

Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *First Holding Company of Cavalier, Inc.*, Cavalier, North Dakota; to acquire 100 percent of the voting shares of Argyle Financial Services, Inc., Argyle, Minnesota, and thereby indirectly acquire voting shares of Argyle State Bank, Argyle, Minnesota.

Board of Governors of the Federal Reserve System, March 12, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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BILLING CODE 6210-01-S

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

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 April 1, 2004.

**A. Federal Reserve Bank of Minneapolis** (Jacqueline G. Nicholas, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Parkers Prairie Bancshares, Inc.*, Parkers Prairie, Minnesota; to acquire Waubun Insurance Agency, Waubun, Minnesota, and thereby engage in insurance agency activities in a town

with a population not exceeding 5,000, pursuant to section 225.28(b)(11)(iii) of Regulation Y.

Board of Governors of the Federal Reserve System, March 12, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0124]

#### Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#170) entitled "Animal Drug User Fees and Fee Waivers and Reductions." The purpose of this document is to provide guidance to industry on the fee waiver provisions of the Animal Drug User Fee Act of 2003 (ADUFA). The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written comments on the guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:** David Newkirk, Center for Veterinary

Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: [dnewkirk@cvm.fda.gov](mailto:dnewkirk@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On November 18, 2003, ADUFA (Public Law 108-130) was enacted. ADUFA amends the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from or a reduction of fees in certain circumstances.

The purpose of the guidance document is to provide guidance on the types of fees FDA is authorized to collect and how to request waivers and reductions from FDA's animal drug user fees. It describes the types of fees and fee waivers and reductions, what information FDA recommends you submit in support of a request for a fee waiver or reduction, how to submit such a request, and FDA's process for reviewing requests.

FDA is making this guidance document immediately available because prior public participation was not feasible or appropriate. ADUFA's user fee provisions are already in effect, and it is essential for the agency to provide guidance on how to request fee waivers and reductions as quickly as possible. Although it was not feasible or appropriate to obtain comments before issuing the guidance, in accordance with this agency's procedures, FDA will accept comments on the guidance at any time.

##### II. Paperwork Reduction Act of 1995

FDA is announcing that a collection of information entitled "Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions" has been approved by the Office of Management and Budget (OMB) under the emergency processing provisions of the Paperwork Reduction Act of 1995 (the PRA). According to the PRA, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910-0540. It expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

##### III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the fee waiver provisions of ADUFA. It does not create or confer any rights for