

company by acquiring 100 percent of the voting shares of First National Bank of the Gulf Coast, Naples, Florida.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166-2034:

1. *Alton Bancshares, Inc.*, Alton, Missouri; to acquire 100 percent of the voting shares of First Community Bank of the Ozarks, Branson, Missouri.

Board of Governors of the Federal Reserve System, November 28, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011-30947 Filed 12-1-11; 8:45 am]

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FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 16, 2011.

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

1. *CenterState Banks, Inc.*, Davenport, Florida; to engage in making, acquiring, brokering, or servicing loans, or other extensions of credit through its subsidiary, R4ALL, Inc., Davenport, Florida, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, November 28, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

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FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (“Commission” or “FTC”).

ACTION: Notice.

SUMMARY: The FTC intends to conduct an evaluation of Admongo, its advertising literacy program for children ages 8–12. The evaluation will involve a randomized controlled trial of the Admongo program in one or more school districts, involving 6,000–8,000 students. This research will be conducted to further the FTC’s mission of protecting consumers from unfair and deceptive marketing. We will consider comments on this proposed research before submitting a request for Office of Management and Budget (OMB) review under the Paperwork Reduction Act (PRA).

DATES: Comments must be submitted on or before January 31, 2012.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Admongo Evaluation, FTC File No. P085200” on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/admongoevaluationpra>, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to David Givens, Economist, Bureau of Economics, Federal Trade Commission, 600 Pennsylvania Avenue NW., Mail Stop NJ-4136, Washington, DC 20580. Telephone: (202) 326-3397.

SUPPLEMENTARY INFORMATION:

I. Background

As the nation’s consumer protection agency, the FTC is responsible for enforcing laws that prohibit unfair and

deceptive advertising and marketing practices. Part of this mission involves educating consumers, including young consumers. In April 2010, the FTC launched a youth-directed multi-media advertising literacy campaign called Admongo and distributed accompanying lesson plans to 100,000 educators in every U.S. public school with a fifth or sixth grade class. Admongo aims to help children from 8 to 12 become more discerning consumers of information. The program has three broad objectives: (1) Raising awareness of advertising and marketing messages; (2) teaching critical thinking skills that will allow children to better analyze and interpret advertisements; and (3) demonstrating the benefits of being an informed consumer. The program teaches students specific skills: How to identify ads, how to identify the ways advertisers target certain groups of consumers, how to spot persuasive techniques commonly employed by ads, and how to apply an understanding of advertising techniques to make smarter purchases. The campaign includes an online game, in-school lesson plans, sample ads that can be used at home and in the classroom, and teacher videos. All materials can be viewed at <http://www.admongo.gov>.

The proposed evaluation will test a large group of students in these skills and then compare the performance of those who have been exposed to the Admongo curriculum with those who have not. The results will give the FTC valuable insight into the optimal design of youth-directed consumer education. The FTC is interested in: The relative effectiveness of in-class versus online instruction, the variation in Admongo’s benefits by age, pre-existing levels of ad literacy by age, and the relationship between ad literacy and academic achievement.¹ The FTC also intends to interview teachers who have used the Admongo lessons in their classrooms. Teacher feedback will help us tailor the lessons to real-world classroom conditions.

II. Paperwork Reduction Act

Under the PRA, 44 U.S.C. 3501–3521, federal agencies must obtain approval (“clearance”) from OMB for each collection of information they conduct or sponsor. “Collection of information” includes disclosure to an agency, third parties, or the public of information by or for an agency through identical questions posed to, or identical reporting, recordkeeping, or disclosure

¹ All student-level data will be stripped of personally identifiable information by participating school districts before it reaches the FTC.

requirements imposed on, ten or more persons. 44 U.S.C. 3502(3)(A). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing an opportunity for public comment before seeking OMB clearance for the information collections presented here.

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information.

A. Description of the Collection of Information and Proposed Use

Subject to OMB approval, the FTC will conduct a randomized trial of the Admongo program in one or more U.S. school districts and involving 6,000–8,000 students ages 8–12. Classrooms in each participating school will be randomly assigned to treatment or control status. In the treatment classrooms, the Admongo lesson plans will be taught over the course of one week, and students will be given in-class time to play the online Admongo game. At the end of the trial, treatment students will take a test in advertising literacy. Students in the control classrooms will take the same test before they are exposed to Admongo.² Admongo's effect on ad literacy will be estimated from the difference in test scores. Additional controls measuring classroom, student, and teacher characteristics will increase the precision of the estimate of Admongo's impact.

B. Estimated Burden Hours

Each student's typical social studies or language arts teacher will teach the Admongo lessons. The paper-based test will last approximately 20 minutes. The time required to experience the Admongo lessons, play the online game, and take the test should total approximately five hours and twenty minutes per student (four 45-minute in-class lessons, one hour of online game playing, one hour of homework assignments, and 20 minutes for the test). With an estimated 6,000–8,000

students involved,³ cumulative burden for students will be in the range of 32,000–42,667 hours. Teachers will require the same time per task as students, but will also need time for lesson planning—estimated at four hours per teacher. Thus, with an estimated 240–320 teachers involved,⁴ their time commitment will range from 2,240 to 2,987 hours. The combined time for the Admongo trial should thus fall in the range of 34,240–45,654 hours.

