

be sent electronically to

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*.

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.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Aaron Friedman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 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.

FDA expects to implement this policy upon publication of the final version of this guidance dependent upon comments received. In the interim, FDA will refrain from issuing final decisions on requests for pediatric-subpopulation designation until the guidance is finalized.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on orphan designation of drugs and biologics for pediatric subpopulations of common diseases. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Orphan> or <https://www.regulations.gov>.

Dated: December 14, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27435 Filed 12–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6580]

Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and 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 FDA staff and industry entitled “Drug Products Labeled as Homeopathic.” This draft guidance describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval.

DATES: Submit either electronic or written comments on the draft guidance by March 20, 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”).