

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. The notices also will 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 October 31, 2000.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Gene Allen Van Meter*, Beaumont, Texas; *Barbara Van Meter*, Beaumont, Texas; *Gene Allen Van Meter, Jr.*, Lumberton, Texas; and *Gary Stephen Van Meter*, Beaumont, Texas all to acquire additional voting shares of *Lamar Bancshares, Inc.*, Beaumont, Texas, and thereby indirectly acquire additional voting shares of *Lamar Bank*, Beaumont, Texas.

Board of Governors of the Federal Reserve System, October 11, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-26542 Filed 10-16-00; 8:45 am]

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FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 00-25132) published on page 58771 of the issue for Monday, October 2, 2000.

Under the Federal Reserve Bank of Kansas City heading, the entry for *Sturm Financial Group, Inc.*, Denver, Colorado, is revised to read as follows:

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Sturm Financial Group, Inc.*, Denver, Colorado; to become a bank holding company by acquiring 100 percent of the voting shares of *Sturm*

Banks of Colorado, Inc., Denver, Colorado, and thereby indirectly acquire *Bank of Cherry Creek N.A.*, Boulder, Colorado, *Bank of Cherry Creek N.A.*, Denver, Colorado, *Mesa National Bank*, Grand Junction, Colorado, *Western National Bank of Colorado*, Colorado Springs, Colorado; *Sturm Banks of Wyoming, Inc.*, Denver, Colorado, and thereby indirectly acquire *American National Bank of Cheyenne*, Cheyenne, Wyoming, *Wyoming Bank & Trust Company N.A.*, Buffalo, Wyoming, *Stockgrowers State Bank N.A.*, Worland, Wyoming, *Bank of Laramie N.A.*, Laramie, Wyoming; and *Sturm Banks of Kansas City, Inc.*, Denver, Colorado, and thereby indirectly acquire *Premier Bank*, Lenexa, Kansas.

In connection with this application, Applicant also has applied to acquire *Community First Data Services, Inc.*, Cheyenne, Wyoming, and thereby engage in data processing activities, pursuant to 225.28(b)(14) of Regulation Y.

In addition to this application, *Sturm Financial Group, Inc.*, Denver, Colorado and *Sturm Banks of Kansas City, Inc.*, Denver, Colorado also have applied to engage in lending activities, pursuant to 225.28(b)(1) of Regulation Y.

Comments on this application must be received by October 26, 2000.

Board of Governors of the Federal Reserve System, October 11, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-26541 Filed 10-16-00; 8:45 am]

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FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

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

TIME AND DATE: 11 a.m., Monday, October 23, 2000.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at

approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 13, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-26784 Filed 10-13-00; 3:25 pm]

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FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice.

SUMMARY: The FTC has investigated several cases in which manufacturers of pharmaceutical drug products and generic competitors have allegedly entered into anticompetitive agreements to delay generic entry. These cases may foreshadow similar anticompetitive agreements that may eliminate the benefits to consumers of generic drug competition. The FTC is considering a study to investigate how generic drug competition has developed in light of certain provisions in the Hatch-Waxman Act that govern entry of generic drug products. Before investigating whether these provisions of the Hatch-Waxman Act encourage generic competition or facilitate the use of anticompetitive strategies, the FTC seeks public comments on its proposed information requests to firms in the pharmaceutical drug industry. Comments will be considered before the FTC submits a request for Office of Management and Budget (OMB) review under the Paperwork Reduction Act.

DATES: Comments must be submitted on or before December 18, 2000.

ADDRESSES: Send written comments to Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580, or by e-mail to genericdrugstudy@ftc.gov. The submissions should include the submitter's name, address, telephone number, and, if available, FAX number and e-mail address. All submissions should be captioned "Generic Drug Study—FTC File No. V000014."

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be addressed to Michael S. Wroblewski, Advocacy Coordinator, Policy Planning, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580; telephone (202) 326-2155, e-mail <mwroblewski@ftc.gov>.

SUPPLEMENTARY INFORMATION: Over the next five years, brand-name drugs with combined U.S. sales approaching \$20 billion will go off patent.¹

Manufacturers seeking to protect the sales of branded drug products may have an incentive and ability to enter into agreements with would-be generic competitors that would slow or thwart the entry of competing generic drug products approved by the Food and Drug Administration pursuant to its authority under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).

