1. Texas Country Bancshares, Inc., Brady, Texas; to acquire 100 percent of the voting shares of Clarity Holdings, Inc., Uvalde, Texas, and thereby indirectly acquire voting shares of National American Bank, Uvalde, Texas.

Board of Governors of the Federal Reserve System, June 29, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–15164 Filed 7–2–04; 8:45 am]

BILLING CODE 6210–01–S

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 July 30, 2004.

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

1. Texas United Nevada, Inc., Carson City, Nevada, and Texas United Bancshares, Inc., LaGrange, Texas; to merge with GNB Bancshares, Inc., Gainesville, Texas, and thereby indirectly acquire voting shares of Guaranty National Bancshares, Inc., Wilmington, Delaware, and GNB Financial, N.A., Gainesville, Texas.

Board of Governors of the Federal Reserve System, June 30, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–15261 Filed 7–2–04; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.—4 p.m., August 5, 2004.

Place: Holiday Inn Select/Decatur, 130 Clairemont Avenue, Decatur, GA 30030.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters To Be Discussed: Agenda items will include discussion of the CDC Futures Initiative and updates on CDC priorities with discussions of program activities including updates on CDC scientific and programmatic activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Robert Delaney, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333. Telephone 404/639–7000.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 29, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15223 Filed 7–2–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0033]

Establishing a Docket for the Factor VIII Inhibitor Public Workshop; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments on the November 21, 2003, public workshop entitled ''Factor VIII Inhibitors'' (the workshop). We are opening the docket because there was insufficient time available during the workshop for a full discussion of the many important topics covered at the workshop.

DATES: Submit written or electronic comments on the workshop, related regulatory and scientific issues, and comments on information submitted to the docket by other interested parties by January 6, 2006.

ADDRESSES: Submit written comments and information related to the workshop to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic and other access to the slide presentations and transcript from the workshop.

FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2003 (68 FR 59942), we published a notice to announce a public workshop entitled ''Factor VIII Inhibitors.'' On November 21, 2003, we, in cosponsorship with the International Association for Biologicals, held the workshop to address regulatory and scientific concerns about inhibitors to Factor VIII induced by Antihemophilic Factor (Factor VIII) products. These inhibitors arise in a significant minority of patients with hemophilia and make replacement therapy problematic. The workshop covered a broad range of

topics. The workshop provided valuable information, but additional time was needed at the close of the meeting for continued dialogue on important topics. At the end of the workshop, we invited written comments to provide an opportunity for a full discussion of issues.

We have established this docket to encourage interested parties to continue to provide information about Factor VIII inhibitors, comments on the workshop, and comments on information submitted to the docket by other interested parties. We also request that those who have already submitted written comments and information to FDA resubmit the same comments to the docket to ensure their adequate consideration since this information was not previously submitted to the docket. We also posted this request for comments and information at *http://www.fda.gov/cber/meetings/fctrvIII112103L.htm*.

Comments submitted to the docket will assist us in determining the need for and feasibility of establishing new inhibitor assay standards and methodologies, stakeholders' opinions about current upper and lower limits of acceptable inhibitor formation in clinical trials, and the use of plasma-derived versus recombinant Factor VIII controls in pharmacokinetic trials, among other issues. We may also consider the information in preparing any future guidance on clinical trials to evaluate potential inhibitor formation from Factor VIII products.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of this notice, the slide presentations and transcript from the workshop, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the slide presentations at *http://www.fda.gov/cber/summaries.htm* and the transcript of the workshop at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: June 24, 2004.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15135 Filed 7–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1981N–0033P]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Antigingivitis/Antiplaque Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products: Triclosan, 0.3 percent maximum, as an antigingivitis ingredient in dental pastes and oral rinses. FDA has reviewed a time and extent application (TEA) for this condition and determined that it is eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether this condition can be generally recognized as safe and effective (GRAS/E) for its proposed OTC use.

DATES: Submit data, information, and general comments by October 4, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that the agency reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) was deleted from the TEA before it was placed on public display.

II. Request for Data and Information

The condition triclosan, 0.3 percent maximum, as an antigingivitis ingredient in dental pastes and oral rinses will be evaluated for inclusion in the monograph being developed for OTC oral health care drug products (21 CFR part 356). FDA will include this condition in its review of antigingivitis/antiplaque drug products. FDA published the advance notice of proposed rulemaking for these products in the **Federal Register** of May 29, 2003 (68 FR 32232). FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for this use, so that FDA can determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use.

Interested persons should, on or before 90 days after the date of publication in the **Federal Register**, submit comments, data, and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments, data, and information are to