 33122
Date Revoked: August 2, 1995
Reason: Failed to maintain a valid surety bond.

License Number: 2656
Name: Air Compak International Inc.
Address: 919 Conestoga Rd., Ste. 312, Rosemont, PA 19010
Date Revoked: August 4, 1995
Reason: Surrendered license voluntarily.

License Number: 287
Name: Lunham & Reeve, Inc.
Address: One World Trade Center, Ste. 3327, New York, NY 10048
Date Revoked: August 17, 1995
Reason: Failed to maintain a valid surety bond.

License Number: 3640
Name: Ruben Posada dba Posada International Cargo
Address: 9432 Bellanca Ave., Ste. 200, Los Angeles, CA 90045
Date Revoked: August 26, 1995
Reason: Failed to maintain a valid surety bond.

License Number: 2965
Name: Kamigumi U.S.A., Inc.
Address: 19401 S. Vermont Ave., Ste. J100, Torrance, CA 90502
Date Revoked: August 31, 1995
Reason: Surrendered license voluntarily.

License Number: 1886
Name: Ocean-Air Forwarding, Inc.
Address: R.D. #1, Burgettstown, PA 15021
Date Revoked: September 6, 1995
Reason: Surrendered license voluntarily.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 95–24068 Filed 9–27–95; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Greene County Bancshares, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application 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 to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than October 20, 1995.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Greene County Bancshares, Inc., Greeneville, Tennessee; to acquire 100 percent of the voting shares of Premier Bancshares, Inc. (formerly Niota Bancshares, Inc.), Niota, Tennessee, and thereby indirectly acquire Premier Bank of East Tennessee (formerly Bank of Niota), Niota, Tennessee.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Thumb Bancorp, Inc., Pigeon, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of Thumb National Bank and Trust Company, Pigeon, Michigan.

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Union Planters Corporation, Memphis, Tennessee; to acquire 100 percent of the voting shares of First Bancshares of Eastern Arkansas, Inc., West Memphis, Arkansas, and thereby indirectly acquire First National Bank in West Memphis, West Memphis, Arkansas.

2. Union Planters Corporation, Memphis, Tennessee; to acquire 100 percent of the voting shares of First Bancshares of N.E. Arkansas, Inc., Osceola, Arkansas, and thereby indirectly acquire First National Bank in Osceola, Osceola, Arkansas.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Metropolitan Bancshares, Inc., Aurora, Colorado; to become a bank holding company by acquiring 100 percent of the voting shares of Wally Bancorp, Inc., Parker, Colorado, and thereby indirectly acquire Community Bank of Parker, Parker, Colorado.

E. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Neighborhood Bancorp, San Diego, California; to become a bank holding company by acquiring 50.1 percent of the voting shares of Neighborhood Development Bank, National Association (in Organization), San Diego, California.

2. Sacramento Commercial Bancorp, Sacramento, California; to become a bank holding company by acquiring 100 percent of the voting shares of Sacramento Commercial Bank, Sacramento, California.

Board of Governors of the Federal Reserve System, September 22, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24074 Filed 9–27–95; 8:45 am]

BILLING CODE 6210–01–F

Peoples Savings Financial Corporation; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application 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 consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the

reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 12, 1995.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Peoples Savings Financial Corporation, Ridgway, Pennsylvania; to engage *de novo* in lending activities, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, September 22, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24075 Filed 9–27–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Investigational New Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational new biological product trials. CBER held its first clinical hold review committee meeting on May 17, 1995. FDA is inviting any interested biological company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational new biological products trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in October 1995. Biological companies may submit review requests for the October meeting before October 10, 1995.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational product. The IND must contain the study protocol, a summary of human and animal experience with the product, and information on the product's characterization, chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of human subjects of research and to help ensure that the quality of any scientific evaluation of a drug is adequate to permit an evaluation of the product's efficacy and safety.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

FDA regulations in § 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a clinical hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold.

A clinical hold is ordered by or on behalf of the director of the division that is responsible for review of the IND. The order identifies the studies under the IND to which the clinical hold applies and explains the basis for the action. The clinical hold order may be made by telephone or other means of rapid communication, or in writing. Irrespective of the 30-day time limit permitted by § 312.42(d), CBER policy provides that within 15 days of the notification of the clinical hold by telephone or other method of rapid communication, the sponsor will be provided with a written explanation of the basis for the clinical hold. In addition to providing a statement of reasons, this ensures that the clinical hold is recorded in CBER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption without notification, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center for Drug Evaluation and Research's (CDER's) practices in imposing clinical holds. First, CDER completed a centerwide review of clinical holds recorded in their management information system. While some differences in practice and procedure were discerned among