

Name: Spartan Overseas Shipping Corp.
Address: 181 South Franklin Ave.,
Valley Stream, NY 11581

Date Revoked: November 1, 1995

Reason: Surrendered license
voluntarily.

License Number: 3382

Name: W.I.D.E. Corporation

Address: 850 Center Drive, Elizabeth, NJ
07201

Date Revoked: November 5, 1995

Reason: Failed to maintain a valid
surety bond.

License Number: 2097

Name: Concept Cargo, Inc.

Address: 8269-8287 N.W. 54th Street,
Miami, FL 33166

Date Revoked: November 20, 1995

Reason: Surrendered license
voluntarily.

License Number: 2825

Name: Henry L. Rosich dba Rosich

Forwarding Company
Address: 409 Warren Boulevard,
Broomall, PA 19008

Date Revoked: November 20, 1995

Reason: Surrendered license
voluntarily.

Bryant L. VanBrakle,

*Director, Bureau of Tariffs, Certification and
Licensing.*

[FR Doc. 95-29928 Filed 12-7-95; 8:45 am]

BILLING CODE 6730-01-M

evidence that would be presented at a
hearing.

Unless otherwise noted, comments
regarding each of these applications
must be received not later than January
2, 1996.

A. Federal Reserve Bank of
Richmond (Lloyd W. Bostian, Jr., Senior
Vice President) 701 East Byrd Street,
Richmond, Virginia 23261:

1. *Scotland Bancorp, Inc.*, Laurinburg,
North Carolina; to become a bank
holding company by acquiring 100
percent of the voting shares of Scotland
Savings Bank, SSB, Laurinburg, North
Carolina.

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

1. *Republic Bancshares, Inc.*, St.
Petersburg, Florida; to become a bank
holding company by acquiring 100
percent of the voting shares of Republic
Bank, St. Petersburg, Florida. Comments
regarding this notice should be received
not later than December 22, 1995.

Board of Governors of the Federal Reserve
System, December 4, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95-29931 Filed 12-07-95; 8:45 am]

BILLING CODE 6210-01-F

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.

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 22, 1995.

A. Federal Reserve Bank of
Richmond (Lloyd W. Bostian, Jr., Senior
Vice President) 701 East Byrd Street,
Richmond, Virginia 23261:

1. *Southern National Corporation*,
Winston-Salem, North Carolina; to
engage *de novo* in making, acquiring, or
servicing loans or other extensions of
credit pursuant to § 225.25(b)(1) of the
Board's Regulation Y.

B. Federal Reserve Bank of Dallas
(Genie D. Short, Vice President) 2200
North Pearl Street, Dallas, Texas 75201-
2272:

1. *South Plains Financial, Inc.*,
Lubbock, Texas; to engage *de novo*
through its subsidiary, South Plains
Financial Services, Inc., Lubbock,
Texas, in providing for others, data
processing and data transmission
services, facilities (including data
processing and data transmission
hardware, software, documentation or
operating personnel), pursuant to §
225.25(b)(7) of the Board's Regulation Y,
and in performing real estate and
personal property appraisals, including
tangible and intangible personal
property, pursuant to § 225.25(b)(13) of
the Board's Regulation Y. These
activities will take place in the state of
Texas.

Board of Governors of the Federal Reserve
System, December 4, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95-29932 Filed 12-8-95; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Scotland Bancorp, 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

Southern National Corporation, et al.; Notice of Applications to Engage *de novo* in Permissible Nonbanking Activities

The companies listed in this notice
have 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.

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA) Notice of Meeting

Pursuant to Public Law 92-463,
notice is hereby given of the meeting of

the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council in January 1996.

The meeting of the SAMHSA National Advisory Council will include discussions concerning SAMHSA's Reauthorization; update on SAMHSA's demonstration program; SAMHSA's Managed Care Initiative, including the role of SAMHSA in developing mental health and substance abuse standards for managed care facilities; report on the Performance Partnership Development Process and Regional Meetings; and a report on the Co-Occurring Meeting. In addition various constituency organizations will be describing their collaborative efforts around the development of performance measures and outcomes monitoring, and exemplary community based programs will be describing their efforts to prevent and treat mental and addictive disorders. Finally, there will be status reports by the Council's work groups on Health Care Reform and Children's Services. Attendance by the public will be limited to space available.

The meeting will also include the review, discussion and evaluation of contract proposals. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c) (3), (4) and (6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Ms. Susan E. Day, Program Assistant, SAMHSA National Advisory Council, 5600 Fishers Lane, Room 12C-15, Rockville, Maryland 20857. Telephone: (301) 443-4640.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Substance Abuse and Mental Health Services Administration, National Advisory Council.

Meeting Date: January 22, 1996.

Place: Omni-Shoreham Hotel, 2500 Calvert Street, N.W., Washington, DC 20008.

Open: January 22, 1996, 9:00 a.m. to 4:30 p.m.

Closed: January 22, 1996, 5:00 p.m. to 6:00 p.m.

Contact: Toian Vaughn, Room 12C-15, Parklawn Building, telephone (301) 443-4640 and FAX (301) 443-1450.

Dated: December 4, 1995.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 95-29934 Filed 12-7-95; 8:45 am]

BILLING CODE 4162-20-P

Food and Drug Administration

[Docket No. 95N-0371]

Interim Definition and Elimination of Lot-by-Lot Release For Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an interim definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. FDA is also announcing that FDA is eliminating lot-by-lot release for licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. After approval, manufacturers of such products are no longer requested to submit samples and protocols for individual lots of products to the Center for Biologics Evaluation and Research (CBER) for routine lot-by-lot release. Manufacturers may begin distributing products affected by this policy after notification by CBER and without awaiting approval of a supplement to their product license applications. This notice is intended to reduce unnecessary burdens for industry without diminishing public health protection.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding lot release: Jerome A. Donlon, Center for Biologics Evaluation and Research (HFM-200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-2200.

Regarding the definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product: Jean M. Olson, Center for Biologics Evaluation and Research (HFM-630), Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: This notice is being issued in accordance with the principles set forth in Executive Order 12866. Executive Order 12866 directs Federal agencies to implement measures that will reform and streamline the regulatory process to avoid unnecessary regulatory burdens. In the November 1995 "Reinventing the Regulation of Drugs Made from Biotechnology" report, the President and Vice President announced a series of regulatory reform initiatives, including FDA's intention to issue a notice eliminating lot-by-lot release for licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. FDA made a commitment to issue the notice within 30 days of the report.

Elimination of Lot-by-Lot Release

Biologics have traditionally been complex mixtures of substances produced primarily from living organisms, and have been difficult to characterize by precise tests. They include vaccines, products made from human or animal blood, and other products made from a variety of materials. Because of the inherent variability of these products, each individual lot of most biological products has been subject to evaluation and testing by CBER prior to release.

Under § 610.2 (21 CFR 610.2), the Director of CBER may require, at any time, that samples of a licensed product, protocols, and test results be submitted to CBER for official release. FDA has invoked lot-by-lot release to help ensure that products continue to meet established standards before they are distributed.

Historically, lot-by-lot release has served an important role in the regulation of biotechnology products and has prevented the distribution of unacceptable lots. However, greater control has been achieved by manufacturers over the production of biotechnology products through in-process controls, process validation, and advances in analytical techniques. For well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products, as defined below, FDA has found that once a company has demonstrated its ability to consistently produce acceptable lots, and has procedures in place that will prevent the release of lots that do not meet release specifications, it is not necessary for FDA to verify that each