The FTC invites comment on: (1) Whether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility; (2) the accuracy of the FTC's estimate of the burden of the proposed collections of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting the information on those who are to respond, including through the use of collection techniques or other form of information technology, *e.g.*, permitting electronic submissions of responses. The FTC will submit the proposed information collection requirements to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

A. Description of the Collection of Information and Proposed Use

The FTC proposes to send information requests to approximately 30 innovator drug companies (*i.e.*, brand-name drug manufacturers) and 60 generic drug companies to examine their use of agreements and other strategies that may affect generic drug competition. The companies to which the information requests would be sent include name-brand pharmaceutical drug companies that have received notice of the filing of an Abbreviated New Drug Application (ANDA), as defined by 21 U.S.C. 355(j), and generic drug companies that have filed such

ANDAs since January 1, 1991. In addition to routine questions about the name, address, and incorporation date of the responding company and its subsidiaries, and the name, business address, and official capacity of the official supervising the company's response, the FTC will ask innovator drug companies to provide answers to the following four questions:

1. Submit all agreements between the company and any person² (including corporations or other business entities acquired since the agreement(s) was (were) executed) executed after January 1, 1991, relating to³ an ANDA, involving any Drug Product.⁴ Examples of such agreements include, but are not limited to: (a) Patent litigation settlements (full or partial) between the company and persons that have filed an ANDA involving any Drug Product; (b) agreements related to the filing (or non-filing) of an ANDA by any applicant (or potential applicant) involving any Drug Product; (c) licensing agreements between the company and persons that have filed an ANDA involving any Drug Product; and (d) agreements related to any acquisition, divestiture, joint venture, alliance, license or merger by the company of any business involving the research, development, manufacture or sale of any Drug Product that is the subject of an ANDA. The company is not required to submit purchase orders for base active materials, equipment and facility contracts, and employment contracts. For any such agreement submitted, also submit all studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluate or analyze the reasons for making such agreement (or any of the provisions in such agreement), and indicate (if not contained in the document itself) the date of preparation,

² The term "person" means any natural person, corporate entity, partnership, association, joint venture, or trust which is engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any Drug Product.

³ The term "relating to" means in whole or in part constituting, containing, concerning, discussing, describing, analyzing, identifying or stating.

⁴ The term "Drug Product" includes any pharmaceutical drug substance the company has listed in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") (regardless of whether the Drug Product is currently listed in the Orange Book) and specifically includes, but is not limited to, drug products which contain certain active ingredients. (A list of such active ingredients will be tailored specifically for each company based on whether the company has been notified that a paragraph IV ANDA has been submitted against it for such drug product.)

and the name and title of each individual who prepared each such document.

2. Identify all patents that the company has filed in the Orange Book and the date of listing (regardless of whether they are currently listed in the Orange Book) relating to any Drug Product for which the company has been notified of the filing of an ANDA by another person. Also indicate if the patent(s) was (were) filed after the company received approval of the New Drug Application, as defined under 21 U.S.C. 355(b) *et seq.*, for the Drug Product. Also submit a copy of each such patent identified and identify whether the patent is owned by, assigned to, or licensed to the company.

3. Identify and list all lawsuits since January 1, 1991 (including the court, date filed, docket number, parties, current or final status (including dates), current or final docket sheet, and any reporter cites) to which the company is or was a party that involve an ANDA paragraph IV certification related to any Drug Product. Submit the complaint, the answer, any motion(s) for summary judgment, and any court orders for each such lawsuit.

4. For each Drug Product for which the company has been notified that an ANDA containing a paragraph IV certification had been filed with the FDA, state the company's sales,⁵ in units and dollars, by dosage for each calendar year since, and including, the year the company was notified of the filing of such ANDA.

In addition to routine questions about the name, address, and incorporation date of the responding company and its subsidiaries, and the name, business address, and official capacity of the official supervising the company's response, the FTC will ask generic drug companies to provide answers to the following five questions:

1. Submit all agreements between the company and any other person⁶ (including corporations or other business entities acquired since the agreement(s) was (were) executed) executed after January 1, 1991, relating to⁷ any ANDA involving any Drug Product.⁸ Examples of such agreements

⁵ The term "sales" means net sales, *i.e.*, total sales after deducting discounts, returns, allowances and excise taxes. "Sales" includes sales of the Drug Product whether manufactured by the company itself or purchased from sources outside the company and resold by the company in the same manufactured form as purchased.

⁶ See n. 2 *supra*.

⁷ See n. 3 *supra*.

⁸ The term "Drug Product" includes any pharmaceutical drug substance listed in the Orange Book (regardless of whether the Drug Product is

¹ National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection" at 3 (August 2000).

include, but are not limited to: (a) Patent litigation settlements (either full or partial) between the company and any Innovator Company;⁹ (b) agreements between the company and any other person related to the filing (or non-filing) of an ANDA by the company involving any Drug Product; (c) licensing agreements entered into with any Innovator Company; and (d) agreements related to any acquisition, divestiture, joint venture, alliance, license or merger by the company of any business involving the research, development, manufacture or sale of any Drug Product that is the subject of an ANDA. The company is not required to submit purchase orders for base active materials, equipment and facility contracts, and employment contracts. For any such agreement submitted, also submit all studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluate or analyze the reasons for making such agreement (or any of the provisions in such agreement), and indicate (if not contained in the document itself) the date of preparation, and the name and title of each individual who prepared each such document.

