of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–03144 Filed 2–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0148]

Complicated Urinary Tract Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Complicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated urinary tract infections (cUTIs). This guidance finalizes the revised draft guidance of the same name issued on February 24, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Complicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of cUTIs.

This guidance includes recommendations for an efficacy endpoint and noninferiority trial design. The efficacy endpoint, based on resolution of clinical symptoms and eradication of bacteria from the urinary tract, was derived from previously conducted clinical trials for the treatment of cUTI. The guidance provides a scientific justification for a noninferiority margin based on historical observational data compared to the results of previously conducted clinical trials. After careful consideration of comments received in response to the revised draft guidance issued on February 24, 2012, important clarifications about trial populations and endpoints for cUTI were included in this guidance. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of cUTI.

Issuance of this guidance fulfills a portion of the requirements of title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03100 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Society of Clinical Research Associates—Food and Drug Administration; ''Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance and Good Clinical Practice''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Public Workshop.

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

clinical investigators, of IRB, and of research sponsors.

Date and Time: The conference will be held on March 11 and 12, (Wednesday and Thursday) 2015, from 8:00 a.m. to 5 p.m.

Location: The conference will be held at the Holiday Inn Golden Gateway Hotel, 1500 Van Ness Ave., San Francisco, CA 91409, 415–441–4000.

Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $159.00 plus applicable taxes (available until February 13, 2015, or until the SOCRA room block is filled).

Contact Person: Jane Kreis, Food and Drug, Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739 or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914. 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *Office@socra.org* Web site: *www.socra.org.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SOCRA member—$575, SOCRA nonmember (includes membership)—$650, Federal Government member—$450.00, Federal Government nonmember—$525.00, FDA Employee—(free) Fee Waived.

If you need special accommodations due to a disability, please contact SOCRA (see Contact Person) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SOCRA designates this education activity for a maximum of 13.3 Continuing Education Credits for SOCRA continuing education (CE) and Nurse continuing nurse education (CNE), SOCRA designates this live activity for a maximum of 13.3 *American Medical Association Physician's Recognition Award* Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. Continuing medical education (CME) for Physicians: SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide CME for physicians. CNE for Nurses: Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, FAX number, and email, along with a check or money order payable to ''SOCRA''. Mail to: SOCRA(see Contact Person for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SOCRA (see Contact Person).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related informed consent, clinical investigation requirements, institutional review board inspections, electronic record requirements, and investigator initiated research Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial: (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with the FDA—Why, When and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; (16) Question and Answer Session/Panel Discussion.

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 workshop helps to achieve objectives set forth in section 406 of the FDA 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.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03118 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Orthopaedic and Rehabilitation Panel of the Medical Devices 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: Orthopaedic and Rehabilitation Panel of the Medical Devices 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 February 20, 2015, from 8 a.m. to 6 p.m.

Location: Hilton/Washington DC North, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Sara Anderson, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1643, Silver Spring, MD 20993–0002, *sara.anderson@fda.hhs.gov,* 301–796–7047, 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