

By Order of the Federal Maritime Commission.

Joseph C. Polking,
Secretary.

Dated: April 3, 1989.

[FR Doc. 89-8146 Filed 4-5-89; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they 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 indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 20, 1989.

A. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *David H. Kipper*, Denver, Colorado; to acquire an additional 1.0 percent of the voting shares of Colonial Bancorp, Denver, Colorado, for a total of 19.96 percent, and thereby indirectly acquire Colonial National Bank, Denver, Colorado.

2. *Wayne Major*, Riverton, Wyoming; to acquire 10.44 percent of the voting shares of Riverton State Bank Holding Company, Riverton, Wyoming, for a total of 12.13 percent, and thereby indirectly acquire Riverton State Bank, Riverton, Wyoming, and Dubois National Bank, Dubois, Wyoming.

3. *Dale Sprague*, Blue Mound, Kansas; to acquire 51 percent of the voting shares of Kansas Unlimited Investments, Inc., Pleasanton, Kansas, and thereby indirectly acquire Bank of Pleasanton, Pleasanton, Kansas.

Board of Governors of the Federal Reserve System, March 31, 1989.

Jennifer J. Johnson,
Associate Secretary of the Board.

[FR Doc. 89-8131 Filed 4-5-89; 8:45 am]

BILLING CODE 6210-01-M

MidAmerica Bank Corp., 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 April 20, 1989.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *MidAmerica Bank Corporation*, Somerville, New Jersey; to become a bank holding company by acquiring 100 percent of the voting shares of Mid Jersey National Bank, Somerville, New Jersey.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *St. Croix Valley Bancshares, Inc.*, Bloomington, Minnesota; to merge with Stillwater Bancorporation, Inc., Stillwater, Minnesota, and thereby indirectly acquire Cosmopolitan State Bank, Stillwater, Minnesota.

C. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Central of Kansas, Inc.*, Junction City, Kansas, and *Central of Kansas V, Inc.*, Junction City, Kansas; to acquire 100 percent of the voting shares of Durham State Bank, Durham, Kansas.

2. *New Hampton Bancshares, Inc.*, Albany, Missouri; to merge with Security Bancshares, Inc., Albany,

Missouri, and thereby indirectly acquire Bank of Gallatin, Gallatin, Missouri.

3. *Security Exchange Bancorp, Inc.*, Duncan, Oklahoma; to acquire 28.96 percent of the voting shares of American National Bank of Duncan, Duncan, Oklahoma.

Board of Governors of the Federal Reserve System, March 31, 1989.

Jennifer J. Johnson,
Associate Secretary of the Board.

[FR Doc. 89-8132 Filed 4-5-89; 8:45 am]

BILLING CODE 6210-01-M

Wells Fargo & Co.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23 (a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23 (a)(2) or (f)) 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 acquire or control voting securities or assets of a company engaged 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 April 28, 1989.

A. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *Wells Fargo & Company*, San Francisco, California; to acquire certain assets of Wells Fargo Mortgage and Equity Trust, San Francisco, California, and thereby engage in making, acquiring, and servicing commercial real estate loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, March 31, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-8133 Filed 4-5-89; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89F-0079]

National Starch and Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that National Starch and Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of the sodium salts of sulfonated styrene and maleic anhydride copolymers as boiler water additives.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that National Starch and Chemical Corp. of Funderne Ave., P.O. Box 6500, Bridgewater, NJ 08807, has filed a petition (FAP 9A4138), proposing that the food additive regulations be amended to provide for the safe use of the sodium salts of sulfonated styrene and maleic anhydride copolymers as boiler water additives.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be

published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: March 29, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-8153 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89F-0078]

Velsicol Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Velsicol Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of *cis* and *trans*-1,4-cyclohexanedimethanoldibenzoate as a component of adhesives used in the manufacture of packaging intended to contact food.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4139), has been filed by Velsicol Chemical Corp., 5600 N. River Rd., Rosemont, IL 60018-5119, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of a mixture of *cis*- and *trans*-1,4-cyclohexanedimethanoldibenzoate as a component of adhesives used in the manufacture of packaging intended to contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: March 29, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-8154 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-01-M

[FDA 225-89-4003]

Memorandum of Understanding Between the Food and Drug Administration and the Ministry of Welfare, Health, and Cultural Affairs of the Netherlands

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Ministry of Welfare, Health, and Cultural Affairs of the Netherlands. This MOU describes the mutual concerns of FDA and the Netherlands in ensuring the quality and integrity of safety evaluation data that support the approval of applications for research or marketing permits for human and animal drugs. The parties recognize that such data must be collected under the principles of Good Laboratory Practice (GLP) that are internationally recognized and that such laboratories should be monitored by effective national inspection programs.

DATE: The agreement became effective December 20, 1988.

FOR FURTHER INFORMATION CONTACT: Walter J. Kustka, Intergovernmental and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-1583.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing this memorandum of understanding.