2. Identify and list all lawsuits since January 1, 1991 (including the court, date filed, docket number, parties, current or final status (including dates), current or final docket sheet, and any reporter cites) to which the company is or was a party involving an ANDA paragraph IV certification. In those cases in which the company is not the sole defendant, describe how litigation expenses are or have been distributed among the parties.

3. Identify when the company began first commercial marketing of a generic version of any Drug Product approved by the FDA since January 1, 1991 in those instances in which the Innovator Company brought an action for infringement of a patent against the company or any other ANDA applicant (or, if applicable, indicate that no such commercial marketing has occurred). Identify when the company received

currently listed in the Orange Book) and specifically includes drug product containing certain active ingredients. (A list of such active ingredients will be tailored specifically for each company based on whether the company has submitted a paragraph IV ANDA for such drug product.)

⁹The term "Innovator Company" means each company (including its predecessors in interest, subsidiaries, affiliates, successors, and assigns) that has filed a New Drug Application, as defined under 21 U.S.C. 355(b) *et seq.* for any Drug Product.

tentative and final approvals from the Food and Drug Administration (FDA) for such Drug Product.

4. Identify each instance in which the company has asserted before a court or before the FDA that a patent was improperly or untimely listed as defined in 21 U.S.C. 355(b) or (c). For each such assertion, submit the pleading(s) in which such assertion was made and any responsive pleading(s).

5. For each Drug Product for which the company has filed an ANDA containing a paragraph IV certification, state the company's sales¹⁰ (if any), in units and dollars, by dosage for each calendar year since, and including, the year the company received approval of such ANDA.

The FTC will obtain the information sought by interrogatories and document requests under section 6(b) of the FTC Act, 15 U.S.C. 46(b). The documents and information obtained through these orders will help the FTC determine whether agreements or other strategies are being used to delay generic drug competition and thus may merit law enforcement action, and to evaluate the effectiveness of the generic drug provisions of the Hatch-Waxman Act. It should be noted that subsequent to this notice any destruction, removal, mutilation, alteration, or falsification of documentary evidence that may be responsive to this information collection within the possession or control of a person, partnership or corporation subject to the FTC Act is subject to criminal prosecution. 15 U.S.C. 50; *see also* 18 U.S.C. § 1505.

B. Estimated Burden Hours

The FTC will ask members of the pharmaceutical industry to answer several written questions and to produce documents related to the answers provided. Because the responses will necessarily vary depending upon the extent to which drug companies have entered into such agreements, listed patents in the Orange Book, engaged in litigation related to ANDAs containing a paragraph IV certification, and commercially marketed particular generic drug products, the FTC has provided a range of estimated response times from 90 hours to 400 hours. The total estimated burden of answering the questions and producing documents per respondent is based on the following:

Organize document and information retrieval: 15–50 hours.

Identify requested information: 15–150 hours.

Retrieve responsive information: 20–80 hours.

Copy requested information: 20–40 hours.

Prepare response: 20–80 hours.

Thus, the cumulative hours burden to produce documents and prepare the response sought will be between 8,100 hours (90 hours × 90 companies) and 36,000 hours (400 hours × 90 companies).

C. Estimated Cost Burden

It is not possible to calculate with precision the labor costs associated with answering the questions and producing the documents requested, as responses will entail participation by management and/or support staff at various compensation levels among many different companies. Individuals among some or all of those labor categories may be involved in the information collection process. Nonetheless, the FTC has assumed that mid-management personnel will handle most of the tasks involved in gathering and producing the responsive information, and has applied an average hourly wage of \$150/hour for their labor. The FTC also has applied an average hourly wage of \$10 for the labor of clerical employees who will copy the responsive materials. Thus, the labor costs per company should range between \$10,700 [(70 hours × \$150/hour) + (20 hours × \$10/hour)] and \$53,000 [(350 hours × \$150/hour) + (50 hours × \$10/hour)].

The FTC estimates that the capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may require that respondent retain copies of the information provided to the Commission, industry members should already have in place the means to store information of the volume requested. In addition, respondents may have to purchase office supplies such as file folders, computer diskettes, photocopier toner, or paper in order to comply with the Commission's requests. The FTC estimates that each respondent will spend \$500 for such costs regarding the information request, for a total additional non-labor cost burden of \$45,000 (\$500 × 90 companies).

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 00-26649 Filed 10-16-00; 8:45 am]

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¹⁰ *See* n. 5 *supra*.