

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.

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 June 19, 1991.

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

1. *Banca Commerciale Italiana S.P.A.*, Milan, Italy; to engage *de novo* through its subsidiary, BCI Capital Corporation, New York, New York, in dealing in ineligible securities pursuant to § 225.25(b)(16) of the Board's Regulation Y.

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

1. *Turtle Lake Bancshares, Inc.*, Turtle Lake, Wisconsin; to engage *de novo* in making and servicing loans pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted in Turtle Lake, Wisconsin.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Southeast Bancorp of Texas, Inc.*, Winnie, Texas; to engage *de novo* through its subsidiary, Southwest Financial Services, Winnie, Texas, in providing management consulting services to depository institutions pursuant to § 225.25(b)(11) of the Board's Regulation Y. These activities will be conducted in the State of Texas and southwest Louisiana.

Board of Governors of the Federal Reserve System, May 23, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-12867 Filed 5-30-91; 8:45 am]

BILLING CODE 6210-01-F

Central Illinois Financial Corporation, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have 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.

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 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 each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than June 19, 1991.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Central Illinois Financial Corporation*, Champaign, Illinois; to acquire Heartland Federal Savings and Loan Association, Mattoon, Illinois, and thereby engage in operating a savings and loan association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

2. *Indiana United Bancorp*, Greensburg, Indiana; to acquire Regional Federal Bancorp, Inc., New

Albany, Indiana, and thereby indirectly acquire Regional Federal Savings Bank, New Albany, Indiana, and thereby engage in operating a savings and loan association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, May 24, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-12867 Filed 5-30-91; 8:45 am]

BILLING CODE 6210-01-F

David T. Kearns, et al.; 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 June 19, 1991.

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

1. *David T. Kearns*, Alexandria, Virginia; to acquire 25.54 percent of the voting shares of S.B.T. Financial, Inc., Townsend, Montana, and thereby indirectly acquire The State Bank of Townsend, Townsend, Montana.

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

1. *H. Leon Brooks*, Beverly Hills, California; to retain 14.95 percent of the voting shares of Professional Bancorp, Inc., Santa Monica, California, and thereby indirectly acquire First Professional Bank, National Association, Santa Monica, California.

Board of Governors of the Federal Reserve System, May 24, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-12869 Filed 5-30-91; 8:45 am]

BILLING CODE 6210-01-F

Siouxland Bank Holding Company; Formation of, Acquisition by, or Merger of Bank Holding Companies; and Acquisition of Nonbanking Company

The company listed in this notice has applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed company has also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) 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, or to engage in such an activity. Unless otherwise noted, these 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 June 19, 1991.

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

1. *Siouxland Bank Holding Company*, Sioux Falls, South Dakota; to become a bank holding company by acquiring 96

percent of the voting shares of Dakota Bankshares, Inc., Fargo, North Dakota, and thereby indirectly acquire Dakota Bank and Trust Co. of Fargo, Fargo, North Dakota, and Hettinger Holding Company, Inc., Hettinger, North Dakota, and thereby indirectly acquire First National Bank of Hettinger, Hettinger, North Dakota.

In connection with this application, Applicant also proposes to acquire Dakota Data Processing, Inc., Fargo, North Dakota, and thereby engage in providing data processing and data transmission services, data bases and facilities for affiliated and nonaffiliated organizations pursuant to § 225.25(b)(7); and Dakota First Trust Company, Fargo, North Dakota, and thereby engage in trust company activities pursuant to § 225.25(b)(3) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, May 24, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91-12870 Filed 5-30-91; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N-0130]

Research Procurement Co.; Opportunity for Hearing on Proposal To Revoke U.S. License No. 692

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment (U.S. License No. 692) and product licenses issued to Research Procurement Co. (RPC) for the manufacture of Source Plasma. The proposed revocations are based on RPC's willful disregard for, and continued noncompliance with, the biologics regulations, which subsume and include the establishment license standards.

DATES: RPC must submit a written request for a hearing by July 1, 1991 and any data justifying a hearing by July 30, 1991. Other interested persons may submit written comments on the proposed revocations by July 1, 1991.

ADDRESSES: Submit a written request for a hearing, any data justifying a hearing, and any written comments on the proposed revocations to the Dockets Management Branch (HFA-305), Food

and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ann Reed Gaines, Center for Biologics Evaluation and Research (HFB-132), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-295-8188.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the establishment (U.S. License No. 692) and product licenses issued to RPC for the manufacture of Source Plasma. RPC's business office is located at 9918A Holmes Rd., Kansas City, MO 64131, while RPC's physical facilities are located at 6040 Troost Ave., Kansas City, MO 64106.