Date: March 29, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

Memorandum of Understanding Between the Food and Drug Administration Department of Health and Human Services The United States of America and the Ministry of Welfare, Health and Cultural Affairs the Netherlands on Good Laboratory Practice

I. Purpose

The¹ signatory parties of the United States of America and The Netherlands

¹ Acting also on behalf of the Ministry of Agriculture and Fisheries, the Ministry of Economic Affairs, the Ministry of Housing, Physical Planning and Environment, and the Ministry of Social Affairs and Employment.

have a concern for assuring and quality and integrity of safety evaluation data that support the approval of applications for research and/or marketing permits for human and animal drugs. The parties recognize that such data must be collected under principles of Good Laboratory Practice (GLP) that are internationally recognized and that laboratories so engaged should be monitored by effective national inspection programs. Accordingly, this Memorandum of Understanding provides for:

- (a) Reciprocal recognition of each country's GLP program,
- (b) Mutual acceptance of test data collected in either country for evaluation of safety, and
- (c) Implementation of procedures for continuing cooperation between the countries.

Inspections of nonclinical laboratories are to be carried out by the respective national authorities.

II. Background

Safety evaluation data submitted for consideration to one national authority are frequently based on studies conducted by laboratories located in another country. Therefore, the standards observed by those laboratories that conduct nonclinical safety studies which are submitted to the authorities of the other country should be in accordance with principles of good laboratory practice. When the safety evaluation data submitted to a national authority originate from a laboratory within the other country, the national authority of the country of origin should be able to provide the other with information that assures that the laboratory is operated in accordance with good laboratory practice.

The GLP authorities in both the United States of America and The Netherlands have established national programs of inspection to verify the compliance of laboratories with the principles of GLP. These principles and the inspection programs are in accord with the Decision of the Council of the Organization for Economic Cooperation and Development (OECD) on "The Mutual Acceptance of Data in the Assessment of Chemicals" (May 12, 1981) including Annex 2, "OECD Principles of Good Laboratory Practice." These standards and procedures are consistent with the July 26, 1983 Recommendation of the OECD Council on "The Mutual Recognition of Compliance with Good Laboratory Practice."

A. Good Laboratory Practices

Both parties have published comparable standards of good laboratory practice that encompass nonclinical laboratory studies for safety evaluation of human and animal drugs.

The inspectors of the Food and Drug Administration (FDA) will rely on regulations relating to Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58) in evaluating the laboratories and auditing the data from the studies conducted in the United States of America.

The inspectors of the Ministry of Welfare, Health and Cultural Affairs will rely on "Beginnelsen voor goede laboratoriumpraktijk," [Regulations for Good Laboratory Practice] published at *Staatsblad 1986 592*, in evaluating the laboratories and auditing the data from the studies conducted in The Netherlands.

B. National Inspection Programs

Both parties assess compliance of a laboratory with the standards of good laboratory practice by having a trained government inspector conduct a laboratory inspection approximately once every two years. The inspection programs permit assessment of current laboratory operations as well as the audit of final reports of selected studies. Laboratories are generally notified in advance and inspectional procedures are mutually consistent between the parties. A report of the results of the inspection is prepared that describes laboratory operations and addresses compliance with GLP.

C. Compliance

Both parties have established satisfactory procedures for compliance with the standards of good laboratory practice. The procedures include, for example, notifying a laboratory of the deficiencies observed, and requesting corrective action within a specified time frame. Failure to correct deficiencies is dealt with by the Food and Drug Administration and the Ministry of Welfare, Health and Cultural Affairs in a variety of ways that include the rejection of specific studies from scientific consideration. The Food and Drug Administration may disqualify laboratories, whereas the Ministry of Welfare, Health and Cultural Affairs rejects specific studies or certification of compliance to laboratories that fail to take corrective action when informed of deficiencies.

III. Substance of the Understanding

A. The parties agree that:

1. Adherence to adequate standards of good laboratory practice is essential to the conduct of high quality safety testing;

2. A national program of periodic inspections conducted by a trained inspectorate is required to monitor adherence to the standards of good laboratory practice;

3. Appropriate compliance procedures are necessary to assure adherence to the standards of good laboratory practice;

4. Studies conducted in accordance with the respective standards of good laboratory practice promulgated by either country are to be acceptable to both parties for evaluation of safety.

B. Each party will:

1. Inform the other party of changes in their good laboratory practice standards and their national inspection program;

2. Provide the other party, regularly, with the names and addresses of nonclinical laboratories operating within their country, the dates the laboratories were inspected, and their compliance designation;

3. Provide upon request of the other party, further information regarding whether or not a specific laboratory or study is in compliance with the good laboratory practice standards;

4. Honor a request by the other party to conduct a GLP inspection or data audit at a specified nonclinical laboratory whenever:

(a) There is serious concern about the quality and integrity of the data submitted to either country,

(b) An inspection has not yet been performed within the last two (2) years, or

(c) An approval of an application for research and/or marketing permit is pending based upon tests performed in a specified testing facility which are important to granting the approval.

In exceptional situations in which the requesting party can justify a special concern, the requesting party may designate one or more of its scientists to participate in the audit of a study.