These estimates are conservative. The Admongo lesson plans, tied to national standards of learning, will satisfy a pre-existing content requirement for participating schools.⁵ Thus, the incremental PRA burden for teachers and students would be much less than the estimates shown above.⁶ For example, if only the time required to take or administer the 20-minute test is considered, the resulting total would be a small fraction of the totals noted above.

A few participating teachers (20–40) also will take part in focus group discussions, lasting approximately 90 minutes. The estimated teacher time in focus groups, including an added hour of round-trip transportation to and from the discussion site, is 50–75 hours. Finally, administering the study will impose a small time burden on school district staff charged with scoring the tests and with compiling a master data set of 8–12 year-old students, stripped of personally identifiable information (to facilitate random assignment to treatment and control groups). These programming and data management tasks should take approximately 10–15 hours.

The cumulative burden for participating students, teachers, and school district staff for the Admongo evaluation will total 34,300–45,744 hours. Again, however, the bulk of this time would be subsumed within pre-existing classroom requirements.

C. Estimated Costs

The cost per respondent should be negligible in both the evaluation and focus group components of the study. The participation of the school district in the evaluation is voluntary, and the district will use the Admongo program

³ Based on an anticipated school district's participation and its approximate student composition at present.

⁴ Based on an estimated class size of 25 students and assuming a unique teacher for each classroom. [6,000 ÷ 25 = 240; 8,000 ÷ 25 = 320]

⁵ See <http://www.admongo.gov/state-standards/>.

⁶ See 5 CFR 1320.3(b)(2)(A) (a collection of information incurred by persons in the normal course of their activities is excluded from "burden" to the extent that the activities necessary to comply with it are "usual and customary").

to meet curriculum requirements. Thus, participation in the evaluation study will not impose any start-up, capital, or labor expenditures beyond those ordinarily incurred by the district to administer curriculum units. Participation by students in the evaluation and teachers in the focus groups also will be voluntary and not impose any start-up, capital, or labor expenditures. Teachers participating in the focus groups will be compensated at the standard rate paid by the contractor to focus group participants. The school district will be compensated for the cost of the staff time to perform the data management and test-scoring tasks.

D. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 31, 2012. Write "Admongo Evaluation, FTC File No. P085200" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, don't include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure

² With this protocol, the FTC gets a valid control group while still providing all experiment participants the benefit of the treatment.

explained in FTC Rule 4.9(c), 16 CFR 4.9(c).⁷ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <http://ftcpublic.commentworks.com/ftc/admngoevaluationpra>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that Web site.

If you file your comment on paper, write "Admngo Evaluation, FTC File No. P085200" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 31, 2012. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

By direction of the Commission.

Donald S. Clark,

Secretary.

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⁷ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0800]

Draft Guidance for Industry on Regulatory Classification of Pharmaceutical Co-Crystals; 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 "Regulatory Classification of Pharmaceutical Co-Crystals." This draft guidance provides applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) with the Center for Drug Evaluation and Research's (CDER's) current thinking on the appropriate classification of co-crystal solid-state forms. This draft guidance also provides information about the data that should be submitted to support the appropriate classification of a co-crystal and the regulatory implications of the classification.

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 either electronic or written comments on the draft guidance by March 1, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT:

Andre Raw, Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8500; or Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug

Administration, Bldg. 21, rm. 1626, 10903 New Hampshire Ave., Silver Spring, MD 20993, (301) 796-1900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Regulatory Classification of Pharmaceutical Co-Crystals." This draft guidance provides applicants of NDAs and ANDAs with CDER's current thinking on the appropriate classification of co-crystal solid-state forms. This draft guidance also provides information about the data that should be submitted to support the appropriate classification of a co-crystal and the regulatory implications of the classification.

Co-crystals are solids that are crystalline materials composed of two or more molecules in the same crystal lattice. These solid-state forms, composed of an active pharmaceutical ingredient (API) with a neutral guest compound co-former, have been the focus of significant interest in drug product development. Pharmaceutical co-crystals have opened the opportunity for engineering solid-state forms designed to have tailored properties to enhance drug product bioavailability and stability, as well as enhance processability of the solid material inputs in drug product manufacture. Pharmaceutical co-crystals are of interest because, unlike a salt form where the components in the crystal lattice are in an ionized state, the molecules in the co-crystal are in a neutral state and interact via nonionic interactions. Thus, pharmaceutical co-crystals offer the advantage of generating a diverse array of solid-state forms, even for APIs that lack ionizable functional groups needed for salt formation.

Traditionally, pharmaceutical solid-state forms of an API are grouped as either polymorphs or salts, and applicable regulatory schemes for these solid-state forms are well-defined. Co-crystals, however, are distinguishable from these traditional pharmaceutical solid-state forms. Unlike polymorphs, which generally speaking contain only the API within the crystal lattice, co-crystals are composed of an API with a neutral guest compound conformer in the crystal lattice. Similarly, unlike salts, where the components in the crystal lattice are in an ionized state, a co-crystal's components are in a neutral state and interact via nonionic interactions.

At present, no regulatory paradigm exists governing co-crystal forms. In response to this need for regulatory