Federal Communications Commission.

**Magalie Roman Salas,**

*Secretary.*

[FR Doc. 01–27782 Filed 11–5–01; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. 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 each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 30, 2001.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

*1. Tri-State Financial Services, Inc.*, Memphis, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Tri-State Bank of Memphis, Memphis, Tennessee.

Board of Governors of the Federal Reserve System, October 31, 2001.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 01–27772 Filed 11–5–01; 8:45 am]

**BILLING CODE 6210–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01D–0432]**

### Draft Guidance for Industry on the Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children; Availability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 ''Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children.'' The Division of Pulmonary and Allergy Drug Products is providing guidance to industry regarding the design, conduct, and evaluation of clinical trials to evaluate the effects of orally inhaled and intranasal corticosteroids on growth in children. This action is important because of recently implemented class labeling of these products with regard to their impact on growth in children. An assessment of the available data supporting the class labeling action has led to recommendations that all drug products of this class be tested by means of a ''growth study.'' The recommendations in this document can provide adequate and well-controlled data that is consistent among drug products and can be included in product labeling.

**DATES:** Submit written or electronic comments on the draft guidance by February 4, 2002. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), 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. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sandy Barnes, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children.'' This draft guidance has been developed by the Division of Pulmonary and Allergy Drug Products, in consultation with the Division of Metabolic and Endocrine Drug Products, to provide guidance in the design, conduct, and evaluation of clinical studies to assess the effects of orally inhaled and intranasal corticosteroids on linear growth.

On July 30 and 31, 1998, the Pulmonary and Allergy Drugs Advisory Committee and the Metabolic and Endocrine Drugs Advisory Committee were jointly convened to discuss the implications of findings in previous clinical studies that indicated that inhaled corticosteroids may, as a class of compounds, affect linear growth in pediatric patients. The joint committees agreed that data were sufficient to justify inclusion of a precautionary statement in the labeling for this class of compounds, but the data were inadequate to precisely determine the decrement in growth velocity resulting from the use of these drug products. Members of the joint committees recommended that companies filing new drug applications for all newly approved corticosteroid products conduct further studies, as post-apptoval phase 4 commitments, to assess the effects of nasally and orally inhaled corticosteroids on growth velocity in prepubertal children.

The draft guidance provides general recommendations for the design and conduct of a ''growth study.'' The Division of Pulmonary and Allergy Drug Products endorses these recommendations to encourage the collection of other evidence that will consistently and accurately describe the effects of intranasal and orally inhaled corticosteroids on growth velocity in children.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).