

be sent electronically to

[Comments.applications@stls.frb.org](mailto:Comments.applications@stls.frb.org);

1. *David Armbrust, Salem, Illinois*; to acquire voting shares of Iuka Bancshares, Inc., Salem, Illinois, and thereby indirectly acquire shares of Iuka State Bank, Iuka, Illinois.

*B. Federal Reserve Bank of Kansas City* (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *David Riordan, Abilene, Kansas*; *Robert Riordan, Solomon, Kansas*; *Dennis Riordan, Salina, Kansas*; *Michael Riordan, St. Charles, Missouri*; and *Kirk Berneking, Salina, Kansas*; to retain voting shares of Solomon Bancshares, Inc., Solomon, Kansas, and thereby indirectly retain shares of Solomon State Bank, Solomon, Kansas.

Board of Governors of the Federal Reserve System, December 15, 2017.

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2017-27408 Filed 12-19-17; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Notice of Closed Meeting

In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting.

The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Name of Committee:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)-PAR15-303, Occupational Safety and Health Education Research Centers (ERC).

*Date:* February 21-23, 2018.

*Time:* 8:30 a.m.-6:00 p.m., EST.

*Place:* The Alexandrian Hotel, 480 King Street Alexandria, VA 22314, 703-549-6080.

*Agenda:* The meeting will include the initial review, discussion, and evaluation of applications received in response to PAR15-303, Occupational Safety and Health Education Research Centers (ERC).

**FOR FURTHER INFORMATION CONTACT:** Michael Goldcamp, Ph.D., Scientific Review Officer/CDC, 1095 Willowdale Road, Mailstop H1808, Morgantown,

West Virginia, 26505, (304) 285-5951; [mgoldcamp@cdc.gov](mailto:mgoldcamp@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office; Centers for Disease Control and Prevention.*

[FR Doc. 2017-27324 Filed 12-19-17; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-6380]

#### Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases; Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases.” FDA intends to no longer grant orphan drug designation to drugs for pediatric subpopulations of common diseases (*i.e.*, diseases or conditions with an overall prevalence of over 200,000 in the United States), unless the use of the drug in the pediatric subpopulation meets the regulatory criteria for an orphan subset, or unless the disease in the pediatric subpopulation is considered a different disease from the disease in the adult population. This will help resolve an unintended loophole in the Pediatric Research Equity Act (PREA) orphan exemption process where a sponsor holding a pediatric-subpopulation designation can submit a marketing application for use of its drug in the non-orphan adult population of that disease, get a pediatric-subpopulation designation for the pediatric subset of the disease, and, due to this designation, be exempt from conducting the pediatric studies normally required under PREA when seeking approval of the adult indication.

**DATES:** Submit either electronic or written comments on the draft guidance by January 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-6380 for “Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.