the voting shares of Table Grove State Bank, Table Grove, Illinois.

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

1. Germantown Capital Corporation, Inc., Germantown, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of First Capital Bank, Germantown, Tennessee.

Board of Governors of the Federal Reserve System, January 10, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.E8–547 Filed 1–15–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0573]

Animal Cloning Risk Assessment; Risk Management Plan; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a risk assessment on animal cloning. FDA's Center for Veterinary Medicine (CVM) developed this risk assessment to evaluate the health risks to animals involved in the process of cloning and to evaluate the food consumption risks that may result from edible products derived from animal clones or their progeny. FDA is also announcing the availability of a risk management plan for animal clones and their progeny. The risk management plan takes into account the risks identified in the risk assessment and sets out measures that FDA will use to manage those risks. In addition, FDA is announcing availability of guidance for industry 179. This guidance describes FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the risk assessment, risk management plan, or the guidance for industry to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send a self-addressed, adhesive label to assist that office in processing your request. Submit written comments on the guidance for industry 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8245, e-mail: *clones@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 3, 2007 (72 FR 136), FDA published a notice of availability with a 90-day comment period to request comments on a draft risk assessment on animal cloning. FDA also announced the availability for public comment of a proposed risk management plan for animal clones and their progeny and a draft guidance for industry describing FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed. In response to requests to extend the comment period on these documents, FDA subsequently published a notice in the **Federal Register** (72 FR 15887, April 3, 2007) extending the comment period for an additional 30 days.

The draft risk assessment evaluated the health effects to animals involved in the process of cloning and evaluated the food consumption risks that may result from edible products derived from animal clones or their progeny. The proposed risk management plan described proposed measures that the agency might use to address animal health and food consumption risks identified in the draft risk assessment that were within the agency's purview. It also described the agency's plans with regard to issues that were not within the agency's authority to manage (e.g., ethics) regarding animal cloning. The draft guidance for industry described FDA's recommendations regarding the introduction of edible products from animal clones and their progeny into the food and feed supply.

FDA has completed a thorough analysis of all comments and additional information received and has updated the documents appropriately. FDA has concluded that meat and milk from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals. FDA, however, in its guidance for industry, is recommending that edible products from clones from animals other than cattle, swine, or goat (e.g., sheep) not be introduced into the human food supply. Whereas the scientific data supports the safety of edible products from clones of cattle, swine, or goat, there is insufficient scientific data to reach this conclusion for edible products from other types of animals.

II. Significance of Guidance

The guidance for industry is a level 1 guidance that is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the topic. The guidance document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

For this level 1 final guidance, FDA concludes that there are no collection of information requirements under the Paperwork Reduction Act of 1995.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance for industry. 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.

Please note that in January 2008 the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

V. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cvm/cloning.htm*.

Dated: January 3, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–675 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0390]

User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Program Will Not Be Implemented

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to inform companies that the Direct-to-Consumer (DTC) television advertisement user fee program will not commence because the necessary user fees for the program were not ''provided in advance in appropriations Acts'' as required by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and the previously issued notice establishing user fee rates for the program for fiscal year (FY) 2008 is being withdrawn.

FOR FURTHER INFORMATION CONTACT: Wayne Amchin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1454, Silver Spring, MD 20993–0002, 301–796–1200, FAX: 301–796–9878, e-mail: *dtcp@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Title I of FDAAA reauthorized the Prescription Drug User Fee Act for FYs 2008 to 2012. In addition, Title I created new section 736A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h–1), which authorized a new and separate user fee program for the advisory review of DTC prescription drug television advertisements. The DTC user fee program would have been available to companies interested in voluntarily submitting to FDA for advisory review a DTC television advertisement, as defined in section 736A(h)(4) of the act. FDAAA provided, however, that if FDA fails to receive at least $11,250,000 in advisory review fees and operating reserve fees combined by 120 days after the legislation is enacted (i.e., by January 25, 2008), the program shall not commence (section 736A(f)(1) of the act). FDAAA also provided that the fees authorized for the DTC program ''shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.'' (section 736A(g)(1) of the act).

On December 26, 2007, the President signed the Consolidated Appropriations Act, 2008 (Public Law 110–161). The law does not appropriate user fee funds for the voluntary review of DTC television advertisements. As a result, under section 736A(g)(1) of the act, FDA does not have the authority to collect and spend user fees for this purpose. Furthermore, as noted previously, section 736A(f)(1) of the act provides that if FDA has not collected at least $11,250,000 in advisory review fees and operating reserve fees combined by 120 days after the legislation is enacted (i.e., by January 25, 2008), the program shall not commence. Therefore, no invoices will be sent. Advertisements voluntarily submitted for FDA review will be reviewed in as timely a manner as resources permit. In addition, FDA is withdrawing the previously issued **Federal Register** notice establishing the user fee rates for this program for FY 2008 (72 FR 70334, December 11, 2007).

Dated: January 10, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–740 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Psychopharmacologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of December 19, 2007 (72 FR 71923). The amendment is being made to reflect changes in the *Location, Contact Person, and Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2007, FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee would be held on February 6, 2008.

On page 71923, in the third column, the *Location* portion of the document is changed to read as follows:

Location: Crowne Plaza/Silver Spring, Kennedy Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301–589–0800.

On page 71923, in the third column, the first sentence of the *Contact Person* portion of the document is changed to read as follows:

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544.

On page 71924, in the first column, the first paragraph of the *Procedure* portion of the document is changed to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 18, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 10, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons