

**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.

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 October 5, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Continental Community Bancorporation, Inc., West Des Moines, Iowa; to become a bank holding company by acquiring up to 80 percent of the voting shares of Polk County Bank, Johnston, Iowa.

Board of Governors of the Federal Reserve System.

Dated: September 15, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011-24065 Filed 9-19-11; 8:45 am]

**BILLING CODE 6210-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Performance Review Board Members**

Title 5, U.S.C. Section 4314(c)(4) of the *Civil Service Reform Act of 1978*,

Public Law 95-454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**.

The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services.

Joel S. Ario,  
Julia G. Bataille,  
Mirtha R. Beadle,  
Melanie M. Bella,  
Sherri A. Berger,  
Angela Billups,  
Gary L. Cantrell,  
Patrick H. Conway,  
Kathleen M. Crosby,  
John Czajkowski,  
Cheryl R. Dammons,  
Michelle S. Davis,  
Nancy E. De Lew,  
Theodore M. Doolittle,  
Gregory J. Downing,  
Ivor D'Souza,  
Kana Enomoto,  
Michael E. Etzinger,  
Douglas B. Fridsma,  
Alexandra B. Garcia,  
Amy L. Haseltine,  
Robert F. Heil Jr.,  
Jay M. Hodes,  
David E. Hohman,  
Barbara J. Holland,  
Richard Ikeda,  
Christine Jones,  
Melanie M. Keller,  
Gia Lee,  
Nancy C. Lee,  
Eric N. Lindblom,  
Michael W. McCauley,  
Eileen C. McDaniel,  
Matthew D. McKearn,  
Joy M. Miller,  
Valerie E. Morgan Alston,  
Michael J. Nelson,  
Dawn M. O'Connell,  
Robert F. Owens Jr.,  
Jennifer L. Parker,  
Aida M. Perez,  
Cheri M. Rice,  
Geoffrey Roth,  
Roberto Ruiz,  
Dorinda A. Salcido,  
Daniel J. Schreiner,  
William B. Schultz,  
Neil Shapiro,  
Jeremy B. Sharp,  
George H. Sheldon,  
Steven D. Silverman,  
Rebecca T. Slifkin,  
Douglas F. Small,  
Nancy K. Stade,  
Christian J. Stenrud,  
Bridgett E. Taylor,  
Brian G. Trent,  
James E. Tyler Jr.,  
Stephen J. Veneruso,  
Karen V. Walker Bryce,  
Luis A. Wilmot,  
Holly J. Wong,  
Robert K. Yee,  
Cheryl L. Ziegler Ragland.

*Non-SES:*

Barbara Bowman,  
Christine Branche,  
Michael Gottesman,  
Anne Haddix,  
Steven Musser,  
Jan Nicholson,  
Steven Pollack,  
Tanja Popovic,  
Steve Redd,  
Sally Rockey,  
Jonathan Sackner-Bernstein,  
Tom Sinks,  
William Slikker,  
Lawrence Tabak,  
Carolyn Wilson,  
Robert Yetter.

Dated: September 13, 2011.

**Denise L. Wells,**

*Deputy Assistant Secretary for Human Resources, Department of Health and Human Services.*

[FR Doc. 2011-24039 Filed 9-19-11; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2011-N-0655]

**Animal Generic Drug User Fee Act; Public Meeting; Request for Comments**

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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Generic Drug User Fee Act (AGDUFA). FDA invites public comment on the AGDUFA program and suggestions regarding the features FDA should propose for the next AGDUFA program.

**Date and Time:** The meeting will be held on November 7, 2011, from 1 p.m. to 4 p.m.

**Location:** The meeting will be held at the Food and Drug Administration, 7519 Standish Pl., 3d floor, rm. A, Rockville, MD 20855. If you require special accommodations, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

**Contact Person:** Donal Parks, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240-276-8688, FAX: 240-276-9744, [Donal.Parks@fda.hhs.gov](mailto:Donal.Parks@fda.hhs.gov); or Patricia Arnwine, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240-276-9724, FAX: 240-276-9744, [Patricia.Arnwine@fda.hhs.gov](mailto:Patricia.Arnwine@fda.hhs.gov).

*Comments:* Regardless of attendance at the meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Comments received by October 26, 2011, will be taken into consideration before the public meeting.

*Transcripts:* Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm> approximately 30 days after the meeting.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

FDA is announcing its intention to hold a public meeting on AGDUFA. The authority for AGDUFA expires September 30, 2013. Without new legislation, FDA will no longer have the authority to collect user fees to fund the generic animal drug review process. Prior to beginning negotiations with the regulated industry on AGDUFA reauthorization, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-13(d)(2)) requires FDA to: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization including specific suggestions for changes to the goals referred to in section 740A(a) of FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA's Web site. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of AGDUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the AGDUFA program thus far?
2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of AGDUFA, and its current status.

