

voting shares of FCB Interim Bank, Ocala, Florida.

Board of Governors of the Federal Reserve System, November 2, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-28531 Filed 11-6-00; 8:45 am]

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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/.

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 November 22, 2000.

A. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Covenant Bancgroup, Inc., Leeds, Alabama; to engage *de novo* through its subsidiary, Raymond James Financial Services, St. Petersburg, Florida, in agency transactional services for customer investments, pursuant to § 225.28(b)(7) of Regulation Y.

Board of Governors of the Federal Reserve System, November 2, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00-28529 Filed 11-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1563]

Draft Guidance for Industry on Carcinogenicity Study Protocol Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Carcinogenicity Study Protocol Submissions." This document is intended to provide guidance on the types of information the Center for Drug Evaluation and Research relies on when evaluating protocols for animal carcinogenicity studies.

DATES: Submit written comments on the draft guidance by February 5, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5476.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Carcinogenicity Study Protocol Submissions." The draft guidance describes the kind of information the agency relies on when evaluating special protocols for animal carcinogenicity studies.

The Prescription Drug User Fee Act of 1992 (PDUFA) was reauthorized in November 1997 (PDUFA 2). In conjunction with PDUFA 2, FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)). The PDUFA goals for special protocol assessment and agreement provide that, upon request, FDA will evaluate within 45 days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Protocols for animal carcinogenicity studies are eligible for this special protocol assessment. This draft guidance is intended to facilitate the agency's review of animal carcinogenicity study protocols.

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on carcinogenicity study protocol submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-28521 Filed 11-6-00; 8:45 am]

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