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 October 20, 2017.

A. Federal Reserve Bank of Minneapolis (Brendan S. Murrin, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Full Service Insurance Agency, Inc.,* Buxton, North Dakota; to acquire 100 percent of the voting shares of First and Farmers Bank Holding Company and thereby indirectly acquire shares of The First and Farmers Bank, both of Portland, North Dakota.

Board of Governors of the Federal Reserve System, September 20, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–20424 Filed 9–22–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4952]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; and inspections of clinical investigators, IRBs, and research sponsors.

DATES: The public workshop will be held on November 15 and 16, 2017, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Wyndham Lake Buena Vista Resort, 1850 Hotel Plaza Blvd., Lake Buena Vista, FL 32830, 407–828–4444.

FOR FURTHER INFORMATION CONTACT: Kim Prenter, Food and Drug Administration, 15100 NW. 67th Ave., Suite 400, Miami Lakes, FL 33014, 305–816–1474, Fax: 305–816–1536; or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292, Fax 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *https://www.socra.org.*

SUPPLEMENTARY INFORMATION:

I. Background

The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to clinical investigations, informed consent, and inspections of clinical investigators and IRBs.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government agencies to small businesses.

II. Topics for Discussion

Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings with FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working with FDA's Center for Biologics Evaluation and Research; and (12) The Inspection Is Over—What Happens Next? Possible FDA Compliance Actions.

III. Participating in the Public Workshop

Registration: Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $129 plus applicable taxes (available until October 16, 2017, or until the SOCRA room block is filled). For additional registration and meeting information, visit *https://www.socra.org/* or *https://www.socra.org/conferences-and-education/live-conferences/fda-clinical-trial-requirements-regulations-compliance-and-gcp-conference/register/.*

Registrations fees are as follows: $575 for SOCRA members, $650 for non-members (includes membership), $450 for Federal Government members, $525 for Federal Government non-members, and fee waived for FDA Employees.

The registration fee covers expenses including refreshments, lunch, materials, and speaker expenses. Registration for the conference is open through November 14, 2017.

If you need special accommodations due to a disability, please contact Kim Prenter (see **FOR FURTHER INFORMATION CONTACT**) at least 10 days in advance.

Other Issues for Consideration: Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of Continuing Medical Education (CME) and Continuing Nursing Education (CNE) credit. CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: The Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. ANCC/PSNA Provider Reference Number: 205–3–A–09.

Dated: September 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20375 Filed 9–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–4474, FDA–2016–M–1915, FDA–2016–M–1837, FDA–2016–M–1916, FDA–2016–M–1914, FDA–2016–M–1917, FDA–2016–M–2182, FDA–2016–M–2183, FDA–2016–M–2184, FDA–2016–M–2185, FDA–2016–M–2332, FDA–2016–M–2334, FDA–2016–M–2333, FDA–2016–M–2485, FDA–2016–M–2498, FDA–2016–M–2499, FDA–2016–M–2500, FDA–2016–M–2649, FDA–2016–M–2650, FDA–2016–M–2651, FDA–2016–M–2735, FDA–2016–M–2974, FDA–2016–M–2971, FDA–2016–M–1972, FDA–2016–M–2973, FDA–2016–M–2975, FDA–2016–M–3430, FDA–2016–M–3431, FDA–2016–M–3913, FDA–2016–M–3653, FDA–2016–M–3914, FDA–2016–M–3915, FDA–2016–M–4046, FDA–2016–M–4344, FDA–2016–M–4458, FDA–2016–M–4459, FDA–2016–M–4483, FDA–2016–M–4657, FDA–2016–M–4530, FDA–2016–M–4653, FDA–2017–M–0180, FDA–2017–M–0181, FDA–2017–M–0229, FDA–2017–M–0560, FDA–2017–M–0831, FDA–2017–M–0661, FDA–2017–M–0971, FDA–2017–M–2652, FDA–2017–M–1121, FDA–2017–M–1122, FDA–2017–M–1228, FDA–2017–M–1845, FDA–2017–M–1227, FDA–2017–M–1713, FDA–2017–M–1714, FDA–2017–M–1950, FDA–2017–M–2594, FDA–2017–M–2766, FDA–2017–M–2767, FDA–2017–M–2768, FDA–2017–M–3103, FDA–2017–M–3200, FDA–2017–M–3430, FDA–2017–M–3579, FDA–2017–M–3580, FDA–2017–M–3778, FDA–2017–M–3839, FDA–2017–M–3928, FDA–2017–M–3982, FDA–2017–M–3990, and FDA–2017–M–3983]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Dockets Management Staff.

ADDRESSES: You may submit comments 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 Nos. FDA–2015–M–4474, FDA–2016–M–1915, FDA–2016–M–1837, FDA–2016–M–1916, FDA–2016–M–1914, FDA–2016–M–1917, FDA–2016–M–2182, FDA–2016–M–2183, FDA–2016–M–2184, FDA–2016–M–2185, FDA–2016–M–2332, FDA–2016–M–2334, FDA–2016–M–2333, FDA–2016–M–2485, FDA–2016–M–2498, FDA–2016–M–2499, FDA–2016–M–2500, FDA–2016–M–2649, FDA–2016–M–2650, FDA–2016–M–2651, FDA–2016–M–2735, FDA–2016–M–2974, FDA–2016–M–2971, FDA–2016–M–1972, FDA–2016–M–2973, FDA–2016–M–2975, FDA–2016–M–3430, FDA–2016–M–3431, FDA–2016–M–3913, FDA–2016–M–3653, FDA–2016–M–3914, FDA–2016–M–3915, FDA–2016–M–4046, FDA–2016–M–4344, FDA–2016–M–4458, FDA–2016–M–4459, FDA–2016–M–4483, FDA–2016–M–4657, FDA–2016–M–4530, FDA–2016–M–4653, FDA–2017–M–0180, FDA–2017–M–0181, FDA–2017–M–0229, FDA–2017–M–0560, FDA–2017–M–0831, FDA–2017–M–0661, FDA–2017–M–0971, FDA–2017–M–2652, FDA–2017–M–1121, FDA–2017–M–1122, FDA–2017–M–1228, FDA–2017–M–1845, FDA–2017–M–1227, FDA–2017–M–1713, FDA–2017–M–1714, FDA–2017–M–1950, FDA–2017–M–2594, FDA–2017–M–2766, FDA–2017–M–2767, FDA–2017–M–2768, FDA–2017–M–3103, FDA–2017–M–3200, FDA–2017–M–3430, FDA–2017–M–3579, FDA–2017–M–3580, FDA–2017–M–3778, FDA–2017–M–3839, FDA–2017–M–3928, FDA–2017–M–3982, FDA–2017–M–3990, and FDA–2017–M–3983 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' 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