

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 will also 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 February 20, 2015.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Business First Bancshares, Inc.*, Baton Rouge, Louisiana; to merge with American Gateway Financial Corporation, Port Allen, Louisiana, and thereby indirectly acquire American Gateway Bank, Baton Rouge, Louisiana.

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

1. *Central Bancshares, Inc.*, Muscatine, Iowa; to acquire 100 percent of the voting shares of Buffalo Prairie State Bank, Buffalo Prairie, Illinois, and simultaneously merge Buffalo Prairie State Bank with and into Central Bancshares, Inc.'s wholly-owned bank, Central State Bank, Muscatine, Iowa.

Board of Governors of the Federal Reserve System, January 21, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015-01269 Filed 1-23-15; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Community Services Block Grant (CSBG) Model Plan Application.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| CSBG State Model Application Plan | 56 | 1 | 10 | 560 |

Estimated Total Annual Burden Hours: 560.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be

identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

OMB No.: 0970-0382.

Sections 676 of the Community Services Block Grant (CSBG) Act requires States, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (Model Application Plan). The application plan must meet statutory requirements prior to being funded with CSBG funds. Applicants have the option to submit a detailed application annually or biannually. Entities that submit a biannual application must provide an abbreviated application the following year if substantial changes to the initial application will occur.

This request is to revise the approved Model Application Plan for States by automating the form, streamlining the information, and incorporating accountability measures. The revised and automated form may impose an added first-use burden; however, this burden will diminish substantially in subsequent years. Copies of the proposed collection of information can be obtained by visiting <http://www.acf.hhs.gov/programs/ocs/programs/csbg>.

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories.

comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-01176 Filed 1-23-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on February 23, 2015, from 8:30 a.m. to 5 p.m., and February 24, 2015, from 8:15 a.m. to 3 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: PCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Background: On November 27, 2013, the Drug Quality and Security Act (DQSA) amended section 503A of the FD&C Act to remove certain provisions regarding the advertising and promotion of compounded drugs and the

solicitation of prescriptions for compounded drugs that were found to be unconstitutional by the U.S. Supreme Court in 2002. By removing the unconstitutional provisions, the law removed uncertainty regarding the validity of section 503A of the FD&C Act, which is applicable to compounders nationwide.

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions under which a human drug product compounded for an identified individual patient based on the receipt of a prescription can qualify for exemptions from three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements for drugs); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications).

The DQSA also created a new section 503B of the FD&C Act, under which a compounder can register as an "outsourcing facility." Drug products compounded at outsourcing facilities may be able to qualify for exemptions from the FDA approval requirements (section 505 of the FD&C Act) and the requirement to label products with adequate directions for use (section 502(f)(1) of the FD&C Act) but will still be subject to CGMP requirements under section 501(a)(2)(B) of the FD&C Act.

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the drug that is compounded does not appear on a list of drugs published by the Secretary that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act).

Another condition in section 503A of the FD&C Act that must be satisfied to qualify for the section 503A exemptions is that bulk drug substances used in a compounded drug must meet one of the following criteria: (I) Comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of Health and Human Services (the Secretary); or (III) if such a monograph does not exist and the drug substance is not a component

of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary (section 503A(b)(1)(A)(i) of the FD&C Act). FDA will discuss drugs proposed for inclusion on these two lists with the Pharmacy Compounding Advisory Committee (committee).

Agenda: On February 23, 2015, during the morning session, the committee will discuss proposed revisions to the list of drug products that may not be compounded under the exemptions provided by the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. The list of products is currently codified at 216.24 (21 CFR 216.24), and FDA is proposing to revise and update the list at § 216.24 for purposes of both sections 503A and 503B of the FD&C Act. On July 2, 2014, FDA published a proposed rule that would add 25 drug products to this list and modify the description of one drug product on this list to add an exception (79 FR 37687, July 2, 2014). FDA received two drug-specific comments on the proposed rule. One comment requested that FDA clarify whether the entry for adenosine phosphate that is currently included on the list (all drug products containing adenosine phosphate) is intended to include all three forms of adenosine phosphate (mono-, di-, and triphosphate). The second comment requested that chloramphenicol tablets, 250 milligrams, be excluded from the list. FDA will discuss both of these comments with the committee.

On February 23, 2015, during the afternoon session, and on February 24, 2015, the committee will discuss proposed criteria for developing the list of bulk drug substances that may be used to compound drug products in accordance with section 503A of the FD&C Act and will discuss six substances nominated for inclusion on the list. On December 4, 2013, and July 2, 2014, FDA published notices in the **Federal Register** (78 FR 72841 and 79 FR 37747) soliciting nominations for this list. At this first meeting of the committee, FDA intends to discuss the following nominated bulk drug substances: Cantharidin, diphenylcyclopropenone, piracetam, silver protein mild, squaric acid dibutyl ester, and thymol iodide. The nominators of these substances will be invited to make a short presentation supporting the nomination. Other nominated substances will be discussed at future committee meetings.

FDA intends to make background material available to the public at no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

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 February 9, 2015. Oral presentations from the public will be scheduled between approximately 10:15 a.m. to 10:45 a.m. and 3:35 p.m. to 3:50 p.m. on February 23, 2015, and between approximately 9:30 a.m. to 9:45 a.m. and 11:45 a.m. to noon on February 24, 2015. Those individuals interested in making 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 February 12, 2015. 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 regarding their request to speak by February 13, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne E. Peterson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 21, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-01267 Filed 1-23-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 9, 2015, from 8 a.m. to 5:15 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: DODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting

cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss new drug application (NDA) 206333, deoxycholic acid injection, a cytolytic drug, submitted by Kythera Biopharmaceuticals, proposed for the improvement in the appearance of moderate-to-severe convexity or fullness associated with submental fat in adults.

During the afternoon session, the committee will discuss pediatric development of systemic products for the treatment of atopic dermatitis with inadequate response to topical prescription therapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

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 February 23, 2015. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making 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 February 12, 2015. 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