5. Participate as an observer in an inspection of a laboratory conducted by the authorities in the other country, with the consent of the laboratory concerned, on occasion in order to maintain a continuing understanding of the other party's inspectional procedures. These inspections are to alternate between the United States of America and The Netherlands, and

6. Recognize the need to protect from public disclosure data and information that are exchanged between the parties and that fall within the definition of a trade secret, or confidential commercial or financial information. If there is a

request from the public for any such information obtained from the other party, that party will be notified of the request prior to release of any information and given an opportunity for consultation.

IV. Participating Parties

- A. Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857
 B. Ministry of Welfare, Health and Culture, P.O. Box 5406, 2280 HK Rijswijk, The Netherlands

V. Liaison Officers

The parties respectively appoint the following officials to serve as liaison officers for all communications regarding matters relative to the Memorandum of Understanding.

A. For the Food and Drug Administration: Director, Division of Compliance Policy, Office of Regulatory Affairs, (currently: Mr. Ernest L. Brisson), 5600 Fishers Lane, Rockville, Maryland 20857.

B. For the Ministry of Welfare, Health and Cultural Affairs: Veterinary Public Health Inspectorate, Head Section GLP, (Currently: Dr. W.H. Konemann), P.O. Box 5406, 2280 HK Rijswijk, The Netherlands.

VI. Duration

This Memorandum of Understanding shall become effective on the date of the last signature and shall remain in effect until either party withdraws from it by written notice to the other party, such written notice to be delivered to the other party at least six months in advance of any such withdrawal. This Memorandum may be amended by mutual written agreement.

Approved and Accepted for the Food and Drug Administration

By: Frank E. Young
 Title: Commissioner of Food and Drugs
 Date: December 16, 1988
 Place: _____

Approved and Accepted for the Ministry of Welfare, Health and Culture

By: J. van Londen
 Title: Director General of Health
 Place: Rijswijk
 Date: December 20, 1988

[FR Doc. 89-8149 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service

Office of the Assistant Secretary for Health, Title VII of the Public Health Service Act; Delegation of Authority

Notice is hereby given that in

furtherance of the delegation of authority to the Assistant Secretary for Health on October 8, 1980, by the Secretary of Health and Human Services, the Assistant Secretary for Health has delegated all of the authorities under Title VII of the Public Health Service Act (42 U.S.C. 292 *et seq.*), as amended, pertaining to health research and teaching facilities and training of professional health personnel to the Administrator, Health Resources and Services Administration. The delegation excluded the authorities to promulgate regulations, to establish advisory committees and councils, to select members to advisory councils, and to submit reports to Congress or to a congressional committee.

The delegation excluded section 794, Statistics and Annual Report.

Redelegation

This authority may be redelegated subject to section 707 of the Public Health Service Act.

Prior Delegations

This delegation superseded the March 27, 1981, delegation to the Deputy Assistant Secretary for Health Research, Statistics, and Technology and the July 12, 1982, delegation to the Administrator, Health Resources Administration. Provision was made for redelegations under Title VII to continue in effect providing they were consistent with this delegation.

Effective Date

This delegation became effective on March 24, 1989.

Ralph R. Reed,

Acting Assistant Secretary for Health.

Date: March 24, 1989.

[FR Doc. 89-8138 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-15-M

Office of the Assistant Secretary for Health, Title VIII of the Public Health Service Act; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority to the Assistant Secretary for Health on October 8, 1980, by the Secretary of Health and Human Services, the Assistant Secretary for Health has delegated all of the authorities under Title VIII of the Public Health Service Act (42 U.S.C. 296 *et seq.*), as amended, pertaining to nurse training to the Administrator, Health Resources and Services Administration, subject to section 856 of the Public Health Service Act. The delegation excluded the authority under section 851

to establish and to select members to the National Advisory Council on Nurse Training, to promulgate regulations, to establish advisory committees and councils, and to select members to advisory councils.

Exercise of these authorities is subject to Health and Human Services policy and requirements for administering section 855 of the Public Health Service Act relating to the prohibition against discrimination by schools on the basis of sex.

Redelegation

This authority may be redelegated.

Prior Delegations

Provision was made for all delegations and redelegations under Title VIII to continue in effect.

Effective Date

This delegation became effective on March 24, 1989.

Ralph R. Reed,

Acting Assistant Secretary for Health.

Date: March 24, 1989.

[FR Doc. 89-8139 Filed 4-5-89; 8:45 am]

BILLING CODE 4160-15-M

Office of the Assistant Secretary for Health, Title XXIV of the Public Health Service Act; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority of January 27, 1989 from the Secretary of Health and Human Services to the Assistant Secretary for Health, the Assistant Secretary for Health has redelegated the authorities delegated to him under Title XXIV, Part A (Formula Grants to States for Home and Community-Based Health Services) and Part B (Subacute Care), to the Administrator, Health Resources and Services Administration. The Assistant Secretary for Health also delegated to the Administrator, Health Resources and Services Administration, the authority under section 2441 (Demonstration Projects for Individuals with Positive Test Results), excluding section 2441(h) of Title XXIV of the Public Health Service Act, as amended. The delegation excluded the authorities to issue regulations, submit reports to Congress or a congressional committee, or appoint members to an advisory committee.

Redelegation

These authorities may be redelegated.