

modifying existing facilities as authorized by a construction permit and determines it is necessary to either discontinue operation or to operate with temporary facilities to continue program service for a period not more than 30 days. Licensees or permittees of directional or nondirectional FM, TV or Class A TV or nondirectional AM must file a notification and comply with 47 CFR 73.1615(a). Licensees or permittees of a directional AM station whose modification does not involve a change in operating frequency must file a notification and comply with 47 CFR 73.1615(b). Licensees or permittees of a directional AM station whose modification does involve a change in frequency and determines it is necessary to discontinue operation for a period not more than 30 days must file a notification and comply with 47 CFR 73.1615(d)(2).

Section 73.1615 informal letter requests (47 CFR § 73.1615). Broadcast stations (AM, FM, TV or Class A TV licensees or permittees) must file an informal letter request under 47 CFR 73.1615(c)(1) when such a station is in the process of modifying existing facilities pursuant to 47 CFR 73.1615(a) or (b) and determines it is necessary to either discontinue operation or to operate with temporary facilities to continue program service for a period of more than 30 days. Licensees or permittees that filed notifications under 47 CFR 73.1615(d)(2) but which determine that it is necessary to discontinue operation for a period more than 30 days must file an informal letter request and comply with 47 CFR 73.1615(d)(1) and (2).

Federal Communications Commission.

**Marlene H. Dortch,**  
Secretary.

[FR Doc. E9-19672 Filed 8-14-09; 8:45 am]

BILLING CODE: 6712-01-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 applications 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 Web site at [www.ffiec.gov/nic/](http://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 September 10, 2009.

**A. Federal Reserve Bank of Atlanta** (Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *Heart of Georgia Bancshares, Inc., Mount Vernon, Georgia*; to acquire 100 percent of the voting shares of The Tattnell Bank, Reidsville, Georgia.

**B. Federal Reserve Bank of San Francisco** (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *Golden Pacific Bancorp, Sacramento, California*; to acquire 100 percent of Gold Country Financial Services, Inc. and thereby indirectly acquire Gold Country Bank, N.A., both of Marysville, California.

Board of Governors of the Federal Reserve System, August 12, 2009.

**Robert deV. Frierson,**  
Deputy Secretary of the Board.

[FR Doc. E9-19630 Filed 8-14-09; 8:45 am]

BILLING CODE 6210-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92-463, notice is hereby given of the twentieth meeting of the Secretary's Advisory

Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 6 p.m. on Thursday, October 8, 2009, and from 8 a.m. to approximately 3:30 p.m. on Friday, October 9, 2009, at the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The main agenda items involve the review of three SACGHS draft reports: a final draft report and its recommendations on gene patents and licensing practices along with comments received on the public consultation draft circulated earlier this year; a public consultation draft report on genetics education and training; and a revised draft paper on direct-to-consumer genetic testing. The first day of the meeting will include an extended period of time for interested members of the public to provide their perspectives on gene patents and licensing practices and their effect on patient access to genetic tests. Members of the public are encouraged to contact the SACGHS Executive Secretary (see below) by September 15, 2009, if they wish to participate in this extended public comment period. Other agenda items include an update on regulations implementing the Genetic Information Nondiscrimination Act, a report on activities of the Clinical Utility and Comparative Effectiveness Task Force, and a brief discussion to initiate the Committee's work on ethical issues related to genomic data sharing.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [carrs@od.nih.gov](mailto:carrs@od.nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as

warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: [http://oba.od.nih.gov/SACGHS/sacghs\\_meetings.html](http://oba.od.nih.gov/SACGHS/sacghs_meetings.html).

Dated: August 10, 2009.

**Jennifer Spaeth,**

*Director, NIH Office of Federal Advisory Committee Policy.*

[FR Doc. E9-19584 Filed 8-14-09; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Sterilization of Persons in Federally Assisted Family Planning Projects (July 17, 2009); Correction

**AGENCY:** Department of Health and Human Services.

**ACTION:** Notice: correction.

**SUMMARY:** The Department of Health and Human Services (HHS) published a document in the **Federal Register** of July 17, 2009, requesting OMB reauthorization of the form "Sterilization of Persons in Federally Assisted Family Planning Projects." The document contained an incorrect citation to the HHS sterilization regulations; incorrectly identified the Office of Population Affairs (OPA), rather than the Public Health Service (PHS), as the agency within HHS that administers programs of health services which are supported by Federal financial assistance and which are required to obtain informed consent from persons undergoing sterilizations; incorrectly described the form that is required to be used to obtain informed consent; and incorrectly referred to the regulations to which the consent form is appended as OPA regulations rather than PHS regulations.

**FOR FURTHER INFORMATION CONTACT:** Sherette Funn-Coleman, 202-690-5683. Corrections:

In the **Federal Register** of July 17, 2009, in FR Doc. OS-0937-0166, on page 34757, in the second column, correct the citation to the sterilization regulations to read:

*Proposed Project:* HHS 42 CFR part 50, subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects—

In the third column, correct the "Abstract" related to the consent form to read as follows:

The consent form solicits information to assure voluntary and informed consent to persons undergoing

sterilization in programs of health services which are supported by Federal financial assistance administered by the Public Health Service (PHS). The form provides additional procedural protections to individuals undergoing sterilization. In order to obtain informed consent, the regulation requires that programs use either the form that is appended to the PHS regulation or another consent form approved by the Secretary.

Dated: August 7, 2009.

**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. E9-19566 Filed 8-14-09; 8:45 am]

BILLING CODE 4150-34-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-P-0443]

#### Determination That DEMADEx (Torsemide) Injection, 20 Milligrams/2 Milliliter (10 Milligrams/Milliliter) and 50 Milligrams/5 Milliliter (10 Milligrams/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its determination that DEMADEx (torsemide) injection, 20 milligrams (mg)/2 milliliter (mL) (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for torsemide injection, 20 mg/2mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), if all other legal and regulatory requirements are met.

#### FOR FURTHER INFORMATION CONTACT:

Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417 (the 1984 amendments)), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA

applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PharmaForce, Inc., submitted a citizen petition dated August 5, 2008 (Docket No. FDA-2008-P-0443), under 21 CFR 10.30 requesting that the agency determine whether DEMADEx (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was withdrawn from sale for reasons of safety or effectiveness. DEMADEx (torsemide) injection is the subject of NDA 20-137, held by Roche Pharmaceuticals (Roche) and was initially approved on August 23, 1993. DEMADEx is indicated for the treatment of edema associated with congestive heart failure, renal disease, or hepatic disease. Roche notified FDA on June 16, 2008, that it was no longer marketing DEMADEx (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), and the drug product was moved to the "Discontinued Drug Product List" section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that DEMADEx (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10