

*Resources, LP*, Docket No. PENN 2007–252–E. (Issues include whether the Administrative Law Judge erred in upholding the Secretary's decision to require that the operators' Emergency Response Plans (ERPs) contain provisions mandating that the operators provide purchase orders for rescue chambers.)

The Commission heard oral argument in these matters on October 23, 2007.

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

**FOR FURTHER INFORMATION CONTACT:** Jean Ellen, (202) 434–9950/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

**Jean H. Ellen,**

*Chief Docket Clerk.*

[FR Doc. 07–5410 Filed 10–26–07; 1:33 pm]

**BILLING CODE 6735–01–M**

## 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/](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 November 26, 2007.

**A. Federal Reserve Bank of Atlanta** (David Tatum, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *1st United Bancorp, Boca Raton, Florida*; to merge with Equitable Financial Group, Inc., and thereby indirectly acquire Equitable Bank, both of Ft. Lauderdale, Florida.

**B. Federal Reserve Bank of St. Louis** (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *Midwest Bancorporation, Inc. and Affiliates Employee Stock Ownership Plan, Poplar Bluff, Missouri*; to acquire additional shares, for total ownership of up to 45 percent, of Midwest Bancorporation, Inc., Poplar Bluff, Missouri, and thereby indirectly acquire First Midwest Bank of Dexter, Dexter, Missouri, and First Midwest Bank of the Ozarks, Piedmont, Missouri.

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

1. *Caldwell Holding Company, Columbia, Louisiana*; to acquire 100 percent of the voting shares of Citizens Progressive Bank, Columbia, Louisiana.

Board of Governors of the Federal Reserve System, October 25, 2007.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E7–21302 Filed 10–29–07; 8:45 am]

**BILLING CODE 6210–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the National Coordinator for Health Information Technology; American Health Information Community Chronic Care Workgroup Meeting

**ACTION:** Announcement of meeting.

**SUMMARY:** This notice announces the 20th meeting of the American Health Information Community Chronic Care Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.)

**DATES:** November 29, 2007, from 1 p.m. to 4 p.m., Eastern Time.

**ADDRESSES:** Mary C. Switzer Building (330 C Street, SW., Washington, DC

20201), Conference Room 4090, Please bring photo ID for entry to a Federal building.

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit/ahic/chroniccare/>.

**SUPPLEMENTARY INFORMATION:** The workgroup will hear testimony on ways to use information technology to better coordinate care for patients with chronic conditions and will discuss this information in light of opportunities to better facilitate patient care coordination. The meeting will be available via Web cast. For additional information, go to: [http://www.hhs.gov/healthit/ahic/chroniccare/cc\\_instruct.html](http://www.hhs.gov/healthit/ahic/chroniccare/cc_instruct.html).

**Judith Sparrow,**

*Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 07–5378 Filed 10–29–07; 8:45 am]

**BILLING CODE 4150–24–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007F–0368]

### Biomim GmbH; Filing of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Biomim GmbH, Industriestrasse 21, Herzogenburg, Austria 3130, has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *Eubacterium* bacterial species in feed for detoxifying trichothecene mycotoxins in the digestive tracts of swine and poultry. **DATES:** Submit written or electronic comments on the petitioner's environmental assessment December 31, 2007.

**ADDRESSES:** You may submit written comments 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>.

**FOR FURTHER INFORMATION CONTACT:** Isabel W. Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, email: [isabel.pocurull@fda.hhs.gov](mailto:isabel.pocurull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP No. 2256) has been filed by Betty J. Pendleton, 768 Arbor Court, Mobile, Alabama 36609, US agent for Biomin GmbH, Industriestrasse 21, Herzogenburg, Austria 3130. The petition proposes to amend the food additive regulations in part 573, Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of *Eubacterium* bacterial species in feed for detoxifying trichothecene mycotoxins in the digestive tracts of swine and poultry.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: October 18, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7-21298 Filed 10-29-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0395]

#### **Draft Guidance for Industry on Acute Bacterial Sinusitis: Developing Drugs for Treatment; 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 "Acute Bacterial Sinusitis: Developing Drugs for Treatment." The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of acute bacterial sinusitis (ABS). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of our current thinking in this area. In addition, it will fulfill a statutory requirement to publish such a guidance enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 28, 2008.

**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 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> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Steve Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134,

Silver Spring, MD 20993-0002, 301-796-1600.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Sinusitis: Developing Drugs for Treatment." The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of ABS. This guidance revises the draft guidance regarding ABS published in 1998. Section 911 of the FDAAA (Public Law 110-85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary for Health and Human Services to "issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis." This guidance will fulfill this statutory requirement.

The design of clinical trials for ABS was the subject of an Anti-Infective Drug Products Advisory Committee meeting on October 28, 2003. In addition, other advisory committee meetings have focused on the development of specific drug products for this indication. As a result of these public discussions, as well as review of pending applications at FDA, the agency's thinking in this area has evolved in recent years, and this guidance informs sponsors of the changes in our recommendations. Specifically, this guidance recommends that ABS clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABS trial designed to show superiority. This guidance also recommends that microbiological information be obtained in at least one of the controlled studies. This guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution as a possible approach to assessing the primary endpoint. As required by FDAAA, this guidance also addresses the use of animal models and surrogate markers in the development of drugs for the treatment of ABS.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of acute bacterial sinusitis. 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