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 This guidance finalizes the revised draft guidance of the same name issued on February 24, 2012.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