FDA has determined that RPC has repeatedly failed to conform to the biologics regulations applicable to the manufacture of Source Plasma. Such failures: (1) Have compromised the continued safety, purity, and potency of the Source Plasma; (2) have compromised the assurance of a continuous and healthy donor population; and (3) constitute grounds for license revocations, as provided in 21 CFR 601.5(b). By publishing this notice of opportunity for a hearing in the *Federal Register*, FDA is initiating proceedings on a proposal to revoke the above licenses, as provided in 21 CFR 12.21(b).

FDA conducted an inspection of RPC on January 24 through 31, 1985. That inspection documented deviations from the regulations that included failure to follow procedures for preventing infusion of red blood cells into the wrong donor, repeated acceptance of a permanently deferred donor, and inaccurate recordkeeping. FDA concluded that these deviations constituted a danger to public health and suspended RPC's licenses pursuant to 21 CFR 601.6(a), by letter dated February 13, 1985. RPC took corrective action, and FDA reinstated the licenses on April 19, 1985.

The FDA inspection of RPC conducted on April 22 through 26, 28, 30, and May 1, 1986, documented continuing deviations from the regulations that included incomplete donor screening and acceptance of unsuitable donors. FDA again concluded that these deviations constituted a danger to public health and again suspended RPC's licenses pursuant to 21 CFR 601.6(a), by letter dated May 22, 1986. RPC took corrective action, and FDA reinstated the licenses on August 22, 1986.

Subsequent FDA inspections of the establishment in January 1987, January 1988, and February 1989 documented

continuing deviations, including improper disposal of bags and tubing that were contaminated with blood, acceptance of repeat donors more often than allowable within a 7-day period of time, acceptance of a donor without the required physical examination, and inadequate performance of donor screening procedures. FDA requested that RPC take voluntary corrective action following each of these inspections.

The most recent FDA inspection of RPC was conducted on September 5 through 18, 1990. That inspection documented continuing deviations that included inadequate explanation of the acquired immunodeficiency syndrome (AIDS) education information to prospective donors, inadequate explanation of the hazards of the plasmapheresis procedure, inadequate space for the private and accurate screening of donors, inadequate and unclean handwashing facilities, inadequate and uncontrolled disposal of biohazardous waste, and inadequate training and supervision of personnel. FDA again suspended RPC's licenses, pursuant to 21 CFR 601.6(a), by letter dated September 27, 1990, because FDA concluded that these deviations constituted a danger to public health.

Based on RPC's inspectional history and the results of an FDA investigation of RPC conducted concurrently with the September 5 through 18, 1990 inspection, FDA determined that grounds for license revocations existed. In the letter dated September 27, 1990, RPC was advised of FDA's intention to initiate proceedings for license revocations, pursuant to 21 CFR 601.6(b)(1), unless RPC: (1) Requested, subject to evaluation and approval by FDA, that the revocations be held in abeyance pending resolution of the license suspensions, as provided in 21 CFR 601.6(b)(2); and (2) detailed the corrective actions that had been undertaken to remedy all deviations noted in the September 1990 inspection report and in the September 27, 1990, letter.

In a letter dated September 25, 1990, written following the September 1990 inspection, and in a letter dated October 3, 1990, written following receipt of the September 27, 1990, letter, RPC detailed the corrective actions that had been taken to remedy the deviations. In the letter dated October 3, 1990, RPC requested that the license revocations be held in abeyance.

By letter dated November 16, 1990, FDA denied RPC's request that the license revocations be held in abeyance. FDA determined that RPC's inspectional history demonstrated a distinct pattern of noncompliance with and careless

disregard for the regulations. FDA concluded that RPC's assurances that corrective actions had been taken, would be adhered to, and would be sustained were not credible and that willfulness existed. In accordance with 21 CFR 601.5(b), RPC was advised that no additional time would be provided in which to demonstrate compliance with the regulations before proceedings would be initiated to revoke RPC's licenses. RPC was offered the option of voluntarily requesting that the licenses be revoked and was advised that, should that option not be elected, FDA would initiate proceedings to revoke the licenses by publishing in the *Federal Register* a notice of opportunity for a hearing on a proposal to revoke the licenses, pursuant to 21 CFR 12.21(b), as provided in 21 CFR 601.5(b).