##### II. What is AGDUFA? What does it do?

The Animal Generic Drug User Fee Act enacted in 2008 (Public Law 110-316; hereinafter referred to as "AGDUFA I") amended the FD&C Act to authorize the FDA's first-ever generic animal drug user fee program. AGDUFA provides FDA with additional funds to enhance the performance of the generic animal drug review process. Furthermore, the authorization of AGDUFA enables FDA's continued assurance that generic animal drug products are safe and effective, and enables FDA's continued support for lower-cost alternatives to brand drugs for consumers. Under AGDUFA, FDA agreed to meet review performance goals for certain submissions over 5 years from fiscal year (FY) 2009 through FY 2013. These review performance goals strive to expedite the review of abbreviated new animal drug applications (ANADAs) and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions.

Under AGDUFA, the industry agreed to pay user fees that are available to FDA, in addition to appropriated funds, to spend on the generic animal drug review process. Moreover, FDA's authority to collect user fees is contingent on a certain level of spending from appropriated funds, as adjusted for inflation.

AGDUFA established increasingly-stringent review performance goals over a 5-year period from FY 2009 through FY 2013. By the final year of AGDUFA, FDA agreed to review and act on 90 percent of the following submission types within the specified time frames:

- Original ANADAs and reactivations within 270 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made during the JINAD process, i.e., prior to the submission of the original ANADAs) within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations within 270 days after the submission date.
- JINAD study submissions within 270 days after the submission date.
- JINAD protocol submissions within 100 days after submission date. JINAD protocol submissions consist of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the

decision to approve or not approve an ANADA or supplemental ANADA.

The additional resources provided under AGDUFA I enabled FDA to completely eliminate the backlog of ANADA and JINAD submissions by August 2010.

FDA has published a number of reports that provide useful background on AGDUFA. AGDUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports and plans can be found at: <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>.

##### III. What information should you know about the meeting?

*A. When and where will the meeting occur? What format will FDA use?*

Throughout this document, FDA has been announcing a public meeting to hear stakeholders' views on what FDA should consider for the AGDUFA II program. In general, the meeting format will include presentations by FDA followed by an open public comment period. Registered speakers for the open public comments will be grouped and invited to speak in the order of their affiliation and time of registration (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry). FDA presentations are planned from 1 p.m. until 2 p.m. The open public comment portion of the meeting for registered speakers is planned to begin at 2 p.m. An opportunity for public comments from meeting attendees will commence following the registered presentations, if time permits.

FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, not on policy issues.

The docket will remain open for either electronic or written comments through December 7, 2011.

*B. What questions would FDA like the public to consider?*

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the AGDUFA program thus far?
2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

*C. How do you register for the meeting or submit comments?*

If you wish to attend and/or present at the meeting, please register by e-mail to [AGDUFAReauthorization@fda.hhs.gov](mailto:AGDUFAReauthorization@fda.hhs.gov) by October 26, 2011. Your e-mail should contain complete contact information for each attendee—name, title, affiliation, address, e-mail, and phone number. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patient and consumer advocacy groups; or the regulated industry. Registration is free and will be on a first-come, first-served basis. Early registration is recommended since seating is limited. FDA may limit the number of participants from each organization based on space constraints. Registrants will receive confirmation once their registrations are accepted. Onsite registration on the day of the public meeting will be based on space availability. FDA will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak. If you need special accommodations, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

In addition, interested persons may submit either electronic or written comments to the Division of Dockets Management (see *Comments*). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration before the public meeting, all comments must be received by October 26, 2011.

*D. Will meeting transcripts be available?*

Please be advised that as soon as the transcript is available, it will be accessible at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be made available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug

Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 13, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-24083 Filed 9-19-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0656]

**Animal Drug User Fee Act; Public Meeting; Request for Comments**

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act (ADUFA). FDA invites public comment on the ADUFA program and suggestions regarding the features FDA should propose for the next ADUFA program.

*Date and Time:* The meeting will be held on November 7, 2011, from 9 a.m. to 12 noon.

*Location:* The meeting will be held at the Food and Drug Administration, 7519 Standish Pl., 3d floor, Rm. A, Rockville, MD 20855. If you require special accommodations, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

*Contact Person:* Donal Parks, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240-276-8688, FAX: 240-276-9744,

[Donal.Parks@fda.hhs.gov](mailto:Donal.Parks@fda.hhs.gov), or Patricia Arnwine, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240-276-9724, FAX: 240-276-9744,

[Patricia.Arnwine@fda.hhs.gov](mailto:Patricia.Arnwine@fda.hhs.gov).

*Comments:* Regardless of attendance at the meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Comments received by October 26, 2011, will be taken into consideration before the public meeting.

*Transcripts:* Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm> approximately 30 days after the meeting.

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

FDA is announcing its intention to hold a public meeting on ADUFA. The authority for ADUFA expires September 30, 2013. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal drug review process. Prior to beginning negotiations with the regulated industry on ADUFA reauthorization, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-13) requires FDA to: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization including specific suggestions for changes to the goals referred to in section 740A(a) of the FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA's Web site. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of ADUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?
2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of ADUFA, and its current status.

**II. What is ADUFA? What does it do?**

The Animal Drug User Fee Act enacted in 2003 (Pub. L. 108-130; hereinafter referred to as "ADUFA I"), authorized FDA to collect user fees that were to be dedicated to expediting the review of animal drug applications in accordance with certain performance goals. The implementation of ADUFA I provided a significant funding increase for the new animal drug application review process, and enabled FDA to