In a telephone call to FDA on December 11, 1990, RPC declined to voluntarily request license revocations. Thus, under 21 CFR 12.21(b), with this notice, FDA is offering an opportunity for a hearing on a proposal to revoke RPC's licenses.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on proposed revocation of licenses are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

FDA has placed copies of letters supporting the proposed license revocations on file under the docket number found in brackets in the heading of this notice in the Dockets Management Branch. Included are the following letters from FDA to RPC: The license suspensions letter, dated February 13, 1985; the license suspensions letter, dated May 22, 1986; the license suspensions letter, dated September 27, 1990; and the letter initiating proceedings for license revocations, dated November 16, 1990. These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any request for a hearing, any data justifying a hearing, or any comments on the proposed revocations must be submitted in writing to the Dockets Management Branch by the dates specified. Two copies of any submissions should be provided, except that individuals may submit one copy. Submissions should be identified with the docket number found in brackets in the heading of this document.

Submissions, except for data and information identified pursuant to 21 CFR 10.20(j)(2)(i) or 18 U.S.C. 1905, are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351 (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701 (21 U.S.C. 321, 351, 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and as redelegated (21 CFR 5.67).

Dated: May 22, 1991.

Gerald V. Quinnan, Jr.,

Acting Director, Center for Biologics, Evaluation and Research.

[FR Doc. 91-12381 Filed 5-30-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0160]

Colorcon; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Colorcon has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polydextrose as a formulation aid in film coatings applied to vitamin and mineral supplement tablets.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that Colorcon, 415 Moyer Blvd., West Point, PA 19486, has filed a petition (FAP 1A4258) proposing to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to provide for the safe use of polydextrose as a formulation aid (film

former/adhesion promoter) in film coatings applied to vitamin and mineral supplement tablets.

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: May 23, 1991.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-12879 Filed 5-30-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0168]

Parexel International Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Parexel International Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of diethylene glycol monoethyl ether as an excipient in vitamin and mineral dietary supplements.

FOR FURTHER INFORMATION CONTACT: Emily Florio, Center for Food Safety and Applied Nutrition (HFF-334, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) [21 U.S.C. 348(b)(5)]), notice is given that Parexel International Corp., One Alewife Place, Cambridge, MA 02140, has filed a petition (FAP 0A4230), on behalf of Gattefosse s.a., Saint-Priest, France, proposing that the food additive regulations be amended to provide for the safe use of diethylene glycol monoethyl ether as an excipient in vitamin and mineral dietary supplements.

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: May 22, 1991.

L. Robert Lake,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-12880 Filed 5-30-91; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Hearing: Reconsideration of Disapproval of Georgia State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on June 25, 1991, in room 512, 101 Marietta Street, Atlanta, Georgia to reconsider our decision to disapprove Georgia State Plan Amendment 89-37.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the Docket Clerk by June 17, 1991.

FOR FURTHER INFORMATION CONTACT: Docket Clerk, HCFA Hearing Staff, Suite 110, Security Office Park, 7000 Security Blvd., Baltimore, Maryland 21207, telephone (301) 597-3013.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove Georgia State Plan Amendment (SPA) number 89-37.

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid Agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the Hearing Officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the Hearing Officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c).

If the hearing is later rescheduled, the Hearing Officer will notify all participants.

Georgia SPA 89-37 seeks protection under section 1902(r)(2) of the Act for a policy which the State believes is more

liberal than that which is used by the Supplemental Security Income (SSI) program. This policy involves disregarding income from title II benefits that are being withheld to recover a prior overpayment. This policy would apply to various optional categorically needy and poverty level-related Medicaid eligibility groups.

The first issue in this matter is whether the application of the policy in question to some of the groups the State proposes to cover could result in individuals receiving Medicaid with incomes which exceed the Federal Financial Participation (FFP) limits at section 1903(f) of the Act. If the FFP limits could be exceeded would this violate sections 1902(a)(4) and (19) of the Act, which requires States' plans to provide such methods of administration as are found necessary by the Secretary for the proper and efficient operation of the plans? These sections also require States to provide for such safeguards as may be necessary to ensure that eligibility for care and services under the plans will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients. The second issue in this matter is whether the State's policy is eligible for protection under section 1902(r)(2) of the Act.

In general, the Medicaid statute requires States to use the eligibility criteria of the SSI program in determining eligibility criteria of the SSI program in determining eligibility for aged, blind, and disabled individuals. (See section 1902(a)(10)(A) of the Act.) Under section 1902(r)(2) of the Act, States may use more liberal methodologies than are used by the cash assistance programs in determining Medicaid eligibility for certain groups of individuals. However, HCFA believes the States may not use more liberal methodologies in determining income eligibility if those methodologies could result in the FFP limits provided for at section 1903(f) of the Act being exceeded.

In SPA 89-37, the State proposes to disregard income from title II benefits that are being withheld to recover prior overpayments. The State would count as income only the amount of the benefit actually received by the individual, rather than the total amount of the title II benefit. The State proposes to apply this policy to the following eligibility groups:

- Individuals eligible for a home and community-based waiver under section 1902(a)(10)(A)(ii)(VI);